

Atara Biotherapeutics, Inc.  
Form 10-K  
March 04, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2015

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

ATARA BIOTHERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware ( State or other jurisdiction of incorporation or organization) 701 Gateway Blvd., Suite 200	46-0920988  (I.R.S. Employer Identification No.)
--	---

South San Francisco, CA (Address of principal executive offices)	94080 (Zip Code)
---	---------------------

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

Edgar Filing: Atara Biotherapeutics, Inc. - Form 10-K

Securities registered pursuant to Section 12(b) of the Act: Common Stock, par value \$0.0001 per share, traded on The Nasdaq Stock Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES  NO

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES  NO

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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  (Do not check if a small reporting company) Small 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 aggregate market value of common stock held by non-affiliates of the Registrant, based on the closing sales price for such stock on June 30, 2015 as reported by The Nasdaq Stock Market, was \$698,303,925. The calculation of aggregate market value excludes 11,292,937 shares held by executive officers, directors and stockholders that the Registrant has concluded are affiliates of the Registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the Registrant.

The number of outstanding shares of the Registrant's Common Stock as of February 15, 2016 was 28,692,220.

DOCUMENTS INCORPORATED BY REFERENCE

Edgar Filing: Atara Biotherapeutics, Inc. - Form 10-K

Portions of the Registrant's definitive proxy statement relating to its 2016 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report where indicated. Such proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

---

ATARA BIOTHERAPEUTICS, INC.

TABLE OF CONTENTS

	Page
<u><b>PART I</b></u>	
Item 1. <u>Business</u>	4
Item 1A. <u>Risk Factors</u>	33
Item 1B. <u>Unresolved Staff Comments</u>	61
Item 2. <u>Properties</u>	61
Item 3. <u>Legal Proceedings</u>	61
Item 4. <u>Mine Safety Disclosures</u>	61
<u><b>PART II</b></u>	
Item 5. <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	62
Item 6. <u>Selected Financial Data</u>	64
Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	64
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	75
Item 8. <u>Financial Statements and Supplementary Data</u>	76
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	95
Item 9A. <u>Controls and Procedures</u>	95
Item 9B. <u>Other Information</u>	96
<u><b>PART III</b></u>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	97
Item 11. <u>Executive Compensation</u>	97
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	97
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	97
Item 14. <u>Principal Accounting Fees and Services</u>	97
<u><b>PART IV</b></u>	
Item 15. <u>Exhibits, Financial Statement Schedules</u>	98

Table of Contents

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such forward-looking statements, which represent our intent, belief or current expectations, involve risks and uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. In some cases you can identify these statements by forward-looking words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect” or the negative or plural of these words or similar expressions. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our expectations regarding the timing of initiating clinical trials, enrolling clinical trials and reporting results of clinical trials for our T-cell programs;
- the likelihood and timing of regulatory approvals for our product candidates;
- the potential market opportunities for commercializing our product candidates;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our expectations regarding the timing of reporting results from our Phase 1 clinical trial of STM 434;
- estimates of our expenses, capital requirements and need for additional financing;
- our expectation that our existing capital resources will be sufficient to enable us to fund our planned operations through 2018;
- our expectations regarding the timing of reporting results from clinical trials being conducted by Memorial Sloan Kettering Cancer Center (“MSK”) of the T-cell product candidates we licensed in 2015;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- the initiation, timing, progress and results of future preclinical studies and clinical trials and our research and development programs;
- the scope of protection we are able to obtain and maintain for our intellectual property rights covering our product candidates;
- our use of proceeds from our public offerings of common stock;
- our financial performance;
- developments and projections relating to our competitors and our industry; and
  - our ability to sell or manufacture approved products at commercially reasonable values.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in this report in greater detail under the heading “1A. Risk Factors” and elsewhere in this report. You should not rely upon forward-looking statements as predictions of future events. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties.

In this Annual Report on Form 10-K, unless the context requires otherwise, “Atara,” “Atara Biotherapeutics,” “Company,” “we,” “our,” and “us” means Atara Biotherapeutics, Inc. and, where appropriate, its subsidiaries.

Table of Contents

PART I

Item 1. Business

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.

T-cells are a type of white blood cell. Cytotoxic T-cells, otherwise known as cytotoxic T lymphocytes, or CTLs, have been shown to have the ability to kill cancer cells. Our T-cell product candidates arise from a platform technology designed to produce off-the-shelf, partially human leukocyte antigen, or HLA, matched cellular therapeutics utilizing CTLs. We licensed rights to these product candidates from Memorial Sloan Kettering Cancer Center, or MSK, in June 2015. Our initial T-cell product candidates 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 in Phase 2 clinical trials for malignancies associated with Epstein Barr Virus, or EBV, including EBV-associated post-transplant lymphoproliferative disorders, or EBV-PTLD. 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. 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. 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. In addition, we entered into a sponsored research collaboration with MSK to discover and develop additional T-cell product candidates. In October 2015, we entered into exclusive license and research agreements with another academic institution. These agreements enable us to access a technology complementary to that which was licensed from MSK and to pursue development of EBV and CMV-CTLs for other indications such as nasopharyngeal carcinoma, or NPC, gastric cancer, and multiple sclerosis, or MS. We are working with this academic institution on the submission to the FDA of one or more investigational new drug applications, or INDs, for these new indications.

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. We commenced a Phase 1 clinical trial of STM 434 for ovarian cancer and other solid tumors in 2014. We have five additional molecularly targeted product candidates that modulate the TGF- $\beta$  pathway in preclinical development.

In clinical trials that enrolled patients with EBV-PTLD following HCT or SOT, efficacy following treatment with EBV-CTL compares favorably with historical data in these patient populations. In rituximab-refractory patients with EBV-PTLD after HCT, treatment with EBV-CTL resulted in one-year overall survival of approximately 60% in two separate clinical trials in comparison with historical data where median survival, or the time by which 50% of patients had died, was 16-56 days. In the setting of rituximab-refractory EBV-PTLD after SOT, similar results were observed, with one-year overall survival of approximately 60% in EBV-CTL-treated patients in comparison with an expected historical one-year survival of 36% in patients with high risk disease similar to the patients treated in the trials. In February 2015, the U.S. Food and Drug Administration, or 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 June 2015, we met with the FDA

to discuss late-stage development to support a potential approval in this indication. Based on guidance from the FDA, we submitted a special protocol assessment, or SPA, for a single arm pivotal trial in rituximab-refractory EBV-PTLD after HCT. We received feedback from the FDA regarding this SPA in which the FDA indicated that a single arm trial with response rate as the primary endpoint may provide an adequate basis for approval but it would be unlikely to grant an SPA for our proposed trial. We intend to continue the dialogue with the FDA regarding this trial design under breakthrough designation and expect to initiate this pivotal trial towards the end of 2016. Additionally, we intend to initiate a randomized pivotal trial in patients with EBV-PTLD after SOT towards the end of 2016. In February 2016, the FDA granted orphan drug designation for EBV-CTL for the treatment of patients with EBV-PTLD after HCT or SOT.

Results from ongoing Phase 2 trials of CMV-CTL have demonstrated similar efficacy in the setting of refractory CMV infection after HCT, with response rates exceeding 60% in patients with CMV viremia and disease resistant to multiple approved and investigational anti-viral therapies. We expect to meet with the FDA in the middle of 2016 to discuss late phase development with CMV-CTL to support approval.

While we evaluate the path to registration for both EBV-CTL and CMV-CTL in these initial indications, 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 can be directed at a broad range of other targets to create future

## Table of Contents

product candidates. We believe that viral antigens are well suited to adoptive immunotherapy given that people with normal immune systems are able to mount robust responses to these viral targets, but immunocompromised patients and some cancer patients are not.

Our lead molecularly targeted product candidate, STM 434, a soluble ActR2B receptor that binds to Activin A, is in a Phase 1 clinical trial that will enroll approximately 70 patients with ovarian cancer and other solid tumors. In October 2015, we received orphan drug designation from the FDA for STM 434 in ovarian cancer, and we believe that novel therapies for clear cell and granulosa cell tumors could qualify for breakthrough therapy designation if supported by appropriate clinical data. Based on its mechanism of action, we also believe that STM 434 has the potential to be the first product to target tumor growth and proliferation through the inhibition of Activin A. STM 434 has a well-characterized mechanism of action and was developed initially, along with our other in-licensed molecularly targeted biologic product candidates, at Amgen, Inc., or Amgen. We are evaluating the remaining five pre-clinical molecularly targeted product candidates to determine the best path forward. Where appropriate, we intend to conduct preclinical studies and file INDs with the FDA for these candidates.

In December 2015, we announced results from a Phase 2 proof-of-concept clinical trial for PINTA 745, a molecularly targeted product candidate, for the treatment of protein energy wasting in patients with end stage renal disease. The trial did not meet its primary endpoint, defined as the percent change from baseline in lean body mass as measured by dual energy x-ray absorptiometry at week 12 following weekly treatment with PINTA 745. PINTA 745 also did not improve physical function, measures of glycemic control and markers of inflammation. There were no treatment related serious adverse events observed in the trial. We intend to complete the trial as designed; however, as a consequence of these results, we have suspended further clinical development of PINTA 745.

Our business model is to license or acquire, develop and commercialize novel therapeutics for serious unmet medical needs with validated targets and established proof of concept. Based on the properties of each of these molecules, including efficacy, safety, pharmacokinetics, affinity and other characteristics, we match each program to clinical indications that we believe maximize its therapeutic potential and may result in an expedited path to market. We believe our management team has the breadth and depth of experience to execute this model. Our management team includes:

- Isaac E. Ciechanover, M.D., our President and Chief Executive Officer, was Executive Director for Business Development at Celgene Corporation, or Celgene. At Celgene, he led the company's venture capital efforts and led licensing and acquisition activities with an aggregate transaction value of more than \$6.7 billion. Those efforts included striking licensing and partnership transactions with cancer therapeutics companies Agios Pharmaceuticals, Inc., Acceleron Pharma Inc. and PTC Therapeutics Inc. Prior to founding Atara, Dr. Ciechanover was a Partner with Kleiner Perkins Caufield & Byers, a leading venture capital firm.
- Christopher Haqq, M.D., Ph.D., our Chief Medical Officer, was Vice President for Clinical Research and Development at Cougar Biotechnology, which was acquired by Johnson & Johnson in 2009. At Cougar Biotechnology, he was the lead clinician for a pivotal prostate cancer trial leading to market approval for Zytiga (abiraterone acetate). He has served as medical monitor for more than ten clinical trials and has contributed to drug development programs for a wide range of molecules, and served as an attending oncology physician and director of a translational laboratory at the University of California, San Francisco.
- Mitchall G. Clark, our Chief Regulatory and Quality Officer, was previously Senior Vice President of Global Regulatory Affairs at Abraxis Bioscience, Inc., or Abraxis, where he submitted and managed five INDs for oncology and cardiovascular drugs, including Abraxane (nanoparticle albumin-bound paclitaxel).
- Gad Soffer, our Chief Operating Officer, previously held various roles at Celgene, including most recently Global Project Leader for Abraxane following Celgene's acquisition of Abraxis, where he led successful regulatory submissions for pancreatic cancer and non-small cell lung cancer.



- John F. McGrath, Jr., our Chief Financial Officer, was previously Executive in Residence and Operating Partner at Kleiner Perkins Caufield & Byers. Prior to that time, he served as Vice President and Chief Financial Officer for Network Equipment Technologies, Inc., a publicly traded company. He has served on the board of directors of the Presidio Fund, a publicly traded mutual fund, and on the boards of directors and as Audit Committee chairman of publicly traded companies Actel Corporation and Endwave Corporation.
- Heather Turner, our General Counsel and Secretary, was previously Senior Vice President, General Counsel and Secretary at Orexigen Therapeutics, Inc., a publicly traded company. Prior to that time, she served as Associate General Counsel - Corporate for Conor Medsystems, Inc., a publicly traded company, and an associate at Cooley LLP, a law firm.

#### Our T-Cell Product Candidates

T-cells are a critical component of the body's immune system and can be harnessed to counteract viral infections and some cancers. By focusing the T-cells on specific proteins involved in cancers and infections, the power of the immune system can be

## Table of Contents

employed to combat these diseases. In June 2015, we exclusively licensed from MSK worldwide rights to three clinical stage T-cell product candidates. We also have an exclusive option to exclusively license from MSK worldwide rights to certain other T-cell programs that are discovered or developed by MSK pursuant to sponsored research funded by us.

Our T-cell product candidates arise from a platform technology designed to produce off-the-shelf, cellular therapeutic options for patients with unmet medical needs. Our initial T-cell product candidates target viral- or cancer-specific antigens. In October 2015, we entered into exclusive license and research agreements with another academic institution. These agreements enable us to access a technology complementary to that which was licensed from MSK and to pursue development of EBV and CMV-CTLs for other indications such as NPC, gastric cancer, and MS. We are working with this academic institution on the submission to the FDA of one or more INDs for these new indications.

Our most advanced T-cell product candidate, EBV-CTL, is in Phase 2 clinical trials for the treatment of EBV-associated malignancies. EBV is the virus that causes mononucleosis and is associated with a number of more severe diseases, including certain malignancies and neurologic conditions, such as MS. EBV-CTL received breakthrough therapy designation from the FDA in February 2015 for the treatment of patients with rituximab-refractory EBV-PTLD after HCT, based on data from two separate clinical trials conducted by MSK. Since licensing our T-cell product candidates, the IND under which these trials were conducted has been transferred to us. In June 2015, we met with the FDA to discuss late-stage development to support a potential approval in this indication. Based on guidance from the FDA, we submitted an SPA for a single arm pivotal trial in rituximab-refractory EBV-PTLD after HCT. We received feedback from the FDA regarding this SPA in which the FDA indicated that a single arm trial with response rate as the primary endpoint may provide an adequate basis for approval but it would be unlikely to grant an SPA for our proposed trial. We intend to continue the dialogue with the FDA regarding this trial design under breakthrough therapy designation and expect to initiate this pivotal trial towards the end of 2016. Additionally, we intend to initiate a randomized pivotal trial in patients with EBV-PTLD after SOT towards the end of 2016. In February 2016, the FDA granted orphan drug designation for EBV-CTL for the treatment of patients with EBV-PTLD after HCT or SOT.

Our second T-cell product candidate, CMV-CTL, targets CMV, an infection that can result in blindness, illness or death, depending on the tissue it affects, in those with weakened immune systems. CMV is also associated with certain malignancies, including glioblastoma multiforme, or GBM. CMV-CTL is currently being investigated in Phase 2 clinical trials sponsored and conducted by MSK for CMV infections that occur in some patients who have received an HCT.

Our third clinical stage T-cell product candidate, WT1-CTL, targets WT1. Abnormal expression of WT1 is seen in a variety of hematologic and solid tumors, including MM, PCL, and ovarian cancer. This product candidate is currently in Phase 1 clinical trials sponsored and conducted by MSK.

Clinical experience with our T-cell product candidates is broad, including in immunocompromised states, as well as in solid and hematologic malignancies. Clinical data for EBV-CTL, CMV-CTL and WT1-CTL have been published in the journal *Blood* and presented at major scientific conferences. We are focusing our initial development and regulatory activities on EBV-CTL in the post-HCT and post-SOT setting and CMV-CTL in the post-HCT setting, which we believe offer a rapid path to marketing approvals if supported by additional clinical data. However, we intend to concurrently explore the clinical utility of our T-cell product candidates in other relevant disease states.

## T-cell Technology Platform

Our T-cell product candidates share a common technology under which T-cells are collected from the blood of third-party donors and then exposed to a selected viral antigen in order to activate them against that particular virus. The resulting activated T-cells are expanded in number, characterized and stored for future therapeutic use in an appropriate partially HLA matched patient, providing an off-the-shelf, cellular therapeutic option for patients. Because these T-cells are off-the-shelf, patients often only need to wait days until they receive treatment. In addition to expanding the activated T-cells, the manufacturing process also leads to substantial reduction in the number of alloreactive cells, which can cause graft versus host disease, or GvHD. We believe this may reduce the risk of GvHD, a serious complication in immunocompromised recipients.

Table of Contents

The process through which EBV-CTLs are generated is shown in the diagram below. First, B-cells derived from the blood of a third-party donor are exposed to a specific strain of the EBV virus to create EBV transformed B lymphoblastoid cell lines, or EBV BLCLs. The BLCLs are irradiated to prevent the BLCLs from growing and then co-cultured with T-cells derived from the blood of the same third-party donor. In this co-culture process, the BLCLs present EBV antigen to the T-cells to activate the T-cells against the EBV virus. These activated EBV-specific T-cells are then sensitized and expanded, while the potentially alloreactive cells contained in the same culture are not expanded. When complete, the cultures are assessed for EBV reactivity, HLA restriction, the absence of allo-specificity and microbial sterility. Once fully characterized in this way, the cell lines are cryopreserved and stored for future therapeutic use as an off-the-shelf therapy.

The donor's blood contains a mix of T-cells, some that have the potential to target EBV-infected cancer cells, and others called alloreactive or allospecific T-cells, which have the potential to target cells recognized as foreign. Administration of bulk third-party lymphocytes that contain a relatively high proportion of allospecific T-cells has the potential to cause severe and life-threatening toxicities such as GvHD when these allospecific T-cells recognize the recipient's native cells as foreign. Our manufacturing process enriches the product for the desired EBV-CTLs while depleting the undesirable allospecific T-cells as they are not stimulated to expand and eventually die. The existing manufacturing process typically results in an approximately 70-fold expansion in the number of EBV-CTLs and reduces by a factor of approximately 20 the number of GvHD-causing allospecific T-cells, compared with the prevalence of these two types of cells in a sample of bulk donor lymphocytes.

In addition to being evaluated for expansion before release for use in clinical trials, cells are also evaluated for HLA restriction. HLA restriction refers to the fact that any given T-cell line will only recognize such T-cell line's target—in this case an EBV protein—when it is bound to a particular HLA. For example, an EBV-CTL restricted by a particular HLA known as HLA A\*02:01 will only kill EBV-infected cells that show that same EBV protein when bound to HLA A\*02:01. This process identifies EBV-CTLs that are specific to the desired target, limiting undesirable off-target killing of other cells.

An appropriate cell line for use in a particular patient is typically defined as being matched with at least two of eight HLA alleles and restricted through a shared HLA allele. In an analysis conducted by MSK and reported at the 2015 American Association for Cancer Research, or AACR, annual meeting, an appropriate cell line was determined to be available for all but one of 200 consecutive unrelated transplant recipients and 100 cord blood transplant recipients. This analysis was based on evaluating these potential patients against a bank of approximately 330 HLA characterized EBV-CTL lines that MSK had generated to date. MSK's clinical experience has yielded an empirically derived, proprietary approach to selecting the appropriate cell line for use in individual patients. We believe this algorithm will ultimately allow us to deliver the therapy efficiently by focusing on a limited set of EBV-CTL lines without compromising our ability to treat a wide range of patients with diverse HLA types.

A similar process is used to generate and characterize CMV-CTL and WT1-CTL, and we also plan to utilize this process to generate diverse banks of targeted cytotoxic T-cell lines against other antigens of interest.

Table of Contents

## EBV-Targeted T-Cells for EBV-PTLD and Other EBV Associated Diseases

EBV is a member of the Herpes virus family and is one of the most common viruses in humans. It is present in all populations, infecting more than 95% of all individuals within the first four decades of life. In healthy individuals, EBV causes infectious mononucleosis, a generally benign self-limiting condition. Following the acute phase of EBV infection, the virus remains present in a small number of B-cells throughout the body; however, it is kept in check by the intact immune system. Though benign in the vast majority of people, EBV has been demonstrated to be involved in the development of many malignancies. In immunocompromised patients, EBV causes lymphomas and other lymphoproliferative disorders, collectively called EBV-PTLD. EBV-PTLD most commonly affects patients after HCT or after SOT. Even in patients with intact immune systems, EBV is associated with various hematologic malignancies and solid tumors including Hodgkin lymphoma, Burkitt's lymphoma, other B-cell malignancies, nasopharyngeal carcinoma and gastric cancer. EBV is also associated with certain diseases of the central nervous system, including multiple sclerosis.

The approximate estimated number of patients per year in the United States and European Union with EBV associated diseases is highlighted in the figure below.

Indication	Estimated Number of Patients
EBV-PTLD after HCT	1,400
EBV-PTLD after SOT	1,700
EBV positive Diffuse Large B cell lymphoma	5,800
EBV positive chemotherapy refractory Hodgkin lymphoma	2,100
EBV positive nasopharyngeal carcinoma	6,000
EBV positive gastric cancer	16,500
Primary and secondary progressive multiple sclerosis	>400,000

EBV-PTLD is a rare but serious complication in recipients of HCT. EBV-PTLD is often severe and sudden in onset and results in death in the majority of HCT patients who develop the disease. A study conducted by the Karolinska Institute that was reported in the journal *Haematologica* noted a three-year survival rate of just 20%. According to the U.S. Department of Health and Human Services, there were 8,338 allogeneic transplants in the United States in 2013, and according to the European Society for Blood and Marrow Transplantation, there were 14,950 allogeneic transplants in the European Union. While autologous transplants, or those obtained from the same individual, still comprise the majority of all transplants in the United States and European Union, the relative proportion of allogeneic transplants, or those obtained from a third-party donor, has increased over time, and we believe this trend will continue due to the increasing utilization of haploidentical transplants and reduced intensity transplants.

The monoclonal antibody, rituximab, is typically used off-label to treat EBV-PTLD, producing initial responses in approximately 55% of treated patients and durable responses in approximately 20% of treated patients. However, for those who relapse after rituximab therapy or fail to respond to rituximab, or for those with CD20 negative lymphoma (which is known to be unlikely to respond to rituximab), EBV-PTLD is frequently lethal. For example, it was reported in 2014 in the journal *Bone Marrow Transplantation* that the median survival period from diagnosis of rituximab-refractory EBV-PTLD in adult HCT patients was 33 days, and in 2014 it was reported in the journal

Haematologica that median survival was 16 days. In 2008, it was reported in the journal Bone Marrow Transplantation that the median survival period from the time of diagnosis in a group of EBV-PTLD patients who received rituximab was 56 days. Taken together, these studies suggest a range of median overall survival, or OS, in the setting of rituximab failure of 16-56 days.

MSK is conducting two separate clinical trials of EBV-CTL that enroll 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 trials are referred to as Study 95-024, initiated in 1995, and Study 11-130, initiated in 2011. Results from these two trials supported the granting of breakthrough therapy designation by the FDA for EBV-CTL in February 2015 for the treatment of rituximab-refractory EBV-PTLD after HCT. Data from these trials was presented at a clinical trials plenary session at the April 2015 AACR Annual Meeting and was subsequently updated at an oral presentation at the June 2015 American Society of Clinical Oncology, or ASCO, Annual Meeting.

In Study 95-024, patients with EBV-PTLD following HCT were treated with EBV-CTL manufactured from T-cells derived from either the primary HCT donor or an unrelated third-party donor. The term primary HCT donor refers to the donor who provided hematopoietic stem cells for the HCT. As one measure of efficacy, response rate was evaluated in these patients. The response rate refers to the proportion of patients treated with EBV-CTL who had either a complete or partial response as best response to treatment when measured by radiographic imaging of the tumor. In a complete response, no visible evidence of tumor following treatment was observed. In a partial response, the tumor was reduced in size by more than 50% but less than 100%.

Table of Contents

In both the primary HCT donor and third-party donor cohorts, similar response rates of approximately 60% were achieved. Such response rates suggest that the efficacy of treatment with primary donor derived and third-party donor derived EBV-CTL are comparable. The similarity in efficacy observed following treatment with third party and primary donor derived EBV- CTL is important, as there are significant limitations associated with a therapy derived from the primary transplant donor. First, it can take approximately eight weeks to generate an EBV-CTL line from blood remaining from the primary HCT donor. In this amount of time and based on historical data, approximately half of those patients who had either failed to respond or who had relapsed after rituximab would likely have succumbed to their EBV-PTLD and died before the cell line was available for therapeutic use. Second, due to the limited quantities of certain HCT donor materials such as umbilical cord blood, it is not possible to make a primary donor derived EBV-CTL line for all patients. Additionally, if the EBV-PTLD is of host rather than donor origin, T-cells derived from the primary HCT donor may not be able to recognize this host tumor, and therefore would not be expected to be effective in combatting the disease. Thus, we believe that the availability of off-the-shelf third-party derived EBV-CTL provides significant practical and therapeutic advantages in the treatment of rituximab-refractory EBV-PTLD. A median of two cycles of third-party derived EBV-CTL were administered in these trials. In each cycle, three doses of EBV-CTL were given weekly for three weeks. In addition, a number of patients with disease located in the central nervous system, or CNS, responded to treatment with EBV-CTL, suggesting that these cells are capable of passing through the blood-brain barrier.

The OS for patients with rituximab-refractory EBV-PTLD after HCT following treatment with third-party derived EBV-CTL was evaluated by MSK as well as presented at ASCO 2015 using industry standard Kaplan Meier, Or K-M, methods. One-year OS was approximately 60% in the patients from Study 95-024 and approximately 70% in the patients from Study 11-130.

Since these trials are ongoing, we expect that these K-M estimates of survival will evolve with ongoing follow-up of the patients and that a median OS may be reached in Study 11-130. However, we believe that these results compare favorably with the historically reported median survival of 16-56 days in the setting of rituximab failure. Moreover, patients who achieve a complete response after EBV-CTL treatment have been noted by MSK to experience durable remissions without relapse of their EBV lymphoma.

The time course of a complete response following multiple cycles of EBV-CTL in a patient with rituximab-refractory EBV-PTLD is shown below using sequential positron emission tomography, or PET, scans. Also shown are the timing of rituximab and EBV-CTL therapy depicted by the corresponding set of arrows, the levels of EBV DNA in the blood as measured by EBV polymerase chain reaction, or EBV PCR, a sensitive and specific technique to detect viral DNA depicted in the corresponding line, as well as the levels of CTL precursors per milliliter of blood, or CTLp/ml, depicted in the corresponding line. CTLp/ml identifies and enumerates activated T-cells.

This patient developed EBV viremia, or high levels of virus in the blood, early post-HCT as noted in the line labeled EBV PCR. Her viremia responded to rituximab, but recurred and it again responded to a second cycle of rituximab. In the interim, she developed a rapidly progressive diffuse large B-cell lymphoma, or DLBCL, that was EBV positive. By week 0, defined as the start of EBV-CTL therapy, the lymphoma is visible in the lymph nodes as well as in the liver and spleen. She received a first cycle of third party EBV-CTL after which she had a partial response. The patient received three subsequent cycles of EBV-CTL after which she achieved a complete response. In conjunction with each cycle of EBV-CTL, expansion of EBV-specific cytotoxic T-cells was detected, as shown





## Table of Contents

in the line labeled CTLp/ml. While these expansions were not durable, they mediated her complete response. The PET scans, in which dark areas correspond to areas of high metabolic activity, show both normal metabolism of organs such as the heart and abnormal metabolism in areas of lymphoma. After treatment with T-cells, the abnormal areas of metabolism recede, indicating eradication of tumor cells. In the final image, no abnormal metabolic activity is observed, reflecting a complete response to EBV-CTL therapy.

The ability to switch from one cell line to another led to the discovery of a hierarchy of HLA restriction. This is highlighted by the example below, in which a patient received three EBV-CTL lines (A, B and C) with different HLA restrictions, but only went into complete response upon administration of a fourth unique EBV-CTL line (D) with a different HLA restriction. We believe that future patients can be treated using a cell line selection algorithm based in part on the hierarchy elucidated in this manner that enables a more efficient choice of EBV-CTL.

Across all patients enrolled in the two trials, reports of treatment related adverse events were low, with few possibly related grade 3 and grade 4 adverse events observed. One patient developed grade 1 skin GvHD responding to topical steroids with no systemic therapy required. No infusion related toxicities or cytokine release syndrome was observed.

In part due to these results, treatment with EBV-CTLs is recognized as a recommended treatment for persistent or progressive EBV-PTLD as set forth in the 2015 National Comprehensive Cancer Network Guidelines. In addition, in December 2013, the FDA granted MSK cost reimbursement for use of the EBV-CTL in MSK's clinical trials.

Since licensing our T-cell product candidates, the IND under which Studies 95-024 and 11-130 were conducted has been transferred to us. In June 2015, we met with the FDA to discuss late-stage development to support a potential approval in EBV-PTLD after HCT. Based on guidance from the FDA, we submitted an SPA for a single arm pivotal trial in rituximab-refractory EBV-PTLD after HCT. We received feedback from the FDA regarding this SPA in which the FDA indicated that a single arm trial with response rate as the primary endpoint may provide an adequate basis for approval but it would be unlikely to grant an SPA for our proposed trial. We intend to continue the dialogue with the FDA regarding this trial design under breakthrough therapy designation and expect to initiate this pivotal trial towards the end of 2016.

### EBV-PTLD after SOT

EBV-PTLD after SOT, also referred to as post-transplant lymphoproliferative disorder, is a spectrum of lymphoid malignant disease associated with the use of immunosuppressive drugs after SOT. Patients with EBV-PTLD, one of the most common neoplastic diseases after SOT, commonly present with stage 3 or 4 disease. Reduction in immunosuppression, antiviral therapy, or surgical resection are common treatments, but many patients with PTLD require systemic therapy, especially those with aggressive lymphoma morphology such as DLBCL. Chemotherapy remains undesirable in PTLD because of myelotoxic side effects of cytotoxic therapy and associated infections and toxic deaths. In addition, recipients of chemotherapy face the prospect of secondary malignancies in the future. Rituximab with or without chemotherapy is often used off-label after reduction in immunosuppressive therapy with a response rate of 44% to 60.5%. In the setting of rituximab-refractory EBV-PTLD after SOT, historical one-year survival of 36% is observed in patients with high risk disease. The rates of EBV-PTLD after SOT vary by organ transplant type and degree of immunosuppression with rates in the adult and pediatric settings ranging from <1% to 3.4% in kidney transplants, <1% to 4.4% in liver transplants, <1% to 15.0% in heart transplants, 2.4% to 9.8% in lung

transplants, 2.0% to 10.0% in heart/lung transplants, and 20.0% to 30.0% in bowel

10

---

## Table of Contents

transplants. In addition, the rates of EBV-PTLD after SOT appear to be higher in children than in adults. One of the unique features of EBV-PTLD after SOT in comparison with the post-HCT setting is that the immunosuppression that ultimately gives rise to the lymphoma is in many cases required chronically and, as a result, the period of time during which an EBV-associated lymphoma may arise extends for the duration of immunosuppression. Although some cases of EBV-PTLD in SOT occur within the first year, many occur years after transplant.

In trials 95-024 and 11-130, patients with EBV-PTLD after SOT were treated with third-party derived EBV-CTL. All patients had failed to respond to or relapsed following rituximab treatment. Most had also progressed after receiving chemotherapy. Additionally, nearly all patients had high risk disease defined as those with age greater than or equal to 60 years, poor performance status, elevated LDH, or presence of disease in the central nervous system, or CNS. Response rate and OS results for these patients were also evaluated by MSK.

The response rate observed in the rituximab-refractory post SOT setting of greater than 50% and the one-year OS of approximately 60% are similar to those observed in the post HCT setting.

Since these trials are ongoing, we expect that these K-M estimates of survival may evolve with ongoing follow-up of the patients. Based on this data, we plan to solicit feedback from the regulatory authorities on the plan for late-phase development to support a potential marketing approval for EBV-CTL in the treatment of EBV-PTLD after SOT.

### Other EBV-Associated Diseases

EBV-associated malignancies can occur even in immunocompetent patients, and include: Burkitt's lymphoma, Hodgkin lymphoma, non-Hodgkin lymphoma such as DLBCL, or NHL, NK T-cell lymphomas, nasopharyngeal carcinoma, or NPC, and gastric cancer. Typically, these malignancies occur many years after primary EBV infection. For Burkitt's lymphoma, approximately 15% to 30% of cases in the United States and European Union are associated with EBV. For Hodgkin lymphoma, approximately 20% to 50% of cases in the United States and European Union are associated with EBV; however, many of these are responsive to chemotherapy. Nearly 100% of NK T-cell lymphomas are associated with EBV. In NPC, the association with EBV is such that regardless of geography nearly 100% of the nonkeratinising tumors and all the tumor cells have been demonstrated to be monoclonally EBV-positive. EBV-positive gastric cancer can make up approximately 10% of all gastric cancers. In some of these tumor types, multiple EBV proteins are associated with the disease and in others, a smaller subset are made.

In the setting of CNS disease, a number of observations implicate EBV in the pathogenesis of MS. For example, MS patients are universally EBV seropositive, there are high levels of anti-EBV antibodies, their T-cells have altered immune function, there is an increase in spontaneous EBV-induced peripheral blood B-cell transformation, there is increased shedding of EBV from saliva, and EBV-infected B-cells and plasma cells accumulate in the brain.

We intend to explore the therapeutic utility of EBV-targeted cellular therapy in a number of these tumor types. We expect to develop specific cellular therapies that target the precise EBV antigen implicated in a disease. As we expand the use of EBV-targeted cellular therapy in these settings, we expect to present data at major scientific meetings and engage regulatory authorities to solicit agreement on the plan for late-phase development to support a marketing approval for EBV-CTL in the treatment of certain of these conditions.

### CMV-Targeted T-cells for CMV Infection and Other CMV Associated Malignancies

CMV, also known as HHV-5, is a member of the Herpes virus family. CMV infection rate gradually increases throughout childhood, and, once infected, an individual carries the virus for life due to the ability of CMV to establish a latent state of infection. It is estimated that CMV infection affects 50% to 90% of the global adult population.

Immunocompromised patients, including HCT and SOT patients, human immunodeficiency, or HIV, patients, and to a lesser extent cancer patients, are at highest risk for developing significant disease syndromes caused by CMV, including interstitial pneumonia, gastrointestinal infection, central nervous system disease, hepatitis, retinitis, and encephalitis. CMV reactivations have also been reported to occur frequently in critically ill immunocompetent patients and are associated with prolonged hospitalization or death. Congenital CMV infection causes deaths and leaves children with permanent disabilities such as hearing loss, vision loss, or mental retardation.

In the oncology setting, CMV is commonly associated with glioblastoma multiforme, or GBM, where approximately 95% of tumors express CMV. In GBM, multiple CMV proteins are associated with the disease.

While there have been many advances in detecting and managing CMV infections, the virus continues to be one of the most important infectious diseases among immunocompromised patients. Antiviral drugs in the form of prophylaxis or preemptive

Table of Contents

treatment strategies have reduced morbidity and mortality, though adverse effects such as neutropenia and toxicity remain a challenge. The emergence of resistance to antiviral drugs also presents challenges to laboratory medicine and patient care.

The approximate estimated number of patients per year in the United States and European Union with refractory CMV infection and associated malignancies is highlighted in the figure below.

Indication	Estimated Number of Patients
Anti-viral resistant CMV after HCT	2,000
Anti-viral resistant CMV after SOT	1,300
Glioblastoma multiforme	21,000
Congenital CMV	9,000

#### CMV Viremia and Disease after HCT

Despite the use of prophylactic and preemptive therapy using small molecule antivirals, many post-HCT patients progress to develop overt, symptomatic CMV viral diseases such as retinal infections that risk permanent blindness, encephalopathy with the risk of permanent brain damage and other serious morbidities. In prophylactic therapy, immunocompromised patients are given antiviral drugs for several months after HCT. In preemptive therapy, patients are intensively monitored for CMV activity using sensitive laboratory methods, and short-term antiviral treatment is given only to those with significant viral counts (CMV viremia) before symptoms and overt CMV disease occur. However, the antiviral drugs used to treat CMV have significant toxicities, including marrow toxicity for ganciclovir, valganciclovir and cidofovir, and renal toxicity for foscarnet and cidofovir. In addition, CMV drug resistance mutations arise during this antiviral therapy.

MSK has conducted one Phase 1 clinical trial and two Phase 2 clinical trials of CMV-CTL that included patients with CMV viremia and CMV disease, in each case resistant to antiviral drug treatment. An interim summary of MSK's clinical experience was reported at the December 2014 ASH Annual Meeting. This analysis evaluated outcomes in patients who were treated with CMV-CTLs after failing a median of four different antiviral drugs. Following the ASH presentation, in January 2015, MSK provided us with a more current summary of its clinical experience to account for additional cycles of CMV-CTL therapy in which certain patients with stable disease and partial responses from the interim summary had converted to complete responses after additional CMV-CTL therapy. Response rates of greater than 60% were noted in patients with antiviral resistant CMV viremia as well as CMV disease. Responses in patients treated for viremia alone with CMV-CTLs were considered to be complete responses if the viremia resolved completely and partial responses if the viral load fell 100-fold or more. Responses in patients treated for overt disease were considered to be complete responses if all detectable CMV viremia and disease resolved and partial responses if patients became asymptomatic.

An additional subset analysis of MSK's clinical experience from the ongoing Phase 2 clinical trial and including patients treated under compassionate use was reported at the December 2015 ASH Annual Meeting. This analysis included patients with refractory CMV disease in the CNS who were treated with either primary donor derived or third-party derived CMV-CTL. Nearly all of these patients were treated with third-party derived CMV-CTL and one

was treated with a primary donor derived CMV-CTL. Patients had received a range of three to six prior therapies before treatment with CMV-CTL. The overall response rate was more than 70%, including seven complete responses and one partial response. Responses in these patients treated for CMV disease in the CNS were considered to be complete responses if all detectable CMV viremia and disease resolved and partial responses if patients became asymptomatic.

We believe this data suggests a high response rate among patients with otherwise refractory CMV viremia and disease. Overall, CMV-CTL therapy was well tolerated and no patients developed de novo GvHD, or a flare-up of prior GvHD, in association with infusion of CMV-CTLs.

Table of Contents

Two individual patient experiences following treatment with CMV-CTL are described below. The graph below shows the time course of a reduction in CMV viremia and a reciprocal increase in the proliferation of CMV-CTL following administration. The improvement in CMV viremia is evidenced by a decline in blood CMV DNA ascertained by CMV PCR. The reciprocal proliferation of CMV-CTL following administration is reflected by the release of interferon-gamma (IFN $\gamma$ [+]) in CMV-CTL detected via flow cytometry; interferon-gamma positivity identifies and enumerates activated T-cells.

The following retinal photographs depict improvement in CMV retinitis for a patient treated with CMV-CTL. The baseline images, labeled “a” and “b”, show the right and left retinae, respectively, at the start of CMV-CTL administration. Subsequent images “c” and “d” capture the response of the patient’s CMV retinitis at six weeks after first CMV-CTL administration. In the retinal images, the dark areas correspond to affected portions of the retina. The response of retinal disease to treatment with CMV-CTL suggests that, as was observed with EBV-CTL, the cells are able to reach areas of the body typically not accessible to systemic therapies.

Based on these results, we intend to continue to support the ongoing Phase 2 clinical trials of CMV-CTL and meet with health authorities to establish a plan for late-phase development to support potential marketing approvals in treatment of anti-viral resistant CMV viremia and symptomatic disease after HCT, including retinitis.

Other CMV-Associated Conditions and Malignancies

CMV is among the most common and important infectious agents among SOT patients. In transplant recipients, the factor that most strongly influences the degree of morbidity and mortality caused by CMV is the type and extent of immunosuppressive therapy. Reactivation can occur in any individual who is latently infected. However, no transplant patient is safe from CMV since this pathogen can also be acquired from the transplanted organ. CMV can also be community acquired following transplantation and is of particular concern in pediatric transplant patients. In SOT patients, particularly those who develop a primary infection during the first three months post-transplant, a specific CMV syndrome consisting of fever, malaise, arthralgia, and neutropenia may be observed. CMV infections have been associated with indirect effects, such as dysfunction or rejection of the transplanted organ; increased risk for bacterial or fungal opportunistic infections; development of EBV-associated post-transplant lymphoproliferative disorder;

## Table of Contents

accelerated atherosclerosis in heart transplant patients; and decreased patient and graft survival. In the absence of antiviral intervention, symptomatic CMV infections occur in approximately: 50% to 75% of heart-lung transplant recipients, 23% of heart transplant recipients, 22% to 29% of liver and pancreas transplant recipients, 8% to 32% of kidney transplant recipients, 50% of kidney-pancreas transplant recipients, and 22% of small-bowel transplant recipients.

Malignant gliomas are the most common primary CNS neoplasms in humans. However, most patients who are diagnosed with a glioblastoma multiforme, which is the most common and malignant form of malignant glioma, still have a mean survival less than two years. In the last few years, multiple investigators have confirmed the presence of CMV in GBM, and multiple CMV gene products are now implicated in biologically relevant GBM signaling pathways. Preclinical studies published in 2013 in the journal *Cancer Research* indicate that CMV may be unique in its ability to promote oncogenesis in the setting of a prior tumor suppressor dysfunction. Given the emerging role of CMV in GBM, antiviral strategies that block CMV expression or stimulate immune attack of CMV-infected cells may prove beneficial as novel therapeutics for GBM, and both direct antiviral strategies and specific CMV-based immunotherapy approaches are showing early promise.

Based on the established proof of concept for CMV-CTL in the treatment of antiviral resistant CMV viremia and disease after HCT, we intend to explore the therapeutic utility of CMV-targeted cellular therapy in a number of other immunocompromised states, including potentially after SOT. In addition, the clinical data with both EBV-CTL and CMV-CTL have demonstrated the ability of these product candidates to access the brain and mediate clinical responses in difficult to treat CNS disease. As a result, we believe that CMV-targeted cellular therapy may provide a novel off-the-shelf cellular therapeutic option for patients with GBM, and we intend to explore its clinical utility in this setting as well. As we expand the use of CMV-CTL in these settings, we expect to present data at major scientific meetings and engage regulatory authorities to solicit agreement on the plan for late-phase development to support potential marketing approval for CMV-CTL in the treatment of certain of these conditions.

### WT1 Targeted T-Cells for Hematologic Malignancies and Solid Tumors

WT1 is an intracellular protein that is overexpressed in a number of cancers, including multiple myeloma, or MM, and non-small cell lung, breast, pancreatic, ovarian, and colorectal cancers. We have two ongoing Phase 1 clinical trials sponsored and conducted by MSK with primary HCT donor derived WT1-CTL. The first is a dose escalation trial of WT1-CTL for residual or relapsed leukemia after HCT. The second is a dose escalation trial of WT1-CTL following T-cell depleted HCT for patients with relapsed or refractory MM, including PCL. In 2011, it was reported in the journal *Blood* that the prognosis of PCL is poor with a median survival of seven to eleven months and that survival is even shorter, two to seven months, when PCL occurs in the context of refractory or relapsing MM. At the ASH 2015 Annual Meeting, MSK presented results from this Phase 1 clinical trial of primary donor-derived WT1-CTLs. In this trial, response assessments were conducted utilizing criteria consistent with those defined by the International Myeloma Working Group.

- Patients with relapsed-refractory MM, including PCL were treated with allogeneic HCT followed by WT1-CTLs.
- At one year, a response rate of greater than 50% was observed in these patients. For these data, the response rate was determined by adding the complete responses to the partial responses and then dividing by the number of patients.
- Two patients who developed a complete response remain in remission for more than one year.
- There were no serious adverse events reported related to treatment with WT1-CTLs.

As these trials complete, we expect our collaborating investigators at MSK to present additional data at upcoming conferences. In addition, based on data from these trials, we expect to explore the clinical utility of WT1-CTL in these hematologic malignancies. In the setting of solid tumors, we believe that treatment with WT1-CTL may be potentiated through combination approaches with other agents.



Additional Platform Expansion Activities

We anticipate that our T-cell technology platform will have utility beyond the current set of targets to which it has been directed. We and MSK have agreed to collaborate on further research to develop additional cellular therapies, which may include T-cell programs targeted against other antigens and chimeric antigen receptor, or CAR-T, cell programs. Pursuant to the existing agreements with MSK, we have an option to license these additional cellular therapies. We believe that viral antigens are well suited to adoptive immunotherapy given that people with normal immune systems are able to mount robust responses to these viral targets, but immunocompromised patients and some cancer patients are not. We also intend to license or acquire additional product candidates or technologies to enhance our existing T-cell technology platform.

Table of Contents

Our Molecularly-Targeted Product Candidates

STM 434, a Targeted Therapy for Ovarian Cancer and Other Solid Tumors

Our lead molecularly targeted product candidate, STM 434, is in a Phase 1 clinical trial in ovarian cancer and other solid tumors, which commenced in 2014. In October 2015, we received orphan drug designation from the FDA for ovarian cancer. STM 434 is a soluble ActR2B receptor-IgG fusion protein that binds the signaling molecule human activin. STM 434 has the potential to be the first product to target tumor growth and proliferation by inhibiting multiple ActR2B ligands, including Activin A. A ligand is a protein that binds a receptor on a cell to trigger a signal. In ovarian cancer, Activin A is a novel and promising target. Published data, including a study in Clinical Cancer Research in 2008, as well as our preclinical data, suggest that Activin A is upregulated in patients with ovarian cancer, and blocking it reduces proliferation of tumor cells. In many solid tumor types, upregulation of Activin A is correlated with poorer prognoses.

Ovarian Cancer

Ovarian cancer is the fifth leading cause of cancer death in women in the United States. According to the National Cancer Institute, there were an estimated 22,192 new ovarian cancer cases and 14,180 ovarian cancer deaths in the United States in 2015. Surgery and cytotoxic chemotherapies are widely used to treat ovarian cancer; however, the outcomes have changed little in 40 years. There were estimated to be approximately 192,500 women suffering from ovarian cancer in the United States in 2012. According to the American Cancer Society, based on patients diagnosed between 2005 and 2011, the blended five-year survival rate is only 45.6% for ovarian cancer patients overall.

Ovarian cancers are divided into three distinct main subtypes:

- serous adenocarcinoma, which accounts for approximately 63% of ovarian tumors in the United States;
- clear cell cancers, which account for up to 11% of ovarian tumors in Western countries and a higher percentage in Asian countries. For example, clear cell cancers have been reported to account for approximately 23% of ovarian tumors in Japan; and
- granulosa cell tumors, which account for approximately 2% to 5% of ovarian tumors in the United States.

Limitations of Current Therapies for Ovarian Cancer

Despite the strong unmet need for better therapies, there have been few new treatment options introduced, and numerous studies, including a 2012 study published in Obstetrics & Gynecology, have shown that clinical outcomes have not improved significantly for several decades. The number of new cases and deaths in the United States per 100,000 people (all races), age-adjusted, is as follows:

## Table of Contents

### First Line Treatment

Surgical therapy for ovarian cancer that has not escaped the ovary can be curative. In other cases, palliative debulking surgery is done. However, for women with advanced or recurrent tumors that have escaped the ovary and involve critical anatomic structures, there are no curative therapies, and chemotherapy is generally employed. When chemotherapy is indicated, treatment for these subtypes vary but are generally based on a foundation of platinum chemotherapy. Response rates and outcomes vary among subtypes.

- Serous tumors have a reported response rate to chemotherapy of 72% to 73%, according to a 2005 study in the journal *Clinical Cancer Research*; however, most patients relapse, resulting in a median survival of approximately 40.8 months, according to a 2010 publication in the *International Journal of Gynecological Cancer*.
- Clear cell tumors have a platinum-based chemotherapy response rate of approximately 11% as reported in a 2006 study in the *British Journal of Cancer*. Median overall survival in patients with clear cell tumors is approximately 21.3 months.
- The data on post-surgery response rates to chemotherapy in the granulosa subtype of ovarian cancer is limited due to its rarity.

### Recurrent Disease Treatment

For patients whose tumors did not respond to first line therapy, or for those whose tumors became unresponsive to platinum chemotherapy, a number of other chemotherapy options may be applied, including liposomal doxorubicin, topotecan and gemcitabine. Despite these therapies, the median survival of platinum chemotherapy resistant ovarian cancer is approximately 13 months.

### Role of Activin A in Ovarian Cancer and Other Solid Tumors

Activin A, a secreted growth factor, is a member of the TGF- $\beta$  superfamily of growth factors, which also includes Activin B, Activin AB, GDF-11 and others. Activin A is widely understood to be involved in the growth and proliferation of ovarian cancer and other solid tumors. Some of the other secreted proteins in this superfamily, including Activin AB, have also been implicated in the growth of these tumors. As reported in *BMC Medical Genomics* in 2010, overexpression of Activin A in support cells called stroma is a key component of a metastasis-associated gene expression signature. This signature predicts shortened survival across a number of cancers including, ovarian, gastric and breast cancers. Overexpression of Activin A is now recognized as a common feature across advanced solid tumors including head and neck, colon, gastric, esophageal, pancreatic and non-small cell lung cancer. In addition to their role in regulating interactions between epithelial cells and stromal cells, activins may be involved in regulating stem cell survival.

Activin A has been found to play a role in the three principal subtypes of ovarian cancer: serous, clear cell and granulosa. For example, the mRNA precursor for activin has been found to be upregulated in approximately 30% of specimens of serous ovarian cancer. At the protein level, as published in 1997 in the *Journal of Clinical Endocrinology and Metabolism*, most typical serous ovarian cancers made serum Activin A.

Many women with ovarian cancer have high levels of Activin A. The utility of high Activin A in ovarian cancer will be explored in the currently ongoing Phase 1 clinical trial.

### Genetic Linkages to Ovarian Cancer Subtypes

Mutations in the BRCA gene have been found in 5% to 10% of serous ovarian tumors, suggesting that there is a genetic link between the activin pathway and ovarian cancer. According to a 2012 publication in the journal *PloS One*,

these patients with BRCA mutations fail to produce the Activin A counter-regulators follistatin and inhibin, implying that these tumors may be unable to switch off activin signaling.

In clear cell ovarian cancer, studies have shown that mutations in the ARID1A gene contribute to tumor proliferation. Specifically, these mutations drive upregulation in the signaling cascade triggered by the ActR2B receptor. Mutations in the ARID1A gene were present in 46% and 55% of ovarian clear cell tumors, as reported in a 2010 publication in *The New England Journal of Medicine* and a 2014 publication in *BMC Cancer*, respectively. We believe that increased levels of activin mimic the effect of ARID1A mutations, and therefore play a similar role in clear cell ovarian cancer.

In granulosa cell ovarian cancer, mutations in the FOXL2 C134W gene have been suggested in several studies to drive the growth of tumors. This mutation was present in 97% of granulosa cell tumors as reported in a 2009 publication in *The New England Journal of Medicine*. In a normal cell, activin is under tight control—FOXL2 protein turns on follistatin when an activin signal is received, and follistatin, a natural inhibitor of activin, then shuts off the activin signal. However, in granulosa cell tumors, mutant FOXL2 C134W is not able to turn on follistatin, and activin signals continue unchecked. These studies have been reported in 2014 in

## Table of Contents

the journal *Biochemical and Biophysical Research Communications* as well as in 2013 in the journal *Molecular and Cellular Endocrinology*.

### Mechanism of Action of STM 434

We believe that STM 434 has the potential to be the first product to address directly the underlying biology of ovarian tumors.

Activin A is known to act through the ActR2B receptor on the surface of ovary cells. When the receptor receives the signal from Activin A, it initiates a cascade of gene transcription that leads to abnormal cell proliferation, cell migration, blood vessel formation and inhibition of programmed cell death. STM 434 is a ligand trap, which mimics the ActR2B receptor, binding Activin A and other ligands that would normally activate this receptor. Several ligand traps based on other receptors have been developed as therapeutic products and commercialized successfully. The choice of a ligand trap for STM 434 conforms mechanistically with the goal of binding Activin A and other secreted proteins associated with the ActR2B receptor and tumor growth.

### Preclinical Studies

Preclinical testing of STM 434 was designed to confirm and quantify its effects in binding Activin A and other ligands with a receptor-like ligand trap. These studies were conducted with STM 217, a close analog of STM 434, which we refer to as STM 434/s. In addition, these studies were carried out in two types of mouse models: TOV-21G mice, which are analogous to patients with clear cell ovarian tumors and carry ARID1A mutations, and inhibin knockout mice, which are analogous to patients with granulosa cell tumors.

Results of the TOV-21G study have shown that blocking Activin A by using a soluble receptor, as both a single therapy and in combination with chemotherapy, led to a reduction in tumor size. In other experiments, knockout mice that were born without inhibin, and therefore had high activin levels that led to granulosa cell ovarian tumors, survived longer after treatment with STM 434/s in comparison to untreated mice. A 2007 publication in the journal *Molecular Human Reproduction* showed that the survival of the knockout mice was greatly improved when they were treated with an ActR2B-Fc fusion similar to STM 434. Other mouse tumor models tested, including renal cell carcinoma, melanoma and small cell lung cancer, were shown to be sensitive to activin levels and antitumor responses were seen when activins were inhibited.

#### TOV-21G Mouse Models (Clear Cell Ovarian Tumors)

In a preclinical study using TOV-21G mice, tumors derived from human clear cell ovarian carcinoma were shown to have high levels of serum Activin A, analogous to those observed in human ovarian cancer patients as described above.

In a subsequent preclinical study that we presented together with Amgen at the American Society of Clinical Oncology meeting in 2013, we evaluated STM 434/s in this TOV-21G model used as both a single agent and in combination with the chemotherapy agent 5-fluorouracil, or 5-FU. STM 434/s was administered subcutaneously weekly at 10.0 mg/kg beginning on day 12. 5-FU was administered for three cycles. The tumor was measured two to three times per week, up to day 52. Results from these experiments showed a statistically significant ( $p < 0.0001$ ) approximately 30% reduction in tumor volume for the agent. Results of the combination experiments demonstrated in the figure below showed an additive ( $p < 0.0001$ ) approximately 70% reduction in tumor growth.



Table of Contents

Additive Effect with 5-FU

In addition, this study examined the anticachectic effects of STM 434/s in this model. Cachexia is a condition associated with significant weight loss often seen in patients with solid tumor cancers. The results of this study showed that the administration of STM 434/s increased body weight of the mice. In addition to demonstrating the antitumor properties of STM 434/s, we believe that this data also demonstrates that an ActR2B soluble receptor may provide an additional benefit to patients by addressing cancer cachexia. We intend to investigate these attributes as part of our planned Phase 1 clinical trial.

Table of Contents

Inhibin Knockout Mouse Model (Granulosa Cell Tumors)

For granulosa cell studies, a knockout mouse model was used with STM 434/s. The study showed that serum Activin A levels in the knockout mice were elevated, and upon treatment with STM 434/s Activin A levels were significantly reduced.

STM 434/s treatment reduced the elevated circulating Activin A in the inhibin knockout mice to the levels in control mice. Serum Activin A was measured before and 14 days after treatment.

Further, this study showed that treatment with STM 434/s reduced ovary size to near normal in comparison to control mice treated with saline. A representative example of the observed reduction in size is shown below. In this study, STM 434/s was administered as a single dose of 30 mg/kg.



## Table of Contents

Lastly, the knockout model treated with STM 434/s showed a statistically significant ( $p < 0.0001$ ) improvement in survival with approximately 90% alive at 133 days of age, as compared to knockout mice treated with saline, where more than 95% had died by this time.

In July 2014, Amgen provided us a draft report from a 2009 eight-week pharmacology study of STM 217, a compound closely related to STM 434 and which we also refer to as STM 434/s, in orchietomized (neutered) male cynomolgus monkeys. This pharmacology study was designed to explore the ability of STM 217 to reverse the effects of androgen deprivation. In the study, two weekly doses of STM 217 were evaluated at 3 mg/kg and 10 mg/kg. The study found that STM 217 was effective in mitigating the muscle and bone loss that accompany androgen deprivation in this animal model.

In addition to the muscle and bone effects, clinical observations from the study included bleeding from the muzzle (similar to human nosebleeds) in some of the monkeys and one animal bleeding from a skin lesion over the buttock. In this study, it was not possible to determine if the bleeding was caused by STM 217. To further characterize this observation, we performed additional in vitro studies of STM 217 and STM 434. Platelets, a component of blood that helps stop bleeding, were evaluated, and neither STM 217 nor STM 434 impacted platelet function. We also evaluated BMP-9, a factor involved in bleeding and blood vessel development known to be mutated in humans with hereditary hemorrhagic telangiectasia, or HHT. Both STM 217 and STM 434 bound to BMP-9 in these studies, suggesting that the bleeding observed with STM 217 could also be observed with STM 434. The observations from the STM 217 report and the in vitro studies we conducted have been shared with the FDA.

As a result of these findings with STM 217, we altered our STM 434 Phase 1 clinical trial protocol to exclude patients at heightened risk of bleeding and enhance the monitoring of patients for bleeding or increased risk for bleeding. These changes were also shared with the FDA.

### Phase 1 Clinical Trial in Ovarian Cancer and Other Solid Tumors

We commenced an open-label Phase 1 clinical trial of STM 434 in 2014 that will enroll approximately 70 patients. The initial dosing schedule for this trial was once every four weeks. This trial is being conducted in three parts:

- Part 1 — Dose escalation trial in patients with advanced solid tumors. Dosing initiated at 0.25 mg/kg. We plan to test up to the maximum tolerated dose, or MTD. Assuming no MTD is reached, we will test ascending doses of STM 434.
- Part 2 — Designed to obtain additional safety and exploratory efficacy data in patients with advanced ovarian cancer, including clear and granulosa cell tumors.
- Part 3 — Designed to study STM 434 in combination with chemotherapy in patients with ovarian cancer who have received prior treatment.

The objectives for our Phase 1 clinical trial are: to test if STM 434 monotherapy is safe and well tolerated; to obtain preliminary efficacy data in ovarian cancer and other solid tumors; to assess safety and preliminary efficacy of STM 434 with liposomal doxorubicin chemotherapy or the current standard of care; and to explore biomarkers predictive of response to treatment. Further objectives include collecting pharmacokinetic data during therapy with STM 434 and defining the recommended Phase 2 dose.



## Table of Contents

Since initiating this trial in October 2014, we have continued to dose and enroll patients. Bleeding has been observed in a subset of patients. Some of these bleeding events were deemed by the treating investigators to be possibly related to treatment with STM 434. Following review of these events by the safety committee, consisting of the trial sponsor and the trial investigators, the associated doses were deemed safe and well tolerated, and the trial is continuing at escalating doses.

Based on data supporting the role of activin in the progression of other solid tumors and the inclusion criteria, we expect that a number of patients included in the dose escalation portion of the Phase 1 clinical trial will have solid tumors in organs other than the ovary. Other tumors may include pancreas, stomach and kidney tumors, where there is a high correlation between Activin A upregulation and the severity and outcome of disease. We expect to release initial data from this Phase 1 clinical trial in the first half of 2016.

### Biomarker Approach

Activin expression is one of a few biomarkers associated with severity in a variety of tumors including ovarian tumors. For this reason, Activin A is one of 12 genes that are measured in colon cancer as part of the clinically validated OncotypeDX<sup>®</sup> colon cancer panel. Our Phase 1 clinical trial is testing whether high levels of Activin A measured at baseline before patients receive STM 434 predict whether they respond to treatment. If levels of Activin A can predict response, this biomarker may be valuable in late-phase trials to improve the trial design and maximize the proportion of patients who respond to STM 434.

In addition, we will be measuring follicle-stimulating hormone, or FSH, levels using a routine laboratory test, to determine the inhibition of activin by STM 434. It is well established that activin negatively regulates FSH, and we therefore can use FSH reduction as a surrogate for activin inhibition. We also plan to conduct ARID1A and FOXL2 mutation testing in our Phase 1 clinical trial. These mutations have been associated with tumor proliferation.

### PINTA 745 for PEW in ESRD

In December 2015, we announced results from the a Phase 2 proof-of-concept clinical trial for PINTA 745, a molecularly targeted product candidate, for the treatment of protein energy wasting in patients with end stage renal disease. The trial did not meet its primary endpoint, defined as the percent change from baseline in lean body mass as measured by dual energy x-ray absorptiometry at week 12 following weekly treatment with PINTA 745. PINTA 745 also did not improve physical function, measures of glycemic control and markers of inflammation. There were no treatment related serious adverse events observed in the trial. We intend to complete the trial as designed; however, as a consequence of these results, we have suspended further clinical development of PINTA 745.

### Molecularly Targeted Product Candidate Pipeline

Our molecularly targeted product candidate pipeline currently consists of five product candidates that were licensed from Amgen in addition to STM 434. The product candidates in this portfolio are closely related to one another in terms of the biology and align with our in-house expertise regarding development, manufacturing, intellectual property strategy and other critical activities. These products share association with the TGF- $\beta$  superfamily of growth factors. At the same time, they represent distinct modes of intervention with potentially different therapeutic applications. These distinctions relate to target specificity, pharmacokinetic/pharmacodynamic relationships and modality. We believe these product candidates have unique characteristics, and, in some cases, demonstrated activity in preclinical studies, which would make them attractive candidates for various indications, including cancer cachexia, a condition that is implicated in up to 30% of cancer deaths with limited existing treatments. We are evaluating these product candidates to determine the best path forward taking into account the results from the PINTA 745 Phase 2

proof-of-concept trial. Where appropriate, we intend to conduct preclinical studies and file IND applications with regulatory authorities for these candidates.

Our molecularly targeted product candidate pipeline licensed from Amgen includes the following:

- ATA 777, a fully human antibody targeting Activin A, which we believe will be well suited for non-oncology indications where chronic dosing and specificity to Activin A is beneficial;
- ATA M43, a fully human anti-ActR2A/2B monoclonal antibody with high affinity to both receptors that is mechanistically similar to programs targeting muscle wasting diseases;
  - STM 217, a soluble ActR2B receptor-IgG Fc fusion protein and a close analog of STM 434; and
- ActR2B5, a soluble ActR2B receptor that can be fused to an IgG Fc receptor; and
  - ATA 842, a humanized antibody targeting myostatin, designed to be more selective than similar programs in the clinic targeting oncologic, orthopedic and renal indications.

21

---

## Table of Contents

### Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our innovative technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and public and private research institutions. Some of these potential competitors may have a more established presence in the market and significantly greater financial, technical and human resources than we have. Our commercial opportunity 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.

### T-Cell Product Candidates

Should our T-cell product candidates be approved for use, we will face substantial competition. In addition to the current standard of care for patients, commercial and academic clinical trials are being pursued by a number of parties in the field of immunotherapy. Early results from these trials have fueled continued interest in immunotherapy. In addition, if approved, our T-cell programs would compete with currently marketed drugs and therapies used for treatment of the following indications, and potentially with drug candidates currently in development for the same indications.

### EBV-PTLD

There are currently no FDA or EMA approved products for the treatment of EBV-PTLD. However, some approved products and therapies are currently used off-label in this setting, and a number of companies and academic institutions that may license therapies to companies in the future are or may be developing new treatments. 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 EBV-CTL. The current treatment for EBV-PTLD involves administration of rituximab as a single agent or in the SOT setting, in combination with chemotherapy regimens. Additionally, a number of companies and academic institutions are developing drug candidates for EBV-PTLD, including Cell Medica Ltd., or Cell Medica, which is conducting Phase 2 clinical trials for Cytorex EBV, an autologous EBV specific T-cell therapy, in NK/T-cell lymphoma.

### CMV Infection

There are numerous approved products and therapies for the treatment of CMV infection, and a number of companies and academic institutions that may license therapies to companies in the future are or may be developing new treatments for CMV infection. 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 the CMV-CTL. Drug therapies approved or commonly used for CMV infection include antiviral compounds such as ganciclovir, valganciclovir, cidofovir or foscarnet.

Additionally, 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 is conducting Phase 3 clinical trials of letermovir, a CMV terminase inhibitor; Vical Inc., or Vical, which is conducting Phase 3 clinical trials for ASP0113, a bivalent plasma DNA CMV vaccine; and ViraCyte, which is conducting Phase 1 clinical trials for Viralym-C, a CMV-specific third party cell therapy product. Chimerix, Inc., or Chimerix, recently announced that brincidofovir, a

lipid conjugated nucleotide analogue of cidofovir, did not meet the primary endpoints of its Phase 3 trials for the prevention of CMV infection in hematopoietic stem cell transplant recipients.

#### Multiple Myeloma including Plasma Cell Leukemia

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<sup>®</sup> (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; and Adaptimmune Therapeutics PLC, which is conducting Phase 1 / 2 clinical trials for a TCR candidate targeting NY-ESO-1.

#### Molecularly Targeted Product Candidates

If approved, STM 434 would compete with currently marketed drugs and therapies used for treatment of the following indications, and potentially with drug candidates currently in development for the same indications.

## Table of Contents

### Ovarian Cancer

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 chemotherapy compound such as liposomal, doxorubicin, paclitaxel or topotecan; olaparib in patients with deleterious or suspected deleterious germline 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.

We are aware of other companies engaged in clinical development of compounds for treatment of ovarian cancer. These include:

- PARP inhibitors such as Tesaro, Inc.'s niraparib;
- angiogenesis inhibitors, such as F. Hoffman-La Roche's bevacizumab (Avastin);
- VEGFR tyrosine kinase inhibitors such as Boehringer Ingelheim GmbH's nintedanib and AstraZeneca plc's recentin;
- selective 17,20-lyase inhibitors such as Takeda Pharmaceutical Co. Ltd.'s TAK-700;
- anti-folates such as Eisai Co. Ltd.'s farletuzumab; and
- other therapies in development, including those from GlaxoSmithKline plc, Amgen and Clovis Oncology, Inc.

### License Agreements

#### MSK Option and License Agreement

In September 2014, we entered into an exclusive option agreement with MSK under which we acquired the right to exclusively license from MSK the worldwide rights to three clinical stage T-cell programs. The initial option period was for 12 months. In exchange for the exclusive option, we paid MSK \$1.25 million in cash and issued 59,761 shares of our common stock to MSK. We and MSK also agreed to collaborate on further research to develop additional cellular therapies, which may include T-cell programs targeted against other antigens and/or CAR-T, and which we also would hold an option to license, if developed.

In June 2015, we exercised the option and entered into a license agreement with MSK. Under the terms of the license agreement, MSK granted us a worldwide, exclusive license under certain patent rights, know-how and a library of T-cells and cell lines, to research, develop, manufacture and commercialize T-cell products specific to CMV, EBV or WT1 that comprise or are based on or made using such licensed rights. MSK also agreed to transfer certain INDs related to the licensed products to us. We have agreed to use commercially reasonable efforts to commercialize the licensed products and, if commercialized, continue active marketing efforts for any commercialized licensed product through the term of the license agreement.

In connection with the option exercise and the execution of the license agreement, we made an upfront cash payment to MSK of \$4.5 million. We are obligated to make additional milestone payments of up to \$33.0 million with respect to the three licensed clinical stage T-cell programs based on achievement of specified development, regulatory and sales-related milestones. We are also required to make escalating mid to high single-digit royalty payments to MSK based on sales of any licensed products. In addition, under certain circumstances, we must make certain minimum annual royalty payments to MSK, which are creditable against earned royalties owed for the same annual period. We are also obligated to pay a low double-digit percentage of consideration we receive for sublicensing the licensed rights.

The license agreement expires for each licensed T-cell product on a licensed product-by-licensed product basis and a country-by-country basis, on the latest of: (i) expiration of the last licensed patent rights related to such licensed product in such country, (ii) expiration of any market exclusivity period granted by law with respect to such licensed product in such country, and (iii) a specified number of years after the first commercial sale of the licensed product in such country. Upon expiration of the license agreement, the licenses granted to us will become non-exclusive royalty-free, perpetual and irrevocable. MSK may terminate the license agreement if we materially breach the agreement and does not cure such breach within a specified period or if we experience certain insolvency events.

#### Amgen License Agreements

In September 2012, we entered into two license agreements with Amgen under which Amgen granted us worldwide exclusive licenses under certain Amgen patent rights and regulatory filings, and non-exclusive licenses under certain Amgen know-how, to



## Table of Contents

develop and commercialize products comprising certain of Amgen's proprietary compounds known as AMG 777, AMG 434, AMG 217, ActR2B5, AMG 842 and M43. We now refer to AMG 777 as ATA 777, AMG 434 as STM 434, AMG 217 as STM 217 and AMG 842 as ATA 842. We have the right, subject to certain limitations, to grant sublicenses under such licensed intellectual property, in connection with licensing the covered products.

Under both of these license agreements, we are responsible for the worldwide development and commercialization of the licensed products, at our cost, are required to use commercially reasonable efforts with respect to such development and commercialization activities, and must meet certain specific diligence obligations. In exchange for these licenses, we issued 410,256 shares of Series A-1 convertible preferred stock. Each of the 410,256 shares of Series A-1 convertible preferred stock converted into one share of common stock immediately prior to completion of our initial public offering. We are obligated to make payments to Amgen upon the achievement of certain development and commercialization milestones totaling up to \$81.5 million for each license agreement, as well as escalating low to mid-single-digit royalties based on sales of the licensed products by us, our affiliates or our sublicensees. We hold the first right to file, prosecute, maintain and enforce all licensed rights under these licenses throughout the world, and Amgen retains certain step-in rights.

Both license agreements with Amgen, unless terminated earlier, will continue on a country-by-country basis until the expiration of the last to expire of all royalty obligations we owe to Amgen, which will occur on the later of (a) the date on which exploitation of a licensed product is no longer covered by a valid claim of a patent under the agreement which covers the product in an applicable country, (b) the loss of regulatory exclusivity in such country, or (c) 10 years after the first commercial sale of the applicable licensed product in such country. Upon expiration of each agreement, we retain non-exclusive rights to the relevant licensed Amgen intellectual property. Amgen may terminate either agreement if we materially breach the agreement and do not cure such breach in a specified notice period, for a failure of our specified diligence obligations, if we experience certain insolvency events, or if we or our sublicensee challenge the patentability, validity or enforceability of any of the Amgen patents licensed under the applicable agreement. We may terminate each agreement for Amgen's uncured material breach, or if our board of directors concludes that, due to safety, efficacy, marketability, patent coverage or competition concerns, the development or commercialization of the relevant licensed product is no longer commercially practicable for us.

## Intellectual Property

### Patents

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing US and non-US patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Additionally, we expect to benefit from a variety of statutory frameworks in the United States, Europe and other countries that relate to the regulation of biosimilar molecules and orphan drug status. These statutory frameworks provide certain periods of regulatory exclusivity for qualifying molecules. See "Government Regulation."

We seek composition-of-matter and method-of-treatment patents for each of our product candidates in key therapeutic areas.

Our in-licensed and proprietary patent estate, on a worldwide basis, is very large and consists of over 100 issued patents and 200 pending patent applications. These figures include in-licensed patents and patent applications to

which we generally hold exclusive commercial rights.

Individual patents extend for varying periods of time depending on the date of filing of the patent application, the priority date claimed and the legal term of patents as determined by the applicable law in the countries in which those patents are obtained.

Generally, patents issued from applications filed in the United States are effective for 20 years from the earliest non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period; however, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. In addition, patent term adjustments can extend term to account for certain delays by the U.S. Patent and Trademark Office, or USPTO, during prosecution before that office. The duration of non-US patents varies in accordance with provisions of applicable local law, but typically, a patent's life is 20 years from the earliest international filing date. Our licensed, issued US patents are expected to expire on dates ranging from 2027 to 2029, and our licensed issued non-US patents are expected to expire on dates ranging from 2023 to 2029, exclusive of possible patent term extensions. Our pending owned and licensed applications with respect to our product candidates, if issued, are expected to expire, as to applications filed in the United States, on dates ranging from 2023 to 2035, and, as to applications filed in jurisdictions outside the

## Table of Contents

United States, on dates ranging from 2023 to 2035, exclusive of possible patent term extensions or adjustments. However, the actual protection afforded by a patent varies on a product- by-product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of extensions of patent term, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

National and international patent laws concerning protein-based biologics such as our products remain highly unsettled. No consistent policy regarding the patent-eligibility or the breadth of claims allowed in such patents has emerged to date among the United States, Europe and other countries. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries can diminish our ability to protect our inventions and enforce our intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that may be granted in our patents or in third-party patents. The biotechnology and pharmaceutical industries are characterized by extensive intellectual property litigation. Our ability to maintain and solidify our proprietary position for our product candidates and technology will depend on our success in obtaining effective claims for any patent and enforcing those claims once a patent is granted. We do not know whether any of the patent applications that we may file or license from third parties will result in the issuance of any patents. The issued patents that we own or may receive in the future may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with sufficient protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of any drug we may develop from our product candidates, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent. The patent positions for our product candidates are summarized below:

### T-cell Technology Patent Portfolio

We hold exclusive rights to one pending US provisional patent application directed to EBV-CTL methods of use claims, one pending US provisional patent application directed to CMV-CTL method of use claims, and two pending US provisional patent applications directed to WT1-CTL method of use claims. In addition, we have exclusively licensed MSK's rights under two pending provisional applications directed to CMV-CTL method of use claims for treatment of CMV retinitis in HIV-infected patients and SOT recipients, which are co-owned by MSK and another entity from which we have not licensed rights. We also hold exclusive rights to one pending international patent application, one pending Argentine patent application, and one pending Taiwanese patent application, all directed to methods of identifying and selecting allogeneic T-cell lines for therapeutic use. The United States patent system permits the filing of provisional and non-provisional patent applications. A provisional patent application is not examined for patentability by the USPTO and automatically expires 12 months after its filing date. As a result, a provisional patent application cannot mature into a patent. Provisional patent applications are often used, among other things, to establish an early effective filing date for a later-filed non-provisional patent application. A non-provisional patent application is examined by the USPTO and can mature into a patent once the USPTO determines that the claimed invention meets the standards for patentability.

### STM 434 Patent Portfolio

We hold exclusive rights to four issued US patents directed to STM 434 relating to composition-of-matter and related methods of use claims, and issued patents or pending patent applications related to STM 434 in many jurisdictions worldwide, including in the United States, Argentina, Australia, Brazil, Botswana, Canada, Chile, China, Colombia, Costa Rica, Algeria, the Eurasian Patent Office, Egypt, the European Patent Office, the Gulf Cooperation Council, Hong Kong, Indonesia, Israel, India, Jordan, Japan, the Republic of Korea, Libya, Morocco, Mexico, Malaysia, New

Zealand, Peru, the Philippines, Singapore, South Africa, Tunisia, Taiwan, Ukraine and Vietnam. The expected expiration dates for these patents and patent applications range from 2026 to 2035, exclusive of possible patent term extensions or adjustments.

#### Trade Secrets

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed by an employee. These agreements may be breached, and we may not have adequate remedies for any such breach or any unauthorized disclosure of our proprietary information. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

## Table of Contents

### Government Regulation

#### Overview of US Government Regulation

The preclinical studies and clinical testing, manufacture, labeling, storage, recordkeeping, advertising, promotion, export, marketing and sales, among other things, of our product candidates are subject to extensive regulation by governmental authorities in the United States and other countries. In the United States, pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. We expect STM 434 to be regulated by the FDA as a biologic and to be reviewed by the Center for Drug Evaluation and Research. Protein therapeutics require the submission of a biologics license application, or BLA, and approval by the FDA prior to being marketed in the United States. Manufacturers of protein therapeutics may also be subject to state regulation.

Our T-cell product candidates, including EBV-CTL and CMV-CTL, are regulated by the FDA as biologics, reviewed by the Center for Biological Evaluation and Research, and will require the submission of BLAs and approval by the FDA prior to being marketed in the United States. For CTL trials conducted at, or sponsored by, institutions receiving NIH funding for recombinant DNA research, prior to the submission of an IND to the FDA, a protocol and related documents must be submitted to, and the study registered with, the NIH Office of Biotechnology Activities, or the OBA, pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules, or the NIH Guidelines. Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA. However, many companies and other institutions, not otherwise subject to the NIH Guidelines, voluntarily follow them. The NIH is responsible for convening the recombinant DNA advisory committee, or RAC, that discusses protocols that raise novel or particularly important scientific, safety or ethical considerations at one of its quarterly public meetings. The OBA will notify the FDA of the RAC's decision regarding the necessity for full public review of a protocol. RAC proceedings and reports are posted to the OBA website and may be accessed by the public.

Failure to comply with FDA requirements, both before and after product approval, may subject us or our partners, contract manufacturers, and suppliers to administrative or judicial sanctions, including FDA refusal to approve applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines and/or criminal prosecution.

The steps required before a biologic may be approved for marketing of an indication in the United States generally include:

- completion of preclinical laboratory tests, animal studies and formulation studies conducted according to good laboratory practices, or GLP, and other applicable regulations;
- submission to the FDA of an investigational new drug, or IND, application, which must become effective before human clinical trials may commence;
- completion of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish that the biological product is “safe, pure and potent”, which is analogous to the safety and efficacy approval standard for a chemical drug product for its intended use;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA preapproval inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with applicable current good manufacturing practices, or cGMP and in the case of our T-cell product candidates, good tissue practices, or GTP; and
- FDA review of the BLA and issuance of a biologics license.

Before conducting studies in humans, laboratory evaluation of product chemistry, toxicity and formulation as well as animal studies to assess the potential safety and efficacy of the biologic candidate must be conducted. Preclinical toxicology studies in animals must be conducted in compliance with FDA regulations. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. In addition to including the results of the preclinical testing, the IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase or phases of the clinical trial lend themselves to an efficacy determination. The IND will automatically become effective 30 days after receipt by the FDA, unless the FDA within the 30-day time period places the IND on clinical hold because of safety concerns about the product candidate or the conduct of the trial described in the clinical protocol included in the IND. The IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

All clinical trials for new drugs and biologics must be conducted under the supervision of one or more qualified principal investigators in accordance with GCP. They must be conducted under protocols detailing the objectives of the applicable phase of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors must also report to the FDA, within certain timeframes, serious and unexpected adverse

## Table of Contents

reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product candidate. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution, approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, and monitor the trial until completed.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap and different trials may be initiated with the same product candidate within the same phase of development in similar or differing patient populations.

Phase 1 clinical studies may be conducted in a limited number of patients or healthy volunteers, as appropriate. The product candidate is initially tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmacodynamics and pharmacokinetics.

Phase 2 usually involves trials in a larger, but still limited, patient population to evaluate preliminarily the efficacy of the product candidate for specific, targeted indications to determine dosage tolerance and optimal dosage and to identify possible short-term adverse effects and safety risks.

Phase 3 trials are undertaken to further evaluate clinical efficacy of a specific endpoint and to test further for safety within an expanded patient population at geographically dispersed clinical trial sites. Phase 1, Phase 2 or Phase 3 testing might not be completed successfully within any specific time period, if at all, with respect to any of our product candidates. Results from one trial are not necessarily predictive of results from later trials. Furthermore, the FDA or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients. A sponsor may request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. An SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins for an SPA to be approved. Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement if public health concerns emerge that were unrecognized at the time of the protocol assessment or the FDA determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun. An SPA does not guarantee that a trial will be successful or will in fact be accepted by FDA as sufficient for approval.

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of a BLA requesting approval to market the product candidate for a proposed indication. Under the Prescription Drug User Fee Act the fees payable to the FDA for reviewing a BLA, as well as annual fees for commercial manufacturing establishments and for approved products, can be substantial but are subject to certain limited deferrals, waivers and reductions that may be available. The fees typically increase each year. Each BLA submitted to the FDA for approval is reviewed for administrative completeness and reviewability within 60 days following receipt by the FDA of the application. If the BLA is found complete, the FDA will file the BLA, triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. The FDA's established goal is to review 90% of priority BLA applications within six months after the application is accepted for filing and 90% of standard BLA applications within 10 months of the acceptance date, whereupon a review decision is to be made. The FDA, however, may not approve a product candidate within these established goals and its review goals are subject to

change from time to time. Further, the outcome of the review, even if generally favorable, may not be an actual approval but a “complete response letter” that describes additional work that must be done before the application can be approved. Before approving a BLA, the FDA may inspect the facility or facilities at which the product is manufactured and will not approve the product unless the facility complies with cGMP. The FDA may deny approval of a BLA if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can extend the review process. FDA approval of any application may include many delays or never be granted. If a product is approved, the approval may impose limitations on the uses for which the product may be marketed, may require that warning statements be included in the product labeling, may require that additional studies be conducted following approval as a condition of the approval, and may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a Risk Evaluation and Mitigation Strategy, or REMS, or otherwise limit the scope of any approval. The FDA must approve a BLA supplement or a new BLA before a product may be marketed for other uses or before certain manufacturing or other changes may be made. Further post-marketing testing and surveillance to monitor the safety or efficacy of a product is required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.



## Table of Contents

Under the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, a statutory pathway has been created for licensure, or approval, of biological products that are biosimilar to, and possibly interchangeable with, earlier biological products licensed under the Public Health Service Act. Also under the BPCIA, innovator manufacturers of original reference biological products are granted 12 years of exclusivity before biosimilars can be approved for marketing in the United States. The implementation of an abbreviated approval pathway for biological products is under the direction of the FDA and is currently being developed. The FDA has issued several draft guidances for industry related to the BPCIA, addressing scientific, quality and procedural issues relevant to an abbreviated application for a biosimilar product. The approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the BLA for the product are subject to comprehensive regulatory oversight. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP and GTP requirements, as applicable and the FDA periodically inspects manufacturing facilities to assess compliance with these standards. Accordingly, manufacturers must continue to spend time, money and effort to maintain compliance.

### Orphan Drug Act

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation. Orphan drug designation must be requested before submitting a BLA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the holder of the approval is entitled to a seven-year exclusive marketing period in the United States for that product except in very limited circumstances. For example, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven-year exclusive marketing period. In addition, holders of exclusivity for orphan drugs are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the drug.

Legislation similar to the Orphan Drug Act has been enacted outside the United States, including in the EU. The orphan legislation in the EU is available for therapies addressing chronic debilitating or life-threatening conditions that affect five or fewer out of 10,000 persons or are financially not viable to develop. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity. The market exclusivity may be extended to 12 years if the sponsor completes a pediatric investigation plan agreed upon with the relevant committee of the EMA.

### Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review and accelerated approval, which are intended to expedite or simplify the process for developing and reviewing promising drugs, or to provide for the approval of a drug on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and

expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of 10 months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a product candidate receiving accelerated approval perform post-marketing clinical trials to confirm the clinically meaningful outcome as predicted by the surrogate marker trial.

In addition to the Fast Track, accelerated approval and priority review programs discussed above, the FDA also provided guidance on breakthrough therapy designation. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for

## Table of Contents

accelerated approval. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives: intensive guidance on an efficient drug development program; intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review; and rolling review.

### Companion Diagnostics

If levels of Activin A can predict response, this companion diagnostic biomarker may be valuable in late-phase trials to improve the trial design and maximize the proportion of patients who respond to STM 434. Companion diagnostics are regulated as medical devices. Diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. If use of companion diagnostic is essential to safe and effective use of a drug or biologic product, then the FDA generally will require approval or clearance of the diagnostic contemporaneously with the approval of the therapeutic product. The FDA has generally required companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic simultaneously with approval of the therapeutic. The review of these in vitro companion diagnostics in conjunction with the review of a cancer therapeutic involves coordination of review by the FDA's Center for Biologics Evaluation and Research and by the FDA's Center for Devices and Radiological Health.

### Reimbursement

In both domestic and foreign markets, sales and reimbursement of any approved products will depend, in part, on the extent to which the costs of such products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. The containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. In addition, there is significant uncertainty regarding the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. If third-party payors do not consider our products to be cost-effective compared to other therapies, the payors may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Within the United States, if we obtain appropriate approval in the future to market any of our current product candidates, we may seek approval and coverage for those products under Medicaid, Medicare and the Public Health Service, or PHS, pharmaceutical pricing program and also seek to sell the products to federal agencies.

Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, manufacturers are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate for each product is set by law and may be subject to an additional discount if certain pricing increases more than inflation.

Medicare is a federal program administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that do not need to be administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the US government and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from

time-to-time.

Medicare Part B covers most injectable drugs given in an in-patient setting, and some drugs administered by a licensed medical provider in hospital outpatient departments and doctors' offices. Medicare Part B is administered by Medicare Administrative Contractors, which generally have the responsibility of making coverage decisions. Subject to certain payment adjustments and limits, Medicare generally pays for Part B covered drugs based on a percentage of manufacturer-reported average sales price.

Drug products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule, or FSS.

FFS participation is required for a drug product to be covered and paid for by certain federal agencies and for coverage under Medicaid, Medicare Part B and the PHS pharmaceutical pricing program. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended to not exceed the price that a manufacturer charges its most-favored non-federal customer for its product. In addition, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TRICARE retail pharmacy program), Coast Guard, and PHS are subject

29

---

## Table of Contents

to a cap on pricing (known as the “federal ceiling price”) and may be subject to an additional discount if pricing increases more than inflation.

To maintain coverage of drugs under the Medicaid Drug Rebate Program, manufacturers are required to extend discounts to certain purchasers under the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics and other entities that receive health services grants from the PHS.

The United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or the Affordable Care Act, which included changes to the coverage and payment for drug products under government health care programs. Adoption of other new legislation at the federal or state level could further limit reimbursement for pharmaceuticals. Outside the United States, ensuring adequate coverage and payment for our products will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. Recent budgetary pressures in many European Union countries are also causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost-containment measures. Cost-control initiatives could decrease the price we might establish for products that we may develop or sell, which would result in lower product revenues or royalties payable to us. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

## Foreign Regulation

In addition to regulations in the United States, we expect to be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval for a product candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Certain countries outside of the United States have a process that requires the submission of a clinical trial application, or CTA, much like an IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country’s requirements, clinical trial development may proceed in that country. In all cases, the clinical trials must be conducted in accordance with GCP and other applicable regulatory requirements.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and

optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period.

As in the United States, we may apply for designation of a product as an orphan drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 11 years of exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product.

#### Additional Regulation

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and

## Table of Contents

waste generated by, our operations. Our research and development involves the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biological products, government control and other changes to the healthcare system of the United States. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payers for medical goods and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect medical or healthcare reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

## Manufacturing

Our initial strategy is to outsource the manufacturing of drug substance and drug product for our preclinical studies and clinical trials. We also outsource fill-finish, packaging, labeling, storage, shipping and distribution. This allows us to rapidly conduct manufacturing activities for multiple programs in parallel. It also allows us to balance the requirements of multiple programs and avoid costly investment in manufacturing infrastructure and personnel before clinical data are available. Our internal capabilities and experience in the manufacturing of protein therapeutics encompass a broad range of activities including cell line development, process development, analytical development, formulation development, clinical and commercial scale GMP manufacturing, quality control and quality assurance. We have less substantial internal technical expertise in the manufacture of cellular therapeutics; however, we are currently building those capabilities through our ongoing hiring activities. This breadth of experience allows us to effectively oversee and direct the activities of our contract manufacturers and testing facilities. In selecting contract manufacturing organizations, or CMOs, to manufacture our product candidates, we generally strive to select the CMO 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. Although this approach, when coupled with the range of CMO capabilities, requires us to utilize multiple CMOs in the manufacturing of our product candidates, we believe it may also mitigate the need for costly and time-consuming process transfers later in development. Ultimately, we believe that our outsourced model and approach to CMO management will allow us to efficiently scale our manufacturing processes to support our current clinical development programs and the potential commercialization of our product candidates. As our product candidates progress towards potential marketing approvals, we may choose to build or acquire through other means our own manufacturing facilities in order to maintain more substantial control over our supply chain.

Our EBV and CMV-CTL product candidates require blood from healthy, consenting third-party donors as starting materials. The manufacturing process involves co-culturing and incubating viral or cancer specific antigen transformed B-cells collected from the blood of third party-donors with T-cells collected from the same donor, all under GTPs. GTPs are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing.

Pursuant to our June 2015 license agreement with MSK, we acquired the right to use certain manufacturing process know-how related to producing clinical research-related drug supply. This included materials to support the manufacturing of clinical trial material including key starting materials and intermediates as well as existing inventory of clinical trial materials. We have entered into an agreement with a CMO to develop and manufacture our EBV-CTL. We are currently in the process of transferring the manufacturing processes from MSK to our CMO. We have also entered into a supply agreement with a third party to ensure we have the necessary blood donated from healthy consenting third-party donors. The transfer of manufacturing processes to our CMO will include modifications to the processes to suit the CMO's facility and capability constraints, improvements in the manufacturing process as well as product comparability testing. Moreover, we will also need to develop commercial-scale manufacturing processes for the EBV-CTLs for the planned pivotal trials, with the proposed dose and schedule to be used in clinical practice and at a cost sufficient to support profitable commercialization. We and our CMOs may be required to make further investments to manufacture product for commercialization, including potentially the construction or acquisition of a wholly-owned manufacturing facility. Our other T-cell product candidates are currently manufactured by MSK using readily available raw materials and established manufacturing procedures.

Our lead molecularly targeted product candidate, STM 434, is manufactured using readily available raw materials and established manufacturing procedures. STM 434 is produced in bioreactors using hamster ovary cells that have been genetically



## Table of Contents

engineered to produce this specific product candidate. All of our other molecularly targeted product candidates, other than PINTA 745, will also be produced in bioreactors using mammalian cells.

Concurrent with the license of our existing molecularly targeted product candidates from Amgen, we acquired certain manufacturing process know-how related to producing clinical research-related drug supply. In the case of STM 434, this included GMP materials to support the manufacturing of clinical trial material. We have already transferred the downstream elements of the STM 434 manufacturing process to a CMO, and we have initiated transfer of the upstream components of the STM 434 manufacturing process to a CMO. We are also developing a refrigerated liquid formulation of the STM 434 drug product. We and our CMOs will be required to make further investments to manufacture product for pivotal studies, as well as for commercialization, including potentially the construction or acquisition of a wholly-owned manufacturing facility. In the case of our earlier stage molecularly targeted product candidates, this know-how was more limited in scope, as these product candidates were pre-master cell bank in stage of development at the time of licensing.

## Employees

As of February 15, 2016, we had 55 employees. All of our personnel are co-employees of Atara and TriNet, a professional human resource service organization. Under our agreement with TriNet, TriNet is a co-employer of our personnel, and is responsible for administering all payroll functions, including tax withholding, and providing health insurance and other benefits for these individuals. We reimburse TriNet for these costs and pay TriNet a fee for its services. We are responsible for, and control, all aspects of the hiring, retention, compensation, management and supervision of our personnel. We consider the terms of our contract with TriNet to be reasonable and customary and believe this arrangement provides substantial benefit to us, in the form of lower costs for employee benefits and reduced administrative burden on us.

## Corporate Information

We were incorporated in Delaware in 2012 and completed our initial public offering in October 2014. Our principal corporate offices are located at 701 Gateway Blvd., Suite 200, South San Francisco, CA 94080 and our telephone number at that address is (650) 278-8930.

## Available Information

Our website address is [www.atarabio.com](http://www.atarabio.com). We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and other materials with the SEC. We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements, and other information with the SEC. Such reports and other information filed by the Company with the SEC are available free of charge on our website at [investors.atarabio.com](http://investors.atarabio.com).

The public may also read and copy any materials filed by Atara with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at [www.sec.gov](http://www.sec.gov).



Table of Contents

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 Annual Report on Form 10-K, including the section of this report titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated and combined 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.

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 year ended December 31, 2015, we reported a net loss of \$57.2 million and we had an accumulated deficit of \$98.1 million as of December 31, 2015.

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.

Table of Contents

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 US 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 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 another academic institution. 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 of up to \$85.0 million to Amgen and up to \$9.0 million to MSK with respect to the three licensed clinical stage T-cell programs upon the achievement of certain development and regulatory approval milestones. We are also obligated to make payments for certain 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.

Table of Contents

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 December 31, 2015, we had total cash, cash equivalents and short-term investments of \$320.5 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 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 US 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



## Table of Contents

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;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- develop manufacturing and distribution processes for our novel T-cell product candidates;
- manufacturing products 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 PINTA 745 Phase 2 proof-of-concept trial did not meet its primary endpoint, and we suspended further development of 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 and 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.

## Table of Contents

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;

37

---

## Table of Contents

- 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 PINTA 745 Phase 2 proof-of-concept trial 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.

Table of Contents

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, 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



## Table of Contents

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 the product candidates we have licensed from Amgen or MSK may also decrease the period of commercial exclusivity under our corresponding product candidate license from Amgen or MSK. 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. 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 for EBV-CTL for EBV-PTLD after HCT or SOT. We have also applied for orphan drug status with the EMA for EBV-associated lymphoproliferative disorder following allogeneic HCT.

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

Table of Contents

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 studies;

41

---

Table of Contents

- 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. We are in the process of transferring this know-how to our CMOs to facilitate the manufacture of additional drug substance and drug product for our preclinical studies and clinical trials using the know-how and supplies we received from Amgen and MSK. 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

42

---

Table of Contents

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 and unusable product. 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 clinics, 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 of EBV-CTL, CMV-CTL and WT1-CTL as well as perform the analysis, publication and presentation of data and results related to these 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 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



Table of Contents

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. We currently 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

Table of Contents

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. Moreover, we will need to transfer the manufacturing know-how developed by and housed at MSK. We are in the process of transferring the manufacturing of EBV-CTLs 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-CMV, CMV-CTL and WT1-CTL may be negatively impacted. We need to identify CMOs for the production of CMV-CTL and WT1-CTL and 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 may need to build our own 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.

Table of Contents

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 2035 for US patents and patent applications, if issued, and from 2026 through 2035 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 US 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 not 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 two 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 recently filed several 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

## Table of Contents

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-US patent offices. Numerous US and non-US 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 requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. 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



Table of Contents

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,

Table of Contents

develop, make, use, offer for sale, sell and import, EBV-CTL, CMV-CTL and WT1-CTL. Two pending provisional applications licensed to us by MSK that are both 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.

## Table of Contents

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 US 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.

## Table of Contents

### 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,



Table of Contents

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.

## Table of Contents

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 2 clinical studies for Cytorex EBV, an autologous EBV specific T-cell therapy in NK/T-cell lymphoma.

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 is conducting Phase 3 clinical trials of letermovir, a CMV terminase inhibitor; Vical Inc., or Vical, which is conducting Phase 3 clinical trials for ASP0113, a bivalent plasma DNA CMV vaccine; and ViraCyte, which is conducting Phase 1 clinical trials for Viralym-C, a CMV-specific allogeneic cell therapy product. Chimerix, Inc., or Chimerix, which is conducting Phase 2 and Phase 3 clinical trials for brincidofovir, a lipid conjugated nucleotide analogue of cidofovir, recently announced that the Phase 3 trials for the prevention of CMV infection in hematopoietic stem cell transplant recipients did not meet the primary endpoints.

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<sup>®</sup> (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; 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.

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

## Table of Contents

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 February 15, 2016, we had 55 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 clinical studies and 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 clinical studies and 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 Chief Medical 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

Table of Contents

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.



## Table of Contents

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.

## Table of Contents

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 coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological 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.

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 December 31, 2015, 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;

57

---

Table of Contents

- 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.

As of December 31, 2015, our executive officers, directors and stockholders that we have concluded are affiliates of us together owned approximately 33% of our outstanding voting stock, assuming no exercise of outstanding options. 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. We will cease to be an “emerging growth

Table of Contents

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. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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.



Table of Contents

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 restricted stock units, or 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. 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.

Table of Contents

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 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters are currently located in South San Francisco, California and consist of 7,038 square feet of leased office space under a sublease that expires in January 2017. Our research and development facility is located in Westlake Village, California and consists of approximately 15,380 square feet of leased office space under a lease that expires in April 2019.

In December 2015, we entered into a lease agreement for approximately 13,670 square feet of office space in South San Francisco, California, which is intended to be our new corporate headquarters. The lease is expected to expire in April 2021.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.



Table of Contents

## PART II

## Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

## Market Information

Our common stock has been listed on The Nasdaq Stock Market under the symbol "ATRA" since October 16, 2014. Prior to that time, there was no public market for our common stock. The following table sets forth for the indicated periods the high and low intra-day sales prices per share for our common stock on The Nasdaq Stock Market.

Year ended December 31, 2014	High	Low
Fourth Quarter (beginning October 16, 2014)	\$35.45	\$9.66
Year ended December 31, 2015	High	Low
First Quarter	\$43.66	\$17.20
Second Quarter	\$64.35	\$36.00
Third Quarter	\$65.56	\$30.49
Fourth Quarter	\$40.80	\$19.50

On February 15, 2016, there were 10 stockholders of record of our common stock and the closing price of our common stock was \$15.41 per share as reported on The Nasdaq Stock Market. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

## Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings for use in the operation of our business and do not intend to declare or pay any cash dividends in the foreseeable future. Any further determination to pay dividends on our capital stock will be at the discretion of our board of directors, subject to applicable laws, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors considers relevant.

## Purchases of Equity Securities by the Issuer or Affiliated Purchasers

There were no repurchases of shares of common stock made during the year ended December 31, 2015.

## Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

## Use of Proceeds from Initial Public Offering of Common Stock

In October 2014, we completed our initial public offering in which 5,750,000 shares of our common stock (inclusive of 750,000 shares from the full exercise by the underwriters of their option to purchase additional shares) were sold at a price of \$11.00 per share, resulting in net proceeds of \$56.5 million. All of the shares issued and sold in the offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No.333-196936), which was declared effective by the SEC on October 15, 2014. There was no material change in the planned use of proceeds from our initial public offering as described in the final prospectus dated October 15, 2014 and filed with the SEC on October 16, 2014. As of March 4, 2016, substantially all of the net proceeds from the initial public offering had been utilized.

#### Stock Performance Graph

Set forth below is a graph comparing the cumulative total return on an indexed basis of a \$100 investment in the Company's common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index commencing on October 16, 2014 (the date our common stock began trading on The Nasdaq Stock Market) and continuing through December 31, 2015. The graph assumes our closing sale price on October 16, 2014 of \$10.65 per share as the initial value of our common stock for indexing purposes. Points on the graph represent the performance as of the last business day of each of the fiscal quarters indicated.

Table of Contents

This performance graph shall not be deemed “soliciting material” or to be “filed” with the SEC for purposes of Section 18 of the Exchange Act or incorporated by reference into any filing of Atara Biotherapeutics, Inc. under the Securities Act or the Exchange Act, except to the extent we specifically incorporate it by reference into such filing. The past performance of our common stock is no indication of future performance.

COMPARISON OF CUMULATIVE TOTAL RETURN\*

Among Atara Biotherapeutics, Inc., the Nasdaq Composite Index and the Nasdaq Biotechnology Index

\* Assumes \$100 invested in our common stock or the related index on October 16, 2014.

63

---

Table of Contents

## Item 6. Selected Consolidated and Combined Financial Data

The following selected consolidated and combined financial data of the Company for each of the periods indicated are derived from the Company's audited consolidated and combined financial statements. The consolidated and combined financial statements of the Company as of December 31, 2015 and 2014 and for the years ended December 31, 2015, 2014 and 2013, and the related reports of the independent registered public accounting firm are included elsewhere in this Annual Report on Form 10-K. The data presented below should be read in conjunction with the Company's financial statements, the notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report.

	Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013	Period from Aug. 22, 2012 (Inception) to December 31, 2012
Consolidated and Combined Statements of Operations and Comprehensive Loss Data:				
	(In thousands, except per share amounts)			
<b>Operating expenses:</b>				
Research and development	\$41,618	\$14,380	\$4,306	\$241
Research and development costs paid to Amgen	—	1,066	553	3,018
General and administrative	16,830	12,710	3,756	834
<b>Total operating expenses</b>	<b>58,448</b>	<b>28,156</b>	<b>8,615</b>	<b>4,093</b>
Loss from operations	(58,448 )	(28,156 )	(8,615 )	(4,093 )
Interest and other income, net	1,218	125	12	—
Loss before provision for income taxes	(57,230 )	(28,031 )	(8,603 )	(4,093 )
Provision (benefit) for income taxes	(9 )	(25 )	170	17
<b>Net loss</b>	<b>\$(57,221 )</b>	<b>\$(28,006 )</b>	<b>\$(8,773 )</b>	<b>\$(4,110 )</b>
<b>Other comprehensive loss:</b>				
Unrealized loss on available-for-sale securities	(418 )	(100 )	—	—
<b>Comprehensive loss</b>	<b>\$(57,639 )</b>	<b>\$(28,106 )</b>	<b>\$(8,773 )</b>	<b>\$(4,110 )</b>
<b>Basic and diluted net loss per common share</b>	<b>\$(2.24 )</b>	<b>\$(5.62 )</b>	<b>\$(9.08 )</b>	<b>\$(5.60 )</b>
Consolidated and Combined Balance Sheet Data:	As of December 31,			
	2015	2014	2013	2012
	(In thousands)			
Cash, cash equivalents and short-term investments	\$320,482	\$104,116	\$51,615	\$4,207
Working capital	\$314,888	\$103,302	\$50,284	\$2,940
<b>Total assets</b>	<b>\$324,975</b>	<b>\$106,122</b>	<b>\$51,828</b>	<b>\$4,290</b>
Convertible preferred stock	\$—	\$—	\$61,091	\$6,711
<b>Total stockholders' equity (deficit)</b>	<b>\$315,100</b>	<b>\$103,182</b>	<b>\$(11,017 )</b>	<b>\$(3,727 )</b>



Item 7. 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 audited consolidated and combined financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual 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 Annual 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.

Table of Contents

T-cells are a type of white blood cell, and cytotoxic T-cells, otherwise known as cytotoxic T lymphocytes, or CTLs, have the ability to kill cancer cells. Our T-cell product candidates arise from a platform technology designed to produce off-the-shelf, partially human leukocyte antigen, or HLA, matched cellular therapeutics. We licensed rights to these product candidates from Memorial Sloan Kettering Cancer Center, or MSK, in June 2015. Our initial T-cell product candidates 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 in Phase 2 clinical trials for malignancies associated with Epstein Barr Virus, or EBV, including EBV-associated post-transplant lymphoproliferative disorders, or EBV-PTLD. 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. 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. 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. In addition, we entered into a sponsored research collaboration with MSK to discover and develop additional T-cell product candidates. In October 2015, we entered into exclusive license and research agreements with another academic institution. These agreements enable us to access a technology complementary to that which was licensed from MSK and to pursue development of EBV and CMV-CTLs for other indications such as nasopharyngeal carcinoma, or NPC, gastric cancer, and multiple sclerosis, or MS. We are working with this academic institution on the submission to the FDA of one or more INDs for these new indications.

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. We commenced a Phase 1 clinical trial of STM 434 for ovarian cancer and other solid tumors in 2014. We have five additional molecularly targeted product candidates that modulate the TGF- $\beta$  pathway in preclinical development.

In February 2015, the U.S. Food and Drug Administration, or 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 June 2015, we met with the FDA to discuss late-stage development to support a potential approval in this indication. Based on guidance from the FDA, we submitted a special protocol assessment, or SPA, for a single arm pivotal trial in rituximab-refractory EBV-PTLD after HCT. We received feedback from the FDA regarding this SPA in which the FDA indicated that a single arm trial with response rate as the primary endpoint may provide an adequate basis for approval but it would be unlikely to grant an SPA for our proposed trial. We intend to continue the dialogue with the FDA regarding this trial design under breakthrough therapy designation and expect to initiate this pivotal trial towards the end of 2016. Additionally, we also intend to initiate a randomized pivotal trial in patients with EBV-PTLD after SOT towards the end of 2016. In February 2016, the FDA granted orphan drug designation for EBV-CTL for the treatment of patients with EBV-PTLD after HCT or SOT. We expect to meet with the FDA in the middle of 2016 to discuss late phase development with CMV-CTL to support approval.

While we evaluate the path to registration for both EBV-CTL and CMV-CTL in these initial indications, 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 can be directed at a broad range of other targets to create future product candidates. We believe that viral antigens are well suited to adoptive immunotherapy given that people with normal immune systems are able to mount robust responses to these viral targets, but immunocompromised patients and some cancer patients are not.

Our lead molecularly targeted product candidate, STM 434, is in a Phase 1 clinical trial that will enroll approximately 70 patients with ovarian cancer and other solid tumors. In October 2015, we received orphan drug designation from the FDA for ovarian cancer. STM 434 is a soluble ActR2B receptor that binds Activin A. We are testing the potential use of Activin A as a biomarker in our Phase 1 clinical trial. We believe that novel therapies for clear cell and granulosa cell tumors could qualify for breakthrough therapy designation. Based on its mechanism of action, we also believe that STM 434 has the potential to be the first product to target tumor growth and proliferation through the inhibition of Activin A.

STM 434 is a novel molecule with a well-characterized mechanism of action. It was developed initially, along with our five other in-licensed molecularly targeted biologic product candidates, at Amgen. Taken together, we believe these product candidates constitute a pipeline of biologics that have benefited from years of investment, resulting in a large patent portfolio, with broad preclinical testing. We are evaluating the remaining five pre-clinical molecularly targeted product candidates to determine the best path forward. Where appropriate, we intend to conduct preclinical studies and file investigational new drug applications, or INDs, with the FDA for these candidates.

## Table of Contents

In December 2015, we announced results from the PINTA 745 Phase 2 proof-of-concept clinical trial for PINTA 745 for the treatment of protein energy wasting, or PEW, in patients with end stage renal disease, or ESRD. The trial did not meet its primary endpoint, defined as the percent change from baseline in lean body mass as measured by dual energy x-ray absorptiometry at week 12 following weekly treatment with PINTA 745. PINTA 745 also did not improve physical function, measures of glycemic control and markers of inflammation. There were no treatment related serious adverse events observed in the trial. We intend to complete the trial as designed; however, as a consequence of these results, we have suspended further clinical development of PINTA 745.

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.

In February 2015, we completed a follow-on offering of 4,147,358 shares of common stock at an offering price to the public of \$18.00 per share. We received net proceeds of approximately \$69.5 million after deducting underwriting discounts and commissions and offering expenses.

In July 2015, we completed a follow-on offering of 3,980,768 shares of common stock at an offering price to the public of \$52.00 per share. We received net proceeds of approximately \$193.9 million, after deducting underwriting discounts and commissions and offering expenses.

We have never generated revenues and have incurred losses since inception. Our net losses were \$57.2 million, \$28.0 million and \$8.8 million for the years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, we had an accumulated deficit of \$98.1 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 December 31, 2015, our cash, cash equivalents and short-term investments totaled \$320.5 million, which we intend to use to fund our operations.

## Financial Overview

### Basis of Presentation and Recapitalization

Atara, Nina, Pinta and Santa Maria were incorporated in August 2012. Atara was originally formed as a management company with the sole purpose of providing management, financial and administrative services for Nina, Pinta and Santa Maria. Prior to our recapitalization on March 31, 2014, the results of operations and financial condition of the four companies are presented on a combined basis as they were under common management and common ownership, with intercompany transactions eliminated.

On March 31, 2014, we implemented a recapitalization in which (a) all the outstanding shares of common stock of Atara were cancelled and forfeited by existing stockholders and (b) the stockholders of Nina, Pinta and Santa Maria exchanged their existing common and convertible preferred stock for newly-issued shares of Atara, in the same proportions and with the same rights and privileges as the outstanding capital stock of Nina, Pinta and Santa Maria, on a collective nine-for-one basis. Atara assumed the separate equity incentive plans sponsored by Nina, Pinta and Santa Maria and all outstanding restricted stock units (“RSUs”) and restricted stock awards (“RSAs”) granted under such plans. At the time of RSU settlement, each employee or consultant will receive one share of common stock of Atara for three RSUs in each of Nina, Pinta, and Santa Maria (collectively, a nine-for-one exchange). We refer to this transaction as our recapitalization. As a result of the recapitalization, Nina, Pinta and Santa Maria became wholly owned subsidiaries of Atara effective March 31, 2014. The recapitalization was accounted for as a combination of businesses under common control and the assets and liabilities of Nina, Pinta and Santa Maria were recorded by Atara at their historical

carrying amounts on March 31, 2014. Beginning March 31, 2014, our financial statements are presented on a consolidated basis, with all intercompany transactions eliminated. Except as otherwise noted, all share and per share amounts presented in this “Management’s Discussion and Analysis of Financial Condition and Results of Operations” give effect to the recapitalization.

#### 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.

## Table of Contents

### 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 of costs incurred in performing research and development activities, including compensation and benefits for research and development employees, including stock-based compensation, an allocation of facility and overhead expenses, 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 and costs associated with product development efforts, preclinical activities and regulatory operations. Research and development costs are expensed as incurred.

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

- advancing EBV-CTL into Phase 3 clinical trials for the treatment of EBV-PTLD after HCT and SOT;
- developing CMV-CTL in refractory CMV infection after HCT;
- continuing development of WT1-CTL in relapsed refractory multiple myeloma, including plasma cell leukemia;
- collaborating with MSK in the discovery and development of additional T-cell programs;
- expanding our licensed T-cell platforms into other indications or 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 completion costs of 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.



## Table of Contents

### General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, allocated facilities costs and other expenses for outside professional services, including legal, patent costs, human resources, and audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation. 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

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated and combined financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 of the accompanying consolidated and combined financial statements.

### Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate and accrue expenses, the largest of which is related to research and development expenses, including those related to clinical trials and drug manufacturing. This process involves reviewing contracts and purchase orders, identifying and evaluating the services that have been performed on our behalf, and estimating the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs.

Costs for preclinical study and clinical trial activities are recognized based on an evaluation of our vendors' progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. For the years ended December 31, 2015 and 2014, there were no material changes from our estimates of accrued research and development expenses. Costs that are paid in advance of performance are deferred as a prepaid expense and amortized over the service period as the services are provided.

### Stock-based Compensation

We account for stock-based compensation expense, including the expense of restricted stock agreements, or RSAs, and grants of restricted stock units, or RSUs, and stock options that may be settled in shares of our common stock,



based on the fair values of the equity instruments issued. The fair value is determined on the measurement date, which is generally the date of grant for employee awards and the date when the service performance is completed for non-employees. The fair value for our RSAs is their intrinsic value, which is the difference between the fair value of the underlying stock at the measurement date and the purchase price. The fair value of our RSUs is the fair value of the underlying stock at the measurement date. The fair value for our stock option awards is determined at the grant date using the Black-Scholes valuation model. For employees' awards with performance-based vesting criteria, we assess the probability of the achievement of the performance conditions at the end of each reporting period and recognize the share-based compensation costs when it becomes probable that the performance conditions will be met. For non-employees' awards with performance-based vesting criteria, we assess all possible outcomes at the end of each reporting period and recognize the lowest aggregate fair value in the range of possible outcomes. The lowest value in the range of possible outcomes may be zero. For awards that are subject to both service and performance conditions, no expense is recognized until it is probable that performance conditions will be met. Stock-based compensation expense for awards with time-based vesting criteria is recognized as expense on a straight-line basis over the requisite service period. Stock-based compensation for awards with performance and other vesting criteria is recognized as expense under the accelerated graded vesting model.

Table of Contents

Key assumptions for the Black-Scholes valuation model used for employee stock awards include:

Expected term – The expected term assumption represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method.

Expected volatility – Expected volatility is estimated using comparable public companies' volatility for similar terms.

Expected dividend – We have not historically declared or paid dividends to our stockholders and have no plans to pay dividends; therefore we have assumed an expected dividend yield of 0%.

Risk-free interest rate – The risk-free interest rate is based on the yields of US Treasury securities with expected terms similar to that of the associated award.

The fair value of non-employee stock options is estimated using the Black-Scholes valuation model with assumptions generally consistent with those used for employee stock options, with the exception of the expected term, which is the remaining contractual life at each measurement date.

Prior to our initial public offering in October 2014, due to the absence of an active market for our common stock, we estimated the fair value of our common stock in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation. Each valuation included estimates and assumptions that required management's judgment, including assumptions regarding the probability and estimated time to completion of our initial public offering. Subsequent to the completion of our initial public offering in October 2014, the fair value of our common stock is based on observable market prices.

Prior to our recapitalization in March 2014, we issued RSAs and RSUs for common stock of Nina, Pinta and Santa Maria to individuals who were employed by or served as consultants of Atara and provided services to Nina, Pinta and Santa Maria through Atara. Because these individuals were not employees of Nina, Pinta or Santa Maria, as these entities were not subsidiaries of Atara until the recapitalization, all of our RSAs and RSUs issued through the date of the recapitalization are deemed to have been issued to non-employees. As such, we determined the estimated fair value of the underlying common stock at the end of each period, as the services were performed.

Income Taxes

We recognize deferred income taxes for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. We periodically evaluate the positive and negative evidence bearing upon the realizability of our deferred tax assets. Based upon the weight of available evidence, which includes our historical operating performance, reported cumulative net losses since inception and difficulty in accurately forecasting our future results, we have maintained a full valuation allowance on the net deferred tax assets for all periods presented. We intend to maintain a full valuation allowance on the U.S. deferred tax assets for the foreseeable future, until sufficient positive evidence exists to support reversal of the valuation allowance.

As of December 31, 2015, we had federal and state net operating loss 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 2032.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, our ability to utilize net operating loss carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if we have experienced an "ownership change." Generally, a Section 382 "ownership change" occurs if one or more stockholders or

groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Similar rules may apply under state tax laws.

We have completed a Section 382 study of transactions in our stock through December 31, 2015. The study concluded that we have experienced at least one ownership change since inception and that our utilization of net operating loss carryforwards will be subject to annual limitations. Further, other provisions of the Code may limit our ability to utilize federal net operating losses incurred before the 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 losses. However, it is not expected that these limitations will result in the expiration of tax attribute carryforwards before they are utilized.

Our unrecognized tax benefits increased by \$2.7 million during the year ended December 31, 2015 as a result of current year tax positions. Of the \$4.3 million cumulative unrecognized tax benefits as of December 31, 2015, \$0.1 million, if recognized, would affect the effective tax rate due to the valuation allowance that currently offsets deferred tax assets. We recognize interest and penalties related to uncertain tax positions as part of the income tax provision and, to date, such interest and penalties have not been material. We are not aware of any items that will significantly increase or decrease our unrecognized tax benefits in the next 12 months.

Table of Contents

## 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, 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 Exchange Act.

## Results of Operations

## Comparison of the Years Ended December 31, 2015, 2014 and 2013

## Research and development expenses

Research and development expenses for the periods indicated were as follows:

	Year ended December 31,			Increase (Decrease)	
	2015	2014	2013	2014 to 2015	2013 to 2014
	(in thousands)				
Research and development	\$41,618	\$14,380	\$4,306	\$27,238	\$10,074
Research and development costs paid to					
Amgen	—	1,066	553	(1,066)	513
Total research and development	\$41,618	\$15,446	\$4,859	\$26,172	\$10,587

Research and development costs paid to Amgen in 2014 comprise a \$1.0 million milestone payment and \$0.1 million for clinical services. The payments to Amgen in 2013 relate to the purchase of clinical supplies. Amgen is no longer considered as a related party as it has no significant influence on our operations.

Research and development expenses by program for the periods indicated were as follows:

Year ended December 31,

	2015	2014	2013	Increase (Decrease) 2014 to 2013 to	
	(in thousands)			2015	2014
EBV-CTL	\$970	\$—	\$—	\$970	\$—
CMV-CTL	78	—	—	78	—
Other T-cell program expenses	9,123	2,000	—	7,123	2,000
PINTA 745	5,651	2,311	1,658	3,340	653
STM 434	5,370	4,389	1,936	981	2,453
ATA 842 and other molecular programs	7,490	624	16	6,866	608
Employee and overhead costs	12,936	6,122	1,249	6,814	4,873
Total research and development	\$41,618	\$15,446	\$4,859	\$26,172	\$10,587

EBV-CTL costs were \$1.0 million in 2015 as compared to zero in 2014, primarily due to development work undertaken following our exercise of the option to license this program from MSK in June 2015 (see below). We anticipate that EBV-CTL costs will increase significantly in 2016 due to the initiation of additional clinical trials for this product candidate.

CMV-CTL costs were \$0.1 million in 2015 as compared to zero in 2014, primarily due to outside services costs associated with the program. We anticipate CMV-CTL costs to increase in 2016 due to support of our ongoing Phase 2 clinical trials.

Table of Contents

Other T-cell program expenses increased by \$7.1 million in 2015 as compared to 2014, primarily due to the cash payment to MSK of \$4.5 million to exercise our option to license certain T-cell programs in June 2015, and \$3.0 million paid to QIMR Berghofer for an exclusive, worldwide license to develop and commercialize allogeneic CTL therapy programs utilizing technology and know-how developed by QIMR Berghofer. In 2014, we recorded \$2.0 million of expense for the exclusive option to license the T-cell programs from MSK, consisting of a \$1.25 million cash payment and the issuance of 59,761 shares of our common stock to MSK with an estimated fair value of \$0.75 million.

PINTA 745 costs increased by \$3.3 million in 2015 as compared to 2014, and by \$0.7 million in 2014 as compared to 2013. The increase in 2015 was primarily due to increased manufacturing costs and clinical trial expenses related to the Phase 2 trial of PINTA 745 for PEW in ESRD patients, which was unblinded in December 2015. Based on the results of the unblinding, we announced that we would be suspending further development of PINTA 745, and an expense of \$0.9 million was recorded in December 2015 related to the termination of a manufacturing agreement for PINTA 745. The increase in 2014 was primarily due to a \$0.9 million increase in outsourced development and third party costs to support the Phase 2 trial, partially offset by a \$0.2 million decrease in outside consultant costs. We anticipate that although certain costs related to completion of the 20-week follow-up portion of this trial and certain other expenses will continue into the first half of 2016, the overall costs for this program will decrease significantly in 2016 as a whole.

STM 434 costs increased by \$1.0 million in 2015 as compared to 2014, and by \$2.5 million in 2014 as compared to 2013. The increase in 2015 was primarily due to manufacturing costs associated with the production of additional clinical drug supply and increased costs related to the Phase 1 clinical trial. The increase in 2014 was primarily due to an increase of \$1.5 million in outside manufacturing costs for clinical drug supply and third party costs related to the Phase 1 clinical trial, which commenced in the second half of 2014, and a \$1.0 million milestone payment to Amgen. We anticipate that STM 434 costs will increase in 2016 due to the continued enrollment of patients in the dose escalation portion of the Phase 1 trial and initiation of the dose expansion portion of the Phase 1 trial.

ATA 842 and other molecular program costs increased by \$6.9 million in 2015 as compared to 2014 primarily due to a \$4.4 million increase in manufacturing costs associated with the production of clinical drug supply and a \$2.4 million increase in preclinical development costs. In 2014, ATA 842 and other molecular program costs consisted of manufacturing costs for clinical drug supply.

Employee and overhead costs increased by \$6.8 million in 2015 as compared to 2014, and by \$4.9 million in 2014 as compared to 2013. The increasing trend over the three years is primarily a result of higher compensation-related costs resulting from increased headcount in support our continuing expansion of research and development activities. In particular, payroll and employee stock-based compensation increased by \$4.1 million and \$1.6 million, respectively, in 2015 as compared to 2014, and by \$1.5 million and \$2.7 million, respectively, in 2014 as compared to 2013. 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

General and administrative expenses for the periods indicated were as follows:

Year ended December 31,	Increase (Decrease)
-------------------------	------------------------

Edgar Filing: Atara Biotherapeutics, Inc. - Form 10-K

	2015	2014	2013	2014 to 2015	2013 to 2014
	(in thousands)				
General and administrative	\$16,830	\$12,710	\$3,756	\$4,120	\$8,954

General and administrative expenses increased by \$4.1 million in 2015 as compared to 2014, and by \$9.0 million in 2014 as compared to 2013. The increase in 2015 was primarily due to a \$1.9 million increase in compensation-related costs driven by increased headcount, a \$1.3 million increase in other outside services costs and a \$1.2 million increase in higher corporate legal and patent fees. The increase in 2014 was primarily due to increases of \$6.1 million in stock-based compensation costs and other payroll related expenses, \$0.9 million in third-party consulting fees and \$0.8 million in accounting fees associated with the audit of our financial statements and in preparation for our initial public offering. We expect that general and administrative costs will continue to increase in 2016 as we continue to expand our operations.

Table of Contents

## Quarterly Results of Operations Data (unaudited)

The following table sets forth our unaudited consolidated and combined statement of operations data for each of the eight quarters in the period ended December 31, 2015. The unaudited quarterly statement of operations data set forth below have been prepared on a basis consistent with our audited annual consolidated and combined financial statements in this Annual Report on Form 10-K and include, in our opinion, all normal recurring adjustments necessary for a fair statement of the financial information contained in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future. The following quarterly financial data should be read in conjunction with our audited consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K.

	Three months ended			
	March 31	June 30	September 30	December 31
2015	(In thousands)			
<b>Operating expenses:</b>				
Research and development	\$5,767	\$11,507	\$8,113	\$16,231
General and administrative	3,544	3,601	4,146	5,539
Total operating expenses	9,311	15,108	12,259	21,770
Loss from operations	(9,311)	(15,108)	(12,259)	(21,770)
Interest and other income, net	153	163	380	522
Loss before provision for income taxes	(9,158)	(14,945)	(11,879)	(21,248)
Provision (benefit) for income taxes	2	—	(11)	—
Net loss	(9,160)	(14,945)	(11,868)	(21,248)
<b>Other comprehensive loss:</b>				
Unrealized gain (loss) on available-for-sale securities	82	(48)	117	(569)
Comprehensive loss	\$(9,078)	\$(14,993)	\$(11,751)	\$(21,817)
Basic and diluted net loss per common share	\$(0.42)	\$(0.62)	\$(0.43)	\$(0.75)

	Three months ended			
	March 31	June 30	September 30	December 31
2014	(In thousands)			
<b>Operating expenses:</b>				
Research and development	\$2,981	\$2,110	\$4,241	\$5,048
Research and development costs paid to Amgen	—	1,066	—	—
General and administrative	4,096	1,358	1,708	5,548
Total operating expenses	7,077	4,534	5,949	10,596
Loss from operations	(7,077)	(4,534)	(5,949)	(10,596)
Interest and other income, net	6	23	30	66
Loss before provision for income taxes	(7,071)	(4,511)	(5,919)	(10,530)
Provision (benefit) for income taxes	(22)	—	—	(3)
Net loss	(7,049)	(4,511)	(5,919)	(10,527)
<b>Other comprehensive loss:</b>				
Unrealized gain (loss) on available-for-sale securities	(11)	11	(11)	(89)



Comprehensive loss	\$ (7,060 )	\$ (4,500 )	\$ (5,930 )	\$ (10,616 )
Basic and diluted net loss per common share	\$ (5.58 )	\$ (3.37 )	\$ (4.20 )	\$ (0.67 )

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 December 31, 2015, we had an accumulated deficit of \$98.1 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

Table of Contents

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, US Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities. Management expects that existing cash and cash equivalents as of December 31, 2015 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:

	December 31,		Increase
	2015	2014	(Decrease)
	(in thousands)		
Cash and cash equivalents	\$23,746	\$21,897	\$1,849
Short-term investments	296,736	82,219	214,517
Total cash, cash equivalents and short-term investments	\$320,482	\$104,116	\$216,366

## Cash Flows

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

	Year ended December 31,		
	2015	2014	2013
	(in thousands)		
Net cash provided by (used in):			
Operating activities	\$(37,156)	\$(16,628)	\$(5,966)
Investing activities	(220,127)	(83,363)	(3)
Financing activities	259,226	70,273	53,377
Net increase (decrease) in cash and cash equivalents	\$1,943	\$(29,718)	\$47,408

## Operating activities

Net cash used in operating activities was \$37.2 million in 2015 as compared to \$16.6 million in 2014. The increase of \$20.6 million was primarily due to a \$29.2 million increase in net loss, partially offset by a \$5.8 million increase in accounts payable and accrued liabilities and a \$2.9 million increase in the amortization of investment premiums and discounts.

Net cash used in operating activities was \$16.6 million in 2014 as compared to \$6.0 million in 2013. The increase of \$10.6 million was primarily due to a \$19.2 million increase in net loss, partially offset by an \$8.4 million increase in

stock-based compensation and a \$0.75 million non-cash charge for research and development expenses related to our exclusive option to license certain T-cell therapies from MSK.

#### Investing activities

Net cash used in investing activities in 2015 consisted primarily of \$379.8 million invested in short-term available-for-sale securities, partially offset by maturities and sales of \$160.1 million.

Net cash used in investing activities in 2014 consisted primarily of \$95.5 million invested in short-term available-for-sale securities, partially offset by maturities of \$12.2 million.

#### Financing activities

Net cash provided by financing activities in 2015 consisting primarily of \$263.4 million in aggregate net proceeds from the sale of common stock in two separate follow-on offerings. These net proceeds were partially offset by \$4.6 million used to pay taxes related to the net share settlement of restricted stock units.

## Table of Contents

Net cash provided by financing activities in 2014 consisted primarily of \$56.5 million in net proceeds from the sale of common stock in our initial public offering and \$13.5 million from the sale of shares of Series B convertible preferred stock.

Net cash provided by financing activities in 2013 consisted of \$53.4 million raised from the sale of shares of convertible preferred stock.

### Operating Capital Requirements

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 have incurred and expect to continue to incur additional costs associated with operating as a public company and we anticipate that we will need 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 for our product candidates;
- the timing and costs of our planned preclinical studies of 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; and
- the extent to which we in-license or acquire other products and technologies.

### Contractual Obligations and Commitments

We lease our current corporate headquarters in South San Francisco, California under a non-cancellable sublease agreement that expires in January 2017. In December 2015, we entered into a new lease agreement for approximately 13,670 square feet of office space in South San Francisco, California, which is intended to be our new corporate headquarters. The new lease is expected to expire in April 2021.

Edgar Filing: Atara Biotherapeutics, Inc. - Form 10-K

In January 2015, we entered into a non-cancellable lease agreement for office and laboratory space in Westlake Village, California. In September 2015, we amended the lease agreement to add additional office space and extend the term of the agreement to April 2019. Aggregate future minimum commitments for our operating leases as of December 31, 2015 are as follows:

	Payments Due by Period				More than 5 Years
	Total	Less than 1 Year	1-3 Years	3-5 Years	
	(in thousands)				
Operating lease obligations	\$ 4,472	\$ 967	\$ 1,950	\$ 1,555	\$ —
Total contractual obligations	\$ 4,472	\$ 967	\$ 1,950	\$ 1,555	\$ —

74

---

## Table of Contents

The above amounts exclude potential milestone and royalty payments related to our license and collaboration agreements, as the achievement of these milestones is currently not fixed and determinable.

We may also 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 preclinical studies and supplies and other services and products for 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. Payments in the table above are based on current operating forecasts, which are subject to change, and do not include any termination fees.

### 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 7A. Quantitative and Qualitative Disclosures about Market Risk

### Interest Rate and Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2015, we had cash and cash equivalents and short-term investments of \$320.5 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase, which could result in a realized loss if we are forced to sell an investment before its scheduled maturity. We currently do not hedge our interest rate risk exposure. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate change in interest rates of 10 basis points would not result in a significant change in the fair market value of our portfolio.

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve this objective, we maintain our portfolio of cash equivalents and short-term and long-term investments in a variety of securities, including money market funds, U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities. These securities are all classified as available-for-sale and consequently are recorded on the balance sheet at fair value, with unrealized gains or losses reported as a separate component of accumulated other comprehensive income (loss). Our holdings of the securities of any one issuer, except obligations of the U.S. Treasury or U.S. Treasury guaranteed securities, do not exceed 5% of our portfolio.

### Foreign Currency Exchange Rate Risk

We are exposed to some degree of foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars, particularly in Euros and British pounds. To manage this risk, we may purchase certain European currencies. We do not make these purchases for trading or speculative purposes, and there

is no guarantee that the related gains and losses will substantially offset each other. In particular, we pay one of our CMOs located outside of the U.S. in British pounds. As of December 31, 2015, we held cash in British pounds valued at \$1.5 million and had certain balances denominated in British pounds. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made, and all monetary balances are translated to U.S. dollars using period-end exchange rate. Gains and losses on these transactions are recorded in interest and other income (expense), net in the statements of operations and comprehensive loss.

A hypothetical 10% change in foreign exchange rates during any of the preceding periods presented would not have had a significant impact on our financial statements.

Table of Contents

Item 8. Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	77
<u>Consolidated Balance Sheets</u>	78
<u>Consolidated and Combined Statements of Operations and Comprehensive Loss</u>	79
<u>Consolidated and Combined Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)</u>	80
<u>Consolidated and Combined Statements of Cash Flows</u>	81
<u>Notes to Consolidated and Combined Financial Statements</u>	82



Table of Contents

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Atara Biotherapeutics, Inc.

South San Francisco, California

We have audited the accompanying consolidated balance sheets of Atara Biotherapeutics, Inc. and its subsidiaries (collectively, the “Company”) as of December 31, 2015 and 2014, and the related consolidated and combined statements of operations and comprehensive loss, convertible preferred stock and stockholders’ equity (deficit), and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated and combined financial statements present fairly, in all material respects, the financial position of Atara Biotherapeutics, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

San Jose, California

March 4, 2016

Table of Contents

Atara Biotherapeutics, Inc.

Consolidated Balance Sheets

(In thousands, except share amounts)

	As of December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	\$23,746	\$21,897
Short-term investments	296,736	82,219
Restricted cash	194	—
Prepaid expenses and other current assets	3,921	1,910
Total current assets	324,597	106,026
Property and equipment, net	270	48
Other assets	108	48
Total assets	\$324,975	\$106,122
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$1,445	\$440
Accrued compensation	2,624	1,225
Accrued research and development expenses	5,112	824
Other accrued liabilities	528	235
Total current liabilities	9,709	2,724
Long-term liabilities	166	216
Total liabilities	9,875	2,940
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock—\$0.0001 par value, 500,000,000 shares authorized as of		
December 31, 2015 and 2014; 28,458,807 and 19,692,937 shares issued and		
outstanding as of December 31, 2015 and 2014, respectively	3	2
Additional paid-in capital	413,725	144,169
Accumulated other comprehensive loss	(518 )	(100 )
Accumulated deficit	(98,110 )	(40,889 )
Total stockholders' equity	315,100	103,182
Total liabilities and stockholders' equity	\$324,975	\$106,122



Table of Contents

Atara Biotherapeutics, Inc.

## Consolidated and Combined Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	Year ended December 31,		
	2015	2014	2013
Operating expenses:			
Research and development	\$41,618	\$14,380	\$4,306
Research and development costs paid to Amgen	—	1,066	553
General and administrative	16,830	12,710	3,756
Total operating expenses	58,448	28,156	8,615
Loss from operations	(58,448 )	(28,156 )	(8,615 )
Interest and other income, net	1,218	125	12
Loss before provision for income taxes	(57,230 )	(28,031 )	(8,603 )
Provision (benefit) for income taxes	(9 )	(25 )	170
Net loss	\$(57,221 )	\$(28,006 )	\$(8,773 )
Other comprehensive loss:			
Unrealized loss on available-for-sale securities	(418 )	(100 )	—
Comprehensive loss	\$(57,639 )	\$(28,106 )	\$(8,773 )
Net loss per common share:			
Basic and diluted net loss per common share	\$(2.24 )	\$(5.62 )	\$(9.08 )
Weighted-average common shares outstanding used to calculate basic			
and diluted net loss per common share	25,583,334	4,985,540	965,825

Table of Contents

Atara Biotherapeutics, Inc.

Consolidated and Combined Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands)

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock	Additional Paid-in Capital	Notes Receivable From Stockholders	Accumulated Other Comprehensive Income Deficit	Total Stockholders' Equity (Deficit)		
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			(Deficit)		
Balance as of December 31, 2017	11,538	4,946	3,532	1,765	—	—	7,462	1	382	—	—	(4,110 )	(3,827 )
Issuance of common stock for net of offering costs of	—	—	—	—	—	—	615	—	—	—	—	—	—
Issuance of Series A convertible preferred stock, net of offering costs of \$124	34,818	14,963	—	—	—	—	—	—	—	—	—	—	—
Issuance of Series A convertible preferred stock for license	—	—	2,006	1,003	—	—	—	—	—	—	—	—	—
Issuance of Series A convertible preferred stock, net of offering costs of \$86	—	—	—	—	43,529	38,414	—	—	—	—	—	—	—
Receivable from stockholder	—	—	—	—	—	—	—	—	(331)	—	—	—	(331)
Income from notes payable from stockholder	—	—	—	—	—	—	—	—	(4 )	—	—	—	(4 )
Issuance of common stock consisting of restricted stock	—	—	—	—	—	—	3,927	—	105	—	—	—	105



Edgar Filing: Atara Biotherapeutics, Inc. - Form 10-K

based														
consolidation														
de														
loss	—	—	—	—	—	—	—	—	—	—	—	—	(28,006)	(2)
normalized loss														
available-for-sale														
securities	—	—	—	—	—	—	—	—	—	—	—	(100)	-	(1)
value as of														
December 31,	—	—	—	—	—	—	19,693	2	144,169	—	(100)	(40,889)	10	
value of														
common stock,														
including discounts														
and offering costs														
total														
166 in														
January 2015	—	—	—	—	—	—	4,147	1	69,486	—	—	—	69	
value of														
common stock,														
including discounts														
and offering costs														
total														
3,053 in														
January 2015	—	—	—	—	—	—	3,981	—	193,947	—	—	—	19	
value of														
common stock														
including offering														
costs of restricted														
stock														
total														
287	—	—	—	—	—	—	287	—	80	—	—	—	80	
settlements,														
including shares														
of restricted														
stock														
total														
327	—	—	—	—	—	—	327	—	(4,647)	—	—	—	(4)	
value of														
common stock														
available for														
exercise														
total														
24	—	—	—	—	—	—	24	—	439	—	—	—	43	
based														
consolidation														
de														
loss	—	—	—	—	—	—	—	—	10,251	—	—	—	10	
normalized loss														
available-for-sale														
securities	—	—	—	—	—	—	—	—	—	—	—	(57,221)	(5)	
value as of														
December 31,	—	\$—	—	\$—	—	\$—	28,459	\$3	\$413,725	\$—	\$(518)	\$(98,110)	\$31	





Table of Contents

Atara Biotherapeutics, Inc.

## Consolidated and Combined Statements of Cash Flows

(In thousands)

	Year ended December 31,		
	2015	2014	2013
<b>Operating activities</b>			
Net loss	\$(57,221 )	\$(28,006 )	\$(8,773 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	10,251	10,101	1,713
Amortization of investment premiums and discounts	3,465	526	—
Non-cash research and development expenses	—	750	—
Depreciation expense	48	6	4
Write off of property and equipment	21	—	—
Loss on foreign exchange	94	—	—
Interest accrued on notes receivable from stockholder	—	(2 )	(4 )
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(767 )	(1,246 )	(158 )
Other assets	(61 )	(37 )	27
Accounts payable	1,005	(164 )	485
Accrued compensation	1,399	894	280
Accrued research and development expenses	4,288	468	356
Other accrued liabilities	293	4	104
Long-term liabilities	29	78	—
Net cash used in operating activities	(37,156 )	(16,628 )	(5,966 )
<b>Investing activities</b>			
Purchase of short-term investments	(379,776)	(95,525)	—
Sales and maturities of short-term investments	160,133	12,208	—
Transfer to restricted cash	(194 )	—	—
Purchase of property and equipment	(290 )	(46 )	(3 )
Net cash used in investing activities	(220,127)	(83,363)	(3 )
<b>Financing activities</b>			
Proceeds from sale of common stock, net of offering costs	263,434	56,455	—
Taxes paid related to net share settlement of restricted stock units	(4,647 )	—	—
Proceeds from exercise of stock options	439	—	—
Proceeds from sale of convertible preferred stock, net of offering costs	—	13,481	53,377
Repayment of notes receivable from stockholder	—	337	—
Net cash provided by financing activities	259,226	70,273	53,377
Effect of exchange rates on cash	(94 )	—	—
Increase (decrease) in cash and cash equivalents	1,849	(29,718)	47,408
Cash and cash equivalents-beginning of period	21,897	51,615	4,207
Cash and cash equivalents-end of period	\$23,746	\$21,897	\$51,615
<b>Non-cash financing activities</b>			
Issuance of common stock related to technology licensing option	\$—	\$750	\$—

Edgar Filing: Atara Biotherapeutics, Inc. - Form 10-K

Issuance of Series A-1 convertible preferred stock to Amgen in exchange for license	\$—	\$—	\$1,003
Change in obligation to issue Series A-1 convertible preferred stock to Amgen	\$—	\$—	\$(1,003)
Issuance of common stock upon vesting of stock awards	\$80	\$90	\$105
Change in other long-term liabilities related to non-vested stock awards	\$(80)	\$(90)	\$226
Restricted stock issued to related party in exchange for notes receivable	\$—	\$—	\$331
Supplemental cash flow disclosure			
Cash paid for taxes	\$3	\$70	\$22

81

---

Table of Contents

Atara Biotherapeutics, Inc.

Notes to Consolidated and Combined Financial Statements

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”). Our molecularly targeted biologics programs were acquired through licensing arrangements with Amgen Inc. (“Amgen”). In December 2015, we announced that we were suspending our PINTA 745 program, which was originally licensed from Amgen. See Note 6 for further information.

In October 2014, we completed our initial public offering (“IPO”) of 5,750,000 shares of common stock at an offering price to the public of \$11.00 per share. We received net proceeds of \$56.5 million, after deducting underwriting discounts and commissions and offering expenses. In connection with the IPO, our outstanding shares of convertible preferred stock were automatically converted into 12,298,515 shares of common stock, resulting in the reclassification of \$74.6 million from mezzanine equity to additional paid-in capital.

In February 2015, we completed a follow-on offering of 4,147,358 shares of common stock at an offering price to the public of \$18.00 per share. We received net proceeds of \$69.5 million, after deducting underwriting discounts and commissions and offering expenses.

In July 2015, we completed a follow-on offering of 3,980,768 shares of common stock at an offering price to the public of \$52.00 per share. We received net proceeds of \$193.9 million, after deducting underwriting discounts and commissions and offering expenses.

2. Summary of Significant Accounting Policies

Basis of Presentation and Recapitalization

The accompanying consolidated and combined financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and the rules and regulations of the US Securities and Exchange Commission (the “SEC”). All share and per-share amounts presented in the consolidated and combined financial statements for the years ended December 31, 2015, 2014 and 2013 and in the notes hereto have been revised to reflect a 1.3-to-1 reverse stock split which became effective July 9, 2014. Certain items in the balance sheets and statements of cash flows have been reclassified from their presentation in prior years.

Atara was originally formed as a management company with the sole purpose of providing management, financial and administrative services for Nina Biotherapeutics, Inc. (“Nina”), Santa Maria Biotherapeutics, Inc. (“Santa Maria”) and Pinta Biotherapeutics, Inc. (“Pinta”). Prior to March 31, 2014, the accompanying financial statements include the operations of Atara, Nina, Pinta and Santa Maria on a combined basis as the four individual companies were under common ownership and common management. All intercompany transactions have been eliminated.

On March 31, 2014, we implemented a recapitalization (the “Recapitalization”) in which (a) all the outstanding shares of common stock of Atara were cancelled and forfeited by existing stockholders and (b) the stockholders of Nina, Pinta and Santa Maria exchanged their existing common and convertible preferred stock for newly-issued shares of Atara, with the same rights and privileges as the outstanding capital stock of Nina, Pinta and Santa Maria. The shares were exchanged on a collective nine-for-one basis. The Recapitalization lacked economic substance as the newly-issued shares have the same rights and privileges as the previously outstanding capital stock of Nina, Pinta and Santa Maria and there was no change in ownership percentages of the individual stockholders. As a result of the Recapitalization, Nina, Pinta and Santa Maria became wholly owned subsidiaries of Atara effective March 31, 2014. The Recapitalization is considered a tax-free exchange for US federal income tax purposes.

Because the four individual companies were under common ownership and the Recapitalization lacked economic substance, we accounted for the Recapitalization as a combination of businesses under common control. The assets and liabilities of Nina, Pinta and Santa Maria were recorded by Atara at their historical carrying amounts on March 31, 2014 and beginning March 31, 2014, the financial statements of Atara are presented on a consolidated basis.

## Table of Contents

### Principles of Consolidation

The consolidated and combined financial statements include the accounts of Atara and its wholly owned subsidiaries, Nina, Pinta, Santa Maria and Atara Biotherapeutics Cayman Limited, a Cayman Islands corporation. All intercompany balances and transactions have been eliminated in consolidation.

### Segment and Geographic Information

We operate and manage our business as one reporting and one operating segment, which is the business of developing and commercializing therapeutics. Our Chief Executive Officer, who is our chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of our assets are located in the United States.

### 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 December 31, 2015, we had an accumulated deficit of \$98.1 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 December 31, 2015 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, 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: ability to obtain future financing; regulatory approval and market acceptance of, and reimbursement for, our product candidates; 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 GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates relied upon in preparing these financial statements include the fair value of common stock and the fair value of preferred stock prior to our IPO and estimates related to clinical trial accruals and stock-based compensation expense. Actual results could differ materially from those estimates.

### Foreign Currency

Transactions and foreign currency-denominated monetary assets and liabilities that are denominated in a foreign currency are translated into U.S. dollars at the current exchange rate on the transaction date and as of each balance sheet date, respectively, with gains or losses on foreign exchange changes recognized in interest and other income (expense), net in the statements of operations and comprehensive loss. As of December 31, 2015, we held British pounds valued at \$1.5 million. There were no foreign currency transactions in prior periods.

#### Cash Equivalents and Short-Term Investments

Cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase, and generally consist of money market funds, U.S. Treasury, government agency and corporate debt obligations, and commercial paper.

## Table of Contents

Investments with original maturities of greater than 90 days are classified as short-term investments on the balance sheet, and consist primarily of U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities.

As our entire investment portfolio is considered available for use in current operations, we classify all investments as available-for-sale and as current assets, even though the stated maturity may be more than one year from the current balance sheet date. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported in accumulated other comprehensive loss, which is a separate component of stockholders' equity in the balance sheet.

The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity, which are both recorded to interest and other income (expense), net in the statements of operations and comprehensive loss.

Changes in the fair value of available-for-sale securities impact the statements of operations only when such securities are sold or if an other-than-temporary impairment is recognized. Realized gains and losses on the sale of securities are determined by specific identification of each security's cost basis. We regularly review our investment portfolio to determine if any security is other-than-temporarily impaired, which would require us to record an impairment charge in the period any such determination is made. In making this judgment, we evaluate, among other things, the duration and extent to which the fair value of a security is less than its cost, the financial condition of the issuer and any changes thereto, our intent to sell, or whether it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. Our assessment on whether a security is other-than-temporarily impaired could change in the future due to new developments or changes in assumptions related to any particular security. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, if any, are recorded to interest and other income (expense), net in the statements of operations and comprehensive loss.

### Fair Value Measurement

The carrying amounts of certain of our financial instruments including cash equivalents, prepaid expenses, accounts payable and accrued liabilities approximate fair value due to their short maturities. Short-term investments are comprised of available-for-sale securities, which are carried at fair value.

### Fair Value of Financial Instruments

Our financial assets and liabilities 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.

Financial assets and liabilities are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis. U.S. Treasury, government agency and corporate debt obligations, and commercial paper and asset-backed securities are valued primarily using market prices of comparable securities, bid/ask quotes, interest rate yields and prepayment spreads and are included in Level 2.

Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. We have no Level 3 financial assets or liabilities.



## Table of Contents

### Property and Equipment, net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, ranging from three to five years. Maintenance and repairs are charged to operations as incurred.

### Long-lived Assets

We evaluate the carrying amount of our long-lived assets whenever events or changes in circumstances indicate that the assets may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount of the asset. To date, there have been no such impairment losses.

### Stock-Based Compensation Expense

We account for stock-based compensation expense, including the expense of restricted common stock awards (“RSAs”) and grants of restricted stock units (“RSUs”) and stock options that may be settled in shares of our common stock, based on the fair values of the equity instruments issued. The fair value is determined on the measurement date, which is generally the date of grant for employee awards and the date when the service performance is completed for non-employees. The fair value for our RSAs is their intrinsic value, which is the difference between the fair value of the underlying stock at the measurement date and the purchase price. The fair value of our RSUs is the fair value of the underlying stock at the measurement date. The fair value for our stock option awards is determined at the grant date using the Black-Scholes valuation model. For employees’ awards with performance-based vesting criteria, we assess the probability of the achievement of the performance conditions at the end of each reporting period and recognize the share-based compensation costs when it becomes probable that the performance conditions will be met. For non-employees’ awards with performance-based vesting criteria, we assess all possible outcomes at the end of each reporting period and recognize the lowest aggregate fair value in the range of possible outcomes. The lowest value in the range of possible outcomes may be zero. For awards that are subject to both service and performance conditions, no expense is recognized until it is probable that performance conditions will be met. Stock-based compensation expense for awards with time-based vesting criteria is recognized as expense on a straight-line basis over the requisite service period. Stock-based compensation expense for awards with performance and other vesting criteria is recognized as expense under an accelerated graded vesting model.

Key assumptions used in the Black-Scholes valuation model used for employee stock awards include:

Expected term – The expected term assumption represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method.

Expected volatility – Expected volatility is estimated using comparable public companies’ volatility for similar terms.

Expected dividend – We have not historically declared or paid dividends to our stockholders and have no plans to pay dividends; therefore we assumed an expected dividend yield of 0%.

Risk-free interest rate – The risk-free interest rate is based on the yield on U.S. Treasury securities with the expected term of the associated award.

The fair value of non-employee stock options is estimated using the Black-Scholes valuation model with assumptions generally consistent with those used for employee stock options, with the exception of the expected term, which is the remaining contractual life at each measurement date.

Prior to our IPO in October 2014, due to the absence of an active market for our common stock, we estimated the fair value of our common stock in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation. Each valuation included estimates and assumptions that required management's judgment, including assumptions regarding the probability and estimated time to completion of our IPO. Subsequent to the completion of our IPO, the fair value of our common stock is based on observable market prices.

#### Research and Development Expense

Research and development expense consists of costs incurred in performing research and development activities, including compensation and benefits for research and development employees, 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, other supplies and costs associated with product development efforts, preclinical activities and regulatory operations, and an allocation of facility and overhead expenses. Research and development costs are expensed as incurred.

## Table of Contents

### Clinical Trial Accruals

Costs for preclinical study and clinical trial activities are recognized based on an evaluation of our vendors' progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services are performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Costs that are paid in advance of performance are deferred as a prepaid expense and amortized over the service period as the services are provided.

### Income Taxes

We use the assets and liabilities method to account for income taxes. We record deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect when the differences are expected to reverse. Valuation allowances are provided when necessary to reduce net deferred tax assets to the amount that is more likely than not to be realized. Based on the available evidence, we are unable, at this time, to support the determination that it is more likely than not that our deferred tax assets will be utilized in the future. Accordingly, we recorded a full valuation allowance as of December 31, 2015 and 2014. We intend to maintain valuation allowances until sufficient evidence exists to support their reversal.

Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

### Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period resulting from transactions from non-owner sources. Our other comprehensive loss is comprised solely of unrealized gains (losses) on available-for-sale securities, and is presented net of taxes. We have not recorded any reclassifications from other comprehensive loss to net loss during any period presented.

### Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers, which will supersede most existing revenue recognition guidance under US GAAP. The core principle of the guidance is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. Entities can choose to apply the standard using either the full retrospective approach or a modified retrospective approach. The new revenue standard will be applied to contracts that are in progress at the date of adoption. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB approved deferral of the effective date of this ASU by one year to December 15, 2017. The ASU's effective date for the Company will be January 1, 2018. We will evaluate the application of this standard when we enter into any contracts with customers.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which will require a reporting entity to evaluate, at each annual and interim reporting period, whether there are conditions or events that raise substantial doubt about the reporting entity's ability to continue as a going concern within one year after the date the financial statements are issued and provide related disclosures. The standard will be effective for annual periods ending after December 15, 2016, with early adoption permitted. We do not expect that the adoption of the new standard will have a significant impact on our consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-05, Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement, which provides guidance to customers about whether a cloud computing arrangement includes a software license. If such an arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If the arrangement does not include a software license, the customer should account for it as a service contract. This ASU will be effective for annual periods beginning after December 15, 2015, and early application is permitted. Entities may apply the new guidance either prospectively to all arrangements entered into or materially modified after the effective date or retrospectively. We adopted this

Table of Contents

standard prospectively on July 1, 2015. Adoption of this standard did not have a material impact on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes, which simplifies the presentation of deferred income taxes. The ASU provides presentation requirements to classify deferred tax assets and liabilities as noncurrent in a classified statement of financial position. The standard is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted for any interim and annual financial statements that have not yet been issued. The new guidance may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. We adopted this standard on December 31, 2015. Adoption of this standard did not have a material impact on our consolidated financial statements.

On January 5, 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, 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 potential effect the new standard will have of the Company's consolidated financial statements.

### 3. Net Loss per Common Share

Basic and diluted net loss per common share is presented, giving effect to the Recapitalization, including cancellation of existing Atara common stock and a nine-for-one share exchange. Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share is computed by dividing the 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. Prior to the date of our IPO, we considered all series of our convertible preferred stock to be participating securities as they were entitled to participate in undistributed earnings with shares of common stock. Due to net losses, there is no impact on the net loss per common share calculation in applying the two-class method since the participating securities had no legal requirement to share in any losses.

Potential dilutive securities, which include convertible preferred stock prior to our IPO, unvested RSAs, unvested RSUs and vested and unvested options 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 December 31,

Edgar Filing: Atara Biotherapeutics, Inc. - Form 10-K

	2015	2014	2013
Unvested restricted common stock awards	233,413	666,091	790,216
Unvested restricted stock units	427,605	721,293	—
Vested and unvested options	3,137,529	313,565	—

Additionally, convertible preferred stock that was outstanding prior to our IPO in October 2014 has been excluded from the computation of diluted net loss per common share, as these securities would have been antidilutive during 2014 and 2013.

Table of Contents

## 4. Financial Instruments

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 December 31, 2015:	Input Level	Total Amortized Cost (in thousands)	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
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
<b>Total available-for-sale securities</b>		<b>319,513</b>	<b>11</b>	<b>(530 )</b>	<b>318,994</b>
Less amounts classified as cash equivalents		(22,259 )	—	1	(22,258 )
<b>Amounts classified as short-term investments</b>		<b>\$297,254</b>	<b>\$ 11</b>	<b>\$ (529 )</b>	<b>\$296,736</b>

As of December 31, 2014:	Input Level	Total Amortized Cost (in thousands)	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
Money market funds	Level 1	\$18,141	\$ —	\$ —	\$18,141
U.S. Treasury obligations	Level 2	466	—	(1 )	465
Government agency obligations	Level 2	12,519	—	(5 )	12,514
Corporate debt obligations	Level 2	60,052	1	(89 )	59,964
Commercial paper	Level 2	1,200	—	—	1,200
Asset-backed securities	Level 2	11,838	2	(8 )	11,832
<b>Total available-for-sale securities</b>		<b>104,216</b>	<b>3</b>	<b>(103 )</b>	<b>104,116</b>
Less amounts classified as cash equivalents		(21,897 )	—	—	(21,897 )
<b>Amounts classified as short-term investments</b>		<b>\$82,319</b>	<b>\$ 3</b>	<b>\$ (103 )</b>	<b>\$82,219</b>

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

	As of December 31, 2015		As of December 31, 2014	
	Amortized Cost (in thousands)	Estimated Fair Value	Amortized Cost (in thousands)	Estimated Fair Value
Maturing within one year	\$211,311	\$211,059	\$78,649	\$78,611

Edgar Filing: Atara Biotherapeutics, Inc. - Form 10-K

Maturing in one to five years	108,202	107,935	25,567	25,505
Total available-for-sale securities	\$319,513	\$318,994	\$104,216	\$104,116

As of December 31, 2015, 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 had no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. During the years ended December 31, 2015, 2014, and 2013, we did not recognize any other-than-temporary impairment loss.

#### 5. Property and Equipment

Property and equipment consists of lab equipment, furniture and fixtures, computer equipment and software, which is depreciated over the estimated useful lives of the assets, ranging from three to five years. Depreciation expense was not material for all periods presented.



Table of Contents

6. 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. At the time of issuance, we estimated the fair value of the stock issued to MSK to be \$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, which at the time was, but is no longer considered, a related party, for the development, manufacturing, use and distribution of products using certain proprietary compounds. Under the terms of these agreements, we paid \$0.25 million in cash and issued 5,538,462 shares of Series A-1 convertible preferred stock (615,384 shares after giving effect to the Recapitalization) to Amgen, for which we estimated the fair value to be \$2.8 million. Both amounts were recorded as research and development expense paid to Amgen in our combined statements of operations and comprehensive loss in 2012. Of the total Series A-1 convertible preferred stock, 2,006,688 and 3,531,774 shares were issued in 2013 and 2012, respectively.

During the year ended December 31, 2014, we purchased clinical services totaling \$0.1 million and made a \$1.0 million milestone payment to Amgen. During the year ended December 31, 2013, we purchased clinical supplies totaling \$0.6 million from Amgen. There were no payments to Amgen in 2015. The above payments to Amgen have been recorded as research and development costs paid to Amgen in our statements of operations and comprehensive loss.

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 years ended December 31, 2015, 2014 and 2013, we incurred expenses of \$1.5 million, \$1.2 million and \$0.8 million, respectively, related to these activities.

We are required to make payments to Amgen of up to \$86.0 million upon the achievement of certain development and regulatory approval milestones, of which \$1.0 million has been paid to date. Of these milestone payments, \$14.0 million relate to milestones for clinical trials. The remaining \$72.0 million relate to milestones for regulatory approvals in various territories and are anticipated to be made no earlier than 2018. Thereafter, we are required to make tiered payments based on achievement of commercial milestones based upon net sales levels. The maximum payments would be \$206.0 million based on sales of over \$1.0 billion for each of three products in a calendar year. In December 2015, we announced that we would be suspending further development of PINTA 745. Consequently, we

expect payments upon the achievement of development and regulatory approval milestones to be no more than \$59.0 million in total and sales-based payments to be no more than \$104.0 million in total.

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.

As of December 31, 2015, Amgen owned 5.1% of our outstanding common stock. Amgen does not have any rights to participate in our product candidates' development and is not represented on our board of directors.

## Table of Contents

QIMR Berghofer Agreements – In October 2015, we entered into an exclusive license agreement and a research and development collaboration agreement with QIMR Berghofer Medical Research Institute (“QIMR Berghofer”). Under the terms of the license agreement, we obtained an exclusive, worldwide license to develop and commercialize allogeneic cytotoxic T-lymphocytes (“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. Under the research and development collaboration agreement, we are required to reimburse the cost of agreed upon development activities. These payments are expensed as incurred and resulted in research and development expense of \$0.2 million for the year ended December 31, 2015. The agreement also provides for various milestone and royalty payments to QIMR Berghofer based on achievement of certain developmental milestones and future product sales, if any.

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 December 31, 2015 and 2014, there were no outstanding obligations for milestones and royalties to MSK, Amgen and QIMR Berghofer.

### 7. Commitments and Contingencies

#### License and Collaboration Agreements

Potential payments related to our license and collaboration agreements, including milestone and royalty payments, are detailed in Note 6. As the achievement of these milestones and royalties are currently not fixed and determinable, such commitments have not been included in our balance sheets.

#### Other Research and Development Agreements

We may also 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 and products for 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.

#### Operating Leases

We lease our corporate headquarters in South San Francisco, California under a non-cancellable sublease agreement that expires in January 2017. In December 2015, we entered into a new lease agreement for office space in South San Francisco, California, which is intended to be our new corporate headquarters. The new lease is expected to expire in April 2021. In connection with the new lease, we were required to issue a letter of credit in the amount of \$0.2 million to the landlord, which expires in December 2016 and is classified as restricted cash in our balance sheet. In January 2015, we entered into a non-cancellable lease agreement for office and laboratory facilities in Westlake Village, California that was scheduled to expire in April 2018. In September 2015, we amended this lease to add additional office space and extend the term of the agreement to April 2019. We also lease office space in New York, under a lease agreement that expires in April 2016. Future minimum commitments for these operating leases are as follows:

	Operating Leases (in thousands)
2016	\$ 967
2017	969
2018	981
2019	734
2020	614
Thereafter	207
<b>Total operating lease commitments</b>	<b>\$ 4,472</b>

Rent expense for the years ended December 31, 2015, 2014 and 2013 were \$0.4 million, \$0.1 million and \$0.1 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

Table of Contents

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 have not recorded any liabilities for these agreements as of December 31, 2015 and 2014.

## 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.

## 8. Stockholders' Equity

Our authorized capital stock consists of 520,000,000 shares, all with a par value of \$0.0001 per share, of which 500,000,000 shares are designated as common stock and 20,000,000 shares are designated as preferred stock. There were no shares of preferred stock outstanding as of December 31, 2015 and 2014.

The following shares of common stock were reserved for future issuance as of December 31, 2015:

	Total Shares Reserved
2014 Equity Incentive Plan	3,916,362
2014 Employee Stock Purchase Plan	432,898
Total reserved shares of common stock	4,349,260

## Restricted Stock Awards

In August 2012, in connection with our formation, our CEO purchased 9,595,384 shares of restricted common stock at a nominal per share purchase price. The shares were issued subject to certain vesting conditions, restrictions on transfer and a Company right of repurchase of any unvested share at their original purchase price. These shares are placed in escrow until vested, and have rights to vote and participate in dividends and distributions. The combined grant date intrinsic value for this award was \$1.7 million, and 7,996,153 of the shares had service and fundraising vesting conditions. Under the service vesting condition, shares vest monthly over 48 months, commencing from the first closing of Series A convertible preferred stock financing on October 22, 2012. The remaining 1,599,231 of these shares were subject to performance milestones and fundraising vesting conditions. The fundraising vesting conditions for all shares were satisfied as of December 31, 2013. All shares subject to service vesting conditions are subject to accelerated vesting in the event of certain change of control transactions.

In March 2013, an Atara employee purchased 2,423,074 shares of restricted common stock for \$0.3 million. The shares were issued under our 2012 Equity Incentive Plan and are subject to certain vesting conditions, restrictions on transfer and a Company right of repurchase of any unvested shares at their original purchase price. These shares are placed in escrow until vested, and have rights to vote and participate in dividends and distributions. Under these agreements, the shares vest as follows: 2,319,228 shares vest over four years, with one-quarter vesting after one year of service and the remainder vesting in equal installments over the subsequent thirty-six months, and 103,846 shares vest upon achievement of certain performance milestones. Vesting of all shares is subject to acceleration of vesting in the event of certain change of control transactions.

The amounts paid for both RSAs were initially recorded as other long-term liabilities. As the shares vest, we reclassify liabilities to equity and report shares as outstanding in the financial statements. On March 31, 2014, these shares were exchanged for 1,335,384 shares of Atara common stock. As of December 31, 2015, 1,101,972 of these shares had vested and are reported as shares outstanding in the financial statements. The remaining 233,413 shares are expected to fully vest in 2016. As both the Chief Executive Officer and the Atara employee were consultants of Nina, Pinta and Santa Maria through the Recapitalization date, we accounted for these RSAs as non-employee stock-based awards. Following the Recapitalization, these RSAs were accounted for as employee awards based upon the fair market value of common stock on March 31, 2014.

## Table of Contents

The weighted average grant date fair value of RSAs granted during the year ended December 31, 2013 was \$0.40. There were no grants of RSAs in the years ended December 31, 2015 and 2014. Stock-based compensation expense related to the RSAs is recorded using accelerated graded vesting model and was \$0.8 million, \$5.2 million and \$1.7 million for the years ended December 31, 2015, 2014 and 2013, respectively. The unrecognized stock-based compensation expense related to unvested RSAs was \$0.2 million as of December 31, 2015 and this expense is expected to be recognized in 2016. The aggregate intrinsic value of unvested RSAs was \$6.1 million as of December 31, 2015.

### Equity Incentive Plan

In March 2014, we adopted the 2014 Equity Incentive Plan (the “2014 EIP”) as part of our Recapitalization. In connection with the Recapitalization, Atara assumed the plans of Nina, Pinta and Santa Maria and all outstanding RSAs and RSUs granted under such plans. At the date of Recapitalization, RSAs and RSUs issued by Nina, Pinta and Santa Maria to Atara employees became employee awards and the awards’ grant dates were established as the Recapitalization date. In May 2014, our board of directors amended and restated our 2014 EIP and the amended plan became effective on October 15, 2014 upon the pricing of our IPO.

The 2014 EIP provides for annual increases in the number of shares available for issuance thereunder on the first business day of each fiscal year, beginning with 2015 and ending in 2024, equal to five percent of the number of shares of the Company’s common stock outstanding as of such date or a lesser number of shares as determined by our board of directors.

As of December 31, 2015, a total of 3,916,362 shares of common stock were reserved for issuance under the 2014 Plan, of which 326,393 shares were available for future grant and 3,589,969 were subject to outstanding options and RSUs.

Under the terms of the 2014 EIP, we may grant options, RSAs and RSUs to employees, directors, consultants and other service providers. RSUs typically require settlement by the earlier of seven years from the date of grant or the service termination (or, for RSUs granted prior to February 2014, two years following the service termination date). Stock options are granted at prices no less than 100% of the estimated fair value of the shares on the date of grant as determined by the board of directors, provided, however, that the exercise price of an option granted to a 10% shareholder cannot be less than 110% of the estimated fair value of the shares on the date of grant. Options granted to employees and non-employees generally vest over four years and expire in seven years.

### Restricted Stock Units and Awards

The RSUs granted prior to our October 2014 IPO had a time-based service condition and a liquidity-based performance condition, and vest when both conditions are met. Prior to our IPO, we determined that the liquidity-based performance condition was not probable of occurring and recorded no stock-based compensation expense related to these RSUs. Upon the closing of our IPO, we recorded \$3.8 million of stock-based compensation expense in our statement of operations and comprehensive loss. The weighted average grant date fair value of RSUs granted during the year ended December 31, 2015, 2014 and 2013 was \$25.15, \$6.53 and \$1.99, respectively. As of December 31, 2015, there was \$1.9 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 1.1 years. The aggregate intrinsic value of the RSUs outstanding as of December 31, 2015 was \$11.9 million.

The following is a summary of RSAs and RSUs 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, 2014	112,740	\$ 0.40	619,303	\$ 4.64
Granted	—	—	87,600	\$ 25.15
Forfeited	—	—	(2,645 )	\$ 8.59
Vested	(64,423 )	\$ 0.40	(276,653 )	\$ 6.12
Unvested as of December 31, 2015	48,317	\$ 0.40	427,605	\$ 7.86
Vested and unreleased			24,835	
Outstanding as of December 31, 2015	—	—	452,440	

Under our RSU net settlement procedures, we withhold shares at settlement to cover the minimum payroll withholding tax obligations. During 2015, we settled 451,306 RSUs, of which 327,383 RSUs were net settled by withholding 123,923 shares. The value of the RSUs withheld was \$4.6 million, based on the closing price of our common stock on the settlement date. This amount was remitted to the appropriate taxing authorities and has been reflected as a financing activity in our statements of cash flows.



Table of Contents

## Stock Options

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

	Number of shares	Weighted Average Exercise Price	Weighted Average Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2014	623,936	\$ 13.69		
Granted	2,610,174	\$ 28.95		
Exercised	(23,822 )	\$ 18.44		
Forfeited or expired	(72,759 )	\$ 37.11		
Outstanding as of December 31, 2015	3,137,529	\$ 25.81	6.42	\$ 12,978
Vested and expected to vest as of December 31, 2015	3,137,529	\$ 25.81	6.42	\$ 12,978
Exercisable as of December 31, 2015	276,909	\$ 17.75	5.75	\$ 2,470

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on December 31, 2015 and the exercise price of outstanding, in-the-money options. As of December 31, 2015, there was \$40.4 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 3.4 years.

Options for 23,822 shares of our common stock were exercised during the year ended December 31, 2015, with an intrinsic value of \$0.6 million. No options were exercised during 2014 and 2013. As we believe it is more likely than not that no stock option related tax benefits will be realized, we do not record any net tax benefits related to exercised options.

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 employee and consultant stock options granted during the periods indicated:

Assumptions:	Year Ended December 31, 2015		Year Ended December 31, 2014	
	Employee	Consultants	Employee	Consultants
Expected term (years)	4.5	7.0	4.5	7.0
Expected volatility	72.4 %	71.5 %	65.7 %	65.8 %
Risk-free interest rate	1.6 %	2.0 %	1.6 %	2.2 %
Expected dividend yield	0.0 %	0.0 %	0.0 %	0.0 %
Weighted-average estimated grant date fair value per share	\$ 16.63	\$ 27.82	\$ 7.29	\$ 8.61

The estimated fair value of stock options that vested in the years ended December 31, 2015, 2014 and 2013 was \$2.9 million, \$0.1 million and zero, respectively.

#### Employee Stock Purchase Plan

In May 2014, we adopted the 2014 Employee Stock Purchase Plan (“2014 ESPP”), which became effective on October 15, 2014 upon the pricing of our IPO. The 2014 ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. No offerings commenced and there were no purchases of shares under the 2014 ESPP in the year ended December 31, 2015.

The 2014 ESPP provides for annual increases in the number of shares available for issuance thereunder on the first business day of each fiscal year, beginning with 2015 and ending in 2024, equal to the lower of (i) one percent of the number of shares of our common stock outstanding as of such date, (ii) 230,769 shares of our common stock, or (iii) a lesser number of shares as determined by our board of directors. As of December 31, 2015, there were 432,898 shares authorized for issuance under the 2014 ESPP.

Table of Contents

## Stock-based Compensation Expense

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

	Year ended December 31,		
	2015	2014	2013
	(in thousands)		
Research and development	\$4,822	\$ 3,258	\$251
General and administrative	5,429	6,843	1,462
Total stock-based compensation	\$10,251	\$ 10,101	\$1,713

## 9. Income Taxes

For the years ended December 31, 2015, 2014 and 2013, all of the loss before provision for income taxes was domestic, and we recorded the following income tax provision:

	Year Ended		
	December 31,		
	2015	2014	2013
Current provision (benefit) for:	(in thousands)		
Federal income taxes	\$(1)	\$(36)	\$153
State income taxes	(8)	11	17
Total current provision (benefit)	\$(9)	\$(25)	\$170

A reconciliation of statutory tax rates to effective tax rates for the years ended December 31, 2015, 2014 and 2013 is as follows:

	Year Ended December 31,		
	2015	2014	2013
Federal income taxes at statutory rate	34.0 %	34.0 %	34.0 %
Non-deductible stock compensation	(0.6 %)	(7.3 %)	(6.8 %)
State income tax, net of federal benefit	—	—	(0.3 %)
Other	—	0.1 %	(0.1 %)
Valuation allowance	(33.4 %)	(26.7 %)	(28.8 %)
Effective tax rate	0.0 %	0.1 %	(2.0 %)

Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities were as follows as of the dates indicated:

	As of December 31,	
	2015	2014
Deferred tax assets:	(in thousands)	
Net operating losses	\$24,219	\$8,220
License fees	5,122	2,279
Stock-based compensation	4,999	1,964
Legal fees	1,436	757
Other	1,249	494
Total deferred tax assets	37,025	13,714
Valuation allowance	(37,025)	(13,714)
Net deferred tax assets	\$—	\$—

We recognize deferred income taxes for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes, as well as for tax attribute carryforwards. We regularly evaluate the positive and negative evidence in determining the realizability of our deferred tax assets. Based upon the weight of available evidence, which includes our historical operating performance and reported cumulative net losses since inception, we maintained a full valuation allowance on the net deferred tax assets as of December 31, 2015 and 2014. We intend to maintain a full valuation allowance on our deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance. The valuation allowance increased by \$23.3 million, \$9.2 million and \$2.9 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Table of Contents

As of December 31, 2015, we had federal and state net operating loss carryforwards for tax return purposes of \$68.8 million and \$68.7 million, respectively. The federal and state net operating loss carryforwards begin to expire in 2032 in various amounts if not utilized. Included in each of these amounts are unrealized federal and state net operating loss deductions resulting from stock option exercises of \$8.9 million. The benefit of these unrealized stock option-related deductions has not been included in the deferred tax assets table above and will be recognized as a credit to additional paid-in capital when realized.

Under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), our ability to utilize net operating loss carryforwards or other tax attributes in any taxable year may be limited if we have experienced an “ownership change.” Generally, a Section 382 “ownership change” occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation’s stock increases its ownership by more than 50% over its lowest ownership percentage within a specified testing period. Similar rules may apply under state tax laws.

We have completed a Section 382 study of transactions in our stock through December 31, 2015. The study concluded that we have experienced at least one ownership change since inception and that our utilization of net operating loss carryforwards will be subject to annual limitations. Further, other provisions of the Code may limit our ability to utilize federal net operating losses 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 losses. However, it is not expected that these limitations will result in the expiration of tax attribute carryforwards prior to utilization.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	(In thousands)
Balance as of December 31, 2013	\$ -
Gross increases for tax positions related to current year	1,014
Gross increases for tax positions related to prior years	629
Balance as of December 31, 2014	1,643
Gross increases for tax positions related to current year	2,671
Balance as of December 31, 2015	\$ 4,314

Of the \$4.3 million total unrecognized tax benefits, \$0.1 million, if recognized, would affect the effective tax rate due to the valuation allowance that currently offsets deferred tax assets. We recognize interest and penalties related to uncertain tax positions as part of the income tax provision and, to date, such interest and penalties have not been material. We are not aware of any items that will significantly increase or decrease our unrecognized tax benefits in the next 12 months. We file income tax returns in the US federal jurisdiction and California. All of our tax years remain open to examination by the US federal and California tax authorities.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

#### Item 9A. 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 December 31, 2015. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2015 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 disclosures. 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.

95

---

## Table of Contents

### Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2015 based on the criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2015.

### Inherent Limitations on Controls and Procedures

Our management, including the Chief Executive and 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 December 31, 2015, 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 December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### Report of the Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Item 9B. Other Information

None.

96

---



Table of Contents

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive proxy statement for our 2016 annual meeting of stockholders, or the Definitive Proxy Statement, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, not later than 120 days after December 31, 2015, and certain information to be included in the Definitive Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

We have adopted a Code of Conduct that applies to our officers, directors and employees which is available on our internet website at [www.atarabio.com](http://www.atarabio.com). The Code of Conduct contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a “code of ethics” within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

Item 14. Principal Accounting Fees and Services

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

97

---

Table of Contents

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Item 8 above.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the financial statements or notes thereto set forth under Item 8 above.

(a)(3) Exhibits.

A list of exhibits filed with this report or incorporated herein by reference can be found in the Exhibit Index immediately following the signature page of this Report.

98

---

Table of Contents

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of South San Francisco, State of California, on the 4<sup>th</sup> day of March, 2016.

Atara Biotherapeutics, Inc.

By: /s/ Isaac E. Ciechanover  
Isaac E. Ciechanover, M.D.  
Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Isaac E. Ciechanover and John F. McGrath, Jr., and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Isaac E. Ciechanover Isaac E. Ciechanover, M.D.	President and Chief Executive Officer (principal executive officer)	March 4, 2016
/s/ John F. McGrath, Jr. John F. McGrath, Jr.	Chief Financial Officer (principal financial and accounting officer)	March 4, 2016
/s/ Eric Dobmeier Eric Dobmeier	Director	March 4, 2016
/s/ Matthew K. Fust Matthew K. Fust	Director	March 4, 2016
/s/ Carol G. Gallagher Carol G. Gallagher, Pharm.D.	Director	March 4, 2016
/s/ William Heiden		

Edgar Filing: Atara Biotherapeutics, Inc. - Form 10-K

William Heiden	Director	March 4, 2016
/s/ Joel S. Marcus Joel S. Marcus	Director	March 4, 2016
/s/ Beth Seidenberg Beth Seidenberg, M.D.	Director	March 4, 2016

Table of Contents

## EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	File No.	Filing Exhibit Date	
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	333-196934	06/20/2014	
3.2	Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	S-1	333-196934	06/20/2014	
4.1	Form of Common Stock Certificate	S-1/A	333-196934	07/10/2014	
4.2	Investor Rights Agreement, by and among Atara Biotherapeutics, Inc. and the stockholders named therein, dated March 31, 2014	S-1	333-196934	06/20/2014	
10.1*	2014 Equity Incentive Plan	S-1/A	333-196934	07/10/2014	
10.2*	Forms of Option Agreement and Option Grant Notice under the 2014 Equity Incentive Plan	S-1	333-196934	06/20/2014	
10.3*	Form of Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the 2014 Equity Incentive Plan	S-1	333-196934	06/20/2014	
10.4*	Nina Biotherapeutics, Inc. 2012 Equity Incentive Plan	S-1	333-196934	06/20/2014	
10.5*	Pinta Biotherapeutics, Inc. 2012 Equity Incentive Plan	S-1	333-196934	06/20/2014	
10.6*	Santa Maria Biotherapeutics, Inc. 2012 Equity Incentive Plan	S-1	333-196934	06/20/2014	
10.7*	Form of Stock Unit Agreement under the Nina Biotherapeutics, Inc. 2012 Equity Incentive Plan, Pinta Biotherapeutics, Inc. 2012 Equity Incentive Plan and Santa Maria Biotherapeutics, Inc. 2012 Equity Incentive Plan	S-1	333-196934	06/20/2014	
10.8*	2014 Employee Stock Purchase Plan	S-1/A	333-196934	07/10/2014	
10.9*	Form of Indemnification Agreement made by and between Atara Biotherapeutics, Inc. and each of its directors and executive officers	S-1	333-196934	06/20/2014	
10.10*	Amended and Restated Executive Employment Agreement by and between Atara Biotherapeutics, Inc. and Isaac E. Ciechanover, dated October 12, 2015	8-K	001-365480	10/16/2015	
10.11*		8-K	001-365480	10/16/2015	

Edgar Filing: Atara Biotherapeutics, Inc. - Form 10-K

Amended and Restated Executive Employment Agreement between  
Atara Biotherapeutics, Inc. and John McGrath, dated October 12,  
2015

- |        |   |     |               |            |
|--------|---|-----|---------------|------------|
| 10.12* | Amended and Restated Executive Employment Agreement between<br>Atara Biotherapeutics, Inc. and Christopher Haqq, dated October<br>12, 2015  | 8-K | 001-365480.3  | 10/16/2015 |
| 10.13* | Amended and Restated Executive Employment Agreement between<br>Atara Biotherapeutics, Inc. and Mitchall G. Clark, dated October<br>12, 2015 | 8-K | 001-365480.4  | 10/16/2015 |
| 10.14* | Amended and Restated Executive Employment Agreement between<br>Atara Biotherapeutics, Inc. and Gad Soffer, dated October 12, 2015           | S-1 | 333-196986.14 | 06/20/2014 |

100

---

Table of Contents

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed
		Form	File No.	Exhibit	Herewith Filing Date
10.15*	Amended and Restated Executive Employment Agreement between Atara Biotherapeutics, Inc. and Heather D. Turner, dated October 12, 2015	S-1/A	333-205340	10.31	07/07/2015
10.16†	Exclusive License Agreement, by and between Amgen Inc. and Nina Biotherapeutics, Inc., dated as of September 7, 2012	S-1/A	333-196916	10.15	07/10/2014
10.17†	Amendment No. 1 to Exclusive License Agreement, by and between Amgen Inc. and Nina Biotherapeutics, Inc., dated as of October 22, 2012	S-1	333-196916	10.16	06/20/2014
10.18†	Amendment No. 2 to Exclusive License Agreement, by and between Amgen Inc. and Nina Biotherapeutics, Inc., dated as of September 7, 2012	S-1	333-196916	10.17	06/20/2014
10.19†	Exclusive License Agreement, by and between Amgen Inc. and Santa Maria Biotherapeutics, Inc., dated as of September 7, 2012	S-1/A	333-196916	10.21	07/10/2014
10.20†	Amendment No. 1 to Exclusive License Agreement, by and between Amgen Inc. and Santa Maria Biotherapeutics, Inc., dated as of October 22, 2012	S-1	333-196916	10.22	06/20/2014
10.21†	Amendment No. 2 to Exclusive License Agreement, by and between Amgen Inc. and Santa Maria Biotherapeutics, Inc., dated as of July 29, 2013	S-1	333-196916	10.23	06/20/2014
10.22†	Amendment No. 3 to Exclusive License Agreement, by and between Amgen Inc. and Santa Maria Biotherapeutics, Inc., dated as of April 4, 2014	S-1	333-196916	10.24	06/20/2014
10.23	Sublease Agreement, by and between Atara Biotherapeutics, Inc. and Accesia, Inc., dated as of September 11, 2014	S-1/A	333-196916	10.28	09/26/2014
10.24†	Exclusive Option Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of September 19, 2014	10-Q	001-365480	10.29	05/11/2015
10.25†	Amendment Number One to the Exclusive Option Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of June 12, 2015	10-Q	001-365480	10.32	08/07/2015
10.26†	Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center,	S-1	333-205340	10.30	06/29/2015



Edgar Filing: Atara Biotherapeutics, Inc. - Form 10-K

dated as of June 12, 2015

- |       |  |      |               |            |   |
|-------|--|------|---------------|------------|---|
| 10.27 | Office Lease, by and between Atara Biotherapeutics, Inc. and BPG Rock Westlake, LLC, dated January 7, 2015                     | 10-Q | 001-365480.33 | 11/06/2015 |   |
| 10.28 | First Amendment to Lease, by and between BPG Rock Westlake, LLC and Atara Biotherapeutics, Inc., dated as of September 9, 2015 | 10-Q | 001-365480.34 | 11/06/2015 |   |
| 10.29 | Office Lease, by and between BXP 611 Gateway Center LP and Atara Biotherapeutics, Inc., dated as of December 9, 2015           |      |               |            | X |
| 21.1  | List of subsidiaries   |      |               |            | X |

101

---

Table of Contents

Exhibit Number	Exhibit Description	Incorporated by Reference File Form No. Exhibit	Filed Herewith Filing Date
23.1	Consent of Independent Registered Public Accounting Firm		X
24.1	Power of Attorney (included on signature page)		X
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 USC 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 Taxonomy Extension Schema Document.		X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.		X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.		X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.		X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.		X

Confidential treatment has been granted for a portion of this exhibit.

\*Indicates management contract or compensatory plan or arrangement.

(1) The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 USC 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.