ATARA BIOTHERAPEUTICS, INC.

FORM 10-K
(Annual Report)

Filed 02/26/15 for the Period Ending 12/31/14

Address	3260 BAYSHORE BOULEVARD BRISBANE, CA 94005
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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, 2014

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	**46-0920988**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
701 Gateway Blvd., Suite 200 South San Francisco, CA	**94080**
(Address of principal executive offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act: Common Stock, Par Value $0.001 Per Share; Common stock 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	☒ ☎☟☐ ■☐♦ ♍♒♏♍& ♓♐ ♋ ♦❍♋●● ❒♏◘☐❒♦♓■♑ ♍☐❍◘♋■♲❶	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 ☒ x

The Registrant did not have a public float on the last business day of its most recently completed second fiscal quarter because there was no public market for the registrant's common equity as of such date.

The number of shares of Registrant's Common Stock outstanding as of February 18, 2015 was 24,360,247.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2015 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report where indicated. Such proxy statement will be filed with the US Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

ATARA BIOTHERAPEUTICS, INC.

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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 reporting results from our Phase 2 clinical trial of PINTA 745;
- our expectations regarding the timing of reporting results from our Phase 1 clinical study of STM 434;
- our expectations regarding the timing of reporting results from clinical studies and trial being conducted by Memorial Sloan Kettering Cancer Center ("MSK") of the T-cell programs we have an option to license;
- the likelihood and timing of regulatory approvals for our product candidates and any product candidates resulting from the T-cell programs we have an option to license;
- the potential market opportunities for commercializing our product candidates and any product candidates resulting from the T-cell programs we have an option to license;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates and any product candidates resulting from the T-cell programs we have an option to license, if approved for commercial use;
- estimates of our expenses, capital requirements and need for additional financing;
- our expectation that our existing capital resources and net proceeds from our public offerings of common stock will be sufficient to enable us to complete our planned confirmatory Phase 2 clinical trial of PINTA 745 and our initial Phase 1 clinical study of STM 434 and fund our operations and capital expenditure requirements into the second half of 2017;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical studies and 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 recently completed 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 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.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel therapeutics for serious unmet medical needs, with an initial focus on muscle wasting conditions and oncology. Our product candidates are biologics targeting myostatin and activin, members of the Transforming Growth Factor-Beta ("TGF-ß"), protein superfamily, which play roles in the growth and maintenance of muscle and many other body tissues. Our lead product candidate, PINTA 745, is in a Phase 2 clinical trial for protein energy wasting ("PEW"), a condition affecting many end-stage renal disease ("ESRD") patients. Our second product candidate is STM 434. We commenced a Phase 1 clinical study of STM 434 for ovarian cancer and other solid tumors in 2014. We have five additional product candidates targeting the TGF-ß pathway in preclinical development. In addition, we have an exclusive option to license several T-cell programs targeting oncology and infectious diseases through an agreement with Memorial Sloan Kettering Cancer Center ("MSK"). We intend to license or acquire additional product candidates to develop and commercialize.

Our lead product candidate, PINTA 745, is a peptibody that binds to and inhibits myostatin, a protein that down regulates muscle growth and maintenance. In a Phase 1 study, PINTA 745 was found to increase muscle mass compared to placebo after one month of weekly dosing, an increase that was statistically significant, indicating that it is more likely than not that the benefit observed in the study was due to drug treatment rather than chance. We are enrolling a US-based Phase 2 clinical trial to further establish the role of PINTA 745 in building muscle mass, as well as to collect data from corresponding functional muscle tests. This trial is being conducted in patients with ESRD who are also suffering from PEW.

PEW is a major complication of ESRD. A recent study we completed with DaVita Clinical Research, a division of DaVita Healthcare Partners Inc., concluded that more than half of DaVita's dialysis population meet the conditions for PEW and, in comparison to the rest of the group, exhibit worse morbidity and mortality. There is currently no approved therapy for patients suffering from PEW.

We believe PINTA 745 is the only potential therapeutic in clinical development to treat this patient population.

In clinical studies conducted of PINTA 745 in men with prostate cancer and in mouse studies in a model of chronic kidney disease ("CKD"), conducted with PINTA 745/s, a version of PINTA 745 that was customized for use in mice, several properties well suited for a potential therapeutic for PEW were observed, including:

- ***Reversing muscle loss*** — PINTA 745 not only stopped muscle wasting, it significantly increased muscle mass after four weeks of treatment.
- ***Anti-inflammatory properties*** — In an animal model of renal disease, PINTA 745/s exhibited significant anti-inflammatory properties, a factor that we believe will be important due to the critical role that inflammation plays in PEW and the overall declining health of ESRD patients.
- ***Dosing schedule*** — PINTA 745 is dosed weekly, which conveniently aligns with dialysis treatment schedules.

We designed the Phase 2 trial to give us insight into potential additional therapeutic areas for PINTA 745. These could include: orthopedic indications; inflammation and inflammatory diseases; age-related sarcopenia (loss of muscle); and cancer cachexia. In each of these conditions, muscle loss prevention, muscle growth and reduction in inflammation resulting from treatment with PINTA 745 could lead to improved physical function and therefore to better outcomes. We expect to release initial data from this Phase 2 clinical trial in the fourth quarter of 2015.

Our second product candidate, STM 434, is in a Phase 1 clinical study that will enroll up to 66 patients with ovarian cancer and other solid tumors. STM 434 is a soluble ActR2B receptor that binds Activin A. Activin has been shown to be involved in the growth and proliferation of ovarian cancer and other tumors, with published evidence of its role at both the genetic (messenger RNA) and protein levels. Activin expression is one of a few biomarkers associated with larger tumor volume and poorer outcomes, including shortened survival in a variety of tumors including ovarian tumors. Published data has shown that serum Activin A levels in ovarian

cancer subjects are elevated in relation to levels in normal subjects. We plan to test the potential use of Activin A as a biomarker in our Phase 1 clinical study.

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 22,240 new ovarian cancer cases and 14,030 ovarian cancer deaths in the United States in 2013. Surgery and cytotoxic chemotherapies are widely used to treat ovarian cancer; however, the outcomes have changed little in 40 years. The proportion of all ovarian cancer patients surviving five years after diagnosis was only 44% based on the National Cancer Institute SEER database for women diagnosed from 2003 to 2009.

Some subtypes of ovarian tumors respond even more poorly to treatment than others and represent opportunities where drug development could be accelerated. In particular, clear cell and granulosa cell tumors are considered resistant to chemotherapy. Our preclinical experiments in animal models of these subtypes indicate that binding Activin A with a soluble receptor could significantly reduce tumor proliferation, reduce tumor volume and potentially increase survival. We believe that novel therapies for clear cell and granulosa cell tumors could qualify for US Food and Drug Administration ("FDA") breakthrough therapy designation, an FDA process designed to accelerate the development and review of drugs intended to treat a serious condition when early studies show that the drug may be substantially better than current treatment, and thereby achieve expedited regulatory approval. 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.

Both PINTA 745 and STM 434 are novel molecules with well-characterized mechanisms of action. They were developed initially, along with our five other in-licensed programs, at Amgen. Taken together, we believe these unique product candidates constitute a pipeline of biologics that have benefited from years of investment, resulting in a large patent portfolio, broad preclinical testing and, in the case of PINTA 745, promising clinical results. We are evaluating the remaining five product candidates to determine the best path forward. Where appropriate, we intend to conduct preclinical studies and file investigational new drug applications ("INDs") with the FDA for these candidates. For example, we are conducting IND-enabling manufacturing and pre-clinical studies for ATA 842, a humanized antibody targeting myostatin.

Our business model is to license or acquire and develop novel therapeutics for serious unmet medical needs with validated molecular 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. 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 study 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. ("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.

Our Strategy

Our goal is to be a leader in the development and commercialization of novel therapeutics for serious unmet medical needs. We are initially focused on muscle wasting conditions and oncology. Key components to achieve this objective include:

- ***Rapidly advance PINTA 745 in clinical development*** — We intend to complete our ongoing Phase 2 clinical trial with PINTA 745 with the goal of obtaining positive results in ESRD patients with PEW. If the data supports it, we intend to seek feedback from health authorities, including the FDA, and advance PINTA 745 to global registration trials in PEW. In parallel, we intend to seek out additional indications for which to explore the therapeutic utility of PINTA 745.
- ***Obtain clinical proof of concept for STM 434*** — We commenced a Phase 1 study with STM 434 to study safety and tolerability as well as early signs of activity in a patient population that includes patients with ovarian cancer and other solid tumors in 2014. We intend to test STM 434 as a single therapy and in combination with other chemotherapy options that are the current standard of care. In the clear cell and granulosa cell subtypes of ovarian cancer, we may seek orphan drug status. If supported by the clinical data, we may seek Breakthrough Therapy designation and pursue clinical trials of STM 434 in these specific subtypes.
- ***Evaluate our product candidates and advance them into the clinic as appropriate*** — Our initial product portfolio includes five additional unique candidates that have not yet entered clinical trials. We will evaluate these candidates and determine which of them to advance and the indications in which to advance them.
- ***Collaborate with MSK in its development of T-cell programs while we evaluate the potential exercise of our exclusive option to license these programs*** — We intend to collaborate with MSK on the development of EBV, CMV, and WT1 targeted T-cell programs, fund research of these and other targeted T-cell programs and obtain guidance from regulatory authorities for late phase development of the most advanced T-cell programs, while we evaluate the potential exercise of our exclusive option to license these programs.
- ***Leverage our relationships and experience to in-license or acquire additional product candidates for development*** — We intend to capitalize on our relationships with both pharmaceutical companies and academic institutions to identify, review and ultimately license or acquire novel product candidates, which our team will develop and commercialize.
- ***Retain worldwide rights for product candidates*** — We intend to maintain worldwide rights to our product candidates in order to maximize their commercial value. We are developing our product candidates in specialty indications in which we believe it is feasible and economically advantageous to build our own commercial organization. However, when compelling opportunities arise, it may be to our advantage to seek collaborations in certain indication areas or geographies. We hold worldwide rights to our entire portfolio, except for PINTA 745, which Amgen licensed to Takeda in Japan.

Our Product Candidates

PINTA 745 for Protein-Energy Wasting in End-Stage Renal Disease Patients

Our lead product candidate, PINTA 745, is a peptibody that binds myostatin and inhibits its corresponding signal transduction, thereby blocking the negative regulation of skeletal muscle growth. We are conducting a Phase 2 trial in patients with ESRD who are also suffering from PEW at six US-based sites, including academic sites, as well as those associated with Fresenius and DaVita, two leading providers of kidney care in the United States. PEW refers to a state of muscle wasting, inflammation and malnutrition that increases patients' risk for infections, cardiovascular disease and other complications. We believe that patients with PEW may benefit from the muscle-building demonstrated in earlier clinical trials and anti-inflammatory properties of PINTA 745 demonstrated in preclinical trials, which are discussed in more detail below. INDs for PINTA 745 were filed by Amgen, the product candidate's previous sponsor, in October 2005 and July 2009. Both of these INDs are open, with our wholly owned subsidiary Pinta as the holder.

Protein-Energy Wasting in ESRD Patients

PEW is a common and serious condition affecting patients on kidney dialysis. Patients with PEW lose significant body mass and suffer from muscle wasting and weakness. In several published studies, PEW has been shown to increase the already high morbidity and mortality associated with ESRD. A study published in 2010 examined 40,950 dialysis patients from 12 countries and showed that PEW increases patients' risk for infections, cardiovascular disease and other complications. Another study published in 2010 examined more than 120,000 dialysis patients and found that patients who lost overall body weight but gained muscle mass had a higher survival rate. Many dialysis patients with PEW experience a lower quality of life due to poor limb strength, low endurance and impaired muscle power. Worsening of walking speed and grip strength, associated with loss of muscle mass, have been shown to be effective predictors of mortality.

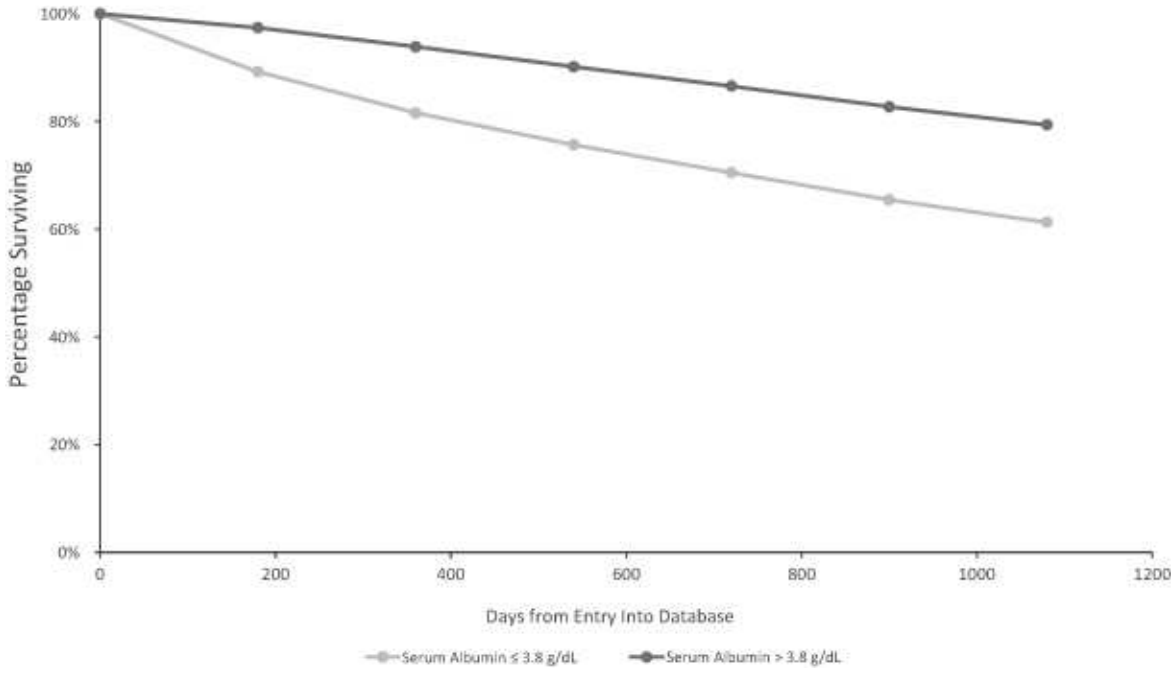
Albumin is the most abundant protein circulating in the blood, and a sensitive indicator of the body's nutritional status. In dialysis patients, a decline in serum albumin indicates a serious overall protein wasting state. In these patients, the ability to predict mortality risk is associated with the presence of muscle wasting or inflammation.

DaVita Study

In order to better understand the market opportunity for PEW therapies in dialysis patients, we collaborated on a study of PEW in dialysis patients with DaVita. DaVita has collected data on over 130,000 renal patients including those enrolled in over 300 clinical trials worldwide in order to better understand the pathology and clinical course of kidney disease. The resulting database is a unique and powerful resource that allows for fast understanding of the disease state and the impact of treatments in kidney disease.

Using the DaVita dialysis database, we were able to characterize patients for the PEW condition and identify those patients at higher risk of morbidity and mortality. We analyzed 56,350 DaVita dialysis patients who began treatment at DaVita between 2009 and 2012 and had at least six months of dialysis. We then followed these patients from the time they entered the database for 1,200 days or until they died or were lost to follow-up. Of these patients, 54% had a serum albumin level less than or equal to 3.8 g/dL six months after beginning dialysis. Among these, approximately 11% of patients died within one year compared to less than 3% of patients whose serum albumin was higher than the 3.8 g/dL dialysis threshold. At the three-year mark, approximately 40% of patients with low serum albumin who had been followed for three years had died in comparison with roughly 21% of patients who had been followed for three years with serum albumin levels above the critical threshold six months after beginning dialysis. We believe that patients with PEW represent a significant cost to the healthcare system. We and DaVita are currently pursuing health economic studies in order to quantify this cost, comparing treatment for those who have PEW to those who do not.

Survival Rates Based Upon Serum Albumin Levels



PEW Market Opportunity

Based on data from the US Renal Data System, we estimate that the current total US dialysis population, excluding patients who had successfully received kidney transplants, is 460,000 patients. Of these patients, we estimate that approximately 250,000 patients suffer from PEW. Worldwide, we believe that more than 800,000 patients suffer from PEW.

Limitations of Current Therapies for PEW

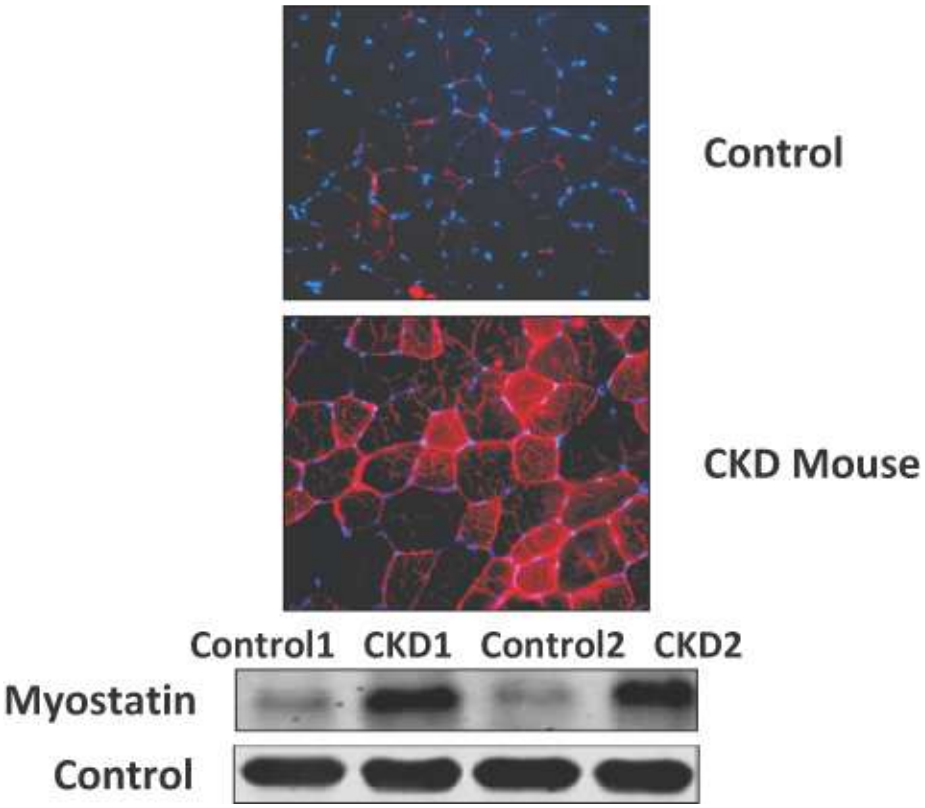
There are no pharmacologic therapies approved by the FDA indicated for PEW. Furthermore, we are not aware of any such therapies in clinical trials for PEW that target myostatin. Current treatment options for muscle wasting include appetite stimulants, nutritional support, corticosteroids, anabolic steroids and human growth hormone. Dietary supplements containing 10 grams of protein or more per day are recommended for PEW patients by consensus guidelines. Long term stabilization of lean body mass, muscle mass or serum albumin levels in patients showing symptoms of PEW or related conditions such as cancer cachexia have not been observed through dietary changes or nutritional supplements.

Biology of Myostatin

Myostatin, a member of the TGF-ß superfamily of growth factors, is highly expressed in skeletal muscle and fat tissue. It acts as a negative regulator of muscle growth and appears to promote fat gain. Through knockout experiments and observation of naturally occurring knockouts of myostatin in mice, cattle, dogs, as well as a human being, there is a body of evidence supporting the role of myostatin in regulating muscle growth. In particular, myostatin has been shown to inhibit the growth of new muscle stem cells as well as play a part in the destruction of muscle through the NF-KB pathway. Animals and humans born without a functioning myostatin gene exhibit muscle overgrowth while otherwise showing no apparent negative effects.

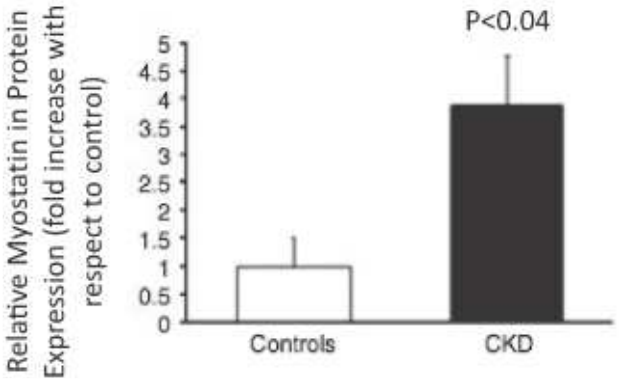
Myostatin inhibition was first characterized and evaluated in the mid-1990s as a potential mechanism for limiting muscle wasting. Several proof-of-concept studies have shown the ability of myostatin inhibitors to build muscle. Several other companies are pursuing myostatin inhibitors for other conditions, including cancer cachexia, Duchenne Muscular Dystrophy and orthopedic indications.

Preclinical studies have shown that myostatin is upregulated, or increased, in the skeletal muscle of mice suffering from CKD. One such study, published in the *FASEB Journal* in 2011, is shown below.

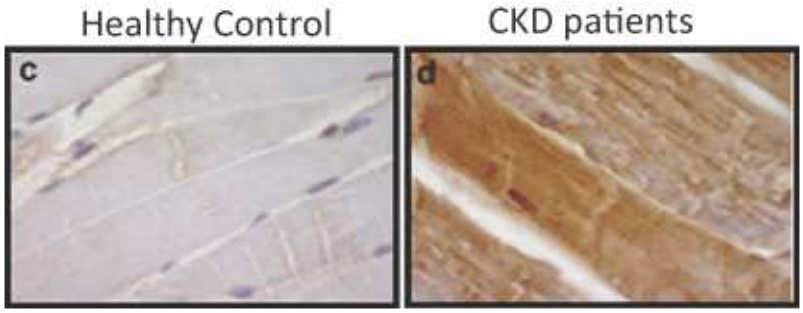


In the two upper images, myostatin upregulation is shown by fluorescence in the muscle cells of a CKD mouse compared to a control mouse. In the two lower images, myostatin protein expression levels are shown in the muscle cells of two CKD mice compared to control mice.

The following charts and images from a study published in *Kidney International* in 2011 show that myostatin is upregulated in skeletal muscle taken from dialysis patients. This was observed both quantitatively and when a thin slice of muscle tissue was examined under a microscope, or histologically.



The p-value is a measure of the likelihood that the data observed are from chance instead of due to the effects of the drug tested. The smaller the p-value, the stronger the likelihood that the data observed resulted from the drug tested rather than from chance. By convention, p-values less than 0.05 are considered significant, indicating a high degree of confidence that the result is due to therapy with the drug and not to chance.



In the upper graphs, myostatin RNA and protein levels are increased in CKD patients compared to healthy controls. In the lower images, myostatin in muscle stains dark in CKD patients compared to healthy controls.

Mechanism of PINTA 745

PINTA 745 is a peptibody, a peptide-antibody combination. The peptide component binds to myostatin, preventing it from docking with its receptors on the surface of muscle cells and blocking its role in inhibiting muscle production and maintenance. Peptibodies, as a class of therapeutics, are well-characterized, with one product on the market and several more, including PINTA 745, in clinical trials. Compelling features of the PINTA 745 peptibody are its:

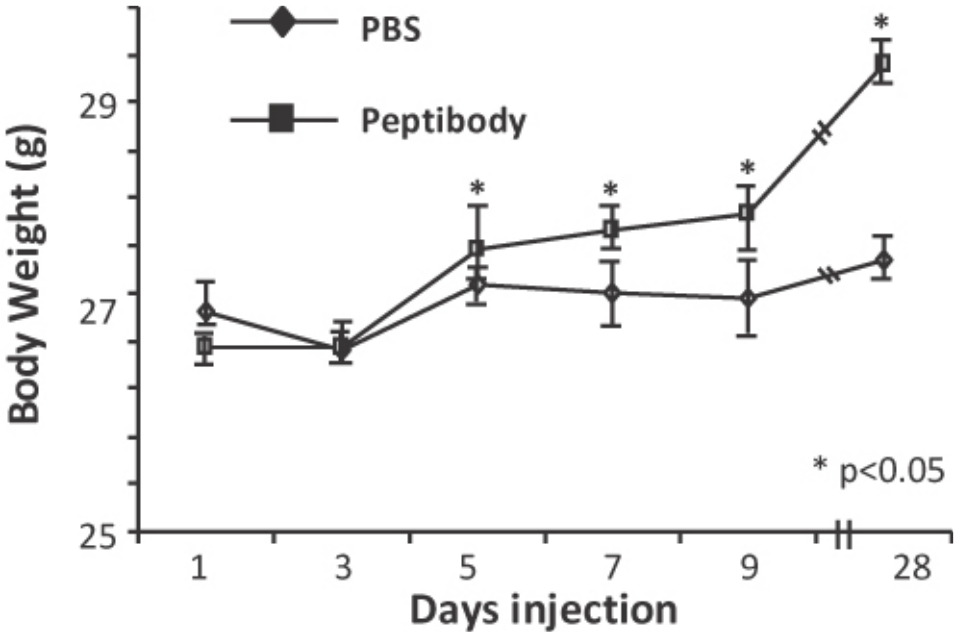
- demonstrated ability to promote muscle growth;
- anti-inflammatory properties, a factor that we believe will be important due to the critical role that inflammation plays in PEW and the overall declining health of ESRD patients; and
- dosing schedule, which conveniently aligns with dialysis treatment schedules.

We believe that the mechanism and pharmacologic properties of PINTA 745 are well-suited to the PEW setting. Preclinical and clinical data describing the effects of PINTA 745 are discussed below.

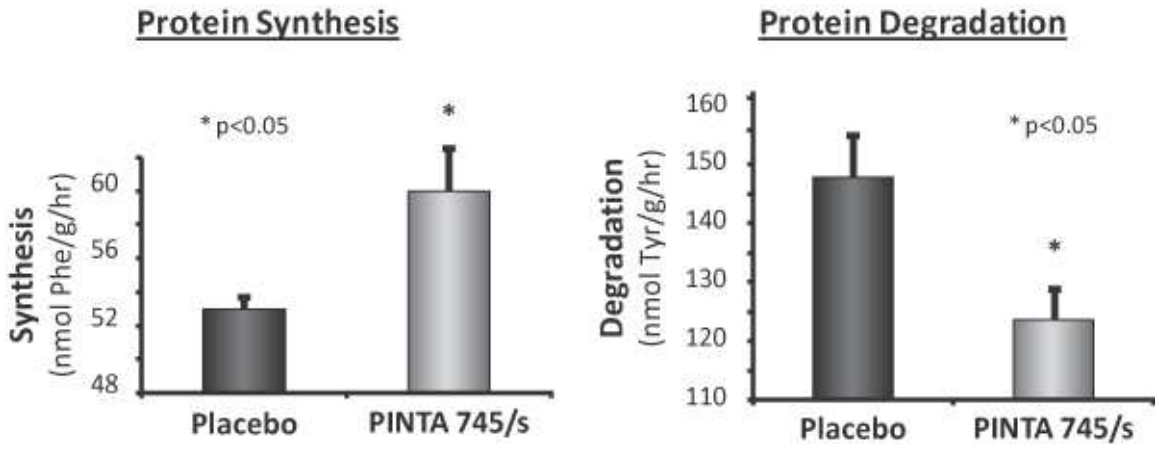
Preclinical Studies

A preclinical study was conducted to determine PINTA 745's effect in mouse models of ESRD. In the 5/6 th -nephrectomy model, a mouse model considered to be the industry standard for studying ESRD and its related effects, PINTA 745/s was shown to reverse body weight loss and reduce skeletal muscle mass and inflammation, which are morbidities associated with PEW. Nephrectomized mice, which have a condition mimicking ESRD and are referred to as CKD mice, and control mice of comparable size and blood urea nitrogen levels were injected either with PINTA 745/s or with saline. The experimental mice were injected subcutaneously at 5.0 mg/kg every other day for 7 to 28 days.

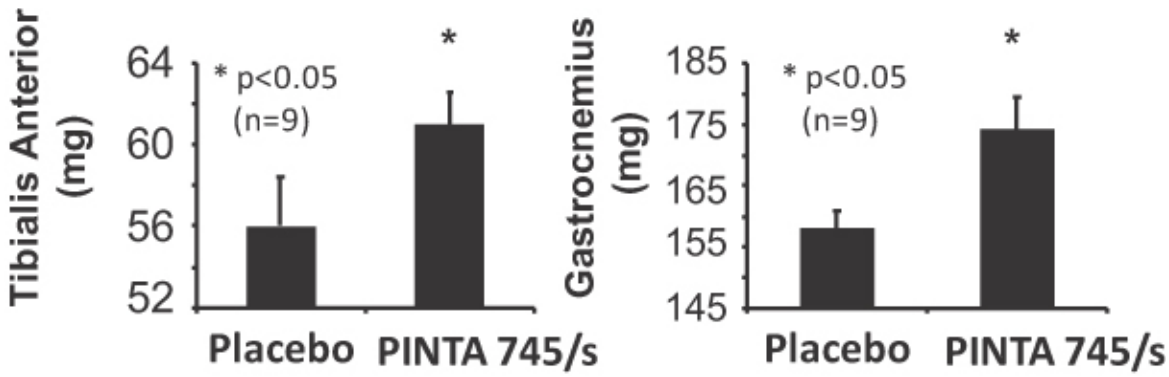
After seven days of PINTA 745/s treatment, the body and muscle weights of the CKD mice increased significantly compared with those in saline-treated CKD mice, an effect that persisted over 28 days.



Protein synthesis—as measured by the uptake of a radiolabeled amino acid tracer—was increased and protein degradation—as measured by the release of a different amino acid tracer—was inhibited. This data underscores PINTA 745/s' role in both forming new muscle and hindering the destruction of existing muscle.



Further, PINTA 745/s increased muscle mass in the two muscles tested after seven days of treatment, the tibialis anterior and the gastrocnemius, an effect that continued over 28 days. In other preclinical studies, increases in muscle mass were observed in mice in doses as low as 0.01 mg/kg, with peak effect at 1.0 and 5.0 mg/kg.



In CKD mice, circulating levels of 10 cytokines, which are mediators of inflammation, were increased in comparison to control mice. PINTA 745/s treatment for seven days decreased the level of these cytokines, suggesting that myostatin inhibition affects CKD-induced inflammation. The five cytokines shown below were the ones that were statistically significantly reduced in CKD mice treated with PINTA 745/s as compared to CKD mice treated with placebo.

Cytokine	Control Mice (pg/ml)	CKD Mice Treated with Placebo (pg/ml)	CKD Mice Treated with PINTA 745/s (pg/ml)	P Values	
				CKD Mice vs. Control Mice	CKD Mice Treated with Placebo vs. CKD Mice Treated with PINTA 745/s
Fibrinogen (µg/ml)	156.75 ± 34.87	2877.5 ± 1007.68	323.25 ± 306.50	0.0016*	0.003*
IFN- γ (pg/ml)	16.15 ± 5.04	17.55 ± 2.58	12.57 ± 2.66	0.638	0.036*
IL-6 (pg/ml)	5.8 ± 0.48	10.48 ± 2.23	3.05 ± 0.73	0.041*	0.036*
M-CSF-1 (ng/ml)	7.31 ± 2.51	11.61 ± 2.08	7.48 ± 1.0	0.039*	0.012*
TNF- α (ng/ml)	0.1 ± 0.06	0.151 ± 0.03	0.075 ± 0.04	0.189	0.033*

* Statistically significant.

Based on these observations, we believe that PINTA 745 has the potential to mitigate the effects of PEW in ESRD patients by increasing muscle formation, stimulating the conversion of muscle stem cells into muscle cells, and decreasing muscle destruction. Furthermore, we believe that PINTA 745 has the potential to decrease inflammation in ESRD patients with PEW, which is an important potential factor often observed with greater morbidity and mortality.

PINTA 745 Phase 1 Clinical Studies — Safety and Tolerability

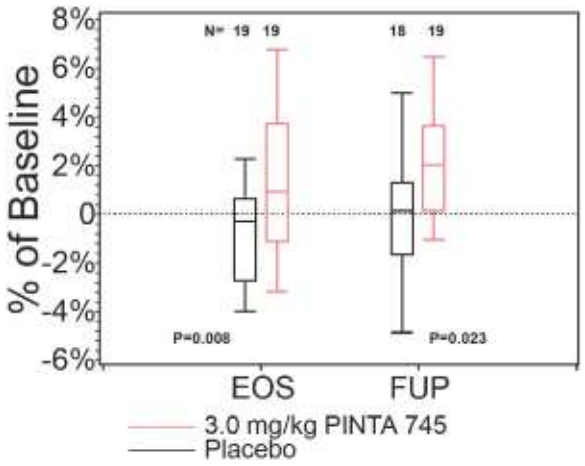
To date, three Phase 1 studies of PINTA 745 have been conducted, two in healthy volunteers and one in prostate cancer patients. PINTA 745 showed both safety and tolerability in all three Phase 1 studies. Across all studies, which enrolled a total of 151 subjects, 48 subjects were exposed to the highest subcutaneous dose of 3.0 mg/kg and no treatment-related serious adverse events were observed. In the healthy volunteer trials, there were observations of some adverse events, mild in severity, that were not dissimilar to those observed in the placebo control group. No serious adverse events, discontinuations due to adverse events or deaths were reported in these trials. The only identified risk from the trials was injection site reactions, which can occur with agents dosed subcutaneously. In the Phase 1 study in prostate cancer patients, events were also mild in severity and similar in the PINTA 745 and placebo groups; one serious adverse event was reported that was considered not related to the drug. As a result, PINTA 745 showed acceptable levels of safety and tolerability.

PINTA 745 Phase 1 Study in Prostate Cancer Patients

A multidose, placebo-controlled, double-blind Phase 1 study of PINTA 745 was carried out by Amgen on 54 men with prostate cancer who were receiving androgen deprivation therapy. This trial assessed both safety and efficacy following four weekly subcutaneous injections. Three Phase 1 dose groups were studied at dose levels of 0.3 mg/kg, 1.0 mg/kg and 3.0 mg/kg, with one placebo arm. This study was published in 2014 in *The Journal of Clinical Endocrinology and Metabolism* .

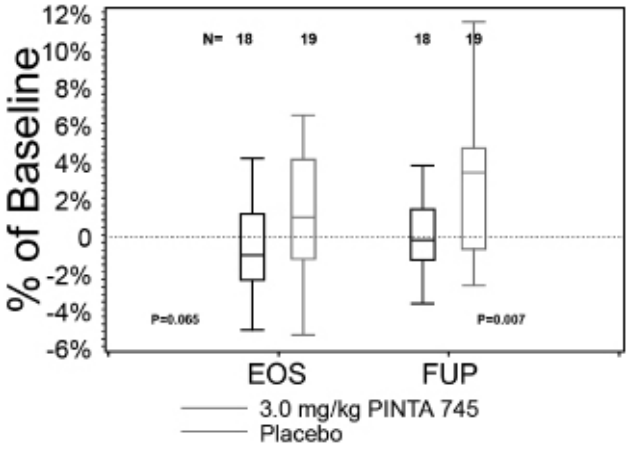
Efficacy parameters that were measured in this study included lean body mass as measured by dual energy X-ray absorptiometry (“DEXA”), and lower-extremity muscle size as measured by CT scan. These methods are considered industry standard imaging techniques for measuring muscle mass or volume. Formal statistical testing for efficacy was conducted in the 3.0 mg/kg group. These statistical tests were not performed in the 0.3 mg/kg group and the 1.0 mg/kg groups because fewer patients were treated at these dose levels than were required for such analyses.

Lean body mass increased significantly in the 3.0 mg/kg dose group. The difference in lean body mass in the PINTA 745 group compared to the placebo group was approximately 2% greater at the end of the treatment period, a difference that increased over the subsequent four weeks of observation after the cessation of treatment, as shown in the following chart. Measurements for both placebo and PINTA 745 were taken at end of study (“EOS”) at day 29, and at follow up (“FUP”) one month after day 29. There was a statistically significant increase in lean body mass at both EOS and FUP for the active arm compared to the control arm. Notably, lean body mass increase persisted at FUP, even without administration of the drug during the follow-up period.



The bottom and top of the boxes represent the first and third quartiles, and the horizontal band inside the box indicates the median value. The ends of the whiskers indicate the minimum and maximum data in the range of observations.

As measured by CT scan, lower extremity muscle size increased significantly in the 3.0 mg/kg group. The muscle size increased in this group by approximately 1.2% at EOS, and further increased to 2.7% from baseline at FUP.



The bottom and top of the boxes represent the first and third quartiles, and the horizontal band inside the box indicates the median value. The ends of the whiskers indicate the minimum and maximum data in the range of observations.

Body fat decreased by 1.7% (p=0.021) in the 3.0 mg/kg group at the end of the treatment period compared to baseline, and the decrease was similar (1.5%, p=0.183) four weeks after the cessation of treatment. The decrease in body fat may reflect the presence of myostatin receptors in fat tissue. Reduced fat mass is an expected pharmacologic finding of myostatin inhibition, observed in multiple preclinical studies using PINTA 745/s as well as in three studies reported in the literature in which ActR2B-Fc fusions were used to inhibit myostatin. All of these studies, published in the *International Journal of Obesity* in 2009, the journal *Endocrinology* in 2012 and the journal *Diabetologia* in 2012, observed reduced fat accumulation in high fat fed mice.

In exploratory efficacy analyses comparing treatment effect and exposure across the dose groups, the 3.0 mg/kg dose appeared to have more impact on lean body mass than the lower doses, which suggests that humans exhibit dose-responsive efficacy from treatment with PINTA 745. This will be investigated in our ongoing clinical trial.

This trial was carried out in a rigorous setting in order to highlight the properties of PINTA 745. We believe that the results were clinically meaningful for the following reasons:

- The increase in muscle mass was statistically significant against the placebo group, with gains of 2% or more observed in response to treatment with PINTA 745.
- The increase in muscle mass was seen after only one month of weekly dosing and persisted beyond treatment (one month following EOS).
- The patients participating in this study were suffering from prostate cancer, which is associated with significant muscle loss. Historical control patients lost as much as 4% of muscle mass over a 12-month period, based on a study published in the journal *Urology* in 2004.

Design of Ongoing Phase 2 clinical trial of PINTA 745 in ESRD patients with PEW

Our ongoing, randomized, double-blind, placebo-controlled trial with PINTA 745 is designed to demonstrate the effect of myostatin inhibition in PEW and lay the foundation for future clinical development. The study will enroll 48 patients, who will be randomized three-to-one (PINTA 745-to-control). PINTA 745 will be given for three months, and then patients will participate in a two month observation period to assess the durability of changes in muscle and inflammation. The primary endpoint of the trial is change in muscle mass seen through radiographic studies at three months versus the control group.

In the current Phase 2 trial in dialysis patients, we are seeking to reproduce and further characterize the muscle-building effect that was observed in prostate cancer patients in the Phase 1 study. To this end, we have made several key changes to the protocol to gain more insight regarding the efficacy and durability of responses.

Design Element	Prior Phase 1 (Prostate)	Current Phase 2 (PEW)	Rationale
Route of Administration	Subcutaneous Injection	Intravenous Injection	Enhances drug exposure and aligns with routine patient management in the dialysis setting
Duration of Therapy	1 month	3 months	Longer-term dosing may enhance muscle growth
Dose of PINTA 745	0.3, 1 and 3 mg/kg given weekly	3 mg/kg weekly; 3 mg/kg loading dose followed by 1 mg/kg maintenance dose; and 6 mg/kg loading dose followed by 2 mg/kg maintenance dose	Higher drug exposure may be more effective while similarly well-tolerated
Duration of follow up	1 month	2 months	Extends information on durability of effect

We also have included two functional muscle assessments as secondary endpoints that were not included in the Phase 1 studies. We will be using stair climbing power and six-minute walk tests in order to identify the appropriate parameters to use for physical function testing in future trials. These assessments have become significantly more common in clinical trials and have formed the basis for regulatory approvals of other agents in different indications. Because these assessments were developed for other patient groups of similar age and functional muscle status, such as patients recovering from a heart attack, we believe that these endpoints are appropriate for use in this population. Once we have demonstrated their feasibility, we may choose one or both of these physical functional assessments for endpoint data in later-stage clinical trials.

Other assessments in the trial include:

- Demonstration of the feasibility of quality of life assessments, such as the kidney disease quality of life assessment as well as assessments of fatigue and anorexia/cachexia.
- Safety monitoring and exposure, including pharmacokinetics (“PK”).
- Effects on the duration of use and dose intensity of supportive care drugs.

Given the robust design features of the Phase 2 trial protocol, we believe that if this trial is successful, it will confirm the potential clinical utility of PINTA 745 in this patient population and help us appropriately design subsequent clinical trials to support applications for regulatory approval.

The design of our Phase 2 trial was created not only to support eventual regulatory approval but also to be able to pilot the assessments that will be needed to obtain reimbursement. For that reason, we chose trial sites that effectively reflect the etiology of ESRD in the United States. Our six sites include academic sites, as well as those associated with DaVita and Fresenius. These centers are representative of the vast majority of the US dialysis market.

Biomarker Approach

As part of our Phase 2 clinical trial protocol, we are measuring serum levels of myostatin in patients to see if we can use it as a biomarker to predict which patients will respond best to treatment.

Status of Ongoing Phase 2 clinical trial of PINTA 745 in ESRD patients with PEW

We have completed enrollment of the first eight patients at the 3 mg/kg weekly dose level. To date, we have observed no dose-limiting toxicities, no treatment-related serious adverse events nor grade 3 or higher adverse events and no anti-drug antibody formation. Adverse events that were deemed possibly related to treatment with PINTA 745 were all grade 1 or 2 in severity, with muscle pain as the most commonly reported treatment-related adverse event. The safety committee, consisting of the clinical trial sponsor and the trial investigators, considered the 3 mg/kg weekly dose to be safe and well tolerated and determined that it would be appropriate to proceed with protocol-specified dose expansion and dose escalation. Pharmacokinetic data from these first eight patients showed that PINTA 745 has a longer half-life in ESRD patients compared with previously studied healthy volunteers and men with prostate cancer. Drug exposure levels in PEW patients at 3 mg/kg were similar to those predicted for 10 mg/kg based on the prior Phase 1 experience. This pharmacokinetic data also showed that an administration schedule consisting of loading doses followed by maintenance doses is appropriate for this patient population in order to rapidly achieve steady-state levels of PINTA 745. As a result, we have amended the protocol to:

- add a new cohort of 20 patients who will receive a loading dose of 3 mg/kg given weekly for three weeks, followed by treatment for an additional nine weeks with a dose of 1 mg/kg given weekly, a regimen that is anticipated to provide drug exposures in PEW patients similar to those achieved in prostate cancer patients who showed statistically significant improvements in lean muscle mass; and
- add a new cohort of 20 patients who will receive a loading dose of 6 mg/kg given weekly for three weeks, followed by treatment for an additional nine weeks with a dose of 2 mg/kg given weekly, to escalate exposure and explore efficacy and safety at a higher dose level.

Additional Opportunities for PINTA 745

We designed the Phase 2 trial to give us insight into potential additional markets for PINTA 745. Those markets could include: orthopedic indications; inflammation and inflammatory disease; age-related sarcopenia; and cancer cachexia. In each of these conditions, we believe muscle growth and reduction in inflammation resulting from treatment with PINTA 745 could lead to better outcomes. As additional data from our clinical and preclinical studies with PINTA 745 emerge, we may initiate clinical studies in other indications.

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

STM 434 is in a Phase 1 clinical study in ovarian cancer and other solid tumors, which commenced in 2014. 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 22,240 new ovarian cancer cases and 14,030 ovarian cancer deaths in the United States in 2013. 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 186,000 women suffering from ovarian cancer in the United States in 2010. According to the American Cancer Society, based on patients diagnosed between 2003 and 2009, the blended five-year survival rate is only 44% for ovarian cancer patients overall.

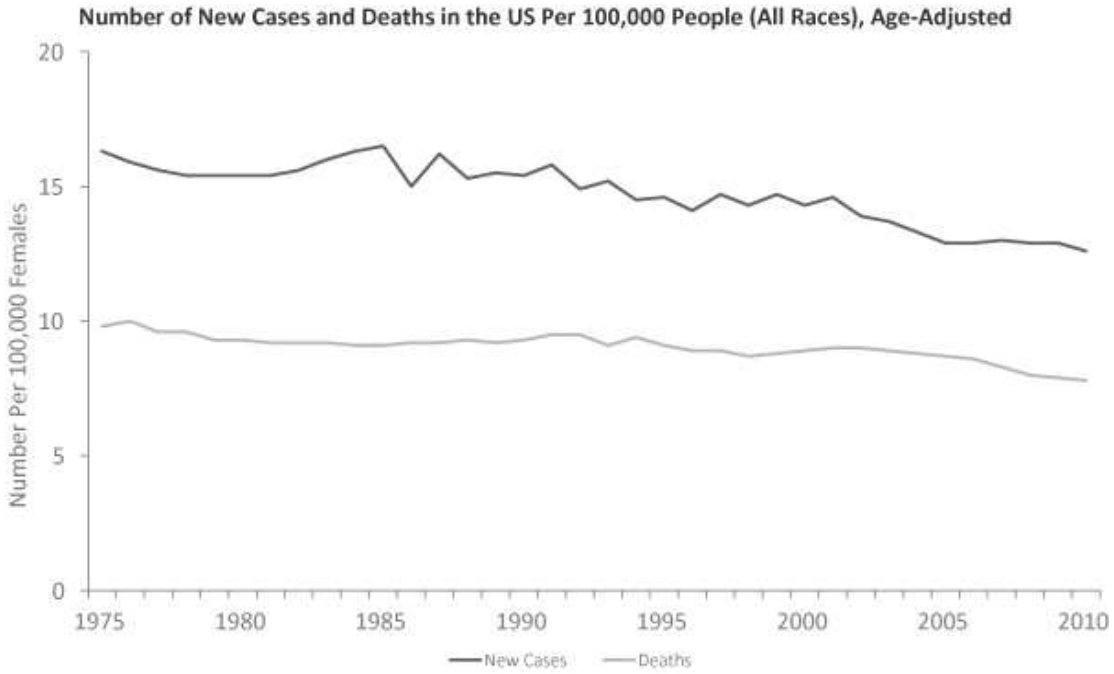
Ovarian cancers are divided into three distinct main subtypes:

- Serous adenocarcinoma, which accounts for approximately 63% of ovarian tumors in the United States.
- Clear cell cancers, which account for approximately 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.

- 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.



Source: National Cancer Institute.

First Line Treatment

Surgical therapy for ovarian cancer that has not escaped the ovary can be curative. In other cases, palliative debulking surgery is often considered. 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 may 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 Cance* r.
- 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

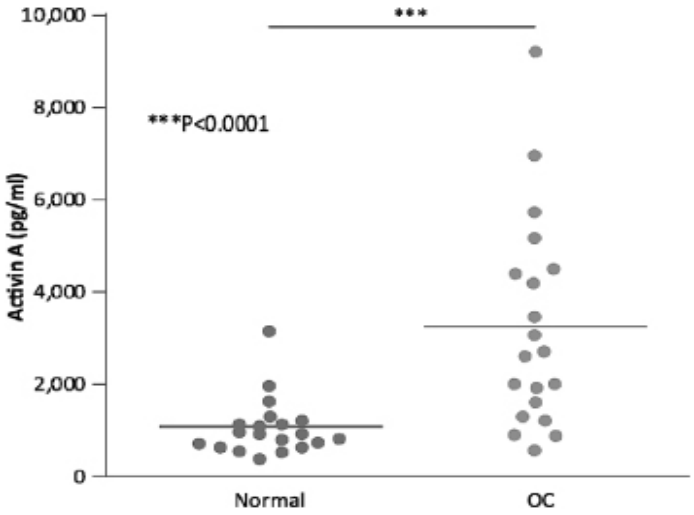
For patients whose tumors did not respond to first line therapy, or for those whose tumors became unresponsive to platinum chemotherapy, a number of other chemotherapy options may be applied, including liposomal doxorubicin, topotecan and gemcitabine. Despite these therapies, the median survival of platinum 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-ß 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, among others, ovarian, gastric and breast cancers. Over-expression 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 also 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 phase 1 study.



Genetic Linkages to Ovarian Cancer Subtypes

In a genetic link between the activin pathway and ovarian cancer, mutations in the BRCA gene have been found in 5 to 10% of serous ovarian tumors. 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 55 of 119 (46%) and 17 of 31 (55%) 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% (86 of 89) 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 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.

STM 434 has a half-life of one to two weeks in monkeys. We are dosing STM 434 every four weeks in our ongoing Phase 1 study. This dosing schedule would align well with the current predominant protocols for administering chemotherapy in both the first-line and the second-line setting in ovarian cancer, which range from weekly to monthly.

Preclinical Studies

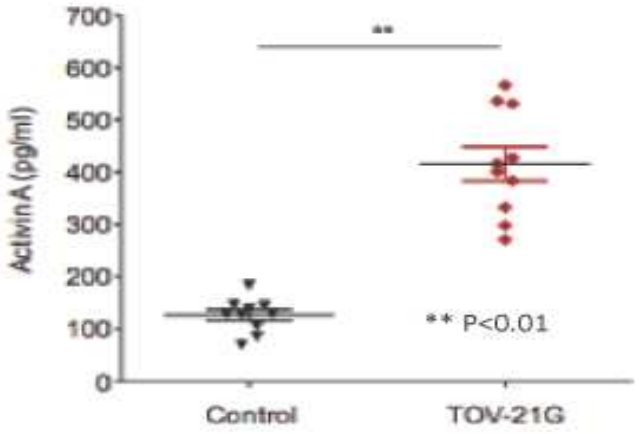
Preclinical testing of STM 434 was designed to confirm and quantify its effects in binding Activin A and other ligands with a receptor-like ligand trap. These studies were conducted with STM 217, a close analog of STM 434, which we refer to as STM 434/s. In addition, these studies were carried out in 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)

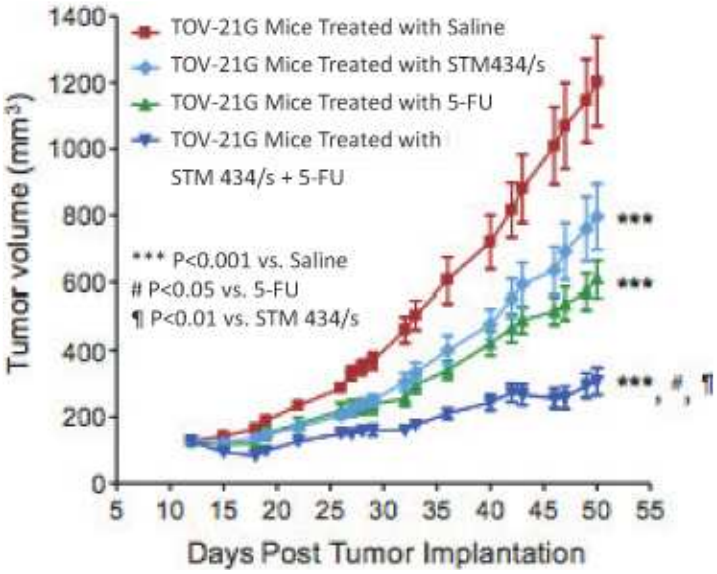
In a preclinical study using TOV-21G mice, tumors derived from human clear cell ovarian carcinoma were shown to have high levels of serum Activin A, analogous to those observed in human ovarian cancer patients as described above.

Serum Activin A

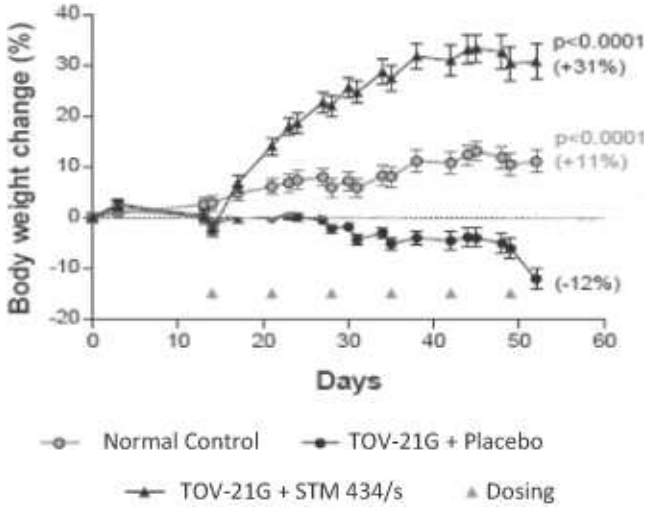


In a subsequent preclinical study that we presented together with Amgen at the American Society of Clinical Oncology meeting in Chicago in 2013, we evaluated STM 434/s in this TOV-21G model used as both a single agent and in combination with the chemotherapy agent 5-fluorouracil ("5-FU"). STM 434/s was 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 reduction in tumor volume for the agent. Results of the combination experiments showed an additive reduction in tumor growth.

Additive Effect with 5-FU



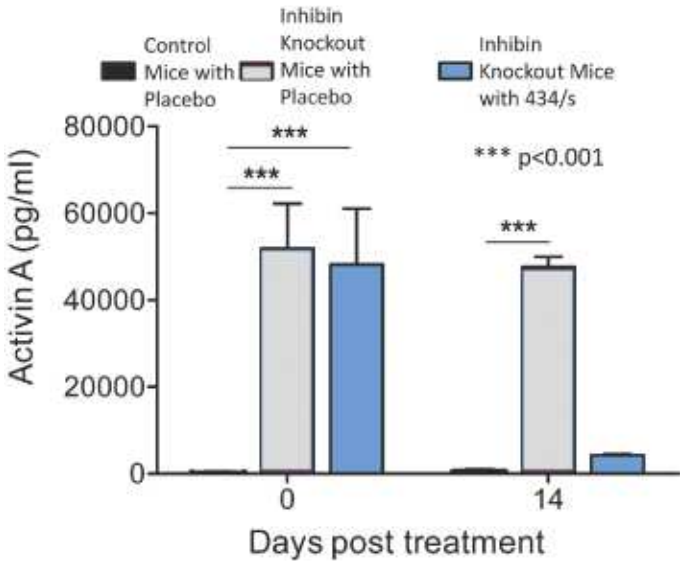
In addition, this study examined the anticachectic effects of STM 434/s in this model. Cachexia is a condition associated with significant weight loss often seen in patients with solid tumor cancers. The results of this study showed that the administration of STM 434/s increased body weight of the mice. 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 study.



Results from these experiments showed a statistically significant (31%, p<0.0001) reduction in tumor volume for the agent. Results of the combination experiments showed an additive (73%, p<0.0001) reduction in tumor growth.

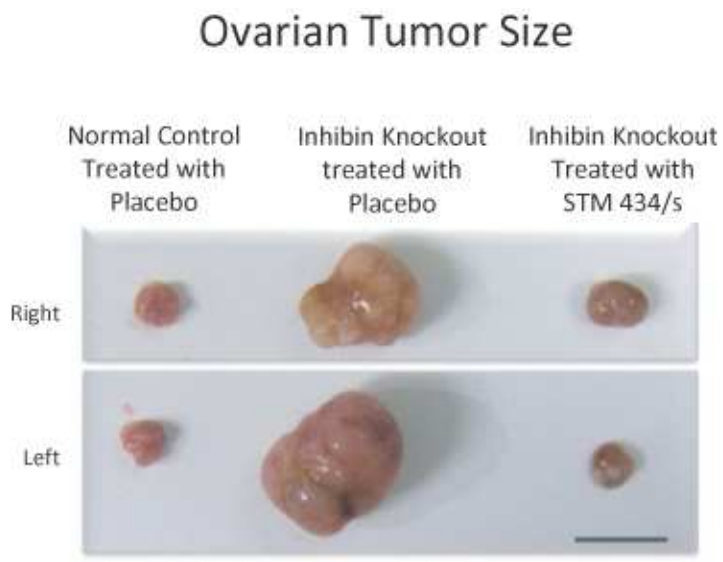
Inhibin Knockout Mouse Model (Granulosa Cell Tumors)

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.

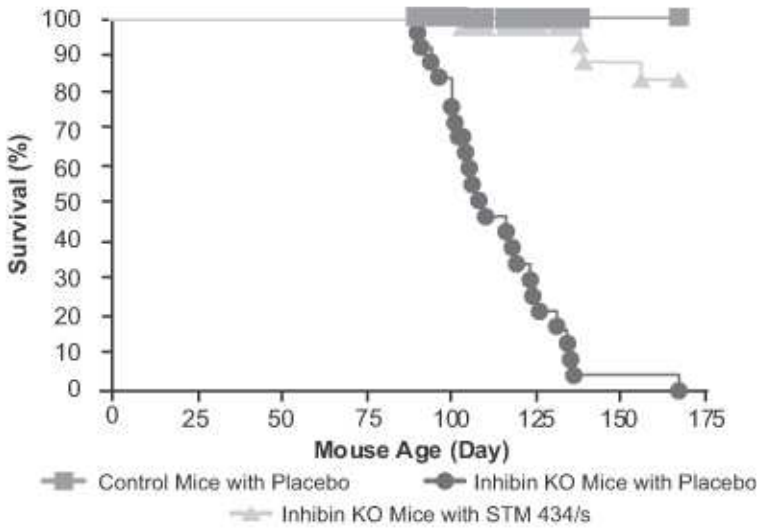


STM 434/s treatment reduced the elevated circulating Activin A in the inhibin knockout mice to the levels in control mice. Serum Activin A was measured before and 14 days after treatment.

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.



Lastly, the knockout model treated with STM 434/s showed a statistically significant ($p<0.0001$) improvement in survival with 90% (20 of 22 mice) alive at 133 days of age, as compared to knockout mice treated with saline, where 96% (23 of 24) had died by this time.



On July 22, 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 orchiectomized (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 ("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 have altered our STM 434 Phase 1 study 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 Study in Ovarian Cancer and Other Solid Tumors

We commenced an open-label Phase 1 study of STM 434 in 2014 that will enroll up to 66 patients, assuming all cohorts are expanded to the maximum number of patients allowed. The dosing schedule for this study is once every four weeks. This study is being conducted in three parts:

- ***Part 1*** — Dose escalation study in patients with advanced solid tumors. Dosing initiated at 0.25 mg/kg. We plan to test up to the maximum tolerated dose ("MTD"). Assuming no MTD is reached, we will test ascending doses of 0.5, 1.0, 2.0 and 4.0 mg/kg.
- ***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 study 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.

Based on data supporting the role of activin in the progression of other solid tumors and the inclusion criteria, we expect that two thirds of the patients included in the dose escalation portion of the Phase 1 study will have solid tumors in organs other than the ovary. A portion of the 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 study 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 colon cancer panel. Our Phase 1 study will test 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 optimize the trial design and maximize the proportion of patients who respond to STM 434.

In addition, we will be measuring follicle-stimulating hormone ("FSH") levels, 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 study. These mutations have been associated with tumor proliferation.

Pipeline

Our pipeline currently consists of five product candidates that were licensed from Amgen in addition to PINTA 745 and STM 434. The members of this initial 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-ß 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. Where appropriate, we intend to conduct preclinical studies and file IND applications with regulatory authorities for these candidates. For example, we are conducting IND-enabling manufacturing and pre-clinical studies for ATA 842. In addition, we have an option to license three clinical stage T-cell programs from MSK as described below.

Research stage programs licensed from Amgen

Our product pipeline licensed from Amgen includes the following:

- *ATA 842* , a humanized antibody targeting myostatin designed to be more selective than similar programs in the clinic targeting oncologic, orthopedic and renal indications;
- *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.

MSK T-Cell Programs

In September 2014, we entered into an exclusive option agreement with MSK, under which we have the right to license (pursuant to a negotiated form of license agreement) the exclusive, worldwide rights to three clinical stage T-cell programs, as well as other T-cell programs that are discovered or developed by MSK pursuant to sponsored research funded by us. Prior to the exercise of the license, we are collaborating with MSK on the development of these three T-cell programs. 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 employed to combat these diseases. The three T-cell programs share a common technology under which T-cells are collected from the blood of third-party donors. The T-cells are then exposed to certain antigens. The resulting activated T-cells are expanded, characterized and stored for future therapeutic use in an appropriate partially human leukocyte antigen ("HLA"), matched patient, providing an "off-the-shelf", allogeneic, cellular therapeutic option for patients. During the manufacturing of the activated T-cells, alloreactive cells, which could potentially cause graft versus host disease ("GvHD"), are eliminated, reducing the risk of GvHD, a serious complication in HCT recipients.

MSK has broad clinical experience with the targeted T-cell programs, including in immunocompromised states, as well as in solid and hematologic malignancies. Our current optioned clinical programs include T-cells directed to three different viral or cancer specific antigens: EBV, CMV and WT1. Two of the T-cell programs are currently in Phase 2 clinical trials and one program is currently in Phase 1 clinical studies, in each case conducted by MSK. The Phase 2 clinical trials are evaluating T-cells activated against EBV and CMV, respectively. EBV is the virus that causes mononucleosis, and in immunocompromised patients it can cause lymphoma and other cancers; CMV is a different virus that can result in blindness, illness or death depending on the tissue it affects in those with weakened immune systems. The Phase 1 clinical studies are evaluating T-cells activated against WT1. Abnormal expression of WT1 is seen in a variety of hematologic and solid tumors including multiple myeloma, acute myeloid leukemia, and ovarian cancer. The current status of these three T-cell programs is highlighted in the table below.

T-Cell Program	Stage of Development	Indication	Highlights of Recent Clinical Data
EBV Targeted T-Cells	Phase 2 clinical trials	EBV lymphoma ("EBV-LPD") following allogeneic hematopoietic cell transplantation ("HCT") from bone marrow or cord blood	68% complete response rate in post-HCT patients (13 of 19 patients) 70% complete response rate in patients who failed rituximab therapy (7 of 10 patients) (1)
CMV Targeted T-Cells	Phase 2 clinical trials	Post-HCT anti-viral drug resistant CMV viremia (high viral count) and symptomatic CMV disease	64% response rate in 25 CMV viremia patients, with 9 complete responses and 7 partial responses; 67% response rate in 9 CMV disease patients, with 5 complete responses and 1 partial response (2)
WT1 Targeted T-Cells	Phase 1 clinical studies	Various cancers, including acute myeloid leukemia ("AML"), multiple myeloma, and ovarian cancer	Data not yet available

(1) Source: *Blood* .
(2) Source: MSK

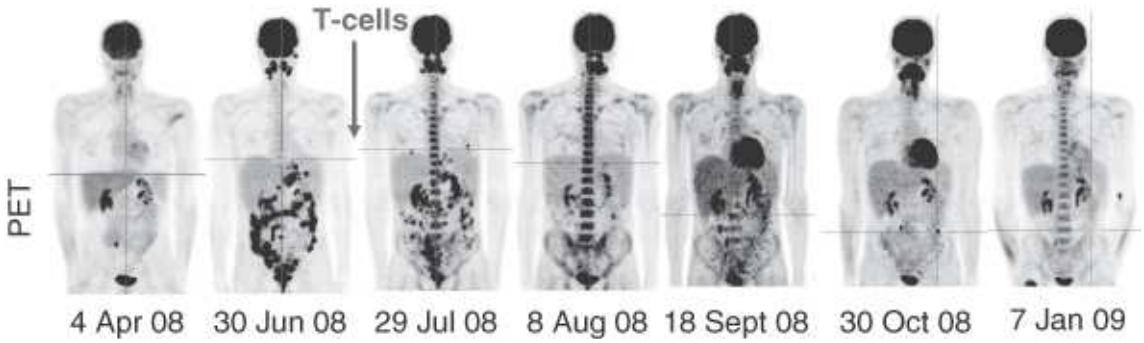
Efficacy and safety data for both the EBV targeted and CMV targeted T-cell programs have been published in the journal *Blood* and are discussed in more detail below.

Our collaboration with MSK will initially focus its development and regulatory activities on the EBV and CMV targeted T-cell programs in the post-HCT setting, which we believe offer the most rapid path to marketing approvals. During the option period, MSK will submit information to the FDA to solicit agreement on the plan for late phase development to support marketing approvals for these programs, with an initial focus on the EBV targeted T-cell program.

EBV Targeted T-cells

In immunocompromised humans, EBV causes lymphomas and other lymphoproliferative disease collectively called EBV-LPD. EBV-LPD is a rare but serious complication in recipients of HCT. EBV-LPD occurs in an estimated 1,200 immunocompromised patients per year in the United States and European Union after HCT. EBV-LPD 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%. The monoclonal antibody rituximab is used off-label to treat this disease, producing initial responses in approximately 55% 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-LPD 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-LPD in adult HCT patients was 33 days, and 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-LPD patients who received rituximab was 56 days.

MSK has conducted two separate clinical trials of the EBV targeted T-cell program ("EBV-CTL") that included patients with EBV-LPD following HCT. In one study, published in 2012 in the journal *Blood* , 19 patients with EBV-LPD following HCT were treated with the EBV-CTL manufactured from T-cells derived from either the primary transplant donor or an unrelated third-party donor. The complete response rate was 68%, meaning that in 13 of 19 patients, no visible evidence of tumor following treatment was observed. Ten of the 19 patients had previously failed rituximab and had suffered a subsequent progression of EBV-LPD. Of these ten patients, seven, or 70%, achieved a complete response with survival after T-cell therapy in these seven patients ranging from 127 days to 10 years. The time course of a complete response following administration of the EBV targeted T-cells in a patient with EBV-associated lymphoma is shown below using sequential positron emission tomography ("PET") scans.



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 the T-cell therapy. Overall, EBV-CTL therapy was well tolerated, with no product-related GvHD noted in this trial.

In part due to these results, treatment with EBV-CTLs is recognized as a recommended treatment for persistent or progressive EBV-LPD as set forth in the 2014 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.

CMV Targeted T-cells

Despite the use of prophylactic and preemptive therapy using small molecule antivirals, many post-HCT patients progress to developing 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. Based on investigator experience, we estimate that anti-viral resistant CMV infection occurs in approximately 1,100 immunocompromised patients per year in the United States and European Union after HCT.

MSK has conducted one Phase 1 clinical study and two Phase 2 clinical trials of its CMV targeted T-cell ("CMV-CTL") program 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 American Society of Hematology ("ASH") Annual Meeting. This analysis evaluated outcomes in 38 patients who were treated with CMV-CTLs after failing a median of 113 days of prior antiviral therapy with 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 date 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. The results from MSK's updated summary are reported in the table below:

CMV Treatment Setting	Number of Patients Treated	Number of Patients Evaluable [3]	Overall Response Rate (%)
Antiviral resistant CMV Viremia [1]	26	25	64% 9 complete responses 7 partial responses
Antiviral resistant CMV Disease [2]	12	9	67% 5 complete responses 1 partial response

(1) 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.

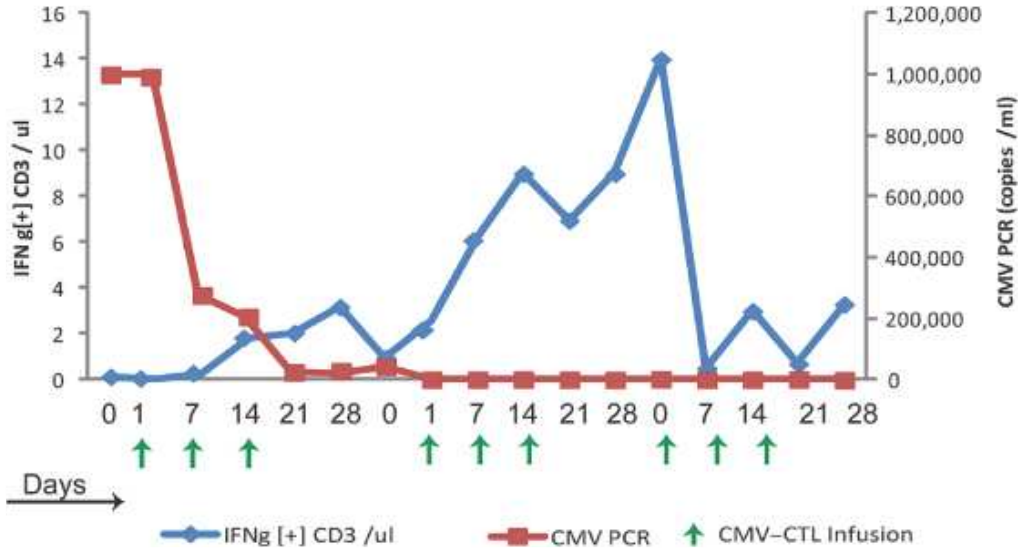
(2) Responses in patients treated for overt disease were considered to be complete responses if all detectable CMV viremia and disease resolved and partial responses if patients became asymptomatic.

(3) Four patients were not evaluable due to receipt of confounding concomitant antiviral medications (n=2), concomitant high dose steroids (n=1) and withdrawal of consent (n=1).

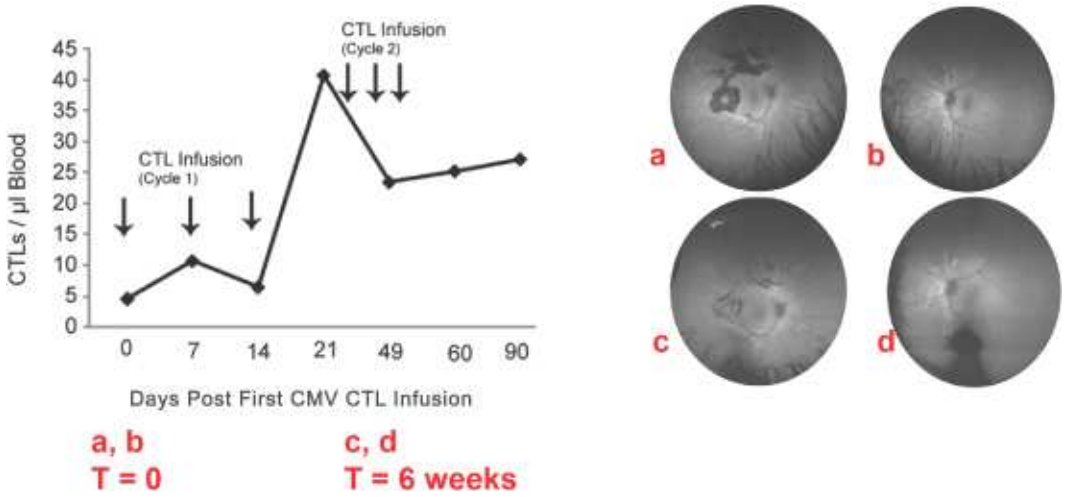
We believe this data suggests a high response rate among patients with otherwise refractory CMV viremia and disease. Overall, CMV-CTL therapy was well tolerated and no patients developed *de novo* GvHD, or a flare-up of prior GvHD, in association with infusion of CMV-CTLs.

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 polymerase chain reaction ("CMV PCR"), a sensitive and specific technique to detect viral DNA. The reciprocal proliferation of CMV-CTL following administration is reflected by the release of interferon-gamma (IFNg[+]) 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.



Additional Activities

We anticipate that MSK’s “off-the-shelf” T-cell technology will have utility beyond the post-HCT setting in a variety of more prevalent disease states. Based on the data generated to date, MSK is expanding the EBV and CMV related clinical programs to evaluate safety and efficacy of these targeted T-cells in solid tumors. We intend to support MSK prior to any exercise of our option to license the T-cell programs in order to speed the time to potential market approvals for EBV and CMV targeted T-cells in these additional disease states should we exercise the option.

Concurrent with entering into the option and license agreement, 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/or CAR-T cell programs, which we also have an option to license.

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.

If approved, PINTA 745 or 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:

Muscle Wasting-Related Indications

There currently are no FDA or European Medicines Agency ("EMA") approved products for the treatment of PEW in dialysis patients and we are not aware of any product candidates in clinical development for this indication. However, products are currently marketed or used off-label for the muscle wasting-related indication for which we are developing PINTA 745, and a number of companies are or may be developing new treatments for muscle wasting indications. The current treatment for PEW and cancer cachexia often involves the administration of readily available nutritional supplements and appetite stimulants including, in some jurisdictions, marijuana. In addition, there are two commercially available steroids, nandrolone and oxandrolone, that are sometimes prescribed off-label for the treatment of weight loss in cancer patients.

Additionally, a number of companies are developing drug candidates for muscle wasting applications, including: Eli Lilly & Co., which is conducting Phase 1 clinical studies and Phase 2 clinical trials for LY2495655, and Pfizer Inc., which is conducting Phase 1 clinical studies for PF-06252616, both of which are myostatin antibodies, to evaluate their ability to increase and improve muscle mass in various patient populations; Novartis Corporation, which is conducting Phase 1 clinical studies and Phase 2 clinical trials for BYM338, an ActR2B antibody, to evaluate its ability to build muscle in patients with various muscle-wasting conditions; Ligand Pharmaceuticals, which is developing LGD-4033, a selective androgen receptor modulator, for muscle wasting; Regeneron Pharmaceuticals, Inc., which is developing REGN1033, a myostatin antibody, in collaboration with Sanofi-Aventis for sarcopenia; Acceleron Pharma, which is developing ACE-083, a modified cysteine knot ligand trap of the TGF-ß superfamily, for diseases in which improved muscle strength may provide a clinical benefit, such as inclusion body myositis and certain forms of muscular dystrophy; and GTx, Inc., which is developing ostarine, a selective androgen receptor modulator for cachexia.

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's niraparib;
- Angiogenesis inhibitors, such as Genentech/Roche's bevacizumab (Avastin);
- VEGFr tyrosine kinase inhibitors such as Boehringer Ingelheim GmbH's nintedanib and AstraZeneca plc's recentin;
- Anti-folates such as Endocyte Inc.'s and Merck & Co. Inc.'s vintafolide and Eisai's farletuzumab; and
- Other therapies in development, including those from GlaxoSmithKline plc, Amgen and Clovis Oncology,

However, there are no targeted therapies approved by the FDA or EMA for the treatment of ovarian cancer that address the underlying biology.

MSK T-Cell Programs

Should we exercise our option to license the MSK T-cell programs and should they 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, the MSK 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-LPD

There currently are no FDA or EMA approved products for the treatment of EBV-LPD. 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 the EBV targeted T-cell therapy from MSK. The current treatment for EBV-LPD involves administration of rituximab or combination chemotherapy regimens. Additionally, a number of companies and academic institutions are developing drug candidates for EBV-LPD, including: Cell Medica Ltd. (“Cell Medica”), which is conducting Phase 2 clinical studies for Cytorex EBV, an autologous EBV specific T-cell therapy, in NK/T-cell lymphoma, and Adcyte LLC (“Adcyte”), which has licensed multi-virus specific T-cells from Baylor University that are currently in clinical trials sponsored by Baylor.

CMV

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 targeted T-cell therapy from MSK. 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, including: Shire plc (“Shire”), which is conducting Phase 2 clinical trials of maribavir, a UL97 protein kinase inhibitor; Merck & Co., Inc. (“Merck”), which is conducting Phase 3 clinical trials of letermovir, a CMV terminase inhibitor; Chimerix, Inc. (“Chimerix”), which is conducting Phase 3 clinical trials for brincidofovir, a lipid conjugated nucleotide analogue of cidofovir; Cell Medica, which is conducting Phase 3 clinical trials for Cytovir CMV, a CMV-specific cell therapy product derived from primary HCT transplant donors; Adcyte, which has licensed multi-virus specific T-cells from Baylor University that are currently in clinical trials sponsored by Baylor.

License Agreements

License for PINTA 745

In September 2012, we entered into a license agreement with Amgen under which Amgen granted us an exclusive license under certain Amgen patent rights and regulatory filings, and a non-exclusive license under certain Amgen know-how, to develop and commercialize throughout the world, excluding Japan, products comprising Amgen’s proprietary compound known as AMG 745, which we now refer to as PINTA 745. We have the right, subject to certain limitations, to grant sublicenses under such licensed intellectual property, in connection with licensing the licensed product. Our exclusive rights are subject to a prior license granted by Amgen to Takeda to the licensed patent rights exclusively in Japan.

Under this agreement, we are responsible for developing and commercializing the licensed product, at our cost, are required to use commercially reasonable efforts with respect to such development and commercialization activities, and must meet specific diligence obligations. We have paid Amgen an upfront license fee of $250,000, issued 205,128 shares of Series A-1 convertible preferred stock, and made $553,000 in payments to date to Amgen for purchases of clinical supplies. Each of the 205,128 shares of Series A-1 convertible preferred stock converted into one share of common stock upon the closing of our initial public offering. We are obligated to make payments to Amgen upon receipt of certain clinical supplies from Amgen, upon the achievement of certain development and commercialization milestones of up to $129.0 million, as well as escalating mid to high 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 throughout the world, except in Japan, where Amgen has the sole right to do so, and Amgen retains certain step-in rights.

This agreement, 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 a 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 the agreement, we retain non-exclusive rights to the licensed Amgen intellectual property. Amgen may terminate the 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 agreement. We may terminate the 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 a licensed product is no longer commercially practicable for us.

Other Amgen License Agreements

In September 2012, we entered into two other 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 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.

MSK Option and License Agreement

In September 2014, we entered into an exclusive option agreement with MSK under which we have the right to license (pursuant to a negotiated form of license agreement) the exclusive, worldwide rights to the three clinical stage T-cell programs of MSK. The initial option period is for twelve months, with extensions available to extend the term up to 27 months at our option. Under the terms of the option agreement, we are obligated to use reasonable efforts to prepare a request to be submitted to the FDA regarding a meeting to discuss pivotal trials for one of the clinical stage T-cell programs. 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 are also obligated to pay MSK an additional amount up to $630,000 if we extend the option period. 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/or CAR-T, and which we also would hold an option to license, if developed.

If we exercise the option and enter into the license agreement with MSK, we will be obligated under the license agreement to pay to MSK an upfront cash payment of $4.5 million and additional payments of up to $33.0 million based on a license fee and achievement of specified development, regulatory and sales-related milestones, and to make royalty payments based on sales of the T-cell therapy products.

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, includes approximately 105 issued patents and 202 pending patent applications, with certain of these pending and issued claims relating to PINTA 745 and STM 434. 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. 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 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 in the United States, Europe or 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 two lead product candidates are summarized below:

PINTA 745 Patent Portfolio

We hold exclusive rights to five issued US patents directed to PINTA 745 relating to composition-of-matter and related methods of use claims, one issued European patent (registered in most countries of the European Patent Convention) and additional issued patents or pending patent applications in many jurisdictions worldwide, including the US, the European Patent Office, Argentina, Australia, Brazil, Canada, China, Egypt, Israel, Japan, the Republic of Korea, Malta, Mexico, Norway, New Zealand, Poland, Serbia, Singapore, Thailand, Taiwan, South Africa, Kosovo, Hong Kong, the Philippines, and Eurasia (validated in Russia). The expected expiration dates for these patents and patent applications range from 2023 to 2035, exclusive of possible patent term extensions or adjustments.

STM 434 Patent Portfolio

We hold exclusive rights to three 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 US, 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, Tunisia, Taiwan, Ukraine, Vietnam, and South Africa. 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 through a relationship with a third party. 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.

Government Regulation

Overview of US Government Regulation

The preclinical studies and clinical testing, manufacture, labeling, storage, record keeping, 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 PINTA 745 and STM 434 to be regulated by the FDA as biologics and to be reviewed by the Center for Drug Evaluation and Research (“CDER”) as proteins intended for therapeutic use. Protein therapeutics require the submission of a biologics license application (“BLA”) and approval by the FDA prior to being marketed in the US. Manufacturers of protein therapeutics may also be subject to state regulation. 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 (“GLPs”) and other applicable regulations;
- submission to the FDA of an IND 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 (“GCPs”) 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 pre-approval inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with applicable current good manufacturing practices ("cGMPs"); and
- FDA review of the BLA and issuance of a biologics license, which is the approval necessary to market a protein therapeutic.

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 GCPs. 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 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 ("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.

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 cGMPs. 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 ("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.

Under the Biologics Price Competition and Innovation Act of 2009 (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 requirements, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP 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.

Activin A has been strongly implicated in two subcategories of ovarian tumors: clear cell tumors and granulosa cell tumors. In these subcategories, we believe that we may be able to obtain orphan drug designation for STM 434 in the United States and, if supported by our clinical data, Breakthrough Therapy designation, and pursue clinical trials of STM 434 as a monotherapy.

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 sponsors complete 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 June 2013, the FDA published a draft Guidance for Industry titled, “Expedited Programs for Serious Conditions—Drugs and Biologics” which provides guidance on FDA programs that are intended to facilitate and expedite development and review of new drugs as well as threshold criteria generally applicable to concluding that a drug is a candidate for these expedited development and review programs. In addition to the Fast Track, accelerated approval and priority review programs discussed above, the FDA also provided guidance on Breakthrough Therapy designation. A request for Breakthrough Therapy designation should be submitted concurrently with, or as an amendment to an IND. FDA has already granted this designation to over 30 new drugs and has recently approved the first Breakthrough Therapy designated drugs.

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 (“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 ("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 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 American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of any of our product candidates, if approved. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products 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.

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 (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 much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application ("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 GCPs 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 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 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. 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 ("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.

Our lead product candidates, PINTA 745 and STM 434, are manufactured using readily available raw materials and established manufacturing procedures. PINTA 745 is a peptibody that is expressed by a recombinant strain of E. Coli. STM 434 is produced in bioreactors using Chinese hamster ovary cells that have been genetically engineered to produce this specific product candidate. All of our other product candidates will also be produced in bioreactors using mammalian cells; however, we have yet to establish master cell banks and manufacturing procedures to support the production of these proteins.

Concurrent with the license of our existing product candidates from Amgen, we acquired certain manufacturing process know-how related to producing clinical research-related drug supply. In the case of PINTA 745 and STM 434, this included GMP materials to support the manufacturing of clinical trial material. In the case of our earlier stage product candidates, this know-how was more limited in scope, as these product candidates are pre- master cell bank in stage of development.

Subsequent investments by the company and our CMOs will be necessary in order to manufacture product for pivotal studies, as well as commercialization. Over time, we will depend on manufacturing campaigns that will require the transfer of manufacturing processes to our CMOs. These may include modifications to the processes to suit the CMO's facility and capability constraints, as well as product comparability testing. We have already transferred the downstream elements of the STM 434 manufacturing process, and we have initiated transfer of the upstream components of the STM 434 manufacturing process. We recently encountered a small number of cracked vials in frozen STM 434 drug product. We believe the problem was adequately addressed by changing the temperature at which the product was frozen. We are also developing a refrigerated liquid formulation of the drug product. We have also initiated process transfer activities for PINTA 745. As we progress further in clinical development to pivotal trials, we will also need to develop commercial scale manufacturing processes for each product candidate consistent with the proposed dose and schedule to be used in clinical practice and at a cost sufficient to support profitable commercialization.

Employees

As of December 31, 2014, we had 18 full-time 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. 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.

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.

I tem 1A. Risk Factors

You should carefully consider all of the risk factors and uncertainties described below, in addition to 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 years ended December 31, 2014 and 2013, we reported a net loss of $28.0 million and $8.8 million, respectively, and we had an accumulated deficit of $40.9 million at December 31, 2014.

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 fail in clinical trials or do not gain regulatory approval, or if approved, fail 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. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market.

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

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

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

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the development and regulatory process for any product candidates, we anticipate incurring significant costs to commercialize these products.

Even if we are able to generate revenues from the sale of our products, 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 continuing the clinical development and manufacturing of PINTA 745, the clinical development and manufacturing of STM 434 and the advancement and expansion of our preclinical research pipeline, including ATA 842 and any T-cell programs we may choose to license from MSK. These expenditures will include costs associated with research and development, potentially acquiring new product candidates, evaluating and potentially exercising our option to license certain T-cell programs from MSK, 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, we are obligated to make additional milestone payments to Amgen of up to $86.0 million upon the achievement of certain development and regulatory approval milestones. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our other product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our other 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, including the exercise of our option to license certain T-cell programs from MSK;
- 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.

Based on our current operating plan, our existing cash and cash equivalents and short-term investments, will be sufficient to fund our projected operating requirements into the second half of 2017. As of December 31, 2014, we had cash and cash equivalents and short-term investments of $104.1 million. In addition, we raised approximately $69.4 million in February 2015 through the sale of our common stock, after deducting underwriting discounts and commissions and offering expenses. 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.

We have incurred substantial losses during our history and do not expect to become profitable in the near future and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. At December 31, 2014, we had federal and state net operating loss carryforwards of approximately $20.6 million, 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 (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 federal net operating loss ("NOL") carryforwards and other pre-change tax attributes (such as research tax credits) to offset future taxable income or taxes may be limited. 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 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 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 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 two 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 will be materially harmed.

We are very early in our development efforts and have only two product candidates, PINTA 745 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;
- manufacturing products at an acceptable cost;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of the product candidates, if and when 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.

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 would materially harm our business.

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

We do not have any products that have gained regulatory approval. Currently, our only licensed clinical-stage product candidates are PINTA 745, which is in a Phase 2 clinical trial, and STM 434, for which we commenced a Phase 1 study in 2014. 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 and clinical studies, generally including two well-controlled Phase 3 trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate.

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

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

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

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

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

The results of preclinical testing or earlier clinical studies are not necessarily predictive of future results, and PINTA 745 and STM 434, and any other product candidate we advance into clinical studies or trials, may not have favorable results in later clinical studies or 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. 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 PINTA 745 or STM 434 or any of our other product candidates in any particular jurisdiction. 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, 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 studies and early clinical trials.

We may experience delays in our ongoing or future clinical studies or trials and we do not know whether planned clinical studies or 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 studies or trials of any of our product candidates on clinical hold in the future. Clinical studies or 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 clinical study;
- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations (“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 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 clinical 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 and clinical studies, that might require modification to the protocol for the 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 drug;
- difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate for use in clinical studies or trials;
- lack of adequate funding to continue the clinical study or trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical 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 the clinical study or trial.

Patient enrollment, a significant factor in the timing of clinical studies or 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 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 clinical studies for STM 434 and clinical trials for PINTA 745 or any future product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these studies or 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 studies or trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our studies may be delayed or our studies could become too expensive to complete. We rely on CROs, other vendors and clinical study or 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 commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any delays in completing our clinical trials for our current product candidates may also decrease the period of exclusivity in our corresponding product candidate license from Amgen. 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 studies or trials in the future, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our studies or trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our studies or 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-market 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. If our Phase 1 clinical study of STM 434 is successful, we intend to apply for orphan drug status for STM 434 for ovarian cancer.

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

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

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

In addition to regulations in the United States, to market and sell our products in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We have had no significant interactions with foreign regulatory authorities to date. 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. 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-market information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by our CMOs and CROs for any post-approval clinical trials that we conduct. For example, if labeling is ultimately approved for PINTA 745, it will likely include restrictions on use due to the specific patient population and manner of use in which the product candidate was evaluated and the safety and efficacy data obtained in those evaluations. In addition, PINTA 745 may be required to include a boxed warning, or “black box,” regarding PINTA 745 being teratogenic, or causing of fetal or embryotic malformations, in animal studies. 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 cGMPs, GCPs 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;
- 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 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 (the "DOJ"), the Office of Inspector General of the Department of Health and Human Services ("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. For example, in the event PINTA 745 obtains regulatory approval, we believe these authorities will closely monitor the use of this product candidate to determine whether it is being used impermissibly as a muscle-builder by athletes and others. 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.

In the United States, engaging in impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that would materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could compromise our ability to become profitable or adversely affect our ability to operate our business.

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. We are in the process of outsourcing the manufacture of additional drug substance and drug product for our preclinical and clinical studies using the know-how and supplies we received from Amgen. Our CMOs will need to conduct significant development work to prepare each of our product candidates for studies, trials and commercial readiness.

Additionally, the process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including but not limited to:

- the process of manufacturing our product candidates 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 processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. Product defects can also occur unexpectedly. For example, in April 2014, we encountered a small number of cracked vials in certain STM 434 drug product lots. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;
- the manufacturing facilities in which our product candidates are made could be adversely affected by earthquakes and other natural disasters, equipment failures, labor shortages, power failures, and numerous other factors; and
- because the MSK T-cell programs we have an option to license are derived from the blood of third-party donors, the process of developing commercializable products may be particularly challenging, even if they otherwise prove to be safe and effective.

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. 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 could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community, including major operators of dialysis 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. Should we exercise our option to license the MSK T-cell programs, we may face challenges in developing these T-cell therapies into commercializable products.

We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

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 non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. 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 of 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 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. We have also relied on studies previously conducted by Amgen. We rely on these parties for the execution of our preclinical and clinical trials, and we control only some aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with GLPs and the Animal Welfare Act requirements. We and our CROs are required to comply with federal regulations and GCPs, 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. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, 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 requirements. In addition, our clinical trials must be conducted with product produced under cGMP 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, within a specified timeframe. Failure to comply with these regulations may require us to repeat preclinical 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. For example, there was an error in the randomization of patients and inventory distribution to our clinical sites for our Phase 2 clinical trial for PINTA 745, resulting in the unblinding of the initial six patients and a restart of the trial. 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, on July 22, 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. Although we believe we now have all data previously generated by Amgen for our licensed product candidates, other data from studies previously conducted by Amgen 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 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 plans to build our own clinical or commercial scale manufacturing capabilities. We currently rely on single source CMOs for the production of our product candidates and on single source suppliers of some of the materials incorporated in our product candidates. To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work will need to increase the scale of production and, for PINTA 745 and STM 434, we will need to demonstrate comparability of the material produced by these CMOs to the material that was previously produced by Amgen. We may need to identify additional CMOs for continued production of supply for our product candidates. 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. 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 physical quality specifications and comparability assessments for these materials, further clinical development of our product candidate would 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 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 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 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 or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secrets and confidentiality agreements to protect the intellectual property related to our technology and product candidates. For our two most advanced product candidates, PINTA 745 and 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 PINTA 745, the expected expiration dates range from 2026 to 2035 for US patents and patent applications, if issued, and from 2023 to 2035 for patents and patent applications, if issued, in jurisdictions outside the United States, exclusive of possible patent term extensions. 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. 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 ("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 for many reasons. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim.

Even if patents have issued or do successfully issue from patent applications, and even if such patents cover our product candidates, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. 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 threaten 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, an interference proceeding in the United States can be initiated by the USPTO or a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. 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 similar opposition proceedings in the European Patent Office or counterpart offices in other jurisdictions regarding our intellectual property rights. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent generally occurs 20 years after it is filed. Although various extensions may be available if certain conditions are met, the life of a patent and the protection it affords is limited. If we encounter delays in our clinical trials or in obtaining regulatory approvals, the period of time during which we could exclusively market any of our product candidates under patent protection, if approved, could be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be vulnerable to competition from biosimilar products. Any loss of patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar or identical to our product candidates, which could harm our business and ability to achieve profitability.

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, 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, *inter partes* reexamination and review proceedings before the USPTO and corresponding 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 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 reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us. Ultimately, we could be prevented from commercializing a product candidate, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

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

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

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

Filing, prosecuting, enforcing and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive. Our or our licensors' intellectual property rights in certain countries outside the United States may be less extensive than those in the United States. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in countries outside the United States, or from selling or importing infringing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection 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 and 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. If we breach any of our license agreements with Amgen, 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 that are important to our business. Our discovery and development platform is built, in part, around patents exclusively in-licensed from Amgen. These agreements generally grant us the exclusive (except as to the licenses to Amgen know-how, which are non-exclusive and limited as to their field of use), worldwide (except with regard to PINTA 745 in Japan, which was previously licensed to Takeda Pharmaceutical Company Limited) license to research, develop, improve, make, use, offer for sale, sell, import, export or otherwise exploit several classes of novel compounds, including PINTA 745 and STM 434. Under our existing 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 non-performance between us and Amgen 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 may have a right to terminate the affected license. The loss of any or all of our license agreements with Amgen could materially adversely affect our ability to proceed to utilize the affected intellectual property in our drug discovery and development efforts, and our ability to enter into future collaboration, licensing and/or marketing agreements for one or more 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 other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination 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 rights of others. An unfavorable outcome in any such proceeding could require us or our licensors to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our or our licensors' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of shares of our common stock.

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

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future decisions by the US Congress, the federal courts and 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 (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 programs we have an option to license 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, thus eroding our competitive position in the market. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

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

Risks Related to Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of dialysis and cancer clinics.

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 major operators of dialysis and cancer clinics. 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 for which the product candidate is approved;
- acceptance by physicians, major operators of cancer and dialysis clinics and patients of the drug as a safe and effective treatment;
- 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 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 major operators of dialysis and cancer clinics, we will not be able to generate significant revenues, which would compromise our ability to become profitable. In particular, the dialysis industry is dominated by two companies, DaVita Healthcare Partners and Fresenius. In the event PINTA 745 fails to be accepted by either of these companies, our ability to generate revenues from PINTA 745 and become profitable would be adversely affected.

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

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

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

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

The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain regulatory approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Modernization Act") changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In particular, all Medicare payments for dialysis treatments to ESRD patients are now made under a single bundled payment rate that provides a fixed payment rate to encompass all goods and services provided during the dialysis treatment, including pharmaceuticals that were historically separately reimbursed to the dialysis providers, irrespective of the level of pharmaceuticals administered or additional services performed. Most lab services that used to be paid directly to laboratories are also included in the bundled payment. Unless we are able to secure an exemption, PINTA 745 may be subject to the bundled payment system. In recent years, Congress has considered further reductions in Medicare reimbursement for drugs administered by physicians. The Center for Medicare and Medicaid Services ("CMS"), the agency that runs the Medicare program, also has the authority to revise reimbursement rates, including under the bundled payment system, and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. While the Medicare Modernization Act and Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. The Affordable Care Act expanded manufacturers' rebate liability to include covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, increased the minimum rebate due for innovator drugs from 15.1% of average manufacturer price ("AMP") to 23.1% of AMP, and capped the total rebate amount for innovator drugs at 100% of AMP. The Affordable Care Act and subsequent legislation also changed the definition of AMP. Furthermore, the Affordable Care Act imposes a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the effect of the Affordable Care Act, it appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. More recently, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare reductions went into effect. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. 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. In addition, should we exercise our option to license certain T-cell programs from MSK and should they be approved for use, we will face additional competition. 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.

Products are currently marketed or used off-label for the muscle wasting-related indications for which the products in our pipeline are being developed, and a number of companies are or may be developing new treatments for muscle wasting indications. These products, as well as promotional efforts by competitors and clinical trial results of competitive products, could significantly diminish any ability to market and sell PINTA 745 and other product candidates focused on muscle wasting-related indications. Today’s treatment for protein-energy wasting and cancer cachexia often involves the administration of readily available nutritional supplements and appetite stimulants including, in some jurisdictions, medical marijuana. In addition, there are two commercially available steroids, nandrolone and oxandrolone, that are sometimes prescribed off-label for the treatment of weight loss in cancer patients. A number of companies are developing drug candidates for muscle wasting applications, including: Eli Lilly & Co., which is conducting Phase 1 clinical studies and Phase 2 clinical trials for LY2495655, and Pfizer Inc., which is conducting Phase 1 clinical studies for PF-06252616, both of which are myostatin antibodies, to evaluate their ability to increase and improve muscle mass in various patient populations; Novartis Corporation, which is conducting Phase 1 clinical studies and Phase 2 clinical trials for BYM338, an ActR2B antibody, to evaluate its ability to build muscle in patients with various muscle-wasting conditions; Ligand Pharmaceuticals, which is developing LGD-4033, a selective androgen receptor modulator, for muscle wasting; Regeneron Pharmaceuticals, Inc., which is developing REGN1033, a myostatin antibody, in collaboration with Sanofi-Aventis for sarcopenia; Acceleron Pharma, Inc., which is developing ACE-083, a modified cysteine knot ligand trap of the TGF-ß superfamily, for diseases in which improved muscle strength may provide a clinical benefit, such as inclusion body myositis and certain forms of muscular dystrophy; and GTx, Inc., which is developing ostarine, a selective androgen receptor modulator for cachexia.

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 Genentech/Roche, which is developing bevacizumab (Avastin) and other potential drug therapies.

There currently are no FDA or EMA approved products for the treatment of EBV-LPD. However, some approved products and therapies are used off-label in the treatment of EBV-LPD, such as rituximab and combination chemotherapy regimens. In addition, a number of companies and academic institutions are developing drug candidates for EBV-LPD, including: Cell Medica, which is conducting Phase 2 clinical studies for Cytorex EBV, an autologous EBV specific T-cell therapy in NK/T-cell lymphoma; and Adcyte, which has licensed multi-virus specific T-cells from Baylor University that are currently in clinical trials sponsored by Baylor. 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, including: Shire, which is conducting Phase 2 clinical trials of maribavir, a UL97 protein kinase inhibitor; Merck, which is conducting Phase 3 clinical trials of letermovir, a CMV terminase inhibitor; Chimerix, which is conducting Phase 3 clinical trials for brincidofovir, a lipid conjugated nucleotide analogue of cidofovir; Cell Medica, which is conducting Phase 3 clinical trials for Cytovir CMV, a CMV-specific cell therapy product derived from primary HCT transplant donors; and Adcyte, which has licensed multi-virus specific T-cells from Baylor University that are currently in clinical trials sponsored by Baylor.

Many of the approved or commonly used drugs and therapies for muscle wasting, ovarian cancer, EBV-LPD and CMV 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 non-competitive before we can recover the expenses of development and commercialization.

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

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

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

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

As of December 31, 2014, we had 18 employees. As our development and commercialization plans and strategies develop, or as a result of any future acquisitions, we will need additional managerial, operational, manufacturing, sales, marketing, financial and other resources. 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 and finance systems; and
- expanding our facilities.

As our operations expand, we will 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 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 ("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, 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; and
- 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 or marketing expenditures; and state and foreign laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

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

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

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

We currently hold $5.0 million in product liability insurance coverage in the aggregate, which we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials with a policy limit that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, this insurance may not provide adequate 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 our CROs 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. 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 February 18, 2015, the reported sale price of our common stock has fluctuated between $9.66 and $35.45 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price of our common stock may be influenced by many factors, including the following:

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

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

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

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

As of January 16, 2015, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates together owned more than 70% 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. As of February 18, 2015, we have 24,360,247 shares of common stock outstanding. The 5,750,000 shares that we sold in our initial public offering in October 2014 and the 4,147,358 shares that we sold in our follow-on public offering in February 2015 may be resold in the public market immediately without restriction, unless purchased by our directors or officers or our stockholders who are subject to a lock-up agreement. Of the remaining shares, 15,839,989 shares of our common stock are restricted as a result of securities laws or lock-up agreements but will be able to be sold as early as April 14, 2015. Moreover, holders of an aggregate of 14,133,898 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 and certain lock-up agreements.

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 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 US generally accepted accounting principles. 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.

For a discussion of our remediation and the actions that we have executed during 2014 to remediate the material weakness see "Item 9A. Controls and Procedures – *Changes in Internal Control over Financial Reporting* " The actions we have taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. While we have remediated this weakness, if we are unable to successfully maintain effective control over financial reporting, and if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with applicable listing requirements of The Nasdaq Stock Market.

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

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

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

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

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

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

Provisions in our certificate of incorporation, and 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.

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 depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the 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 approximately 7,000 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 2,285 square feet of leased office space under a lease that expires in March 2015.

In January 2015, we entered into a non-cancellable lease agreement for approximately 5,000 square feet of office and laboratory space in Westlake Village, California. The lease term expires in April 2018.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.

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 Global Select 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 Global Select Market.

	2014	
	High	Low
Fourth Quarter (beginning October 14, 2014)	$ 35.45	$ 9.66

On February 18, 2015, there were 25 stockholders of record of our common stock and the closing price of our common stock was $20.08 per share as reported on the Nasdaq Global Select 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, 2014

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.

Sales of Unregistered Securities

From January 1, 2014 through October 15, 2014, the date of completion of our initial public offering, we granted to employees, consultants and directors options to purchase an aggregate of 554,959 shares of common stock pursuant to our equity incentive plans, having exercise prices ranging from $11.00 to $12.55 per share, as well as restricted stock units for an aggregate of 477,444 shares of common stock.

During this period, we also issued and sold 1,695,913 (15,263,263 shares prior to our recapitalization on March 31, 2014) shares of our Series B preferred stock to investors for a total purchase price of $13.5 million. These shares converted into common stock upon the closing of our initial public offering.

In September 2014, we issued 59,761 shares of common stock at $12.55 per share to MSK in connection with the execution of our exclusive license agreement with MSK.

The offers, sales and issuances of the securities described above were deemed to be exempt from registration under the Securities Act under either (a) Rule 701 promulgated under the Securities Act as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701 or (b) Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates and instruments issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

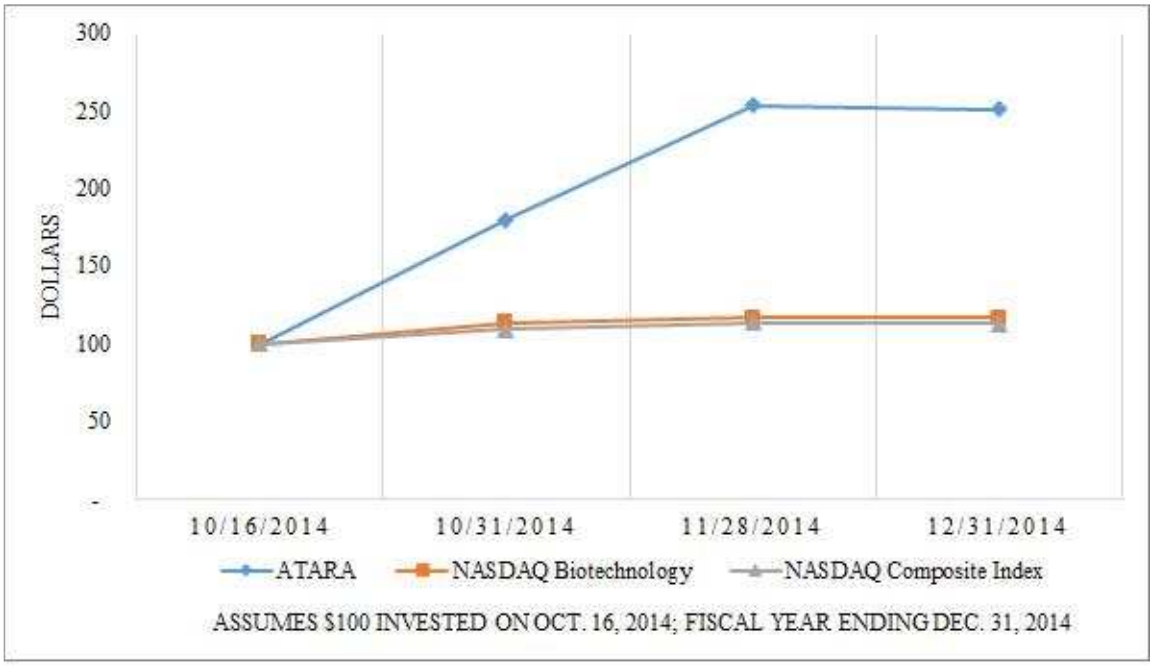
Use of Proceeds from Initial Public Offering of Common Stock

In October 2014, we sold an aggregate of 5,750,000 shares of our common stock (inclusive of 750,000 shares of common stock from the full exercise of the overallotment option of shares granted to the underwriters) at a price to the public of $11.00 pursuant to an effective registration statement on Form S-1 (File No. 333-201728). Goldman, Sachs & Co., Citigroup Global Markets Inc. and Jefferies LLC acted as the underwriters. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on October 16, 2014 pursuant to Rule 424(b) under the Securities Act. Pending the uses described, we have invested the net proceeds in short-term, investment-grade interest-bearing securities such as money market funds.

Stock Performance Graph

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.

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 (US) Index and the Nasdaq Biotechnology Index commencing on October 16, 2014 (the date our common stock began trading on the Nasdaq Global Select Market) and continuing through December 31, 2014. The past performance of our common stock is no indication of future performance. The graph assumes our closing sale price on October 16, 2014 of $10.65 per share as the initial value of our common stock and not the initial offering price of $11 per share.



Item 6. Selected Consolidated and Combined Financial Data

The following selected consolidated and combined financial data of the Company for each of the years in the period through December 31, 2014 are derived from the audited consolidated and combined financial statements. The consolidated and combined financial statements of the Company as of December 31, 2014 and 2013 and the reports of the independent registered public accounting firm are included elsewhere in this annual report. The data presented below should be read in conjunction with the financial statements of the Company, the notes to the financial statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report.

Consolidated and Combined Statements of Income Data	Year ended December 31, 2014	Year ended December 31, 2013	Period from August 22, 2012 (Inception) to December 31, 2012
	(In thousands, except per share information)		
Operating Expenses:			
Research and development	$ 14,380	$ 4,306	$ 241
Research and development costs paid to Amgen	1,066	553	—
In-process research and development acquired from Amgen	—	—	3,018
General and administrative	12,710	3,756	834
Total operating expenses	28,156	8,615	4,093
Loss from operations	(28,156)	(8,615)	(4,093)
Interest income	125	12	—
Loss before provision for income taxes	(28,031)	(8,603)	(4,093)
Provision (benefit) for income taxes	(25)	170	17
Net loss	$ (28,006)	$ (8,773)	$ (4,110)
Comprehensive loss	$ (28,106)	$ (8,773)	$ (4,110)
Basic and diluted net loss per common share	$ (5.62)	$ (9.08)	$ (5.60)

Consolidated and Combined Balance Sheet Data	As of December 31, 2014	2013	2012
		(In thousands)	
Cash, cash equivalents and investments	$ 104,116	$ 51,615	$ 4,207
Working capital	$ 103,302	$ 50,284	$ 2,940
Total assets	$ 106,122	$ 51,828	$ 4,290
Total stockholders' equity (deficit)	$ 103,182	$ (11,017)	$ (3,727)

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. 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 novel therapeutics for serious unmet medical needs, with an initial focus on muscle wasting conditions and oncology. Our product candidates are biologics targeting myostatin and activin, members of the TGF-ß protein superfamily, which play roles in the growth and maintenance of muscle and many other body tissues. Our lead product candidate, PINTA 745, is in a Phase 2 clinical trial for PEW in ESRD patients. Our second product candidate is STM 434. We commenced a Phase 1 clinical study of STM 434 for ovarian cancer and other solid tumors in 2014. We have five additional product candidates targeting the TGF-ß pathway in preclinical development. In addition, we have an exclusive option to license certain T-cell programs from MSK. We intend to license or acquire additional product candidates to develop and commercialize.

Our current product candidate portfolio was acquired through licensing arrangements with Amgen in exchange for convertible preferred stock and future milestone payments and royalties. Through these arrangements, we obtained licenses to patent rights and the ability to use certain proprietary know-how to develop and commercialize a portfolio of seven product candidates. The arrangement did not provide for the acquisition of employees, facilities or ongoing services. We are responsible for obtaining all regulatory approvals and developing commercial scale manufacturing processes to enable eventual commercialization of these product candidates. Under the terms of these agreements, we made an upfront payment of $250,000 and issued 615,384 shares of Series A-1 convertible preferred stock on a combined basis to Amgen. We are also required to make additional payments of up to $86.0 million to Amgen based upon the achievement of certain development and regulatory approval milestones, as well as additional payments based on achievement of commercial milestones and future net sales of products resulting from development of these product candidates, if any. Of the $86.0 million, $14.0 million in potential payments relate to milestones for clinical trials.

We have only 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 and clinical studies and providing general and administrative support for these operations.

In October 2014, we completed our initial public offering 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 approximately $56.5 million, after deducting underwriting discounts and commissions and offering expenses. In connection with our initial public offering, our 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 the fourth quarter of 2014.

In February 2015, we completed a follow-on public offering of 4,147,358 share of common stock at an offering price of $18.00 per share. We received net proceeds of approximately $69.4 million after deducting underwriting discounts and commissions and offering expenses.

We have never generated revenues and have incurred net losses since inception. Our net losses were $28.0 million, $8.8 million and $4.1 million for the years ended December 31, 2014 and 2013 and the period from August 22, 2012 (inception) to December 31, 2012. As of December 31, 2014, we had an accumulated deficit of $40.9 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative expenses associated with our operations. Our cash and cash equivalents and short-term investment balances at December 31, 2014 totaled $104.1 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 formed as a management company with the sole purpose of providing management, financial and administrative services for Nina, Pinta and Santa Maria. Since inception, Atara, Nina, Pinta and Santa Maria have been under common management and common ownership for all periods and as of all dates prior to our recapitalization on March 31, 2014, we have presented the results of operations and financial condition of the four companies on a combined basis. The combined financial statements include the accounts of the four individual companies since inception, 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 RSUs and restricted stock awards 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.

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:

- increase enrollment and completion of our Phase 2 clinical trial of PINTA 745;
- increase enrollment and completion of our Phase 1 clinical study of STM 434;
- process development and manufacturing of drug supply for ATA 842 to support IND-enabling studies; and
- evaluate our exclusive option to license certain T-cell programs from MSK.

In addition to our product candidates that are in clinical development, we believe it is important to continue our substantial investment in a diverse pipeline 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 studies 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 drop-out 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.

In-process Research and Development Acquired from Amgen

In-process research and development expenses acquired from Amgen consist of the value of the preferred stock issued to Amgen and the upfront cash payment of $250,000 made to Amgen as consideration paid for our Amgen licenses. As the licensed compounds are at an early stage of development and the underlying technology has no alternative future uses, the total consideration was expensed in 2012.

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, human resources, 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. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and marketable securities as well as interest on notes receivable issued to one of our employees related to the purchase of restricted common stock.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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 accrued research and development expenses. This process involves reviewing contracts and purchase orders, identifying services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service 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, 2014 and 2013 and the period from August 22, 2012 (inception) to December 31, 2012, there have been no material changes to 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.

Estimated Fair Value of Series A-1 Convertible Preferred Stock

In consideration for the licenses of our product candidate portfolio, we issued 615,384 shares of Series A-1 convertible preferred stock and paid $250,000 to Amgen. We estimated the fair value of our Series A-1 preferred stock to be $2.8 million by using the option pricing model ("OPM") backsolve method. OPM treats the rights of the holders of shares of preferred and common stock as equivalent to call options on any value of the enterprise above certain break points of value based upon the liquidation preferences of the holders of preferred stock, as well as their rights to participation and conversion. Thus, the estimated value of the Series A-1 convertible preferred stock can be determined by estimating the value of its portion of each of these call option rights. The OPM backsolve method derives the implied equity value of a company from a recent transaction involving the company's own securities issued on an arm's-length basis. This implied equity value was then allocated to each part of our capital structure, including our Series A-1 convertible preferred stock and common stock. Significant assumptions used at the time of valuation included an estimated volatility of 53.3%, a risk free interest rate of 0.28% and time to a liquidity event of 2.25 years.

Stock-based Compensation

We account for stock-based compensation expense, including the expense of restricted common stock awards 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 restricted common stock awards 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.

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 has 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 US 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 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 restricted stock awards 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 restricted stock awards 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 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 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 US deferred tax assets for the foreseeable future until sufficient positive evidence exists to support reversal of the valuation allowance.

At December 31, 2014 and 2013, we had federal and state net operating loss carryforwards of approximately $20.6 million and $7.2 million, respectively, which, if not utilized, begin to expire in various amounts beginning in the year 2032.

Under Section 382 of 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 transaction in our stock through December 31, 2014. 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.

We had no unrecognized tax benefits as of December 31, 2013. During the year ended December 31, 2014, the amount of gross unrecognized tax benefits increased by $1.6 million. $1.0 million of this amount related to current year tax positions and remainder related to prior year tax positions. Of the $1.6 million total unrecognized tax benefits, none, 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 twelve months.

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, 2014, 2013 and Comparison of the Period from August 22, 2012 (Inception) to December 31, 2012

Research and development expenses

	Year ended December 31, 2014	2013	Period from August 22, 2012 (Inception) to December 31, 2012	Increase (Decrease) 2013 to 2014	Increase (Decrease) 2012 to 2013
			(in thousands)		
Research and development	$ 14,380	$ 4,306	$ 241	$ 10,074	$ 4,065
Research and development costs paid to Amgen	1,066	553	-	513	553
Total research and development	$ 15,446	$ 4,859	$ 241	$ 10,587	$ 4,618

Research and development expenses increased during the years ended December 31, 2014, 2013 and the period from August 22, 2012 (inception) to December 31, 2012 consisted of the following costs by program:

	Year ended December 31, 2014	2013	Period from August 22, 2012 (Inception) to December 31, 2012	Increase (Decrease) 2013 to 2014	Increase (Decrease) 2012 to 2013
			(in thousands)		
PINTA 745	$ 2,311	$ 1,658	$ 15	$ 653	$ 1,643
STM 434	4,389	1,936	66	2,453	1,870
ATA 842	624	16	-	608	16
Option to license T-cell therapies	2,000	-	-	2,000	-
Employee and overhead costs	6,122	1,249	160	4,873	1,089
Total research and development	$ 15,446	$ 4,859	$ 241	$ 10,587	$ 4,618

PINTA 745 costs increased by $0.7 million in 2014 as compared to 2013 due primarily to a $0.9 million increase in outsourced development and third party costs to support the Phase 2 clinical trial that commenced during the fourth quarter of 2013. This increase was partially offset by a $0.2 million decrease in outside consultant costs incurred in 2014 as compared to 2013.

PINTA 745 costs increased by $1.6 million in 2013 as compared to 2012 primarily due to a $0.4 million increase in outside consultants' costs and $0.7 million of direct costs to support the Phase 2 clinical trial that commenced during the fourth quarter of 2013. In addition, in 2013 and as part of our licenses with Amgen, we purchased clinical drug and placebo supplies for $0.6 million, which we will use in our Phase 2 trial. In the future, we anticipate that costs related to the future clinical drug supply will increase as we contract with a third party supplier to manufacture these materials.

STM 434 program costs increased by $2.5 million in 2014 as compared to 2013 due to a $1.0 million milestone payment to Amgen, $1.5 million in increased outside manufacturing costs for clinical drug supply and third party costs related to the Phase 1 clinical study of STM 434, which commenced in the second half of 2014.

STM 434 program costs increased by $1.9 million in 2013 as compared to 2012 primarily due to $1.5 million in outside manufacturing costs for clinical drug supply and approximately $0.4 million of outside consultants' costs in preparation for the Phase 1 clinical study of STM 434 that commenced in 2014.

The option to license T-cell therapies costs for the 2014 year included upfront expense of $2.0 million for our exclusive option agreement with MSK for the worldwide license rights to three clinical stage T-cell therapies. In exchange for the exclusive option, we paid $1.25 million in cash and issued 59,761 shares of our common stock to MSK. The estimated fair value of the common stock issued to MSK was $750,000.

Employee and overhead costs increased by $4.9 million in 2014 as compared to 2013 and by $1.1 million in 2013 as compared to 2012. The increasing trend over the three years is primarily a result of increased compensation-related costs resulting from increased headcount and recruiting expenses. In particular, wages and employee stock-based compensation increased by $1.5 million and $2.7 million, respectively, in 2014 as compared to 2013 and by $0.7 million and $0.3 million respectively in 2013 as compared to 2012. The employee stock-based compensation increase was due to an overall increase in the awards granted under our employee incentive plan, as well as the vesting of certain awards upon the closing of our initial public offering in October 2014.

General and administrative expenses

	Year ended December 31,		Period from August 22, 2012 (Inception) to December 31, 2012	Increase (Decrease) 2013 to 2014	Increase (Decrease) 2012 to 2013
	2014	2013			
	(in thousands)				
General and administrative	$ 12,710	$ 3,756	$ 834	$ 8,954	$ 2,922

General and administrative expenses increased by $9.0 million in 2014 as compared to 2013 due to a $6.1 million increase in stock-based compensation costs and other payroll related expenses, $0.9 million in third party consulting fees and $0.8 million of increased accounting fees associated with the audit of our financial statements and costs to prepare for our initial public offering.

General and administrative expenses increased by $2.9 million in 2013 as compared to 2012 primarily due to a $1.2 million increase in stock-based compensation costs, $0.8 million of legal fees associated with patent filings and maintenance and $0.5 million of additional personnel costs. Personnel costs and stock-based compensation costs were higher in 2013 due to increased headcount and a full year of expenses in 2013, compared to only four months in 2012.

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, 2014. 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
2014	(In thousands)			
Operating expenses:				
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 income	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)
Other comprehensive loss, net of tax:				
Unrealized losses on investments	(11)	11	(11)	(89)
Other comprehensive loss	(11)	11	(11)	(89)
Comprehensive loss	$ (7,060)	$ (4,500)	$ (5,930)	$ (10,616)

	Three months ended			
	March 31	June 30	September 30	December 31
2013	(In thousands)			
Operating expenses:				
Research and development	$ 354	$ 569	$ 1,134	$ 2,249
Research and development costs paid to Amgen	—	—	550	3
General and administrative	932	792	868	1,164
Total operating expenses	1,286	1,361	2,552	3,416
Loss from operations	(1,286)	(1,361)	(2,552)	(3,416)
Interest income	2	4	3	3
Loss before provision for income taxes	(1,284)	(1,357)	(2,549)	(3,413)
Provision (benefit) for income taxes	14	26	(13)	143
Comprehensive and net loss	$ (1,298)	$ (1,383)	$ (2,536)	$ (3,556)

Liquidity and Capital Resources

We have incurred cumulative losses and negative cash flows from operations since our inception in 2012, and we had an accumulated deficit of $40.9 million as of December 31, 2014. It will be several years, if ever, before we have a product candidate ready for commercialization, and we anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

In October 2014, we completed our initial public offering and received net proceeds of approximately $56.5 million, after deducting underwriting discounts and commissions and offering expenses. In February 2015, we completed a follow-on offering of 4,147,358 shares of common stock at a public offering price of $18.00 per share. We received net proceeds of approximately $69.4 million, after deducting underwriting discounts and commissions and offering expenses.

Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our cash and cash equivalents and short-term investments are held in bank and custodial accounts and consist of money market mutual funds, corporate bonds, U.S. government securities, asset-back securities and commercial paper. Management expects that existing cash and cash equivalents as of December 31, 2014, combined with the proceeds of our follow-on public offering in February 2015 will be sufficient to fund our current operating plan through the second half of 2017.

Working capital was $103.3 million and $50.3 million as of December 31, 2014 and 2013, respectively. Included in working capital were cash and cash equivalents and short-term investments of $104.1 million and $51.6 million as of December 31, 2014 and 2013, respectively.

Our cash and cash equivalents and short-term investments balances were as follows:

	Year ended December 31,		Increase
	2014	2013	(Decrease)
	(in thousands)		
Cash and cash equivalents	$ 21,897	$ 51,615	$ (29,718)
Short-term available-for-sale investments	82,219	—	82,219
Total cash and cash equivalents and short-term available-for-sale investments	$ 104,116	$ 51,615	$ 52,501

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,		Period from August 22, 2012 (Inception) to	Increase (Decrease)	Increase (Decrease)
	2014	2013	December 31, 2012	2013 to 2014	2012 to 2013
	(in thousands)				
Net cash provided by (used in):					
Operating activities	$ (16,628)	$ (5,966)	$ (825)	$ (10,662)	$ (5,141)
Investing activities	(83,363)	(3)	(9)	(83,360)	6
Financing activities	70,273	53,377	5,041	16,896	48,336
Net increase (decrease) in cash and cash equivalents	$ (29,718)	$ 47,408	$ 4,207	$ (77,126)	$ 43,201

Operating activities

For the year ended December 31, 2014, cash used by operating activities increased by $10.7 million over the prior year. This increase was primarily due to the $19.2 million increase in net loss between years, offset in part by the $8.4 million increase in stock-based compensation and the $0.8 million non-cash charge for research and development expenses related to our exclusive option to license certain T-cell therapies from MSK.

For the year ended December 31, 2013, cash used by operating activities increased by $5.1 million over the period from August 22, 2012 (inception) to December 31, 2012. The increase was primarily due to the $4.7 million increase in net loss between periods and the $2.8 million non-cash charge for in-process research and development acquired from Amgen in 2012. These increases in cash used by operating activities were offset in part by the $1.4 million increase in stock-based compensation in 2013.

Investing activities

Net cash used in investing activities during the year ended December 31, 2014 consisted primarily of $95.5 million invested in short-term available-for-sale securities, offset by maturities of $12.2 million.

Financing activities

For the year ended December 31, 2014, cash provided by financing activities was $70.3 million, versus $53.4 million for the year ended December 31, 2013 and $5.0 million for the period from August 22, 2012 (inception) to December 31, 2012. 2014 financing activities consisted primarily of $56.5 million 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. 2013 and 2012 financing activities consisted primarily of $53.4 million and $5.0 million, respectively, 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 and cash equivalents, including the proceeds from our February 2015 follow-on public offering, will be sufficient to enable us to complete planned preclinical and clinical trials for our lead product candidates into the second half of 2017. 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 and Off-Balance Sheet Arrangements

Contractual Obligations and Commitments

We lease our corporate headquarters in South San Francisco, California under a non-cancellable sublease agreement that expires in Jan 2017. We lease office and laboratory facilities in Westlake Village, California under a non-cancellable lease agreement that expires in March 2015. In January 2015, we entered into a non-cancellable lease agreement for office and laboratory facilities in Westlake Village, California under an agreement that expires in April 2018. Future minimum commitments for these three operating leases are as follows:

	Payment Due by Period (in thousands)				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations	$ 773	$ $ 278	$ 453	$ 42	$ -
Total contractual obligations	$ 773	$ 278	$ 453	$ 42	$ -

In addition, our other long-term liabilities include $74,501 related to uncertain tax positions as of December 31, 2014. Due to uncertainties in the future timing of potential tax audits, the timing of the resolution of these positions is uncertain and we are unable to make a reasonably reliable estimate of the timing of payments in individual years beyond 12 months. As a result, this amount is not included in the above table

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for pre-clinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material. As of December 31, 2014, other than our leases for office and laboratory space, we had no material contractual obligations or commitments that will affect our future liquidity

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

We are exposed to market risk related to changes in interest rates. As of December 31, 2014 and 2013 we had cash and cash equivalents and short-term available-for-sale investments of $104.1 million, and $51.6 million, respectively. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of US 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. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% increase in interest rates would not have a material effect on the fair market value of our portfolio.

Item 8. Financial Statements and Supplementary Data

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 and combined balance sheets of Atara Biotherapeutics, Inc. and its subsidiaries (collectively, the "Company") as of December 31, 2014 and 2013, and the related consolidated and combined statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for the years ended December 31, 2014 and 2013 and for the period from August 22, 2012 (inception) to December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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 their internal control over financial reporting. Our audit 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 the Company as of December 31, 2014 and 2013, and the consolidated and combined results of its operations and its cash flows for the years ended December 31, 2014 and 2013 and for the period from August 22, 2012 (inception) to December 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

San Jose, California
February 26, 2015

ATARA BIOTHERAPEUTICS, INC.
Consolidated and Combined Balance Sheets
(In thousands, except share amounts)

	December 31, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	$ 21,897	$ 51,615
Short-term available-for-sale investments	82,219	—
Prepaid expenses and other current assets	1,910	193
Total current assets	106,026	51,808
Property and equipment, net	48	8
Other assets	48	12
Total assets	$ 106,122	$ 51,828
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 440	$ 606
Accrued compensation	1,225	331
Income tax payable	1	155
Other accrued liabilities	1,058	432
Total current liabilities	2,724	1,524
Other long-term liabilities	216	230
Total liabilities	2,940	1,754
Commitments and contingencies (Note 5)		
Series A convertible preferred stock—$0.0001 par value, liquidation preference of $20,088 as of December 31, 2013	—	19,909
Series A-1 convertible preferred stock—$0.0001 par value, liquidation preference of $3,000 as of December 31, 2013	—	2,768
Series B convertible preferred stock—$0.0001 par value, liquidation preference of $52,000 as of December 31, 2013	—	38,414
Stockholders' equity (deficit):		
Common stock—$0.0001 par value, 19,692,937 and 12,003,891 shares issued and outstanding as of December 31, 2014 and 2013, respectively	2	1
Additional paid-in capital	144,169	2,200
Notes receivable from stockholder	—	(335)
Accumulated other comprehensive loss	(100)	—
Accumulated deficit	(40,889)	(12,883)
Total stockholders' equity (deficit)	103,182	(11,017)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 106,122	$ 51,828

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

	Year ended December 31, 2014	Year ended December 31, 2013	Period from August 22, 2012 (Inception) to December 31, 2012
Operating Expenses:			
Research and development	$ 14,380	$ 4,306	$ 241
Research and development costs paid to Amgen	1,066	553	—
In-process research and development acquired from Amgen	—	—	3,018
General and administrative	12,710	3,756	834
Total operating expenses	28,156	8,615	4,093
Loss from operations	(28,156)	(8,615)	(4,093)
Interest income	125	12	—
Loss before provision for income taxes	(28,031)	(8,603)	(4,093)
Provision (benefit) for income taxes	(25)	170	17
Net loss	$ (28,006)	$ (8,773)	$ (4,110)
Other comprehensive loss, net of tax:			
Unrealized losses on investments	(100)	—	—
Other comprehensive loss	(100)	—	—
Comprehensive loss	$ (28,106)	$ (8,773)	$ (4,110)
Net loss per common share:			
Basic and diluted net loss per common share	$ (5.62)	$ (9.08)	$ (5.60)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	4,985,540	965,825	733,294

ATARA BIOTHERAPEUTICS, INC.
Consolidated and Combined Statement 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 Stockholder	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance at inception (August 22, 2012)	—	$ —	—	$ —	—	$ —	—	$ —	$ —	$ —	$ —	$ —	$
Issuance of common stock for cash	—	—	—	—	—	—	7,231	1	90	—	—	—	
Issuance of Series A preferred stock for cash, net of offering costs of $54	11,538	4,946	—	—	—	—	—	—	—	—	—	—	
Issuance of Series A-1 preferred stock for license fee to Amgen	—	—	3,532	1,765	—	—	—	—	—	—	—	—	
Issuance of common stock upon vesting of stock awards	—	—	—	—	—	—	231	—	—	—	—	—	
Stock-based compensation expense	—	—	—	—	—	—	—	—	292	—	—	—	
Net loss	—	—	—	—	—	—	—	—	—	—	—	(4,110)	(4
Balance at December 31, 2012	11,538	4,946	3,532	1,765	—	—	7,462	1	382	—	—	(4,110)	(3
Issuance of common stock for cash, net of offering costs of $1	—	—	—	—	—	—	615	—	—	—	—	—	
Issuance of Series A preferred stock for cash, net of offering costs of $124	34,818	14,963	—	—	—	—	—	—	—	—	—	—	
Issuance of Series A-1 preferred stock for license fee to Amgen	—	—	2,006	1,003	—	—	—	—	—	—	—	—	
Issuance of Series B preferred stock for cash, net of offering costs of $86	—	—	—	—	43,529	38,414	—	—	—	—	—	—	
Notes receivable from stockholder	—	—	—	—	—	—	—	—	—	(331)	—	—	
Interest income accrued on notes receivable from stockholder	—	—	—	—	—	—	—	—	—	(4)	—	—	
Issuance of common stock upon vesting of stock awards	—	—	—	—	—	—	3,927	—	105	—	—	—	
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,713	—	—	—	1
Net loss	—	—	—	—	—	—	—	—	—	—	—	(8,773)	(8
Interest income accrued on notes receivable from stockholder													
Balance at December 31, 2013	46,356	19,909	5,538	2,768	43,529	38,414	12,004	1	2,200	(335)	—	(12,883)	(11
Issuance of Series B preferred stock, net of offering costs of $19	—	—	—	—	15,263	13,481	—	—	—	—	—	—	
Interest income accrued on notes receivable from stockholder	—	—	—	—	—	—	—	—	—	(2)	—	—	
Repayment of notes receivable from stockholder	—	—	—	—	—	—	—	—	—	337	—	—	
Issuance of common stock upon vesting of stock awards	—	—	—	—	—	—	645	—	20	—	—	—	
Recapitalization (Note 2)	(41,205)	—	(4,923)	—	(52,260)	—	(11,346)	(1)	1	—	—	—	
Issuance of common stock upon vesting of stock awards—post Recapitalization	—	—	—	—	—	—	282	—	70	—	—	—	
Issuance of common stock for research and development expenses related to technology licensing option	—	—	—	—	—	—	60	—	750	—	—	—	
Conversion of preferred stock	(5,151)	(19,909)	(615)	(2,768)	(6,532)	(51,895)	12,298	1	74,572				74
Issuance of common stock, net of discounts and offering costs of $6,794	—	—	—	—	—	—	5,750	1	56,455	—	—	—	56
Stock-based compensation expense	—	—	—	—	—	—	—	—	10,101	—	—	—	10
Accumulated other comprehensive loss	—	—	—	—	—	—	—	—	—	—	(100)	—	
Net loss	—	—	—	—	—	—	—	—	—	—	—	(28,006)	(28
Balance at December 31, 2014	—	$ —	—	$ —	—	$ —	19,693	$ 2	$ 144,169	$ —	$ (100)	$ (40,889)	$ 103

ATARA BIOTHERAPEUTICS, INC.
Consolidated and Combined Statements of Cash Flows
(In thousands)

	Year ended December 31, 2014	Year ended December 31, 2013	Period from August 22, (Inception) to December 31, 2012
Operating activities			
Net loss	$ (28,006)	$ (8,773)	$ (4,110)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash research and development expenses	750	—	—
In-process research and development acquired from Amgen	—	—	2,768
Depreciation expense	6	4	—
Investment premium amortization, net	526	—	—
Stock-based compensation expense	10,101	1,713	292
Interest accrued on notes receivable from stockholder	(2)	(4)	—
Changes in operating assets and liabilities:			
Other assets	(37)	27	(39)
Prepaid expenses and other current assets	(1,246)	(158)	(35)
Accounts payable	(164)	485	121
Income tax payable	(154)	148	7
Other accrued liabilities	626	312	120
Accrued compensation	894	280	51
Other long-term liabilities	78	—	—
Net cash used in operating activities	(16,628)	(5,966)	(825)
Investing activities			
Purchase of short-term investments	(95,525)	—	—
Maturities of short-term investments	12,208	—	—
Purchase of property and equipment	(46)	(3)	(9)
Net cash used in investing activities	(83,363)	(3)	(9)
Financing activities			
Proceeds from sale of common stock, net of offering costs	56,455	—	91
Repayment of notes receivable from stockholder	337	—	—
Proceeds from sale of unvested restricted stock	—	—	4
Proceeds from sale of convertible preferred stock	13,500	53,587	5,000
Offering costs incurred in connection with sale of convertible preferred stock	(19)	(210)	(54)
Net cash provided by financing activities	70,273	53,377	5,041
Increase (decrease) in cash and cash equivalents	(29,718)	47,408	4,207
Cash and cash equivalents-beginning of period	51,615	4,207	—
Cash and cash equivalents-end of period	$ 21,897	$ 51,615	$ 4,207
Non-cash financing activities			
Issuance of common stock for research and development expenses related to technology licensing option	$ 750	$ —	$ —
Issuance of Series A-1 convertible preferred stock to Amgen in exchange for license	$ —	$ 1,003	$ 1,765
Change in obligation to issue Series A-1 convertible preferred stock to Amgen	$ —	$ (1,003)	$ 1,003
Issuance of common stock upon vesting of stock awards	$ 90	$ 105	$ —
Change in other long-term liabilities related to non-vested stock awards	$ (90)	$ 226	$ —
Restricted stock issued to related party in exchange for notes receivable	$ —	$ 331	$ —
Supplemental cash flow disclosure —Cash paid for taxes	$ 70	$ 22	$ 9

ATARA BIOTHERAPEUTICS, INC.
Notes to Consolidated and Combined Financial Statements

1. Organization and Description of Business

Atara Biotherapeutics, Inc. ("Atara", "we" or "our") was incorporated in August 2012 in Delaware. We are a clinical-stage biopharmaceutical company developing novel therapeutics, with an initial focus on biologics for muscle wasting conditions and oncology. Our product candidate portfolio was acquired through licensing arrangements with Amgen Inc. ("Amgen") in exchange for convertible preferred stock, milestone payments and commitments for future royalties. See Note 4 for further information.

In October 2014, we completed our initial public offering 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 approximately $56.5 million, after deducting underwriting discounts and commissions and offering expenses. In connection with the initial public offering, the Company's 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 secondary 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 $69.4 million, after deducting underwriting discounts and commissions and offering expenses.

2. Summary of Significant Accounting Policies

Basis of Presentation and Recapitalization

All share and per-share amounts presented in the consolidated and combined financial statements for the years ended December 31, 2014, 2013 and 2012 and in the notes hereto have been revised to reflect a 1.3-to-1 reverse stock split which became effective July 9, 2014. 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"). These financial statements include the financial position, results of operations, and cash flows of the Company, including its wholly-owned subsidiaries. All inter-company accounts and transactions have been eliminated.

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 since inception. All intercompany transactions have been eliminated.

On March 31, 2014, our boards of directors approved and 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 the Company are presented on a consolidated basis.

Liquidity

We have incurred significant operating losses since inception and have relied on private equity financings to fund our operations prior to our initial public offering. At December 31, 2014, we had an accumulated deficit of $40.9 million. As we continue to incur losses, our transition to profitability will depend on the successful development, approval and commercialization of product candidates and on the achievement of sufficient revenues to support our cost structure. We may never achieve profitability, and unless and until we do, we will need to continue to raise additional capital. Management expects that existing cash and cash equivalents as of December 31, 2014 will be sufficient to fund our current operating plan into the second half of 2017.

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 consolidated and combined financial statements include the fair value of common stock and the fair value of preferred stock prior to our initial public offering and estimates related to clinical trial accruals and stock-based compensation expense. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

Cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase, consisting of money market funds that earn interest and dividends overnight, corporate bonds and agency bonds.

Investments

Our available-for-sale investments consist primarily of corporate bonds, US government securities, asset-backed securities and commercial paper. Investments with original maturities of greater than 90 days are classified as short-term available-for-sale securities on the consolidated and combined balance sheets.

Our investments in available-for-sale securities are reported at fair value. Unrealized gains and losses related to changes in the fair value of securities are recognized in accumulated other comprehensive loss, net of tax, on our consolidated and combined balance sheets. Changes in the fair value of available-for-sale securities impact the statements of operations only when such securities are sold or 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, and 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.

Fair Value Measurement

The carrying amounts of certain of our financial instruments including cash equivalents, 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.

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, corporate bonds, US government securities, asset-backed securities and commercial paper backed by US Government or private insurers, 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.

Fair Value of Financial Instruments

Our financial assets and liabilities carried at fair value are primarily comprised of investments in money market funds, corporate bonds, US government securities, asset-backed securities and commercial paper. The fair value accounting guidance requires that assets and liabilities be carried at fair value and classified in one of the following three categories:

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 were no transfers between Level 1, Level 2, and Level 3 since inception.

The following table represents the fair value hierarchy for our financial assets and financial liabilities measured at fair value on a recurring basis:

	Total Fair Value	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)
		(in thousands)	
At December 31, 2014:			
Cash equivalents:			
Money market funds	$ 18,141	$ 18,141	$ -
Agency bonds	1,750	-	1,750
Corporate bonds	2,006	-	2,006
Short-term available-for-sale investments:			
Corporate bonds	57,958	-	57,958
Agency bonds	10,764	-	10,764
Treasury bonds	465	-	465
Commercial paper	1,200	-	1,200
Asset-backed securities	11,832	-	11,832
At December 31, 2013:			
Cash equivalents:			
Money market funds	$ 51,615	$ 51,615	$ -

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. Corporate bonds, US government securities, asset-backed securities and commercial paper 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 and liabilities.

Available-for-sale investments are carried at fair value and are included in the table above under short-term available for sale investments. The aggregate market value, cost basis, and gross unrealized gains and losses of available-for-sale investments by major security type are as follows:

	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Fair Value
	(in thousands)			
At December 31, 2014:				
Corporate bonds	$ 58,046	$ 1	$ (89)	$ 57,958
Agency bonds	10,769	—	(5)	$ 10,764
Treasury bonds	466	—	(1)	$ 465
Commercial paper	1,200	—	—	$ 1,200
Asset-backed securities	11,838	2	(8)	$ 11,832
Total short-term available-for-sale investments	$ 82,319	$ 3	$ (103)	$ 82,219

The amortized cost and fair value of available-for-sale debt investments, by contractual maturity, were as follows:

	Total Amortized Cost	Total Fair Value
	(in thousands)	
At December 31, 2014:		
Maturing within one year	$ 56,752	$ 56,714
Maturing in one to five years	25,567	25,505
Total short-term investments	$ 82,319	$ 82,219

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.

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.

Convertible Preferred Stock

We recorded issued convertible preferred stock at fair value on the dates of issuance. The convertible preferred stock was recorded outside of stockholders' deficit because the shares contain liquidation features that were not solely within our control. In connection with our initial public offering in October 2014, 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. We have no outstanding convertible preferred stock at December 31, 2014.

Estimated Fair Value of Series A-1 Convertible Preferred Stock

In consideration for the licenses of our product candidate portfolio, we issued 5,538,462 shares of Series A-1 convertible preferred stock (615,384 shares after giving effect to the Recapitalization) and paid $250,000 to Amgen.

We estimated the fair value of our Series A-1 preferred stock to be $2.8 million by using the option pricing model ("OPM"), backsolve method. OPM treats the rights of the holders of shares of preferred and common stock as equivalent to call options on any value of the enterprise above certain break points of value based upon the liquidation preferences of the holders of preferred stock, as well as their rights to participation and conversion. Thus, the estimated value of the Series A-1 convertible preferred stock can be determined by estimating the value of its portion of each of these call option rights. The OPM backsolve method derives the implied equity value of a company from a recent transaction involving the company's own securities issued on an arm's-length basis. This implied equity value was then allocated to each part of our capital structure, including our Series A-1 convertible preferred stock and common stock. Significant assumptions included an estimated volatility of 53.3%, a risk free interest rate of 0.28% and a time to exit of 2.25 years.

Stock-Based Compensation Expense

We account for stock-based compensation expense, including the expense of restricted common stock awards 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 restricted common stock awards 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 US 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 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.

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, 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.

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 liability 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, 2014 and 2013. We intend to maintain valuation allowances until sufficient evidence exists to support its 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. Other comprehensive loss includes net loss and unrealized losses on available-for-sale investments.

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 initial public offering, we considered all series of our convertible preferred stock to be participating securities as they are 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 have no legal requirement to share in any losses.

Potential dilutive securities, which include convertible preferred stock prior to our initial public offering, unvested restricted common stock awards, unvested restricted stock units and vested and unvested options have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per common share and be 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 shares of potentially dilutive securities give effect to the Recapitalization, and have been excluded from the computations of diluted net loss per common share as the effect of including such securities would be antidilutive:

	Year ended December 31,	
	2014	2013
Convertible preferred stock	9,835,335	5,797,612
Unvested restricted common stock	666,091	790,216
Unvested restricted stock units	721,263	—
Vested and unvested options	313,565	—
	11,536,254	6,587,828

In addition, 70,900 options have been excluded from the above table as the exercise prices of the underlying options were greater than the average fair value of our common stock for the periods presented.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (the "FASB") issued a new accounting standard to provide guidance on the presentation of management's plans, when conditions or events raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The new standard is effective for fiscal years ending after December 15, 2016. The adoption of this standard is not expected to have a material impact on our financial statements.

In June 2014, the FASB amended the definition of a development-stage entity in the Master Glossary of the Accounting Standards Codification. The amendments simplified the financial reporting for development-stage companies by eliminating inception-to-date reporting requirements specific to development stage entities. The revised guidance is effective for annual periods beginning after December 15, 2014; however we early adopted the guidance in the second quarter of 2014. The adoption of this guidance impacted our financial statement presentation, but did not have a material impact on our financial position or results of operations and cash flows.

In May 2014, the FASB issued a new accounting standard, *Revenue from Contracts with Customers (Topic 606)*, which supersedes the revenue recognition requirements in the current standard, *Revenue Recognition* . The new standard is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. It 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. The new standard's effective date for us will be January 1, 2017. We will evaluate the application of this standard when we enter into any contracts with customers.

3. Property and Equipment

Property and equipment consists of 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.

4. Significant Agreements

Related Party License Agreements - In September 2012, we entered into three license agreements with Amgen for the development, manufacturing, use and distribution of products using certain proprietary compounds. Under the terms of these agreements, we paid $250,000 and issued 5,538,462 shares of Series A-1 convertible preferred stock (615,384 shares after giving effect to the Recapitalization) to Amgen. As described further in Note 5, we may also be required to make additional payments to Amgen based upon the achievement of specified development, regulatory, and commercial milestones, as well as mid-single-digit percentage royalties on future sales of products resulting from development of these purchased technologies, if any. 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.

The license agreements with Amgen did not provide for the acquisition of employees, facilities or ongoing services and we determined that the acquired license rights did not constitute an acquisition of a business. As the licensed compounds were in an early stage of development, and the underlying technology has no alternative future uses, the $3.0 million total of the upfront payment of $250,000 and the $2.8 million value of the Series A-1 convertible preferred stock issuable under the agreements was recorded as acquired in-process research and development expense in our combined statements of operations and comprehensive loss for the period from August 22, 2012 (inception) to December 31, 2012. Milestones and royalties are contingent upon future events and will be recorded as expense when it is probable that the milestones will be achieved and we can reasonably estimate payment amounts.

In 2012, we issued 3,531,774 shares of Series A-1 convertible preferred stock valued at $1.8 million to Amgen and recorded a liability of $1.0 million for the value of the remaining 2,006,688 shares of Series A-1 convertible preferred stock that we were obligated to issue to Amgen. These shares were issued in 2013.

During the year ended December 31, 2014, we purchased clinical services totaling $66,000 and made a $1.0 million milestone payment to Amgen. During the year ended December 31, 2013, we purchased clinical supplies totaling $552,772 from Amgen. These payments to Amgen have been recorded as research and development costs paid to Amgen in our consolidated and combined statement of operations and comprehensive loss.

At December 31, 2014, Amgen owns 7.4% 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.

Exclusive Option Agreement – In September 2014, we entered into an exclusive option agreement with Memorial Sloan Kettering Cancer Center ("MSK") under which we have the option to acquire the exclusive worldwide license rights to the three clinical stage T-cell therapies of MSK. The initial option period is for twelve months, with extensions available to extend the term up to 27 months at the option of Atara. Under the terms of the option agreement, we are obligated to use reasonable efforts to prepare a request to be submitted to the US Food and Drug Administration (the "FDA") regarding a meeting to discuss pivotal trials for one of the clinical stage T-cell therapies. 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 estimated the fair value of the common stock issued to MSK to be $750,000. This total of $2.0 million was recorded as research and development expense in our consolidated and combined statement of operations and comprehensive loss in 2014. We will be obligated to pay MSK an additional amount up to $630,000 if we extend the option period.

If we extend the option and enter into the license agreement with MSK, we will be obligated under the license agreement to pay to MSK an upfront cash payment of $4.5 million and additional payments of up to $33.0 million based on a license fee and achievement of specified development, regulatory and sales-related milestones, and to make mid-single-digit percentage royalty payments based on sales of the T-cell therapy products.

5. Commitments and Contingencies

Operating Leases

We lease our corporate headquarters in South San Francisco, California under a non-cancellable sublease agreement that expires in January 2017. We lease office and laboratory facilities in Westlake Village, California under a non-cancellable lease agreement that expires in March 2015. In January 2015, we entered into a non-cancellable lease agreement for office and laboratory facilities in Westlake Village, California under an agreement that expires in April 2018. Future minimum commitments for these three operating leases are as follows:

	Operating Leases (in thousands)
2015	$ 278
2016	313
2017	140
2018	42

Rent expense for the years ended December 31, 2014 and 2013 and the period from August 22, 2012 (inception) to December 31, 2012 were $103,167, $57,553 and $8,250, respectively.

Related Party License Agreements

Under the terms of our license agreements with Amgen, we are obligated to make additional milestone payments to Amgen of up to $86.0 million upon the achievement of certain development and regulatory approval milestones. 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 2017. Thereafter, we are obligated 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 billion for each of three products in a calendar year. We are also obligated to pay mid-single-digit percentage tiered royalties on future net sales of products which are developed and approved as defined by the agreements. 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. As of December 31, 2013 and December 31, 2014, there were no outstanding obligations due to Amgen. We made a $1.0 million milestone payment to Amgen in the second quarter of 2014.

In accordance with terms of the agreements, we use commercially reasonable efforts to pay costs related to the preparation, filing, prosecution, defense and maintenance of the patents covered by the license agreements. During the years ended December 31, 2014 and 2013 and the period from August 22, 2012 (inception) to December 31, 2012, we incurred expenses of $1,212,135, $821,238 and $73,298, respectively, related to the preparation, filing and maintenance of patents.

Indemnification Agreements

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations. We also have indemnification obligations to our directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date and we believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recorded any liabilities for these agreements as of December 31, 2014 and 2013.

6. Convertible Preferred Stock

In October 2014, in connection with the completion of our initial public offering, all outstanding shares of Series A convertible preferred stock, Series A-1 convertible preferred stock and Series B convertible preferred stock were converted into 12,298,515 shares of common stock and $74.6 million of mezzanine equity was reclassified to additional paid-in capital. As of December 31, 2014, there were no shares of convertible preferred stock issued and outstanding.

As of December 31, 2013, convertible preferred shares issued and authorized were as follows:

	As of December 31, 2013							
	Nina		Pinta		Santa Maria		Combined Total	
	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value
	(dollars in thousands)							
Issued and outstanding:								
Series A convertible preferred stock	15,452,114	$ 2,306	15,452,114	$ 9,963	15,452,114	$ 7,640	46,356,342	$ 19,909
Series A-1 convertible preferred stock	1,846,154	573	1,846,154	1,355	1,846,154	840	5,538,462	2,768
Series B convertible preferred stock	14,509,579	2,496	14,509,579	17,960	14,509,579	17,958	43,528,737	38,414
	31,807,847	$ 5,375	31,807,847	$ 29,278	31,807,847	$ 26,438	95,423,541	$ 61,091
Authorized:								
Series A convertible preferred stock	15,452,114		15,452,114		15,452,114		46,356,342	
Series A-1 convertible preferred stock	1,846,154		1,846,154		1,846,154		5,538,462	
Series B convertible preferred stock	16,960,012		16,960,012		16,960,012		50,880,036	
	34,258,280		34,258,280		34,258,280		102,774,840	

Original issuance prices of Series A conver tible preferred stock, prior to issuance costs, were $0.152, $0.650 and $0.498 per share, for Nina, Pinta and Santa Maria, respectively, or $1.30 per share on a combined basis. Original issuance prices of Series B convertible preferred stock, prior to issuance costs were $0.173, $1.240 and $1.240 per share, for Nina, Pinta and Santa Maria, respectively, or $2.653 per share on a combined basis. Amgen contributed licenses for issued Series A-1 convertible preferred stock with fair values of $0.310, $0.734 and $0.455 per share for Nina, Pinta and Santa Maria, respectively, or $1.500 per share on a combined basis.

In connection with the Recapitalization on March 31, 2014, the stockholders of Nina, Pinta and Santa Maria exchanged three shares of each company's preferred stock for one share of Atara preferred stock (a collective nine-for-one basis). The deemed original issuance prices of the new Atara preferred shares, for the calculation of the dividends and liquidation preference discussed below are $3.900, $4.875, and $7.960 for Series A, Series A-1, and Series B, respectively.

Nina, Pinta and Santa Maria issued convertible preferred stock with the same rights and privileges to the same investors. As of December 31, 2013, Atara had not issued any convertible preferred stock. In connection with the Recapitalization on March 31, 2014, Atara issued convertible preferred stock with the same rights and privileges and with the same ownership percentages as the convertible preferred stock previously issued by Nina, Pinta and Santa Maria. Convertible preferred stock holders had an optional right to convert to common stock, and had dividends rights and liquidation rights in preference to holders of common stock.

7. Stockholders' Equity (Deficit)

Our authorized capital stock consists of 520 million shares, all with a par value of $0.0001 per share, of which 500 million shares are designated as common stock and 20 million shares are designated as preferred stock. Common stock authorized, issued and outstanding and additional paid-in capital as of December 31, 2014 and 2013 were as follows:

	Authorized	Outstanding
As of December 31, 2013	162,461,535	12,003,891
Issuance of common stock upon vesting of awards	—	644,710
Recapitalization:		
Cancellation of Atara shares	(923,076)	(923,076)
Tender of Nina, Pinta and Santa Maria shares	(161,538,459)	(11,725,525)
Issuance of Atara shares	17,948,717	1,302,835
Issuance of common stock upon vesting of awards - post Recapitalization	—	281,826
Issuance of common stock for research and development expenses related to technology licensing option	—	59,761
Issuance of common stock in initial public offering	482,051,283	5,750,000
Conversion of preferred stock in connection with initial public offering		12,298,515
As of December 31, 2014	500,000,000	19,692,937

	As of December 31, 2013									
	Nina		Pinta		Santa Maria		Atara		Combined Total	
	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value
					(dollars in thousands)					
Issued and outstanding:										
Common stock, par value	3,693,605	$ —	3,693,605	$ —	3,693,605	$ 1	923,076	$ —	12,003,891	$ 1
Additional paid-in capital	—	147	—	1,017	—	1,036	—	—	—	2,200
	3,693,605	$ 147	3,693,605	$ 1,017	3,693,605	$ 1,037	923,076	$ —	12,003,891	$ 2,201
Authorized	53,846,153		53,846,153		53,846,153		923,076		162,461,535	

We have reserved the following shares of common stock for issuance:

	December 31, 2014	December 31, 2013 (prior to Recapitalization)
Conversion of Series A convertible preferred stock	—	46,356,342
Conversion of Series A-1 convertible preferred stock	—	5,538,462
Conversion of Series B convertible preferred stock	—	43,528,737
Common stock available for grant of stock awards	1,814,196	17,021,923
Common stock issuable for options and RSUs outstanding and non-vested restricted stock	1,962,679	10,458,793
	3,776,875	122,904,257

Restricted Common Stock

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 $1,704,094 and 7,996,153 of the shares have 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. 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 $331,170. The combined grant date intrinsic value for this award was $98,500. The shares were issued under our 2012 Equity Incentive Plan (as discussed below) 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 restricted common stock was purchased with secured promissory notes totaling $331,170. During 2014, the outstanding balances were repaid.

The amounts paid for both restricted stock purchases were initially recorded as other long-term liabilities. As shares vest, we reclassify liabilities to equity and report shares as outstanding in the consolidated and combined statements of convertible preferred stock and stockholders' equity (deficit). Prior to the Recapitalization, 4,802,450 shares had vested and were classified as equity. On March 31, 2014, these shares were exchanged for 533,605 shares of Atara common stock. Restricted shares not vested at March 31, 2014 totaled 7,216,006 shares and these shares were exchanged for 801,778 shares of Atara restricted common stock. As of December 31, 2014, 815,437 of these restricted shares were vested and are classified as equity. Restricted shares not vested totaled 519,952 shares or $140,265 at December 31, 2014.

As both the Chief Executive Officer and the Atara employee were consultants of Nina, Pinta and Santa Maria through the Recapitalization date, we initially accounted for these awards as non-employee stock-based awards. Following the Recapitalization, these awards were accounted as employee awards based upon the fair market value of common stock on March 31, 2014. Stock-based compensation expense related to these awards is recorded using accelerated graded vesting model and was $5.2 million, $1.7 million and $292,180 for the years ended December 31, 2014, 2013 and for the period from August 22, 2012 (inception) to December 31, 2012.

The unrecognized stock-based compensation expense related to this unvested restricted stock is $1,015,622 at December 31, 2014 and this expense is expected to be recognized over the remaining service periods through 2016. The aggregate intrinsic value of unvested restricted stock is $13,768,444 at December 31, 2014.

Equity Incentive Plans

In March 2014, we adopted the 2014 Equity Incentive Plan (the "2014 plan") as part of our Recapitalization. In connection with the Recapitalization, Atara assumed the plans of Nina, Pinta and Santa Maria and all outstanding RSUs and restricted stock awards granted under such plans. At the date of Recapitalization, RSUs and restricted stock awards 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 plan and the amended plan became effective on October 15, 2014 upon the pricing of our initial public offering. The maximum number of shares of our common stock that may be issued pursuant to stock awards under the 2014 plan is 3,526,153 shares, including 1,294,041 shares that were previously available for issuance under the 2012 plans.

The number of shares of our common stock reserved for issuance pursuant to stock awards under our 2014 plan will automatically increase on January 1 of each year for a period of up to ten years, beginning on January 1, 2015 and ending on and including January 1, 2024, by 5% of the number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The number of shares of our common stock available for issuance under the 2014 plan is 1,814,196 at December 31, 2014.

Under the terms of the 2014 plan, we may grant options, restricted stock awards and RSUs to employees, directors, consultants and other service providers. Employees typically receive an award upon commencement of employment and non-employee members of our board of directors receive an award in connection with their appointment. Generally, if any shares subject to an award expire, or are forfeited, terminated or cancelled without the issuance of shares, the shares are added back into the total shares available for issuance under the 2014 plan.

RSUs typically expire at 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 initial public offering had a time-based service condition and a liquidity-based performance condition, and vest when both conditions are met. We determined that the liquidity-based performance condition was not probable of occurring and have recorded no stock-based compensation expense related to the RSUs prior to our initial public offering. Upon the closing of our initial public offering in October 2014, we recorded $3.8 million of stock-based compensation expense in our consolidated and combined statement of operations for the quarter ended December 31, 2014. The remaining unrecognized stock-based compensation expense relating to nonvested RSUs will be recognized as the RSUs vest over the remaining service periods through 2018. As of December 31, 2014, there was $2.7 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 2.9 years. The aggregate intrinsic value of the RSUs outstanding at December 31, 2014 was $21.9 million.

The following is a summary of RSU activity, including the restricted stock award discussed above, under our 2014 plan:

	Restricted Stock Awards		RSUs	
	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2013	1,663,700	$ 0.05	2,598,074	$ 0.19
Granted	—	-	5,375,742	$ 0.61
Vested	(144,951)	$ 0.05	—	—
Recapitalization	(1,349,999)		(7,087,857)	
Subtotal post-Recapitalization	168,750	$ 0.40	885,959	$ 4.23
Granted	—	—	13,692	$ 12.55
Forfeited	—	—	(80,860)	$ 7.84
Vested	(56,010)	$ 0.40	(199,488)	$ 2.24
Unvested at December, 2014	112,740	$ 0.40	619,303	$ 4.64

Stock Options

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

	Number of shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2013	—			
Granted (weighted-average grant date fair value of $7.37 per share)	625,859	$ 13.69		
Forfeited	(1,923)	$ 12.55		
Balance at December, 2014	623,936	$ 13.69	6.76	$ 8,387,861
Stock options vested and expected to vest at December 31, 2014	623,936	$ 13.69	6.76	$ 8,387,861
Exercisable at December 31, 2014	14,375	$ 11.00	6.79	$ 226,406

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on December 31, 2014 and the exercise price of outstanding, in-the-money options. As of December 31, 2014, there was $4.7 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 3.73 years. No options were exercised in 2014.

The fair value of each option issued was estimated at the date of grant using the Black-Scholes valuation model with the following weighted-average assumptions:

	Year Ended December 31, 2014	
	Employees	Non-Employees
Risk-free interest rate	1.58% - 1.74%	1.9% - 2.4%
Expected life of options in years	4.5	6.5 - 7.0
Expected volatility of underlying stock	65.7%	65.8%
Expected dividend yield	0.0%	0.0%

Stock-based Compensation Expense

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

	Year ended December 31,		
	2014	2013	2012
Research and development	$ 3,258	$ 251	$ —
General and administrative	6,843	1,462	292
	$ 10,101	$ 1,713	$ 292

Employee Stock Purchase Plan

Our board of directors adopted the Employee Stock Purchase Plan (the "ESPP") in May 2014 and the ESPP became effective on October 15, 2014 upon the pricing of our initial public offering. The ESPP is administered by our board of directors and the Compensation Committee of our board of directors. The ESPP provides for twelve-month offering periods, and each offering period will include purchase periods, which will be the approximately six-month period commencing with one exercise date and ending with the next exercise date. Employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the exercise date. The maximum number of shares of our common stock that may be issued under the ESPP is 230,769 shares; however, the number of shares of our common stock reserved for issuance under our ESPP will automatically increase each year for a period of up to ten years, beginning on January 1, 2015 and continuing through and ending on January 1, 2024, by the lesser of (i) 1% of the total number of shares of our capital stock outstanding on the December 31 of the preceding calendar year, (ii) 230,769 shares of our common stock, or (iii) a lower number as determined by our board of directors. No purchases of shares were made under the ESPP in 2014.

8. Income Taxes

For the years ended December 31, 2014 and 2013 and the period from August 22, 2012 (inception) to December 31, 2012, all of the loss before provision for income taxes was domestic. The Company recorded the following income tax provision:

	Year Ended December 31, 2014	Year Ended December 31, 2013	Period from August 22, 2012 (Inception) to December 31, 2012
		(in thousands)	
Current provision (benefit) for:			
Federal income taxes	$ (36)	$ 153	$ 14
State income taxes	11	17	3
Total current provision (benefit)	$ (25)	$ 170	$ 17

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 31, 2014 and 2013 and the period from August 22, 2012 (inception) to December 31, 2012 is as follows:

	Year Ended December 31, 2014	Year Ended December 31, 2013	Period from August 22, 2012 (Inception) To December 31, 2012
Federal income taxes at statutory rate	34.0%	34.0%	34.0%
Nondeductible stock compensation	(7.3%)	(6.8%)	(1.4%)
State income tax, net of federal benefit	(0.0%)	(0.3%)	(0.1%)
Other	0.1%	(0.1%)	—
Valuation allowance	(26.7%)	(28.8%)	(32.9%)
Effective tax rate	0.1%	(2.0%)	(0.4%)

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:

	December 31, 2014	December 31, 2013
	(in thousands)	
Deferred tax assets:		
Net operating losses	$ 8,220	$ 2,874
License fees	2,279	1,121
Stock-based compensation	1,964	—

	December 31, 2014	December 31, 2013
	(in thousands)	
Legal fees	757	343
Other	494	140
Total deferred tax assets	13,714	4,478
Valuation allowance	(13,714)	(4,478)
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, 2014 and 2013. 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 $9.2 million, $2.9 million, and $1.6 million for the years ended December 31, 2014 and 2013 and the period from August 22, 2012 (inception) to December 31, 2012, respectively.

We had federal and state net operating loss carryforwards of approximately $20.6 million at December 31, 2014 and $7.2 million at December 31, 2013. The federal and state net operating loss carryforwards begin to expire in 2032 in various amounts if not utilized.

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 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, 2014. 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 at December 31, 2013	$ —
Gross increases for tax positions related to the current year	1,014
Gross increases for tax positions related to prior years	629
Balance at December 31, 2014	$ 1,643

Of the $1.6 million total unrecognized tax benefits, none, 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 twelve 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, 2014. Based on that evaluation, and the remediation of the material weakness identified in our internal control over financial reporting as of December 31, 2013, as described below, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2014 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.

Management's Annual Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

Attestation Report of the 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."

Changes in Internal Control over Financial Reporting

Our management previously 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. We have concluded that this material weakness in our internal control over financial reporting was due to the fact that we did not yet have the appropriate resources with the appropriate level of experience and technical expertise to oversee our closing and financial reporting processes.

In order to remediate this material weakness, we have taken the following actions since December 31, 2013:

- we have hired a full-time controller and transitioned our Chief Financial Officer from a consulting role to a full-time chief financial officer role;
- we have hired and are continuing to actively seek additional accounting and finance staff members to augment our current staff and to improve the effectiveness of our closing and financial reporting processes; and
- we have formalized and implemented our accounting policies and internal controls and the related documentation and we have strengthened our financial statements review procedures and the supervisory reviews by our management that are performed during the financial close process and which support the accurate and timely preparation of consolidated financial statements that are fairly presented in accordance with US generally acceptable accounting principles.

These improvements to our internal control infrastructure were implemented in the second half of 2014, and were in place in connection with the preparation of our financial statements for the year ended December 31, 2014. As such, we believe that the remediation initiative outlined above was sufficient to remediate the material weakness in internal control over financial reporting as discussed above.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item is incorporated herein by reference to the sections titled “Executive Officers and Other Executive Management,” “Proposal No. 1—Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance” and “Section 16 (a) Beneficial Ownership Reporting Compliance” in our definitive proxy statement with respect to our 2015 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation

Information required by this Item is incorporated herein by reference to the section titled “Executive Compensation” and “Director Compensation” in our definitive proxy statement with respect to our 2015 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

Information required by this Item is incorporated herein by reference to the sections titled “Security Ownership of Certain Beneficial Owners and Management,” and “Equity Compensation Plan Information” in our definitive proxy statement with respect to our 2015 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

Information required by this Item is incorporated herein by reference to the sections titled “Transactions With Related Persons” and “Information Regarding the Board of Directors and Corporate Governance Independence of the Board of Directors” in our definitive proxy statement with respect to our 2015 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K

Item 14. Principal Accounting Fees and Services

Information required by this Item is incorporated herein by reference to the section titled "Proposal No. 2 — Ratification of Selection of Independent Registered Public Accounting Firm" in our definitive proxy statement with respect to our 2014 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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.

		Incorporated by Reference				Filed Herew
Exhibit Number	**Exhibit Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	333-196936	3.2	06/20/2014	
3.2	Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	S-1	333-196936	3.4	06/20/2014	
4.1	Form of Common Stock Certificate.	S-1/A	333-196936	4.1	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	333-196936	4.2	06/20/2014	
10.1+	2014 Equity Incentive Plan.	S-1/A	333-196936	10.1	07/10/2014	
10.2+	Forms of Option Agreement and Option Grant Notice under the 2014 Equity Incentive Plan.	S-1	333-196936	10.2	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	333-196936	10.3	06/20/2014	
10.4+	Nina Biotherapeutics, Inc. 2012 Equity Incentive Plan.	S-1	333-196936	10.4	06/20/2014	
10.5+	Pinta Biotherapeutics, Inc. 2012 Equity Incentive Plan.	S-1	333-196936	10.5	06/20/2014	
10.6+	Santa Maria Biotherapeutics, Inc. 2012 Equity Incentive Plan.	S-1	333-196936	10.6	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	333-196936	10.7	06/20/2014	
10.8+	2014 Employee Stock Purchase Plan.	S-1/A	333-196936	10.8	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	333-196936	10.9	06/20/2014	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herew
		Form	File No.	Exhibit	Filing Date	
10.10+	Amended and restated offer letter agreement between Atara Biotherapeutics, Inc. and Isaac E. Ciechanover, dated March 31, 2014.	S-1	333-196936	10.10	06/20/2014	
10.11+	Amended and restated offer letter agreement between Atara Biotherapeutics, Inc. and Christopher Haqq, dated March 31, 2014.	S-1	333-196936	10.11	06/20/2014	
10.12+	Amended and restated offer letter agreement between Atara Biotherapeutics, Inc. and John F. McGrath, Jr., dated March 31, 2014.	S-1	333-196936	10.12	06/20/2014	
10.13+	Amended and restated offer letter agreement between Atara Biotherapeutics, Inc. and Mitchall G. Clark, dated March 31, 2014.	S-1	333-196936	10.13	06/20/2014	
10.14+	Amended and restated offer letter agreement between Atara Biotherapeutics, Inc. and Gad Soffer, dated March 31, 2014.	S-1	333-196936	10.14	06/20/2014	
10.15 †	Exclusive License Agreement, by and between Amgen Inc. and Nina Biotherapeutics, Inc., dated as of September 7, 2012.	S-1/A	333-196936	10.15	07/10/2014	
10.16 †	Amendment No. 1 To Exclusive License Agreement, by and between Amgen Inc. and Nina Biotherapeutics, Inc., dated as of October 22, 2012.	S-1	333-196936	10.16	06/20/2014	
10.17 †	Amendment No. 2 To Exclusive License Agreement, by and between Amgen Inc. and Nina Biotherapeutics, Inc., dated as of September 7, 2012.	S-1	333-196936	10.17	06/20/2014	
10.18 †	Exclusive License Agreement, by and between Amgen Inc. and Pinta Biotherapeutics, Inc., dated as of September 7, 2012.	S-1/A	333-196936	10.18	07/10/2014	
10.19 †	Amendment No. 1 To Exclusive License Agreement, by and between Amgen Inc. and Pinta Biotherapeutics, Inc., dated as of October 22, 2012.	S-1	333-196936	10.19	06/20/2014	
10.20 †	Amendment No. 2 To Exclusive License Agreement, by and between Amgen Inc. and Pinta Biotherapeutics, Inc., dated as of June 28, 2013.	S-1	333-196936	10.20	06/20/2014	
10.21 †	Exclusive License Agreement, by and between Amgen Inc. and Santa Maria Biotherapeutics, Inc., dated as of September 7, 2012.	S-1/A	333-196936	10.21	07/10/2014	
10.22 †	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	333-196936	10.22	06/20/2014	
10.23 †	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	333-196936	10.23	06/20/2014	
10.24 †	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	333-196936	10.24	06/20/2014	
10.25	Office Lease, by and between Atara Biotherapeutics, Inc. and Freeway Properties III, dated as of August 12, 2013.	S-1	333-196936	10.25	06/20/2014	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herew
		Form	File No.	Exhibit	Filing Date	
10.26	Sublease, by and between Atara Biotherapeutics, Inc. and XDX, Inc., dated as of January 10, 2013.	S-1	333-196936	10.26	06/20/2014	
10.27	Consent to Sublease, by and among Atara Biotherapeutics, Inc., XDX, Inc. and BMR-Bayshore Boulevard LLC, dated as of January 14, 2013.	S-1	333-196936	10.27	06/20/2014	
10.28	Sublease Agreement, by and between Atara Biotherapeutics, Inc. and Accesia, Inc., dated as of September 11, 2014.	S-1/A	333-196936	10.28	09/26/2014	
21.1	List of subsidiaries					X
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 U.S.C Section 1350 as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002. .					X
101.INS	XBRL Instance Document.					X
101.SCH	XBRL 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 LinkbaseDocument.					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 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of 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 26th day of February, 2015.

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*)	February 26, 2015
/s/ John F. McGrath, Jr. John F. McGrath, Jr.	Chief Financial Officer (*principal financial and accounting officer*)	February 26, 2015
/s/ Matthew K. Fust Matthew K. Fust	Director	February 26, 2015
/s/ Carol Gallagher Carol Gallagher, Pharm.D.	Director	February 26, 2015
/s/ Joel S. Marcus Joel S. Marcus	Director	February 26, 2015
/s/ Beth Seidenberg Beth Seidenberg, M.D.	Director	February 26, 2015
/s/ Eckard Weber Eckard Weber, M.D.	Director	February 26, 2015

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herew
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	333-196936	3.4	06/20/2014	
3.2	Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	S-1	333-196936	3.4	06/20/2014	
4.1	Form of Common Stock Certificate.	S-1/A	333-196936	4.1	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	333-196936	4.2	06/20/2014	
10.1+	2014 Equity Incentive Plan.	S-1/A	333-196936	10.1	07/10/2014	
10.2+	Forms of Option Agreement and Option Grant Notice under the 2014 Equity Incentive Plan.	S-1	333-196936	10.2	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	333-196936	10.3	06/20/2014	
10.4+	Nina Biotherapeutics, Inc. 2012 Equity Incentive Plan.	S-1	333-196936	10.4	06/20/2014	
10.5+	Pinta Biotherapeutics, Inc. 2012 Equity Incentive Plan.	S-1	333-196936	10.5	06/20/2014	
10.6+	Santa Maria Biotherapeutics, Inc. 2012 Equity Incentive Plan.	S-1	333-196936	10.6	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	333-196936	10.7	06/20/2014	
10.8+	2014 Employee Stock Purchase Plan.	S-1/A	333-196936	10.8	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	333-196936	10.9	06/20/2014	
10.10+	Amended and restated offer letter agreement between Atara Biotherapeutics, Inc. and Isaac E. Ciechanover, dated March 31, 2014.	S-1	333-196936	10.10	06/20/2014	
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\+ 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 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-199508 on Form S-8 of our report dated February 26, 2015, relating to the consolidated and combined financial statements of Atara Biotherapeutics, Inc. and its subsidiaries (collectively, the "Company") which report expresses an unqualified opinion appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2014.

/s/ DELOITTE & TOUCHE LLP

San Jose, California

February 26, 2015

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER

PURSUANT TO

SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, John McGrath, certify that:

1. I have reviewed this Annual Report on Form 10-K of Atara Biotherapeutics, Inc.;

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

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

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

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: February 26, 2015

/s/ John McGrath
John McGrath
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER

PURSUANT TO

SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Isaac Ciechanover, certify that:

1. I have reviewed this Annual Report on Form 10-K of Atara Biotherapeutics, Inc.;

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

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

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

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: February 26, 2015

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

Exhibit 32.1

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

In connection with the Annual Report of Atara Biotherapeutics, Inc. (the "Company") on Form 10-K for the year ended December 30, 2014, as filed with the Securities and Exchange Commission (the "Report"), Isaac Ciechanover, Chief Executive Officer of the Company, and John McGrath, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: February 26, 2015

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

/s/ John McGrath
John McGrath
Chief Financial Officer
(Principal Financial and Accounting Officer)