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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2016

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 001-36548

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**ATARA BIOTHERAPEUTICS, INC.**

(Exact name of Registrant as specified in its Charter)

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**Delaware**  
(State or other jurisdiction of incorporation or organization)

**46-0920988**  
(I.R.S. Employer Identification No.)

**611 Gateway Blvd., Suite 900**  
**South San Francisco, CA**  
(Address of principal executive offices)

**94080**  
(Zip Code)

(Registrant's telephone number, including area code: **(650) 278-8930**)

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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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company)

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

The number of outstanding shares of the Registrant's Common Stock as of October 31, 2016 was 28,860,635 shares.

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ATARA BIOTHERAPEUTICS, INC.

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**ATARA BIOTHERAPEUTICS, INC.**  
**Condensed Consolidated Balance Sheets**  
**(Unaudited)**  
**(In thousands, except share and per share amounts)**

	September 30, 2016	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 46,013	\$ 23,746
Short-term investments	232,134	296,736
Restricted cash	194	194
Prepaid expenses and other current assets	3,889	3,921
Total current assets	282,230	324,597
Property and equipment, net	2,085	270
Other assets	102	108
Total assets	<u>\$ 284,417</u>	<u>\$ 324,975</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 4,463	\$ 1,445
Accrued compensation	3,156	2,624
Accrued research and development expenses	5,109	5,112
Other accrued liabilities	960	528
Total current liabilities	13,688	9,709
Long-term liabilities	527	166
Total liabilities	14,215	9,875
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock—\$0.0001 par value, 500,000,000 shares authorized as of September 30, 2016 and December 31, 2015; 28,842,125 and 28,458,807 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	3	3
Additional paid-in capital	429,088	413,725
Accumulated other comprehensive income (loss)	35	(518)
Accumulated deficit	(158,924)	(98,110)
Total stockholders' equity	270,202	315,100
Total liabilities and stockholders' equity	<u>\$ 284,417</u>	<u>\$ 324,975</u>

*See accompanying notes.*

**ATARA BIOTHERAPEUTICS, INC.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
**(Unaudited)**  
**(In thousands, except per share amounts)**

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Operating expenses:				
Research and development	\$ 18,802	\$ 8,113	\$ 43,040	\$ 25,387
General and administrative	7,140	4,146	19,448	11,291
Total operating expenses	<u>25,942</u>	<u>12,259</u>	<u>62,488</u>	<u>36,678</u>
Loss from operations	(25,942)	(12,259)	(62,488)	(36,678)
Interest and other income, net	576	380	1,684	696
Loss before provision (benefit) for income taxes	(25,366)	(11,879)	(60,804)	(35,982)
Provision (benefit) for income taxes	7	(11)	10	(9)
Net loss	<u>\$ (25,373)</u>	<u>\$ (11,868)</u>	<u>\$ (60,814)</u>	<u>\$ (35,973)</u>
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	(158)	117	553	151
Comprehensive loss	<u>\$ (25,531)</u>	<u>\$ (11,751)</u>	<u>\$ (60,261)</u>	<u>\$ (35,822)</u>
Net loss per common share:				
Basic and diluted net loss per common share	<u>\$ (0.88)</u>	<u>\$ (0.43)</u>	<u>\$ (2.12)</u>	<u>\$ (1.46)</u>
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	<u>28,801</u>	<u>27,675</u>	<u>28,670</u>	<u>24,628</u>

*See accompanying notes.*

**ATARA BIOTHERAPEUTICS, INC.**  
**Condensed Consolidated Statements of Cash Flows**  
**(Unaudited)**  
**(In thousands)**

	Nine months ended September 30,	
	2016	2015
<b>Operating activities</b>		
Net loss	\$ (60,814)	\$ (35,973)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	15,128	7,287
Amortization of investment premiums and discounts	2,811	1,714
Depreciation expense	210	21
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(602)	(2,514)
Other assets	6	(50)
Accounts payable	3,018	1,413
Accrued compensation	532	337
Accrued research and development expenses	(3)	1,713
Other accrued liabilities	433	263
Long-term liabilities	420	25
Net cash used in operating activities	(38,861)	(25,764)
<b>Investing activities</b>		
Purchases of short-term investments	(252,279)	(285,390)
Sales of short-term investments	187,508	34,349
Maturities of short-term investments	127,749	50,352
Purchases of property and equipment	(2,025)	(19)
Net cash provided by (used in) investing activities	60,953	(200,708)
<b>Financing activities</b>		
Proceeds from sale of common stock, net of offering costs	—	263,434
Taxes paid related to net share settlement of restricted stock units	(75)	(4,588)
Proceeds from exercise of stock options	250	195
Net cash provided by financing activities	175	259,041
Increase in cash and cash equivalents	22,267	32,569
Cash and cash equivalents at beginning of period	23,746	21,897
Cash and cash equivalents at end of period	\$ 46,013	\$ 54,466
<b>Non-cash investing and financing activities</b>		
Issuance of common stock upon vesting of stock awards	\$ 60	\$ 60
Change in long-term liabilities related to non-vested stock awards	\$ (60)	\$ (60)
Property and equipment purchases included in liabilities	\$ 129	\$ —
<b>Supplemental cash flow disclosure</b>		
Cash paid for taxes	\$ 10	\$ 2

*See accompanying notes.*

**ATARA BIOTHERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. Description of Business**

Atara Biotherapeutics, Inc. (“Atara”, “we”, “our” or “the Company”) was incorporated in August 2012 in Delaware. Atara is a clinical-stage biopharmaceutical company focused on developing meaningful therapies for patients with severe and life-threatening diseases that have been underserved by scientific innovation. We have two groups of product candidates: (a) allogeneic, or third-party derived, antigen-specific T-cells, and (b) molecularly targeted biologics.

Our T-cell programs were acquired through licensing arrangements with Memorial Sloan Kettering Cancer Center (“MSK”) and Queensland Institute of Medical Research (“QIMR Berghofer”). Our molecularly targeted biologics programs were acquired through licensing arrangements with Amgen Inc. (“Amgen”). See Note 5 for further information.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and following the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the Company’s annual consolidated financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015, and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair statement of the Company’s consolidated financial information. The results of operations for the nine month period ended September 30, 2016 are not necessarily indicative of the results to be expected for the full year or any other future period. The condensed balance sheet as of December 31, 2015 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete consolidated financial statements.

**Significant Risks and Uncertainties**

We have incurred significant operating losses since inception and have relied on public and private equity financings to fund our operations. As of September 30, 2016, we had an accumulated deficit of \$158.9 million. As we continue to incur losses, our transition to profitability will depend on the successful development, approval and commercialization of product candidates and on the achievement of sufficient revenues to support our cost structure. We may never achieve profitability, and unless and until we do, we will need to continue to raise additional capital. Management expects that our cash, cash equivalents and short-term investments as of September 30, 2016 will be sufficient to fund our planned operations through 2018.

**Concentration of Credit Risk and Other Uncertainties**

We place cash and cash equivalents in the custody of financial institutions that management believes are of high credit quality, the amount of which at times, may be in excess of the amount insured by the Federal Deposit Insurance Corporation. We also have short-term investments in money market funds, U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities, which can be subject to certain credit risk. However, we mitigate the risks by investing in high-grade instruments, limiting our exposure to any one issuer, and monitoring the ongoing creditworthiness of the financial institutions and issuers.

We are subject to certain risks and uncertainties and believe that changes in any of the following areas could have a material adverse effect on future financial position or results of operations: our ability to obtain future financing; regulatory approval and market acceptance of, and reimbursement for, our product candidates, if approved; performance of third-party clinical research organizations and manufacturers upon which we rely; development of sales channels; protection of our intellectual property; litigation or claims against us based on intellectual property, patent, product, regulatory or other factors; and our ability to attract and retain employees necessary to support our growth.

## Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions, and judgments that affect the amounts reported in the financial statements and accompanying notes. Significant estimates relied upon in preparing these financial statements include estimates related to clinical trial and other accruals, stock-based compensation expense, fair values of investments and income taxes. Actual results could differ materially from those estimates.

## Recent Accounting Pronouncements

In January 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities (Subtopic 825-20)*, which amends the guidance in U.S. GAAP on the classification and measurement of financial instruments. Although the ASU retains many current requirements, it significantly revises an entity’s accounting related to the classification and measurement of investments in equity securities and the presentation of certain fair value changes for financial liabilities measured at fair value. The ASU also amends certain disclosure requirements associated with the fair value of financial instruments. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2017, with early adoption permitted for certain changes. The Company has not yet determined the method of adoption and the potential effect the new standard will have on the Company’s consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which is intended to increase the transparency and comparability in the reporting of leasing arrangements by generally requiring leased assets and liabilities to be recorded on the balance sheet. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018, with early adoption permitted. The Company has not yet determined the method of adoption and the potential effect the new standard will have on the Company’s consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification in the statement of cash flows. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2016, with early adoption permitted. The Company has not yet determined the method of adoption and the potential effect the new standard will have on the Company’s consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Loss (Topic 326): Measurement of Credit Losses on Financial Instruments*, which significantly changes how companies measure and recognize credit impairment for many financial assets. The new current expected credit loss model will require companies to immediately recognize an estimate of credit losses expected to occur over the remaining life of the financial assets that are in the scope of the standard. The ASU also makes targeted amendments to the current impairment model for available-for-sale debt securities. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019, with early adoption permitted. The Company has not yet determined the method of adoption and the potential effect the new standard will have on the Company’s consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which clarifies how certain cash receipts and cash payments should be presented and classified in the statement of cash flows. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2017, with early adoption permitted. The Company has not yet determined the method of adoption and the potential effect the new standard will have on the Company’s consolidated financial statements.

## 3. Net Loss per Common Share

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of common share equivalents. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of shares of common stock and common share equivalents outstanding for the period. Common share equivalents are only included in the calculation of diluted net loss per common share when their effect is dilutive.

Potential dilutive securities, which include unvested restricted stock awards (“RSAs”), unvested restricted stock units (“RSUs”), vested and unvested options to purchase common stock (“options”) and shares to be issued under our employee stock purchase plan (“ESPP”) have been excluded from the computation of diluted net loss per share as the effect is antidilutive. Therefore, the denominator used to calculate both basic and diluted net loss per common share is the same in all periods presented.

The following table represents the potential common shares issuable pursuant to outstanding securities as of the related period end dates that were excluded from the computation of diluted net loss per common share as their inclusion would have an antidilutive effect:

	As of September 30,	
	2016	2015
Unvested RSAs	18,510	333,652
Unvested RSUs	1,371,269	453,449
Vested and unvested options	3,744,176	543,990
ESPP share purchase rights	15,888	—

#### 4. Financial Instruments

Our financial assets are measured at fair value on a recurring basis using the following hierarchy to prioritize valuation inputs, in accordance with applicable GAAP:

Level 1: Quoted prices in active markets for identical assets or liabilities that we have the ability to access

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data such as quoted prices, interest rates and yield curves

Level 3: Inputs that are unobservable data points that are not corroborated by market data

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. We recognize transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs. There have been no transfers between Level 1, Level 2, and Level 3 in any periods presented.

The following tables summarize the estimated fair value and related valuation input hierarchy of our financial assets measured on a recurring basis, which were comprised solely of available-for-sale securities as of each period end:

As of September 30, 2016:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
(in thousands)					
Money market funds	Level 1	\$ 37,397	\$ —	\$ —	\$ 37,397
U.S. Treasury obligations	Level 2	75,107	42	(5)	75,144
Government agency obligations	Level 2	24,834	19	(6)	24,847
Corporate debt obligations	Level 2	126,587	31	(66)	126,552
Commercial paper	Level 2	900	—	—	900
Asset-backed securities	Level 2	13,262	18	—	13,280
Total available-for-sale securities		278,087	110	(77)	278,120
Less amounts classified as cash equivalents		(45,988)	—	2	(45,986)
Amounts classified as short-term securities		<u>\$ 232,099</u>	<u>\$ 110</u>	<u>\$ (75)</u>	<u>\$ 232,134</u>

As of December 31, 2015:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
(in thousands)					
Money market funds	Level 1	\$ 16,364	\$ —	\$ —	\$ 16,364
U.S. Treasury obligations	Level 2	599	—	(1)	598
Government agency obligations	Level 2	36,480	1	(88)	36,393
Corporate debt obligations	Level 2	203,767	8	(339)	203,436
Commercial paper	Level 2	999	—	—	999
Asset-backed securities	Level 2	61,304	2	(102)	61,204
Total available-for-sale securities		319,513	11	(530)	318,994
Less amounts classified as cash equivalents		(22,259)	—	1	(22,258)
Amounts classified as short-term securities		<u>\$ 297,254</u>	<u>\$ 11</u>	<u>\$ (529)</u>	<u>\$ 296,736</u>



The amortized cost and fair value of our available-for-sale securities by contractual maturity were as follows:

	As of September 30, 2016		As of December 31, 2015	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
	(in thousands)		(in thousands)	
Maturing within one year	\$ 225,940	\$ 225,953	\$ 211,311	\$ 211,059
Maturing in one to five years	52,147	52,167	108,202	107,935
Total available-for-sale securities	<u>\$ 278,087</u>	<u>\$ 278,120</u>	<u>\$ 319,513</u>	<u>\$ 318,994</u>

As of September 30, 2016, certain available-for-sale securities had been in a continuous unrealized loss position, each for less than twelve months. As of this date, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the respective issuers, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. During the three and nine months ended September 30, 2016 and 2015, we did not recognize any other-than-temporary impairment loss.

## 5. License and Collaboration Agreements

**MSK Agreements** – In September 2014, we entered into an exclusive option agreement with MSK under which we had the right to acquire the exclusive worldwide license rights to three clinical stage T-cell therapies from MSK. In exchange for the option, we paid \$1.25 million in cash and issued 59,761 shares of our common stock to MSK, which at the time of issuance had an estimated fair value of \$0.75 million. The total of \$2.0 million was recorded as research and development expense in our statements of operations and comprehensive loss.

In June 2015, we exercised our option and entered into an exclusive license agreement with MSK. In connection with the execution of the license agreement, we paid \$4.5 million in cash to MSK, which was recorded as research and development expense in our statement of operations and comprehensive loss.

We are required to make additional payments of up to \$33.0 million to MSK based on achievement of specified regulatory and sales-related milestones, as well as mid-single-digit percentage tiered royalty payments based on future sales of products resulting from the development of the licensed product candidates, if any. In addition, under certain circumstances, we are required to make certain minimum annual royalty payments to MSK, which are creditable against earned royalties owed for the same annual period. We are also required to pay a low double-digit percentage of any consideration we receive for sublicensing the licensed rights. The license agreement expires on a product-by-product and country-by-country basis on the later of: (i) expiration of the last licensed patent rights related to each licensed product, (ii) expiration of any market exclusivity period granted by law with respect to each licensed product, and (iii) a specified number of years after the first commercial sale of the licensed product in each country. Upon expiration of the license agreement, Atara will retain non-exclusive rights to the licensed products.

**Amgen License Agreements** - In September 2012, we entered into three license agreements with Amgen. In accordance with terms of the agreements with Amgen, we use commercially reasonable efforts to prepare, file, prosecute, defend and maintain the patents covered by the license agreements. During the three months ended September 30, 2016 and 2015, we incurred expenses of \$0.3 million and \$0.5 million, respectively, related to these activities. During the nine months ended September 30, 2016 and 2015, we incurred expenses of \$0.8 million and \$1.3 million, respectively, related to these activities.

In December 2015, we announced that we would be suspending further development of PINTA 745 and in June 2016, we returned the rights related to this and the ATA 842 program to Amgen. Under the remaining license agreements, potential payments of up to \$58.0 million are due to Amgen upon the achievement of development and regulatory approval milestones and payments of up to \$104.0 million are due upon the achievement of sales-based milestones.

We are also required to pay mid-single-digit percentage tiered royalties on future net sales of products which are developed and approved as defined by the agreements, if any. Our royalty obligations as to a particular licensed product will be payable, on a country-by-country and product-by-product basis, until the later of (a) the date of expiration of the last to expire valid claim within the licensed patents that covers the manufacture, use or sale, offer to sell, or import of such licensed product by us or a sublicense in such country, (b) loss of regulatory exclusivity, or (c) 10 years after the first commercial sale of the applicable licensed product in the applicable country. These agreements expire at the end of all royalty obligations to Amgen and, upon expiration, the licenses will be fully paid, royalty-free, irrevocable and non-exclusive.

**QIMR Berghofer Agreements** – In October 2015, we entered into an exclusive license agreement and a research and development collaboration agreement with QIMR Berghofer.

Under the terms of the license agreement, we obtained an exclusive, worldwide license to develop and commercialize allogeneic cytotoxic T-lymphocyte (“CTL”) therapy programs utilizing technology and know-how developed by QIMR Berghofer. In consideration for the exclusive license, we paid \$3.0 million in cash to QIMR Berghofer, which was recorded as research and development expense in our statement of operations and comprehensive loss in the fourth quarter of 2015. In September 2016, the exclusive license agreement and research and development collaboration agreement were amended and restated. Under the amended and restated agreements, we obtained an exclusive, worldwide license to develop and commercialize additional CTL programs as well as the option to license additional technology in exchange for \$3.3 million in cash, which was recorded as research and development expense in our statement of operations and comprehensive loss in the third quarter of 2016 and paid in October 2016. The amended and restated license agreement also provides for various milestone and royalty payments to QIMR Berghofer based on future product sales, if any.

Under the terms of the amended and restated research and development collaboration agreement, we are also required to reimburse the cost of agreed-upon development activities related to programs developed under the collaboration. These payments are expensed on a straight-line basis over the related development periods and resulted in research and development expense of \$0.3 million and \$0.9 million for the three and nine months ended September 30, 2016, respectively. The agreement also provides for various milestone payments to QIMR Berghofer based on achievement of certain developmental and regulatory milestones.

Milestones and royalties under each of the above agreements are contingent upon future events and will be recorded as expense when it is probable that the milestones will be achieved or royalties are due. As of September 30, 2016 and December 31, 2015, there were no outstanding obligations for milestones and royalties to MSK, Amgen and QIMR Berghofer.

## **6. Commitments and Contingencies**

### **License and Collaboration Agreements**

Certain potential payments related to our license and collaboration agreements, including milestone and royalty payments, are detailed in Note 5. As the achievement of these milestones and royalties are currently not fixed and determinable, such commitments have not been included in our condensed consolidated balance sheets.

### **Other Research and Development Agreements**

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies, and with other vendors for pre-clinical studies, supplies and other services for our operating purposes. These contracts generally provide for termination on notice, with the exception of potential termination charges related to one of our contract manufacturing agreements in the event certain minimum purchase volumes are not met. As of September 30, 2016 and December 31, 2015, there were no amounts accrued related to termination charges for minimum purchase volumes not being met.

## Operating Leases

In December 2015, we entered into a lease agreement for our new corporate headquarters in South San Francisco, California, which is expected to expire in April 2021. In connection with the lease, we issued a letter of credit for \$0.2 million to the landlord, which expires in December 2016 and is classified as restricted cash in our condensed consolidated balance sheet. In May 2016, we subleased our previous corporate facility to a third party through January 2017. Other leased property includes a facility in Westlake Village, California under a lease agreement that expires in April 2019. As of September 30, 2016, future minimum commitments for our operating leases were as follows:

Periods Ending December 31,	Operating Leases	
	(in thousands)	
Remaining 2016	\$	375
2017		1,294
2018		980
2019		732
2020		613
Thereafter		259
Total operating lease commitments	\$	4,253
Less income from sublease		70
Net minimum operating lease commitments	\$	4,183

Rent expense for the three months ended September 30, 2016 and 2015 was \$0.3 million and \$0.1 million, respectively. Rent expense for the nine months ended September 30, 2016 and 2015 was \$0.9 million and \$0.3 million, respectively.

## Indemnification Agreements

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations. We also have indemnification obligations to our directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date and we believe the fair value of these indemnification agreements is minimal. Accordingly, we did not record liabilities for these agreements as of September 30, 2016 and December 31, 2015.

## Contingencies

From time to time, we may be involved in legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business or otherwise. The ultimate outcome of any litigation is uncertain and unfavorable outcomes could have a negative impact on our results of operations and financial condition. Regardless of outcome, litigation can have an adverse impact on us because of the defense costs, diversion of management resources and other factors. We are not currently involved in any material legal proceedings.

## 7. Stockholders' Equity

The following shares of common stock were reserved for future issuance as of September 30, 2016:

	Total Shares Reserved
2014 Equity Incentive Plan	9,182,558
2014 Employee Stock Purchase Plan	663,667
Total reserved shares of common stock	9,846,225

## Restricted Stock Awards

In August 2012 and March 2013, our chief executive officer and one other Atara employee purchased RSAs with certain service and performance conditions. As of September 30, 2016, 1,316,875 of these shares had vested and are reported as shares outstanding in the financial statements. The remaining 18,510 shares vest in October 2016. Stock-based compensation expense related to the RSAs is recorded using accelerated graded vesting model and was \$32,000 and \$0.2 million for the three months ended September 30, 2016 and 2015, respectively, and \$0.2 million and \$0.8 million for the nine months ended September 30, 2016 and 2015, respectively. There is no unrecognized stock-based compensation expense related to unvested RSAs as of September 30, 2016. The aggregate intrinsic value of unvested RSAs was \$0.4 million as of September 30, 2016.

## 2014 Equity Incentive Plan (“2014 EIP”)

Our 2014 EIP permits the issuance of options, RSAs, RSUs and other types of awards to employees, directors and consultants.

In June 2016, our stockholders approved an increase of 4,000,000 shares to the shares reserved for issuance under the 2014 EIP. As of September 30, 2016, a total of 9,182,558 shares of common stock were reserved for issuance under the 2014 Plan, of which 5,140,848 were subject to outstanding options and RSUs and 4,041,710 shares were available for future grant.

### Restricted Stock Awards and Units

The following is a summary of RSA and RSU activity under our 2014 EIP:

	RSAs		RSUs	
	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2015	48,317	\$ 0.40	427,605	\$ 7.86
Granted	—		1,142,697	\$ 17.83
Forfeited	—		(44,746)	\$ 11.87
Vested	(48,317)	\$ 0.40	(154,287)	\$ 6.33
Unvested as of September 30, 2016	—		1,371,269	\$ 16.21
Vested and unreleased			25,403	
Outstanding as of September 30, 2016			1,396,672	

As of September 30, 2016, there was \$17.4 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 2.0 years. The aggregate intrinsic value of the RSUs outstanding as of September 30, 2016 was \$29.9 million. Under our RSU net settlement procedures, we withhold shares at settlement to cover the minimum payroll withholding tax obligations. During the nine months ended September 30, 2016, we settled 153,719 RSUs, of which 149,468 RSUs were net settled by withholding 4,251 shares. The value of the RSUs withheld was approximately \$75,000 based on the closing price of our common stock on the settlement date. These amounts were remitted to the appropriate taxing authorities and have been reflected as a financing activity in our condensed consolidated statements of cash flows.

### Stock Options

The following is a summary of option activity under our 2014 EIP:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)		Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2015	3,137,529	\$ 25.81			
Granted	804,700	\$ 20.39			
Exercised	(18,947)	\$ 13.15			
Forfeited or expired	(179,106)	\$ 25.41			
Outstanding as of September 30, 2016	3,744,176	\$ 24.79	5.90	\$	6,279
Vested and expected to vest as of September 30, 2016	3,744,176	\$ 24.79	5.90	\$	6,279
Exercisable as of September 30, 2016	924,752	\$ 24.50	5.49	\$	2,369

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on September 30, 2016 and the exercise price of outstanding, in-the-money options. As of September 30, 2016, there was \$37.1 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 2.9 years. Options for 18,947 and 11,844 shares of our common stock were exercised during the nine months ended September 30, 2016 and 2015, with an intrinsic value of \$0.2 million and \$0.4 million, respectively, as calculated based on the exercise date.

The fair value of each option issued was estimated at the date of grant using the Black-Scholes valuation model. The following table summarizes the weighted-average assumptions used as inputs to the Black-Scholes model, and resulting weighted-average grant date fair values of stock options granted during the period indicated:

	<u>Nine months ended September 30, 2016</u>		<u>Nine months ended September 30, 2015</u>	
	<u>Employees</u>	<u>Consultants</u>	<u>Employees</u>	<u>Consultants</u>
<b>Assumptions:</b>				
Expected term (years)	4.5	6.9	4.5	7.0
Expected volatility	69.0%	66.1%	71.8%	71.5%
Risk-free interest rate	1.3%	1.7%	1.4%	2.0%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
<b>Fair Value:</b>				
Weighted-average estimated grant date fair value per share	\$ 11.23	\$ 11.57	\$ 19.15	\$ 27.83
Options granted	795,700	9,000	1,106,699	9,000
Total estimated grant date fair value	<u>\$ 8,935,000</u>	<u>\$ 104,000</u>	<u>\$ 21,189,000</u>	<u>\$ 250,000</u>

The estimated fair value of stock options that vested during the nine months ended September 30, 2016 and 2015 was \$10.4 million and \$1.9 million, respectively.

#### 2014 Employee Stock Purchase Plan ("2014 ESPP")

As of September 30, 2016, there were 663,667 shares authorized for issuance under the 2014 ESPP. The 2014 ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Eligible employees can purchase shares of the Company's common stock at 85% of the lower of the fair market value of the common stock at (i) the beginning of a 12-month offering period, or (ii) at the end of one of the two related 6-month purchase periods. No participant in the 2014 ESPP may be issued or transferred shares of common stock valued at more than \$25,000 per calendar year. In June 2016, the first offering under the 2014 ESPP commenced for the period from June 1, 2016 through May 31, 2017, and the Company recorded \$0.2 million and \$0.3 million of stock-based compensation expense in relation to this offering in the three and nine months ended September 30, 2016. There were no purchases of shares under the 2014 ESPP in the nine months ended September 30, 2016.

#### Stock-based Compensation Expense

Total stock-based compensation expense related to all employee and non-employee awards was as follows:

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
	(in thousands)		(in thousands)	
Research and development	\$ 2,551	\$ 899	\$ 7,231	\$ 3,439
General and administrative	2,718	1,335	7,897	3,848
Total stock-based compensation expense	<u>\$ 5,269</u>	<u>\$ 2,234</u>	<u>\$ 15,128</u>	<u>\$ 7,287</u>

#### 8. Income Taxes

As of September 30, 2016, the Company had unrecognized tax benefits under ASC 740 *Income Taxes*, of approximately \$4.6 million. As of this date, the total amount of unrecognized tax benefits that would affect the Company's effective tax rate, if recognized, was \$0.1 million. The Company currently has a full valuation allowance against its U.S. net deferred tax assets, which would impact the timing of the effective tax rate benefit should any uncertain tax position be favorably settled in the future.

During July 2016, the Company licensed certain intellectual property rights to a wholly-owned subsidiary outside the United States. Although the license of intellectual property rights between consolidated entities did not result in any gain in the consolidated statements of operations and comprehensive loss, the transaction generated a taxable gain in the U.S. However, as this gain is offset by current and existing tax losses, there was no cash tax impact from the transaction in the periods presented. As a result of the transaction, there was an increase of \$0.3 million in unrecognized tax benefits during the three months ended September 30, 2016. The Company expects to record an uncertain tax benefit of \$1.1 million during the next 12 months. The Company's policy is to account for interest and penalties related to uncertain tax positions as a component of the income tax provision. The amount of accrued interest and penalties as of September 30, 2016 was immaterial.

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

### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included elsewhere in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016. This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

#### Overview

We are a clinical-stage biopharmaceutical company focused on developing meaningful therapies for patients with severe and life-threatening diseases that have been underserved by scientific innovation. We have two groups of product candidates: (a) allogeneic, or third-party derived, antigen-specific T-cells, and (b) molecularly targeted biologics. Our most advanced product candidate, EBV-CTL, is expected to enter two Phase 3 trials by the end of 2016. We have additional product candidates at various stages of development.

T-cells are a type of white blood cell, and cytotoxic T-cells, otherwise known as cytotoxic T lymphocytes, or CTLs, can mount an immune response against an antigen or antigens in order to combat viral infection or disease. Our clinical stage T-cell product candidates use cells from healthy donors. These cells are trained to recognize an antigen, then expanded, characterized, banked, and held as inventory. The cells are then partially human leukocyte antigen, or HLA-matched to a patient in need, and are ready to infuse in patients in approximately three to five days.

Our initial T-cell product candidates are CTLs that target viral- or cancer-specific antigens and are designed to harness the body's immune system to counteract specific viral infections and cancers. Our most advanced T-cell product candidate, EBV-CTL, is entering into Phase 3 trials for Epstein-Barr virus, or EBV-associated post-transplant lymphoproliferative disorders, or EBV-PTLD. We licensed rights to this product candidate from Memorial Sloan Kettering Cancer Center, or MSK, in June 2015. EBV-PTLD is a cancer affecting some patients who have received an allogeneic hematopoietic cell transplant, or HCT, a solid organ transplant, or SOT, or are otherwise immunocompromised. We recently submitted our final protocols for these Phase 3 trials to the U.S. Food and Drug Administration, or FDA, and both of these trials are on track to commence by the end of 2016. In June 2016, we opened a multi-center expanded access protocol, or EAP, trial of EBV-CTL at several transplant centers. The EAP is intended to provide access to patients with EBV-PTLD in advance of opening our Phase 3 trials, and ensure continued availability of EBV-CTL to patients who do not qualify for enrollment into the Phase 3 clinical trials.

In February 2015, the FDA granted breakthrough therapy designation for EBV-CTL in the treatment of rituximab-refractory EBV-PTLD after HCT. Breakthrough therapy designation is an FDA process designed to accelerate the development and review of drugs intended to treat a serious condition when early trials show that the drug may be substantially better than current treatment. In February 2016, the FDA granted orphan drug designation for EBV-CTL for the treatment of patients with EBV-PTLD after HCT or SOT, and in March 2016, the European Medicines Agency, or EMA, granted orphan drug designation for EBV-CTL for the treatment of patients with EBV-PTLD.

EBV-CTL was accepted into the EMA's Adaptive Licensing Program and in June 2016, the EMA classified our EBV-CTL product candidate as an Advanced Therapy Medicinal Product, or ATMP. ATMP classification was established to regulate cell and gene therapy, support development of these products and provide a benchmark for the level of quality compliance for pharmaceutical practices. It can also provide developers with scientific regulatory guidance, help clarify the applicable regulatory framework and development path, provide access to all relevant services and incentives offered by the EMA and can also be advantageous when submitting clinical trial dossiers to national EU regulatory authorities.

In October 2016, the EMA granted access to its newly established Priorities Medicines, or PRIME, regulatory initiative for EBV-CTL in the treatment of patients with rituximab refractory EBV-PTLD after HCT. Access to the PRIME initiative is granted by the EMA to support the development and accelerate the review of new therapies to treat patients with unmet medical need. The criteria for the PRIME initiative require early clinical evidence that the therapy offers a therapeutic advantage over existing treatments or benefits patients with limited treatment options. This designation provides appointment of a rapporteur, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process. For EBV-CTL in the treatment of rituximab-refractory EBV-PTLD after HCT, we are scheduled to have a Scientific Advice meeting with the EMA and health technology assessment groups in the fourth quarter of this year.

We are also developing EBV-CTLs in other indications such as nasopharyngeal carcinoma, or NPC. Our collaborating investigators at MSK presented clinical results on the use of EBV-CTLs in patients with stage 4 recurrent NPC at the June 2016 American Society of Clinical Oncology, or ASCO, Annual Meeting. We expect to initiate a Phase 2 clinical trial evaluating EBV-CTLs in combination with another anti-cancer therapy for the treatment of NPC in 2017.

Our second T-cell product candidate, CMV-CTL, is in Phase 2 clinical trials for cytomegalovirus, or CMV, an infection that occurs in some patients who have received an HCT or SOT or are otherwise immunocompromised. In the first quarter of 2016, we transferred the investigational new drug application, or IND, from MSK to us. We recently met with the FDA for an end of Phase 2 meeting to discuss late stage development of allogeneic CMV-CTLs for the treatment of anti-viral refractory or resistant CMV infection following either HCT or SOT. We expect to initiate a Phase 3 trial in 2017, once we have completed discussions with the FDA on trial designs. In October 2016, the EMA granted orphan drug designation for CMV-CTL for the treatment of CMV infection in patients with impaired cell-mediated immunity.

Our third T-cell product candidate, WT1-CTL, targets cancers expressing the antigen Wilms Tumor 1, or WT1, and is currently in Phase 1 clinical trials. At the 2015 American Society of Hematology, or ASH, Annual Meeting, MSK presented results from this Phase 1 clinical trial of primary donor-derived WT1-CTLs. Based on data from these trials, we expect to explore the clinical utility of WT1-CTL in these hematologic malignancies, including plasma cell leukemia, or PCL.

In October 2015, we entered into exclusive license and research and development agreements with Queensland Institute of Medical Research, or QIMR Berghofer. In September 2016, both agreements were amended and restated. These agreements, as amended, enable us to access a technology that we believe is complementary to that which was licensed from MSK and to pursue development of CTLs for other EBV-related diseases such as gastric cancer and multiple sclerosis, or MS, as well as other CTL therapies targeting human papilloma virus, or HPV, and the BK virus. We are working with QIMR Berghofer to initiate clinical trials utilizing allogeneic CTLs in these new indications.

While we evaluate the path to registration for both EBV-CTL and CMV-CTL, we intend to concurrently explore the clinical utility of these T-cell product candidates or other cellular therapies in other relevant disease states to expand their potential applicability. In addition, we believe that T-cells are versatile and can be directed at a broad range of other targets to create future product candidates. To date, we have demonstrated clinical proof of concept across both viral and non-viral targets in conditions ranging from liquid and solid tumors to infections and immune-mediated disease, one in which the body's immune system attacks an organ system.

Our molecularly targeted product candidates are biologics that inhibit myostatin and activin, members of the Transforming Growth Factor-Beta, or TGF- $\beta$ , protein superfamily, which play roles in the growth and maintenance of muscle and many other body tissues. Our lead molecularly targeted product candidate is STM 434, which has received orphan drug designation from the FDA for ovarian cancer. We commenced a Phase 1 clinical trial of STM 434 for ovarian cancer and other solid tumors in 2014. The dose escalation stage of our Phase 1 trial for STM 434 is expected to complete by the end of this year.

We do not yet manufacture any of our product candidates. We currently outsource the manufacturing of drug substance and drug product for our preclinical studies and clinical trials to contract manufacturing organizations, each a CMO. We also outsource fill-finish, packaging, labeling, storage, shipping and distribution. This approach has allowed us to rapidly conduct manufacturing activities for multiple programs in parallel. We select CMOs to manufacture our product candidates based on the particular technical needs of the product candidate. In addition, we aim to work with CMOs that possess the requisite scale, expertise and experience to support clinical as well as commercial product manufacturing, which may mitigate the need for costly and time-consuming process transfers later in development. We recently received feedback from the FDA regarding our comparability protocol designed to compare EBV-CTL material manufactured by our CMO with material previously produced at MSK and have commenced production of full scale EBV-CTL lots for the EAP and the Phase 3 trials. We intend to build our own cellular manufacturing facility.

We have a limited operating history. Since our inception in 2012, we have devoted substantially all of our resources to identify, acquire and develop our product candidates, including conducting preclinical studies and clinical trials and providing general and administrative support for these operations.

We have never generated revenues and have incurred losses since inception. Our net loss was \$60.8 million for the nine months ended September 30, 2016, and as of September 30, 2016, we had an accumulated deficit of \$158.9 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative expenses associated with our operations. As of September 30, 2016, our cash, cash equivalents and short-term investments totaled \$278.1 million, which we intend to use to fund our operations.



## Financial Overview

### Revenues

To date, we have not generated any revenues. We do not expect to receive any revenues from any product candidates that we develop until we obtain regulatory approval and commercialize our products or enter into collaborative agreements with third parties.

### Research and Development Expenses

The largest component of our total operating expenses since inception has been our investment in research and development activities, including the preclinical and clinical development of our product candidates. Research and development expenses consist primarily of compensation and benefits for research and development employees, including stock-based compensation; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the costs of acquiring and manufacturing clinical trial materials and other supplies; payments under licensing and research and development agreements; other outside services and consulting costs; and an allocation of facilities and overhead expenses. Research and development costs are expensed as incurred.

We plan to increase our research and development expenses as we continue the development of our product candidates. Our current planned research and development activities include the following:

- advancing EBV-CTLs into Phase 3 clinical trials for the treatment of EBV-PTLD after HCT and SOT;
- developing CMV-CTL in antiviral refractory CMV infection after HCT;
- continuing development of WT1-CTL in relapsed refractory multiple myeloma, including plasma cell leukemia;
- collaborating with MSK and QIMR Berghofer in the discovery and development of additional T-cell programs;
- expanding our licensed T-cell platforms into other indications, including NPC and MS or additional viral targets;
- completing our Phase 1 clinical trial of STM 434;
- process development and manufacturing of drug supply to support clinical trials and IND-enabling studies;
- evaluating our other molecularly targeted product candidates and advancing them into the clinic as appropriate; and
- leveraging our relationships and experience to in-license or acquire additional product candidates or technologies.

In addition, we believe it is important to invest in the development of new product candidates to continue to build the value of our product candidate pipeline and our business. We plan to continue to advance our most promising early product candidates into preclinical development with the objective to advance these early-stage programs to human clinical trials over the next several years.

Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, and expenses of our ongoing as well as any additional clinical trials and other research and development activities;
- future clinical trial results;
- uncertainties in clinical trial enrollment rates or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- significant and changing government regulation; and
- the timing and receipt of any regulatory approvals.

The process of conducting the necessary clinical research to obtain FDA approval is costly and time consuming and the successful development of our product candidates is highly uncertain. The risks and uncertainties associated with our research and development projects are discussed more fully in the section of this report titled "1A. Risk Factors." As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and costs to complete our research and development projects, or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

## General and Administrative Expenses

General and administrative expenses consist primarily of compensation and benefits for general and administrative employees, including stock-based compensation; outside professional service costs, including legal, patent, human resources, audit and accounting services; and allocated facilities costs. We anticipate that our general and administrative expenses will continue to increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates.

## Interest and Other Income, net

Interest and other income, net consists primarily of interest earned on our cash, cash equivalents and short-term investments.

## Critical Accounting Policies and Significant Judgments and Estimates

There have been no significant changes during the nine months ended September 30, 2016 to our critical accounting policies and significant judgments and estimates as disclosed in our management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2015.

## Emerging Growth Company Status

We are an "emerging growth company" as defined in the JOBS Act, and therefore we may take advantage of certain exemptions from various public company reporting requirements. As an "emerging growth company",

- we will avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- we will provide less extensive disclosure about our executive compensation arrangements; and
- we will not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

However, we are choosing to irrevocably opt out of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards. We will remain an "emerging growth company" for up to five years from the date of our initial public offering, although we will cease to be an "emerging growth company" upon the earliest of: (1) December 31, 2019; (2) the last day of the first fiscal year in which our annual gross revenues are \$1 billion or more; (3) the date on which we have, during the previous rolling three-year period, issued more than \$1 billion in non-convertible debt securities; and (4) the date on which we are deemed to be a "large accelerated filer" as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act").

## Results of Operations

### Comparison of the Three and Nine Months Ended September 30, 2016 and 2015

#### Research and development expenses

Research and development expenses consisted of the following costs, by program:

	<u>Three months ended September 30,</u>		<u>Increase</u> <u>(Decrease)</u>	<u>Nine months ended September 30,</u>		<u>Increase</u> <u>(Decrease)</u>
	<u>2016</u>	<u>2015</u>		<u>2016</u>	<u>2015</u>	
	<u>(in thousands)</u>			<u>(in thousands)</u>		
EBV-CTL	\$ 2,500	\$ 194	\$ 2,306	\$ 5,852	\$ 256	\$ 5,596
CMV-CTL	1,772	30	1,742	2,146	30	2,116
Other T-cell program expenses	7,058	200	6,858	14,558	4,846	9,712
STM 434 and other molecular programs	(118)	4,471	(4,589)	803	11,477	(10,674)
Employee and overhead costs	7,590	3,218	4,372	19,681	8,778	10,903
Total research and development	<u>\$ 18,802</u>	<u>\$ 8,113</u>	<u>\$ 10,689</u>	<u>\$ 43,040</u>	<u>\$ 25,387</u>	<u>\$ 17,653</u>

EBV-CTL costs increased to \$2.5 million and \$5.9 million in the three and nine months ended September 30, 2016, as compared to \$0.2 and \$0.3 million in the comparative 2015 periods, primarily due to development work undertaken following our exercise of the option to license this program from MSK in June 2015. We anticipate that EBV-CTL costs will continue to increase in 2016 as compared to 2015 due to the preparation for and initiation of Phase 3 clinical trials for this product candidate.

CMV-CTL costs increased to \$1.8 million and \$2.1 million in the three and nine months ended September 30, 2016, primarily due to development work undertaken following our exercise of the option to license this program from MSK in June 2015.

Other T-cell program expenses were \$7.1 million and \$14.6 million in the three and nine months ended September 30, 2016, as compared to \$0.2 million and \$4.8 million in the comparative 2015 periods. The 2016 amounts primarily comprise manufacturing costs for product that can be used across all of our T-cell programs and \$3.3 million expensed for license-related and other upfront fees that were paid to QIMR Berghofer in October 2016 as a result of the expansion of our collaboration with them, including a license to additional CTL programs as well as the option to license additional technology. The amount for the nine months ended September 30, 2015 includes \$4.5 million for the exercise of our option to license T-cell therapies from MSK. We anticipate that our T-cell program expenses will continue to increase in 2016 as compared to 2015.

STM 434 and other molecular program expenses, which include costs related to PINTA 745 and ATA 842, were \$(0.1) million and \$0.8 million in the three and nine months ended September 30, 2016, as compared to \$4.5 million and \$11.5 million in the comparative 2015 periods. The decreases in each comparative period were primarily due to reduced spending on PINTA 745 and ATA 842 following the suspension of clinical development in December 2015. The negative expense in the three months ended September 30, 2016 was due to a reversal of accruals for closeout of activities for which final invoices were less than amounts accrued. We anticipate that costs related to STM 434 and other molecular program expenses will continue to decrease in 2016 as compared to 2015 following the return of rights related to the PINTA 745 and ATA 842 programs to Amgen in June 2016.

Employee and overhead costs increased to \$7.6 million and \$19.7 million in the three and nine months ended September 30, 2016, as compared to \$3.2 million and \$8.8 million in the comparative 2015 periods. The increase between the three-month periods was primarily due to a \$1.3 million increase in payroll costs and a \$1.7 million increase in stock-based compensation expense as a result of increased headcount in support of our continuing expansion of research and development activities and, to a lesser extent, higher consulting and outside services costs. The increase between the nine-month periods was primarily due to a \$4.6 million increase in payroll costs and a \$3.8 million increase in stock-based compensation expense, also as a result of increased headcount, and to a lesser extent, higher consulting and outside services costs. We anticipate that employee and overhead costs will continue to increase in future periods as we continue to expand our research and development activities.

#### *General and administrative expenses*

	<u>Three months ended September 30,</u>		<u>Increase (Decrease)</u>	<u>Nine months ended September 30,</u>		<u>Increase (Decrease)</u>
	<u>2016</u>	<u>2015</u>		<u>2016</u>	<u>2015</u>	
	(in thousands)			(in thousands)		
General and administrative	\$ 7,140	\$ 4,146	\$ 2,994	\$ 19,448	\$ 11,291	\$ 8,157

General and administrative expenses increased to \$7.1 million and \$19.4 million in the three and nine months ended September 30, 2016, as compared to \$4.1 million and \$11.3 million in the comparative 2015 periods. The increase between the three-month periods was primarily due to a \$1.4 million increase in stock-based compensation expense driven by new award grants and a \$0.9 million increase in payroll and related costs driven by increased headcount, and, to a lesser extent; higher consulting and outside services costs. The increase between the nine-month periods was primarily due to a \$4.0 million increase in stock-based compensation expense and a \$2.7 million increase in payroll and related costs driven by increased headcount and, to a lesser extent higher consulting and outside services costs. We expect that general and administrative costs will continue to increase in 2016 as we continue to expand our operations.

#### *Income taxes*

As of September 30, 2016, we had unrecognized tax benefits under ASC 740 *Income Taxes*, of approximately \$4.6 million. As of this date, the total amount of unrecognized tax benefits that would affect our effective tax rate, if recognized, was \$0.1 million. We currently have a full valuation allowance against our U.S. net deferred tax asset, which would impact the timing of the effective tax rate benefit should any uncertain tax position be favorably settled in the future.

During July 2016, we licensed certain intellectual property rights to a wholly-owned subsidiary outside the United States. Although the license of intellectual property rights between consolidated entities did not result in any gain in the consolidated statements of operations and comprehensive loss, the transaction generated a taxable gain in the U.S. However, as this gain is offset by current and existing tax losses, there was no cash tax impact from the transaction in the periods presented. As a result of the transaction, there was an increase of \$0.3 million in unrecognized tax benefits during the three months ended September 30, 2016. We expect to record an uncertain tax benefit of \$1.1 million during the next 12 months. Our policy is to account for interest and penalties related to uncertain tax positions as a component of the income tax provision. The amount of accrued interest and penalties as of September 30, 2016 was immaterial.

## Liquidity and Capital Resources

### Sources of Liquidity

Since our inception in 2012, we have funded our operations primarily through the issuance of common and preferred stock.

We have incurred losses and negative cash flows from operations in each year since inception. As of September 30, 2016, we had an accumulated deficit of \$158.9 million. It will be several years, if ever, before we have a product candidate ready for commercialization, and we anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Cash in excess of immediate requirements is invested in accordance with our written investment policy, primarily with a view to liquidity and capital preservation. Currently, our cash, cash equivalents and short-term investments are held in bank and custodial accounts and consist of money market funds, U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities. Management expects that existing cash and cash equivalents as of September 30, 2016 will be sufficient to fund our planned operations through 2018.

Our cash, cash equivalents and short-term investments balances as of the dates indicated were as follows:

	September 30, 2016	December 31, 2015
	(in thousands)	
Cash and cash equivalents	\$ 46,013	\$ 23,746
Short-term investments	232,134	296,736
Total cash, cash equivalents and short-term investments	<u>\$ 278,147</u>	<u>\$ 320,482</u>

### Cash Flows

#### Comparison of the Nine Months Ended September 30, 2016 and 2015

The following table details the primary sources and uses of cash for each of the periods set forth below:

	Nine months ended September 30,	
	2016	2015
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (38,861)	\$ (25,764)
Investing activities	60,953	(200,708)
Financing activities	175	259,041
Net increase in cash and cash equivalents	<u>\$ 22,267</u>	<u>\$ 32,569</u>

#### Operating activities

Net cash used in operating activities was \$38.9 million in the 2016 period as compared to \$25.8 million in the 2015 period. The increase of \$13.1 million was primarily due to a \$24.8 million increase in net loss, partially offset by a \$7.8 million increase in stock-based compensation, a \$2.6 million increase in operating assets and liabilities, and a \$1.1 million increase in the amortization of investment premiums and discounts.

### *Investing activities*

Net cash provided by investing activities in the 2016 period consisted primarily of \$127.7 million from maturities and \$187.5 million of sales of available-for-sale securities partially offset by \$252.3 million used to purchase available-for-sale securities and \$2.0 million in purchases of property and equipment. Net cash used in investing activities during the 2015 period consisted primarily of \$285.4 million used to purchase available-for-sale securities, partially offset by \$50.4 million received from maturities and \$34.3 million from sales of available-for-sale securities.

### *Financing activities*

Net cash used in financing activities in the 2016 period was \$0.2 million. Net cash provided by financing activities in the 2015 period was \$259.0 million, consisting of \$263.4 million net proceeds from the sale of common stock, partially offset by \$4.6 million used to pay taxes related to the net share settlement of restricted stock units.

## **Operating Capital Requirements and Plan of Operations**

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of and seek regulatory approvals for our product candidates, and begin to commercialize any approved products. We are subject to all of the risks inherent in the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need to raise substantial additional funding in connection with our continuing operations.

We expect that our existing cash, cash equivalents and short-term investments will be sufficient to fund our planned operations through 2018. In order to complete the process of obtaining regulatory approval for our lead product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidates, if approved, we will require substantial additional funding.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and costs of our planned clinical trials and preclinical studies for our product candidates;
- our success in establishing and scaling commercial manufacturing capabilities;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- subject to receipt of regulatory approval, revenues received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights;
- the extent to which we in-license or acquire other products and technologies; and
- the timing of capital expenditures.

## **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.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

During the nine months ended September 30, 2016, there were no material changes to our interest rate risk disclosures, market risk disclosures and foreign currency exchange rate risk disclosures reported in our Annual Report on Form 10-K for the year ended December 31, 2015.

### **Item 4. Controls and Procedures**

#### ***Evaluation of Disclosure Controls and Procedures***

Under the supervision of our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) of the Exchange Act as of September 30, 2016. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2016 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

#### ***Inherent Limitations on Controls and Procedures***

Our management, including our Chief Executive Officer and our Chief Financial Officer and Principal Accounting Officer, does not expect that our disclosure controls and procedures and our internal controls will prevent all error and all fraud. A control system, no matter how well designed and operated, can only provide reasonable assurances that the objectives of the control system are met. The design of a control system reflects resource constraints; the benefits of controls must be considered relative to their costs. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been or will be detected. As these inherent limitations are known features of the financial reporting process, it is possible to design into the process safeguards to reduce, though not eliminate, these risks. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns occur because of simple error or mistake. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events. While our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, there can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. While our Chief Executive and Financial Officer and Principal Accounting Officer have concluded that, as of September 30, 2016, the design of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, was effective, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

#### ***Changes in Internal Control over Financial Reporting***

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended September 30, 2016 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

None.

### Item 1A. Risk Factors

*Investing in our common stock involves a high degree of risk. You should carefully consider all of the risk factors and uncertainties described below, in addition to the other information contained in this Quarterly Report on Form 10-Q, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited condensed consolidated financial statements and related notes, before investing in our common stock. If any of the following risks materialize, our business, financial condition and results of operations could be seriously harmed. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment. We have marked with an asterisk (\*) those risk factors that reflect substantive changes from the risk factors included in our previously filed Annual Report on Form 10-K for the year ended December 31, 2015.*

#### **Risks Related to Our Financial Results and Capital Needs**

***We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.\****

We are a clinical-stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from product sales to date, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. For the three months ended September 30, 2016, we reported a net loss of \$25.4 million and we had an accumulated deficit of \$158.9 million as of September 30, 2016.

We do not expect to generate revenues for many years, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for our product candidates and any additional product candidates we may acquire, and potentially begin to commercialize product candidates that may achieve regulatory approval. 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 revenues. If any of our product candidates fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We anticipate that our expenses will increase in the future as we continue to invest in research and development of our existing product candidates, investigate and potentially acquire new product candidates and expand our manufacturing and commercialization activities.

***We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.\****

Our company was formed in August 2012. Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights and conducting product development activities for our product candidates. We have not yet demonstrated our ability to successfully complete any Phase 2 or Phase 3 clinical trials, obtain regulatory approval, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization for any of our product candidates. In addition, the adoptive immunotherapy technology underlying our T-cell product candidates, EBV-CTL, CMV-CTL and WT1-CTL, is new and largely unproven. Any predictions about our future success, performance or viability, particularly in view of the rapidly evolving cancer immunotherapy field, may not be as accurate as they could be if we had a longer operating history or approved products on the market.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

***We currently have no source of revenues. We may never generate revenues or achieve profitability.***

To date, we have not generated any revenues from product sales or otherwise. Even if we are able to successfully achieve regulatory approval for our product candidates, we do not know when we will generate revenues or become profitable, if at all. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to successfully commercialize products, including any of our current product candidates, and other product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenues and achieve profitability also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical trials;
- complete and submit BLAs to the FDA and obtain U.S. regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities in Europe, Asia and other jurisdictions;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;
- set commercially viable prices for our products, if any;
- establish and maintain supply and manufacturing relationships with reliable third parties and ensure adequate, legally globally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop manufacturing and distribution processes for our novel T-cell product candidates;
- obtain commercial quantities of our products at acceptable cost levels;
- achieve market acceptance of our products, if any;
- attract, hire and retain qualified personnel;
- protect our rights in our intellectual property portfolio;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves in the markets in which we choose to commercialize on our own; and
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets.

Our revenues for any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenues from sales of such products, even if approved. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidate. As a result, even if we generate revenues, we may not become profitable and may need to obtain additional funding to continue operations. 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 may be forced to reduce our operations.

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

We expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of EBV-CTL, CMV-CTL, WT1-CTL, STM 434 and the advancement and expansion of our preclinical research pipeline. We also expect to expend resources for the development and manufacturing of product candidates and the technology we recently licensed from QIMR Berghofer. These expenditures will include costs associated with research and development, potentially acquiring new product candidates or technologies, conducting preclinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. Under the terms of our license agreements with Amgen and MSK, we are obligated to make payments upon the achievement of certain development, regulatory and commercial milestones. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.



Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful;
- the cost of commercialization activities for our product candidates, if any of these product candidates is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs to in-license future product candidates or technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing technologies or other adverse market developments.

We believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our planned operations through 2018. As of September 30, 2016, we had total cash, cash equivalents and short-term investments of \$278.1 million. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We do not have any committed external source of funds. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

***Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.\****

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings. 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. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends. If we raise additional funds from third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidates, or grant to others the rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

Our ability to use federal and state net operating loss, or NOL, carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all or a portion of our NOL carryforwards. As of December 31, 2015, we had federal and state NOL carryforwards for tax return purposes of \$68.8 million and \$68.7 million, respectively, which, if not utilized, begin to expire in various amounts beginning in the year 2032. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if over a rolling three-year period, the cumulative change in our ownership exceeds 50% (as determined under applicable Treasury regulations), our ability to utilize our U.S. NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset future taxable income or taxes may be limited. We completed a Section 382 study of transactions in our stock through December 31, 2015 and concluded that we have experienced at least one ownership change since inception and our utilization of NOL carryforwards will therefore be subject to annual limitation. Our ability to utilize our NOL carryforwards may be further limited as a result of subsequent ownership changes. Similar rules may apply under state tax laws. Further, other provisions of the Code may limit our ability to utilize NOLs incurred before our recapitalization to offset income or gain realized after the recapitalization, unless such income or gain is realized by the same entity that originally incurred such NOLs. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited. Such limitations could result in the expiration of our NOL carryforwards before they can be utilized and, if we are profitable, our future cash flows could be adversely affected due to our increased tax liability.

**Risks Related to the Development of Our Product Candidates**

***We are very early in our development efforts and have only four product candidates in clinical development. All of our other product candidates are still in preclinical development. If we or our collaborators are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be materially harmed.\****

We are very early in our development efforts. We have four product candidates, EBV-CTL, CMV-CTL, WT1-CTL and STM 434, in clinical development. All of our other product candidates are currently in preclinical development. We have invested substantially all of our efforts and financial resources in identifying and developing potential product candidates and conducting preclinical studies, clinical trials and manufacturing activities. Our ability to generate revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- completion of preclinical studies and clinical trials with positive results;
- receipt of regulatory approvals from applicable authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing or making arrangements with third-party manufacturers for commercial manufacturing capabilities;
- develop manufacturing and distribution processes for our novel T-cell product candidates;
- manufacturing our product candidates at an acceptable cost;
- launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others;
- acceptance of the product candidates, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidates;
- protecting our rights in our intellectual property portfolio;
- maintaining a continued acceptable safety profile of the products following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our products and technology.

For example, in December 2015, we announced that our Phase 2 proof-of-concept trial of PINTA 745 did not meet its primary endpoint, and we suspended further development of PINTA 745 and ATA 842, a compound that is related to PINTA 745. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which could materially harm our business.

***Our future success is dependent on the regulatory approval of our product candidates.***

We do not have any products that have gained regulatory approval. Currently, our only clinical-stage product candidates are EBV-CTL, CMV-CTL, which are in Phase 2 clinical trials, and WT1-CTL and STM 434, which are in Phase 1 clinical trials. Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our product candidates in a timely manner. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, generally including two well-controlled Phase 3 trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn.

***Our T-cell product candidates, EBV-CTL, CMV-CTL and WT1-CTL, represent new therapeutic approaches that present significant challenges.\****

Our future success is dependent in part on the successful development of T-cell immunotherapies in general and our EBV-CTL, CMV-CTL and WT1-CTL product candidates in particular. Because these programs represent a new approach to immunotherapy for the treatment of cancer and other diseases, developing and commercializing our product candidates subject us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities, which have very limited experience with the development and commercialization of T-cell therapies;
- developing and deploying consistent and reliable processes for procuring blood from consenting third-party donors, isolating T-cells from the blood of such donors, activating the isolated T-cells against a specific antigen, characterizing and storing the resulting activated T-cells for future therapeutic use, selecting and delivering an appropriate partially HLA matched cell line from among the available T-cell lines, and finally infusing these activated T-cells into patients;
- utilizing these product candidates in combination with other therapies, which may increase the risk of adverse side effects;
- educating medical personnel regarding the potential side effect profile of each of our product candidates;
- developing processes for the safe administration of these products, including long-term follow-up for all patients who receive these product candidates;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process these product candidates;
- developing a manufacturing process and distribution network that can provide a stable supply with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities; and
- developing therapies for types of diseases beyond those initially addressed by our current product candidates.

We cannot be sure that the manufacturing processes used in connection with our T-cell product candidates, EBV-CTL, CMV-CTL and WT1-CTL, will yield satisfactory products that are safe and effective, comparable to those T-cells produced by MSK historically, scalable or profitable.

Moreover, public perception of safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to the novel treatment mechanics. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt this novel therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

***The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our existing product candidates in clinical trials, and any other product candidate we advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.\****

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials. For example, in December 2015, we announced that our Phase 2 proof-of-concept trial of PINTA 745 did not meet its primary endpoint even though earlier clinical trials and preclinical studies had indicated that it might be effective to treat protein energy wasting in patients with end stage renal disease. Despite the results reported in earlier preclinical studies or clinical trials for our product candidates, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market EBV-CTL, CMV-CTL, WT1-CTL, STM 434 or any of our other product candidates in any particular jurisdiction. For example, our EBV-CTL, CMV-CTL and WT1-CTL product candidates have only been evaluated in single-center trials under investigator-sponsored INDs held by MSK, utilizing a different response criteria and endpoints from those we may utilize in later clinical trials. The findings may not be reproducible in multi-center trials we conduct. In addition, the Phase 2 clinical trials with EBV-CTL enrolled a heterogeneous group of patients with a variety of EBV-associated malignancies, including but not limited to EBV-PTLD after HCT and EBV-PTLD after SOT. These Phase 2 trials were not prospectively designed to evaluate the efficacy of EBV-CTL in the treatment of a single disease state for which we may later seek approval. Efficacy data from prospectively designed trials may differ significantly from those obtained from retrospective subgroup analyses. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome.\****

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. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and clinical trials.

We may experience delays in our ongoing or future clinical trials and we do not know whether planned clinical trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. There can be no assurance that the FDA will not put clinical trials of any of our product candidates on clinical hold in the future. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a trial;
- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations, or 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;
- delay or failure in obtaining institutional review board, or IRB, approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in subjects completing a trial or returning for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party clinical trial managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- delay or failure in adding new trial sites;

- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- feedback from the FDA, the IRB, data safety monitoring boards or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a trial;
- a decision by the FDA, the IRB, a comparable foreign regulatory authority, or us, or a recommendation by a data safety monitoring board or comparable foreign regulatory authority, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a product candidate;
- difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate to start or to use in clinical trials;
- lack of adequate funding to continue a trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or
- changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the severity of the disease under investigation, the proximity of subjects to clinical sites, the patient referral practices of physicians, the eligibility criteria for the trial, the design of the clinical trial, ability to obtain and maintain patient consents, risk that enrolled subjects will drop out or die before completion, competition for patients from other clinical trials, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. We may not be able to initiate or continue to support clinical trials of EBV-CTL, CMV-CTL, WT1-CTL, STM 434 or any future product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete. We rely on CROs, other vendors and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the approval and commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any delays in completing our clinical trials for our product candidates may also decrease the period of commercial exclusivity. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***Our product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.***

Undesirable side effects caused by our product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. For example, hypoxia has been observed in some patients receiving CMV-CTLs for the treatment of their CMV pneumonitis. As a result of safety or toxicity issues that we may experience in our clinical trials, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including that:

- we may be forced to suspend marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- we may be required to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

***We may not be able to obtain orphan drug exclusivity for our product candidates.\****

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. The FDA has granted us orphan drug status for STM 434 for ovarian cancer and both the FDA and the EMA have granted us orphan status for EBV-CTL for EBV-PTLD after HCT or SOT. Recently, the EMA also granted us orphan status for CMV-CTL for CMV infection in patients with impaired cell-mediated immunity.

Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a new drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

***Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.***

In addition to regulations in the United States, to market and sell our products in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the United States require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in the European Union, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished, our business prospects could decline and this could materially adversely affect our business, results of operations and financial condition.

***Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.\****

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by our contract manufacturing organizations, or CMOs, and CROs for any post-approval clinical trials that we conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, current Good Clinical Practices, or GCP, current good tissue practices, or cGTP, and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our products and generate revenues.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of the Department of Health and Human Services, or HHS, state attorneys general, members of Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA. Any actual or alleged failure to comply with labeling and promotion requirements may have a negative impact on our business.

***Regulations, guidelines and recommendations published by various government agencies and organizations may affect the use of our product candidates.***

Although treatment with EBV-CTL is recognized as a recommended treatment for persistent or progressive EBV-PTLD as set forth in the 2015 National Comprehensive Cancer Network Guidelines, future guidelines from governmental agencies, professional societies, practice management groups, private health/science foundations and organizations involved in various diseases may relate to such matters as product usage, dosage, and route of administration and use of related or competing therapies. Changes to these recommendations or other guidelines advocating alternative therapies could result in decreased use of our product candidates, which may adversely affect our results of operations.



***We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.\****

Concurrent with the license of our existing product candidates, we acquired manufacturing process know-how and certain intermediates, as well as certain supplies intended for clinical use, from Amgen and MSK. To facilitate the manufacture of additional drug substance and drug product for our preclinical studies and clinical trials using this manufacturing process know-how, we undertook the process of transferring this know-how to our CMOs. We have completed the transfer of this know-how received from MSK to our CMO and are still in the process of transferring this know-how from Amgen to our CMO. Transferring manufacturing processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We and our CMOs will need to conduct significant development work to transfer these processes and manufacture each of our product candidates for studies, trials and commercial launch readiness. We cannot be certain that all relevant know-how has been adequately incorporated into the manufacturing process until the completion of studies intended to demonstrate the comparability of material previously produced by Amgen or MSK with that generated by our CMO. The inability to manufacture comparable drug substance at our CMOs could delay the continued development of our product candidates.

The processes by which our product candidates are manufactured were initially developed by Amgen and MSK for clinical purposes. We intend to evolve these existing processes for more advanced clinical trials or commercialization. Developing commercially viable manufacturing processes is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including cost overruns, potential problems with process scale-up, process reproducibility, stability issues, consistency and timely availability of reagents or raw materials. The manufacturing facilities in which our product candidates will be made could be adversely affected by earthquakes and other natural disasters, equipment failures, labor shortages, power failures, and numerous other factors.

Additionally, the process of manufacturing biologics and cellular therapies is complex, highly regulated and subject to several risks, including but not limited to:

- the process of manufacturing biologics and cellular therapies is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing and distribution processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. Product defects can also occur unexpectedly. For example, in April 2014, we encountered a small number of cracked vials in certain STM 434 drug product lots. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to allow us to investigate and remedy the contamination; and
- because EBV-CTL, CMV-CTL and WT1-CTL are manufactured from the blood of third-party donors, the process of developing products that can be commercialized may be particularly challenging, even if they otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination in the donor material or ingress of microbiological material at any point in the process may result in contaminated or unusable product. Such contaminations could result in delays in the manufacture of products which could result in delays in the development of our product candidates. Furthermore, the product ultimately consists of many individual cell lines, each with a different HLA profile. As a result, the selection and distribution of the appropriate cell line for therapeutic use in a patient will require close coordination between clinical and manufacturing personnel.

Any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our drug substance and drug product which could delay the development of our product candidates. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for our products, if approved, could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community, and cancer treatment centers, which could adversely affect our ability to operate our business and our results of operations.

***We may not successfully identify, acquire, develop or commercialize new potential product candidates.***

Part of our business strategy is to expand our product candidate pipeline by identifying and validating new product candidates, which we may develop ourselves, in-license or otherwise acquire from others. In addition, in the event that our existing product candidates do not receive regulatory approval or are not successfully commercialized, then the success of our business will depend on our ability to expand our product pipeline through in-licensing or other acquisitions. We may be unable to identify relevant product candidates. If we do identify such product candidates, we may be unable to reach acceptable terms with any third party from which we desire to in-license or acquire them.

***We may not realize the benefits of strategic alliances that we may form in the future.***

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. If we license products or acquire businesses, 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. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic alliances agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

**Risks Related to Our Dependence on Third Parties**

***We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if we lose any of our CROs, we may not be able to obtain regulatory approval for or commercialize our product candidates on a timely basis, if at all.***

We have relied upon and plan to continue to rely upon third-party CROs and contractors to monitor and manage data for our ongoing preclinical and clinical programs. For example, our collaborating investigators at MSK manage the conduct of the ongoing clinical trials for WT1-CTL as well as perform the analysis, publication and presentation of data and results related to this program and the EBV-CTL and CMV-CTL programs. We are also relying on CROs to perform similar services for our ongoing clinical trial of STM 434. We have also relied on studies previously conducted by Amgen and MSK. We are utilizing a CRO for our EAP trial of EBV-CTL and intend to utilize a CRO for our planned trials for EBV-PTLD after HCT and SOT. We rely on these parties for the execution of our preclinical studies and clinical trials, and we control only some aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices, or GLP, and the Animal Welfare Act requirements. We and our CROs are required to comply with federal regulations, GCP, which are international standards meant to protect the rights and health of patients that are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our products in clinical development, and cGTP, which are standards designed to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable diseases. Regulatory authorities enforce GCP and cGTP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP or cGTP, 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 regulatory applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP or cGTP requirements. In addition, our clinical trials must be conducted with product produced under cGMP and cGTP requirements. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, [clinicaltrials.gov](http://clinicaltrials.gov), within a specified timeframe. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process and result in adverse publicity.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources, including experienced staff, to our ongoing clinical, nonclinical and preclinical programs. They may also have relationships with other entities, some of which may be our competitors. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CRO or contractor errors could cause our results of operations and the commercial prospects for our product candidates to be harmed, our costs to increase and our ability to generate revenues to be delayed.

Our internal capacity for clinical trial execution and management is limited and therefore we have relied on third parties. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results or data in a timely manner or may fail to perform at all. For example, in July 2014, we became aware of a draft report for a preclinical study conducted with STM 217, a compound similar to STM 434 that we also licensed from Amgen. Results from this study led to the amendment of our planned clinical trial for STM 434. Other data from studies or trials previously conducted by Amgen or MSK may emerge in the future. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so timely or on commercially reasonable terms.

***We have no experience manufacturing our product candidates on a clinical or commercial scale and have no manufacturing facility. We are dependent on third parties for the manufacturing of our product candidates and our supply chain, and if we experience problems with any of these third parties, the manufacturing of our product candidates could be delayed.\****

We do not own or operate facilities for the manufacturing of our product candidates and currently we have no commitments to build our own clinical or commercial scale manufacturing capabilities. We currently rely on single source CMOs for the production of the product candidates we have licensed from Amgen and on single source suppliers of some of the materials incorporated in these product candidates. In the case of EBV-CTL, CMV-CTL and WT1-CTL, we currently rely on MSK for the production of these product candidates and acquisition of the materials incorporated in or used in the manufacturing or testing of these product candidates. To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing of STM 434, the CMOs with whom we currently work will need to increase the scale of production and demonstrate comparability of the material produced by these CMOs to the material that was previously produced by Amgen. To meet our projected needs for clinical and commercial materials to support our activities through regulatory approval and commercial manufacturing of EBV-CTL, CMV-CTL and WT1-CTL, we will need to transition the manufacturing of such materials to a CMO and/or our own facility, and such CMOs or we will need develop relationships with suppliers of critical starting or other materials, increase the scale of production and demonstrate comparability of the material produced at these facilities to the material that was previously produced by MSK. We recently completed the transfer of the manufacturing process developed by and housed at MSK for EBV-CTL to our CMO. Transferring manufacturing processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We cannot be certain that all relevant know-how has been adequately incorporated into the manufacturing process until the completion of studies intended to demonstrate the comparability of material previously produced by Amgen or MSK with that generated by our CMOs. If we are not able to successfully transfer this know-how our ability to manufacture EBV-CTL, CMV-CTL and WT1-CTL may be negatively impacted. We may need to identify additional CMOs for continued production of supply for all of our product candidates. In addition, given the manufacturing process for our T-cell product candidates, the number of CMOs who possess the requisite skill and capability to manufacture our T-cell product candidates is limited. We have not yet identified alternate suppliers in the event the current CMOs that we utilize are unable to scale production, or if we otherwise experience any problems with them. We intend to build our own cellular manufacturing facility. Manufacturing biologic drugs is complicated and tightly regulated by the FDA and comparable regulatory authorities around the world, and although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers, transfer manufacturing procedures to these alternative suppliers, and demonstrate comparability of material produced by such new suppliers. New manufacturers of any product would be required to qualify under applicable regulatory requirements. These manufacturers may not be able to manufacture our compounds at costs, or in quantities, or in a timely manner necessary to complete development of our product candidates or make commercially successful products. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. In addition, should the FDA not agree with our product candidate specifications and comparability assessments for these materials, further clinical development of our product candidate could be substantially delayed and we would incur substantial additional expenses.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial resources to meet its obligations under the manufacturing agreement, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP, cGTP and similar foreign standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. Any failure by our third-party manufacturers to comply with cGMP or cGTP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate for an ongoing clinical trial could considerably delay initiation or completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates could be delayed or there could be a shortage in supply, which could impair our ability to generate revenues from the sale of our product candidates.

### **Risks Related to Our Intellectual Property**

*If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.\**

We rely upon a combination of patents, trade secrets and confidentiality agreements to protect the intellectual property related to our technology and product candidates. For our most advanced molecularly-targeted product candidate, STM 434, we own or license a number of issued patents and pending patent applications covering the product candidates' compositions of matter and methods of use. For STM 434, the expected expiration dates range from 2027 through 2036 for U.S. patents and patent applications, if issued, and from 2026 through 2036 for patents and patent applications, if issued, in jurisdictions outside the United States, exclusive of possible patent term extensions. The T-cell product candidates and platform technology we have licensed from MSK are protected primarily as confidential know-how and trade secrets. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is generally uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U.S. Patent and Trademark Office, or USPTO, and non-US patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents.

Consequently, the patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim.

Even if patents have issued or do successfully issue from patent applications, and even if such patents cover our product candidates, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. In three of our pending patent applications exclusively licensed from MSK, directed to use of CMV-CTL to treat CMV retinitis in HIV-infected patients or SOT recipients, we do not have exclusive rights, due to one of the named inventors being an employee of an entity other than MSK and ensuing co-ownership of the applications with MSK of this other entity from which we do not presently have a license. There is no guarantee that we will be able to obtain a license from this other entity on commercially reasonable terms, or at all. If this entity licenses its rights elsewhere, our competitors might gain access to this intellectual property. Also, the possibility exists that others will develop products on an independent basis which have the same effect as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could jeopardize our ability to commercialize our product candidates. In addition, 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. Any of these outcomes could have an adverse impact on our business.

If patent applications that we hold or in-license with respect to our technology or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us. We have filed a number of patent applications covering our product candidates. We cannot offer any assurances about which, if any, patents will be issued with respect to these pending patent applications, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful challenge to these patents or any other patents owned by or exclusively licensed to us could deprive us of rights necessary for the successful commercialization of any product candidate that we or our collaborators may develop. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications that have never had a claim with an effective filing date on or after March 16, 2013, an interference proceeding in the United States can be initiated by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications or patents. Similarly, we could become involved in derivation proceedings before the USPTO to determine inventorship with respect to our patent applications. We may also become involved in opposition proceedings in the European Patent Office or counterpart offices in other jurisdictions regarding our intellectual property rights. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent generally occurs 20 years after it is filed. Although various extensions may be available if certain conditions are met, the life of a patent and the protection it affords is limited. If we encounter delays in our clinical trials or in obtaining regulatory approvals, the period of time during which we could exclusively market any of our product candidates under patent protection, if approved, could be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be vulnerable to competition from biosimilar products. Any loss of patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar or identical to our product candidates, which could harm our business and ability to achieve profitability.

Furthermore, the research resulting in certain of our licensed patent rights and technology was funded by the U.S. government. As a result, the government has certain rights, such as march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to practice the invention for or on behalf of the United States. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, results of operations, financial condition and future prospects.

***If we are sued for infringing the intellectual property rights of third parties, such litigation could be costly and time-consuming and could prevent or delay our development and commercialization efforts.***

Our commercial success depends, in part, on us and our collaborators not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and *inter partes* and post-grant review proceedings before the USPTO and non-U.S. patent offices. Numerous U.S. and non-U.S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable.

Third parties may assert infringement claims against us based on existing or future intellectual property rights, alleging that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacturing of our product candidates that we failed to identify. For example, applications filed before November 29, 2000, and certain applications filed on or after that date that will not be filed outside the United States, remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. In addition, pending patent applications that have been published, including some of which we are aware, could be later amended in a manner that could cover our product candidates or their use or manufacture. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and believe that we are free to operate in relation to any of our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which may block our efforts or potentially result in any of our product candidates or our activities infringing such claims. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity in a district court proceeding requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and proving invalidity in an inter partes review proceeding in the USPTO requires a showing of a preponderance of the evidence. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted, which could have a material adverse effect on us. If any issued third-party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until such patent expired. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us. Ultimately, we could be prevented from commercializing a product candidate, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company 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 if we are found to have willfully infringed a patent, or to redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We may also elect to enter into license agreements in order to settle patent infringement claims prior to litigation, and any such license agreement may require us to pay royalties and other fees that could be significant.

We may face claims that we misappropriated the confidential information or trade secrets of a third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, which could limit our ability to develop our product candidates. We are not aware of any material threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, programs or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting, enforcing and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive. Our or our licensors' intellectual property rights in certain countries outside the United States may be less extensive than those in the United States. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in countries outside the United States, or from selling or importing infringing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or where we do not have exclusive rights under the relevant patent(s) to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection but where enforcement is not as strong as that in the United States. These infringing products may compete with our product candidates in jurisdictions where we or our licensors have no issued patents or where we do not have exclusive rights under the relevant patent(s), or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so competing. 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 and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our and our licensors' proprietary rights generally. Proceedings to enforce our and our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly, could put our and our licensors' patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and even if we or our licensors are successful the damages or other remedies awarded, if any, may not be commercially meaningful.

***We have in-licensed a significant portion of our intellectual property from Amgen and MSK. If we breach any of our license agreements with Amgen or MSK, we could lose the ability to continue the development and potential commercialization of one or more of our product candidates.\****

We hold rights under a number of license agreements with Amgen and MSK that are important to our business. Our discovery and development platform is built, in part, around patent rights exclusively in-licensed from Amgen and MSK. The Amgen agreements generally grant us an exclusive (except as to the licenses to Amgen know-how, which are non-exclusive and limited as to their field of use), worldwide license to research, develop, improve, make, use, offer for sale, sell, import, export or otherwise exploit several classes of novel compounds, including STM 434. The MSK agreement generally grants us an exclusive license to research, develop, make, use, offer for sale, sell and import, EBV-CTL, CMV-CTL and WT1-CTL. Three pending applications licensed to us by MSK that are all directed to methods of treating CMV retinitis in HIV-infected patients or SOT recipients, are co-owned by MSK and another entity, and thus our exclusive license from MSK does not convey exclusive rights under those applications. Under our existing Amgen and MSK license agreements, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales, as well as other material obligations. If there is any conflict, dispute, disagreement or issue of nonperformance between us and Amgen or MSK regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy diligence or payment obligations under any such agreement, we may be liable to pay damages and Amgen or MSK may have a right to terminate the affected license. The loss of any or all of our license agreements with Amgen or our license agreement with MSK could materially adversely affect our ability to proceed to utilize the affected intellectual property in our drug discovery and development efforts, our ability to enter into future collaboration, licensing and/or marketing agreements for one or more affected product candidates and our ability to commercialize the affected product candidates. The risks described elsewhere pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure by us or our licensors to obtain, maintain and enforce these rights could have a material adverse effect on our business.



***We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business and on our stock price.***

Third parties may infringe our patents, the patents of our licensors, or misappropriate or otherwise violate our or our licensors' intellectual property rights. Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. In the future, we or our licensors may elect to initiate legal proceedings to enforce or defend our or our licensors' intellectual property rights, to protect our or our licensors' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, third parties may initiate legal proceedings against us or our licensors to challenge the validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time-consuming. Many of our or our licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. Accordingly, despite our or our licensors' efforts, we or our licensors may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect our rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Interference or derivation proceedings provoked by third parties, brought by us or our licensors or collaborators, or brought by the USPTO or any non-US patent authority may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as reexamination or opposition proceedings, *inter partes* review or other preissuance or post-grant proceedings in the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any such proceeding could require us or our licensors to cease using the related technology and commercializing our product candidates, 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 or our licensors a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our or our licensors' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent.

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 shares of our common stock.

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' 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 future decisions by the U.S. Congress, the federal courts and/or the USPTO, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to US patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could have a material adverse effect on our business and financial condition.

***If we are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our technology could be materially adversely affected and our business could be harmed.***

In addition to seeking the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and other elements of our technology, discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. The T-cell product candidates and platform technology we have licensed from MSK are protected primarily as confidential know-how and trade secrets. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our EBV-CTL, CMV-CTL or WT1-CTL product candidates, thus eroding our competitive position in the market. Trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the United States. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could materially adversely affect our business, results of operations and financial condition.

#### **Risks Related to Commercialization of Our Product Candidates**

***Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and cancer treatment centers.***

Even if we obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, healthcare payors, patients or the medical community, including cancer treatment centers. Market acceptance of any of our product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the clinical indications and patient populations for which the product candidate is approved;
- acceptance by physicians, major cancer treatment centers and patients of the drug as a safe and effective treatment;
- the adoption of novel cellular therapies by physicians, hospitals and third-party payors;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- any restrictions on use together with other medications;
- the prevalence and severity of any side effects;

- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our products as well as competitive products;
- the development of manufacturing and distribution processes for our novel T-cell product candidates;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts and those of our collaborators.

If any of our product candidates are approved but fail to achieve market acceptance among physicians, patients, healthcare payors or cancer treatment centers, we will not be able to generate significant revenues, which would compromise our ability to become profitable.

***Even if we are able to commercialize our product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the United States and in other countries in which we seek to commercialize our products, which could harm our business.***

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain regulatory approval.

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

***Recently enacted and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates and affect the prices we may obtain.***

The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain regulatory approval. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be.

In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

***Price controls may be imposed in foreign markets, which may adversely affect our future profitability.***

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we, or our collaborators, may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.\****

We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product candidates. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. Competition could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate meaningful revenues and have a negative impact on our results of operations. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates.

There are currently no FDA or EMA approved products for the treatment of EBV-PTLD. However, some approved products and therapies are used off-label in the treatment of EBV-PTLD, such as rituximab and combination chemotherapy regimens. In addition, a number of companies and academic institutions are developing drug candidates for EBV-PTLD and other EBV associated diseases including: Cell Medica Ltd., or Cell Medica, which is conducting Phase 1 clinical trials for baltaleucel-T, an autologous EBV specific T-cell therapy in post-transplant lymphoproliferative disorder.

Drug therapies approved or commonly used for CMV infection include antiviral compounds such as ganciclovir, valganciclovir, cidofovir and foscarnet. In addition, a number of companies and academic institutions are developing drug candidates for CMV infection and other CMV-associated diseases, including: Shire Plc, or Shire, which has completed Phase 2 clinical trials of maribavir, a UL97 protein kinase inhibitor; Merck & Co. Inc., or Merck, which recently announced the Phase 3 clinical trials of letermovir, a CMV terminase inhibitor met their primary endpoint; and Vical Inc., or Vical, which is conducting Phase 3 clinical trials in patients undergoing an allogeneic stem cell transplant evaluating ASP0113, a therapeutic bivalent plasma DNA CMV vaccine. In addition, Helocyte, Inc., is conducting two Phase 2 clinical trials for a CMV MVA-vaccine and a CMV peptide vaccine in patients undergoing an allogeneic hematopoietic stem cell transplant; Novartis AG, or Novartis Pharmaceuticals, is conducting Phase 1/2 clinical trials for CSJ-148, a monoclonal antibody combination therapy; VBI Vaccines Inc., is conducting Phase 1 clinical trials for VBI-1501A, an eVLP vaccine; Hookipa Biotech, is conducting Phase 1 clinical trials for HB101, a bivalent vaccine and ViraCyte, is conducting Phase 1 clinical trials for Viralym-C, a CMV-specific allogeneic cell therapy product.

Several products are approved for the treatment of relapsed or refractory multiple myeloma, including Kyprolis (marketed by Amgen Inc.), Revlimid and Pomalyst (marketed by Celgene Corporation), Velcade (marketed by Millennium Pharmaceuticals, Inc.) and Darzalex (marketed by Janssen Research & Development, LLC). In addition, a number of companies and institutions are developing drug candidates for relapsed or refractory multiple myeloma including: AB Science SA, which is conducting a Phase 3 clinical trial for masitinib, a tyrosine kinase inhibitor; Array Biopharma Inc., which is conducting Phase 2 clinical trials for filanesib, a kinesin spindle protein inhibitor; Karyopharm Therapeutics, which is conducting Phase 2 clinical trials for Selinxor and Phase 1/2 trials for KPT-8602, both small-molecule nuclear transport inhibitors; Sanofi, which is conducting Phase 1/2 clinical trials for SAR-650984, an anti-CD38 monoclonal antibody; Altor Bioscience Corporation, which is conducting Phase 1/2 studies for ALT-803, an IL-15 super agonist; RedHill Biopharma Ltd., which is conducting Phase 1/2 clinical trials for Yeliva, a sphingosine kinase-2 selective inhibitor; bluebird bio, Inc., which is conducting Phase 1/2 clinical trials for bb2121, a CART candidate targeting BCMA; and Adaptimmune Therapeutics PLC, which is conducting Phase 1/2 clinical trials for a TCR candidate targeting NY-ESO-1.

There are numerous approved products and therapies for ovarian cancer, and a number of companies are or may be developing new treatments for ovarian cancer and other solid tumors. These therapies, as well as promotional efforts by competitors and clinical trial results of competitive products, could significantly diminish any ability to market and sell STM 434. Approved drug therapies for ovarian cancer include: chemotherapy with platinum compounds such as cisplatin or carboplatin and taxane compounds such as paclitaxel or docetaxel; bevacizumab in combination with a chemotherapy compound such as liposomal doxorubicin, paclitaxel or topotecan; olaparib in patients with deleterious or suspected deleterious germline breast cancer susceptibility gene, known as BRCA, mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy; and hormone therapies including goserelin, leuprolide, tamoxifen, letrozole, anastrozole and exemestane. A number of companies are developing drug candidates for ovarian cancer and other solid tumors, including, but not limited to F. Hoffman-La Roche, which is developing bevacizumab (Avastin) and other potential drug therapies; Takeda Pharmaceutical Company, Ltd., or Takeda, which is developing TAK-700, an estrogen and testosterone synthesis inhibitor; Vascular Biogenics Ltd., or VBL Therapeutics, which is developing VB-111, an anti-angiogenic agent; and AstraZeneca PLC, which is developing AZD1775, a Wee1 kinase inhibitor and Merck, which is developing pembrolizumab (Keytruda). In addition, multiple companies, such as Merck and AstraZeneca PLC, are developing checkpoint inhibitor treatments.

Many of the approved or commonly used drugs and therapies for ovarian cancer, EBV-PTLD, CMV and relapsed or refractory multiple myeloma are well-established and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and other drugs and nutritional supplements are available on a generic basis. Insurers and other third-party payors may encourage the use of generic products or specific branded products. We expect that, if any of these product candidates is approved, it will be priced at a significant premium over competitive generic products. This pricing premium may make it difficult for us to differentiate these products from currently approved or commonly used therapies and impede adoption of our product, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our products continue in clinical development.

Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or noncompetitive before we can recover the expenses of development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.***

We do not currently have an organization for the sale, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenues and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies. If we are not successful in commercializing our current or future product candidates either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

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

As of October 31, 2016, we had 87 employees. We need to grow the size of our organization in order to support our continued development and potential commercialization of our product candidates. In particular, we will need to add substantial numbers of additional personnel and other resources to support our development and potential commercialization of EBV-CTL, CMV-CTL and WT1-CTL. As our development and commercialization plans and strategies continue to develop, or as a result of any future acquisitions, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources will increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our preclinical studies and clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

As our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and preclinical studies and clinical trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

***Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.***

We are highly dependent upon our personnel, including Isaac E. Ciechanover, M.D., our President, Chief Executive Officer and founder, and Christopher Haqq, Ph.D., M.D., our EVP, Chief Scientific Officer. Our employment agreements with Drs. Ciechanover and Haqq are at-will and do not prevent them from terminating their employment with us at any time. The loss of the services of either of them could impede the achievement of our research, development and commercialization objectives.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business.

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

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute will constrain our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers; and
- marketing expenditures; and state and foreign laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.***

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or 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 and results of operations, including the imposition of significant fines or other sanctions.

***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.



***If we and our third-party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.\****

We and our third-party manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our or our third-party manufacturers' use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials with a policy limit that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, this insurance may not provide adequate cover age against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could adversely affect our business, financial condition, results of operations and prospects.

***Our business and operations would suffer in the event of computer system failures or security breaches.***

Our internal computer systems, and those of MSK, our CROs, our CMOs, and other business vendors on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and our business could be otherwise adversely affected.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. Two of our corporate locations are located in California, an area prone to earthquakes. 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 our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

#### **Risks Related to Ownership of Our Common Stock**

***Our stock price has been and will likely continue to be volatile and may decline regardless of our operating performance.\****

Our stock price has fluctuated in the past and can be expected to be volatile in the future. From October 16, 2014, the first date of trading of our common stock, through September 30, 2016, the reported sale price of our common stock has fluctuated between \$9.66 and \$65.56 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price of our common stock may be influenced by many factors, including the following:

- the success of competitive products or technologies;
- regulatory actions with respect to our product candidates or products or our competitors' product candidates or products;
- actual or anticipated changes in our growth rate relative to our competitors;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other risks described in this “Risk Factors” section.

***We may be subject to securities litigation, which is expensive and could divert management attention.***

The market price of our common stock has been volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

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

Our executive officers, directors and stockholders own a significant portion of our outstanding voting stock. These stockholders may be able to determine the outcome of 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. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, certain holders of shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

***We are an “emerging growth company” and are taking advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors.\****

We are an “emerging growth company,” as defined in the JOBS Act, and we are taking advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be for up to five years from the date of our initial public offering. We will cease to be an “emerging growth company” upon the earliest of: (1) December 31, 2019; (2) the last day of the first fiscal year in which our annual gross revenues are \$1 billion or more; (3) the date on which we have, during the previous rolling three-year period, issued more than \$1 billion in non-convertible debt securities; and (4) the date on which we are deemed to be a “large accelerated filer” as defined in the Exchange Act.

***Our status as an “emerging growth company” under the JOBS Act may make it more difficult to raise capital as and when we need it.***

Because of the exemptions from various reporting requirements provided to us as an “emerging growth company” we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

***We have incurred and will continue to incur increased costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.***

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with 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 Stock 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, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted and will adopt additional rules and regulations, such as mandatory “say on pay” voting requirements, that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the potential for future 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.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and make some activities more time-consuming and costly. To the extent 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.

***We previously identified and remediated a material weakness in our internal control over financial reporting. We may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. 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 the United States. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Prior to the completion of our initial public offering, we were a private company with limited accounting personnel and other resources to address our internal control over financial reporting. During the course of preparing for our initial public offering, we determined that we had a material weakness in our internal control over financial reporting as of December 31, 2013 relating to the design and operation of our closing and financial reporting processes.

While we have remediated this weakness, if we are unable to successfully maintain effective control over financial reporting, and if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with applicable listing requirements of The Nasdaq Stock Market.

***Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of potential gain.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, 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 will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions or in-licenses, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our employees, non-employee directors and consultants. Future grants of RSUs, options and other equity awards and issuances of common stock under our equity incentive plans will result in dilution and may have an adverse effect on the market price of our common stock.

***Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that will:

- permit our board of directors to issue up to 20,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and
- provide that special meetings of our stockholders may be called only by the board of directors or by such person or persons requested by a majority of the board of directors to call such meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. For example, our board is divided into three classes. Each class has a three-year term. These classes make it more difficult to replace a majority of our directors in a short period of time. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

***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. In the event securities or industry analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail 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**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

Exhibit No.	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	333-196936	3.2	6/20/2014	
3.2	Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	S-1	333-196936	3.4	6/20/2014	
4.1	Form of Atara Biotherapeutics, Inc. Common Stock Certificate.	S-1/A	333-196936	4.1	7/10/2014	
4.2	Investor Rights Agreement of Atara Biotherapeutics, Inc., dated March 31, 2014.	S-1	333-196936	4.2	6/20/2014	
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1(1)	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Schema Document					X
101.CAL	XBRL Calculation Linkbase Document					X
101.LAB	XBRL Labels Linkbase Document					X
101.PRE	XBRL Presentation Linkbase Document					X
101.DEF	XBRL Definition Linkbase Document.					X
(1)	The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.					

**SIGNATURES**

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

**ATARA BIOTHERAPEUTICS, INC.**

Date: November 4, 2016

By: /s/ Isaac Ciechanover  
Isaac Ciechanover  
President and Chief Executive Officer  
(Duly Authorized Officer and Principal  
Executive Officer)

By: /s/ John F. McGrath, Jr.  
John F. McGrath, Jr.  
Executive Vice President and Chief Financial Officer  
(Duly Authorized Officer and Principal  
Financial and Accounting Officer)



## Index to Exhibits

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**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER**  
**PURSUANT TO**  
**SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)**

I, Isaac Ciechanover, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Atara Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2016

/s/ Isaac Ciechanover  
\_\_\_\_\_  
Isaac Ciechanover  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER****PURSUANT TO****SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)**

I, John F. McGrath, Jr. certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Atara Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2016

/s/ John F. McGrath, Jr.

John F. McGrath, Jr.

Chief Financial Officer

(Principal Financial and Accounting Officer)

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

In connection with the Quarterly Report of Atara Biotherapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2016, as filed with the Securities and Exchange Commission (the "Report"), Isaac Ciechanover, Chief Executive Officer of the Company, and John McGrath, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (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 4, 2016

/s/ Isaac Ciechanover

Isaac Ciechanover  
Chief Executive Officer  
(Principal Executive Officer)

/s/ John F. McGrath, Jr.

John F. McGrath, Jr.  
Chief Financial Officer  
(Principal Financial and Accounting Officer)