

Atara Biotherapeutics, Inc.
Form S-1
June 29, 2015
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As filed with the Securities and Exchange Commission on June 29, 2015.

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ATARA BIOTHERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)
701 Gateway Blvd., Suite 200

46-0920988
(I.R.S. Employer
Identification Number)

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South San Francisco, California 94080

(650) 278-8930

(Address, including zip code and telephone number, of Registrant's principal executive offices)

Isaac E. Ciechanover, M.D.

Chief Executive Officer

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. "

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	..	Accelerated filer	..
Non-accelerated filer	p (Do not check if a smaller reporting company)	Smaller reporting company	..

CALCULATION OF REGISTRATION FEE

Title of securities to be registered	Proposed maximum	Amount of
	aggregate offering price ⁽¹⁾⁽²⁾	registration fee
Common Stock, par value \$0.0001 per share	\$143,750,000	\$16,704

- (1) Includes the offering price of any additional shares that the underwriters have the option to purchase from the Registrant.
- (2) Estimated solely for the purpose of computing the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion. Dated June 29, 2015.

\$125,000,000

Common Stock

We are offering \$125,000,000 of shares of our common stock or, assuming a public offering price of \$52.62 per share, the last reported sale price of our common stock on The Nasdaq Global Select Market on June 26, 2015, 2,375,522 shares of our common stock. Our common stock is listed on The Nasdaq Global Select Market under the symbol ATRA.

We are an emerging growth company under applicable Securities and Exchange Commission rules and are subject to reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 12 to read about factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Proceeds to us, before expenses	\$	\$

(1) We refer you to Underwriting beginning on page 132 for additional information regarding total underwriting compensation. We have granted the underwriters an option to purchase up to an additional \$18,750,000 of shares of common stock at the public offering price, less underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on _____, 2015.

Goldman, Sachs & Co.

Citigroup

Canaccord Genuity

JMP Securities

SunTrust Robinson Humphrey

Prospectus dated _____, 2015

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We have not authorized anyone to provide you with any information or to make any representation, other than those contained or incorporated by reference in this prospectus or in any free writing prospectus we have prepared. We take no responsibility for, and provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only in circumstances and in jurisdictions where it is lawful to do so. The information contained or incorporated by reference in this prospectus is accurate only as of its date, regardless of the time of delivery of this prospectus or of any sale of our common stock.

Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourself about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

Atara, Atara Biotherapeutics, the Atara logo and other trade names, trademarks or service marks of Atara appearing in this prospectus are the property of Atara. Trade names, trademarks and service marks of other companies appearing in this prospectus are the property of their respective holders.

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PROSPECTUS SUMMARY

*This summary highlights information contained or incorporated by reference in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should read the entire prospectus carefully, including the section titled **Risk Factors** and the information in our filings with the Securities and Exchange Commission, or SEC, incorporated by reference in this prospectus. Unless the context suggests otherwise, references in this prospectus to Atara, Atara Biotherapeutics, we, us and our refer to Atara Biotherapeutics, Inc. and, where appropriate, its subsidiaries.*

Atara Biotherapeutics, Inc.

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, oncology and viral-associated diseases. We have two groups of product candidates: molecularly targeted biologics and allogeneic, or third-party derived, antigen-specific T-cells, a type of white blood cell. Our molecularly targeted product candidates are biologics that inhibit myostatin and activin, members of the Transforming Growth Factor-Beta, or TGF- β , protein superfamily, which play roles in the growth and maintenance of muscle and many other body tissues. Our lead molecularly targeted product candidate, PINTA 745, is in a Phase 2 clinical trial for protein energy wasting, a condition affecting many end-stage renal disease patients. Our second molecularly targeted 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 molecularly targeted product candidates that modulate the TGF- β pathway in preclinical development. Our T-cell product candidates arise from a platform technology designed to produce off-the-shelf, partially human leukocyte antigen matched cellular therapeutics. We licensed these product candidates from Memorial Sloan Kettering Cancer Center, or MSK, in June 2015. Our initial T-cell product candidates target viral- or cancer-specific antigens and are designed to harness the body's immune system to counteract specific viral infections and cancers. Our most advanced T-cell product candidate, EBV-CTL, is in Phase 2 clinical trials for malignancies associated with Epstein-Barr Virus, including EBV-associated lymphoproliferative diseases, or EBV-LPD. EBV-LPD is a cancer affecting some patients who have received an allogeneic hematopoietic cell transplant, or HCT, or a solid organ transplant, or SOT, or are otherwise immunocompromised. In February 2015, the US Food and Drug Administration, or the FDA, granted Breakthrough Therapy designation for EBV-CTL in the treatment of rituximab-refractory EBV-LPD after HCT, commonly known as bone marrow transplant. Our second T-cell product candidate, CMV-CTL, is in Phase 2 clinical trials for cytomegalovirus, or CMV, an infection that occurs in some patients who have received an HCT, SOT, or are otherwise immunocompromised. Our third T-cell product candidate, WT1-CTL, targets cancers expressing the antigen Wilms Tumor 1 and is currently in Phase 1 clinical studies.

Our Novel Approach to Treat Protein Energy Wasting in ESRD Patients: PINTA 745

Our lead molecularly targeted 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 end-stage renal disease, or ESRD, who are also suffering from protein-energy wasting, or PEW, a condition characterized by muscle wasting, inflammation and malnutrition.

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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 the patients in DaVita's dialysis population met the conditions for PEW and, in comparison to the rest of the group, exhibited worse morbidity and mortality. 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.

There is currently no approved therapy for patients suffering from PEW. We believe PINTA 745 is the only 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, or 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. Our ongoing US-based Phase 2 trial is a 48-patient, randomized, double-blind, placebo-controlled trial that, in addition to providing us with assessments of change in muscle mass and muscle strength, will give us insight into potential additional markets for PINTA 745. These could include: orthopedic indications; inflammation and inflammatory diseases; age-related sarcopenia, or loss of muscle; and cancer cachexia, a syndrome of progressive weight loss. 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 better outcomes. As of June 30, 2015, we had enrolled 12 of the planned 48 patients, and we expect to release preliminary top-line data from this Phase 2 clinical trial in the fourth quarter of 2015.

Our Novel Approach to Treat Ovarian Cancer: STM 434

Our second molecularly targeted product candidate, STM 434, is in a Phase 1 clinical study that will enroll approximately 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, or 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 are testing 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

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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 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. 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 molecularly targeted biologic programs, at Amgen Inc., or 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, or INDs, with the FDA for these candidates. For example, we are conducting IND-enabling manufacturing and preclinical studies for ATA 842, a humanized antibody targeting myostatin.

T-Cell Therapy for Cancer and Viral-Associated Diseases: MSK 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. In June 2015, we exclusively licensed from MSK worldwide rights to three clinical stage T-cell product candidates. We also have an exclusive option to exclusively license from MSK worldwide rights to certain other T-cell programs that are discovered or developed by MSK pursuant to sponsored research funded by us.

Our most advanced T-cell product candidate, EBV-CTL, is in Phase 2 clinical trials for the treatment of EBV-associated malignancies. EBV is the virus that causes mononucleosis and is associated with a number of more severe diseases, including certain malignancies and neurologic conditions, such as multiple sclerosis. EBV-CTL received Breakthrough Therapy designation from the FDA in February 2015 for the treatment of patients with rituximab-refractory EBV-LPD after HCT, based on data from two separate clinical trials conducted by MSK. We recently met with the FDA to discuss late-stage development to support a potential approval in this indication. Based on guidance from the FDA, we intend to conduct a pivotal study in rituximab-refractory EBV-LPD after HCT and expect to submit a special protocol assessment for this pivotal study. In addition, we had preliminary discussions with the FDA regarding late-stage development in the setting of rituximab-refractory EBV-LPD after SOT, and we will be incorporating this feedback into our subsequent development plans in this indication.

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

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Our third clinical stage T-cell product candidate, WT1-CTL, targets Wilms Tumor 1, or WT1. Abnormal expression of WT1 is seen in a variety of hematologic and solid tumors, including multiple myeloma, acute myeloid leukemia and ovarian cancer. This product candidate is currently in Phase 1 clinical trials sponsored and conducted by MSK.

Clinical experience with our T-cell product candidates is broad, including in immunocompromised states, as well as in solid and hematologic malignancies. Selected data from clinical studies of our three T-cell product candidates are summarized in the table below.

T-Cell Program	Stage	Indication	Recent Clinical Data Highlights	Number of Patients Who Received Prior Therapy	Historical Outcomes Data
EBV-CTL	Phase 2 clinical trials	EBV lymphoma (EBV-LPD) following allogeneic hematopoietic cell transplantation (HCT) from bone marrow or cord blood	62% response rate in 26 patients treated with EBV-CTL derived from primary HCT donors with 16 complete responses (CR) and zero partial responses (PR) 65% response rate in 34 patients treated with EBV-CTL derived from third-party donor, with 19 CR and three PRs; one-year overall survival (OS) range 56.3-71.8%;	13 of 26 received prior rituximab All received prior rituximab	Historical median survival in rituximab refractory patients is 16-56 days
		EBV-LPD following solid organ transplantation (SOT)	two-year OS range 46.9-63.8% 62% response rate in 13 patients treated with third-party derived EBV-CTL with one CR, seven PRs;	All received prior rituximab; 11 of 13 had received prior chemotherapy; 12 of 13 patients had high risk disease	Historical data show 33% OS at two years in patients with incomplete response to rituximab
CMV-CTL	Phase 2 clinical trials	Post-HCT antiviral drug resistant CMV viremia (high viral count) and symptomatic CMV disease	two-year OS of 57.7% 64% response rate in 25 CMV viremia patients treated with third-party derived CMV-CTL, with nine CRs and seven PRs;	All received prior antiviral therapy; median of four prior therapies including experimental therapies	Uncontrolled CMV disease leads to high rates of morbidity and mortality (for example, CMV pneumonitis confers a four-fold higher risk of death)
		Various cancers, including acute myeloid leukemia (AML), multiple myeloma	67% response rate in nine CMV disease patients, with five CRs and one PR Data not yet available		
WT1-CTL	Phase 1 clinical studies			Not Applicable	Not Applicable

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We are focusing our initial development and regulatory activities on EBV-CTL in the post-HCT and post-SOT setting and CMV-CTL in the post-HCT setting, rare conditions which we believe offer a rapid path to marketing approvals, if supported by additional clinical data. However, we intend to explore the clinical utility of our T-cell product candidates in other more prevalent disease states.

We anticipate that our T-cell technology platform will have utility beyond the current set of targets to which it has been directed. We and MSK have agreed to collaborate on further research to develop additional cellular therapies, which may include T-cell programs targeted against other antigens and chimeric antigen receptor, or CAR-T cell programs, and which we have an option to license. For example, we may develop cellular therapies with MSK or others directed towards other viral targets such as human papilloma virus, or HPV, which is associated with cervical cancer, anal cancer, and head and neck cancer, and John Cunningham virus, which causes progressive multifocal leukoencephalopathy and is associated with a subset of solid tumors. We also intend to license or acquire additional product candidates or technologies to enhance our existing T-cell technology platform.

Our Management Team

We believe our management team has the breadth and depth of experience to execute our business model. Our management team includes:

Isaac E. Ciechanover, M.D., our President and Chief Executive Officer, was Executive Director for Business Development at Celgene Corporation, or Celgene. At Celgene, he led the company's venture capital efforts and led licensing and acquisition activities with an aggregate transaction value of more than \$6.7 billion. 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, Inc., or 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 served as an attending oncology physician and director of a translational laboratory at the University of California, San Francisco.

Mitchell G. Clark, our Chief Regulatory and Quality Officer, was previously Senior Vice President of Global Regulatory Affairs at Abraxis Bioscience, Inc., or Abraxis, where he submitted and managed five INDs for oncology and cardiovascular drugs including Abraxane.

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.

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Our Strategy

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

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, oncology and viral-associated diseases. Key components of our strategy to achieve this objective include:

rapidly advance PINTA 745 in clinical development, initially for PEW;

obtain clinical proof of concept for STM 434, initially for ovarian cancer and other solid tumors;

evaluate our other molecularly targeted product candidates and advance them into the clinic as appropriate;

rapidly advance EBV-CTL in clinical development for the treatment of EBV-LPD after HCT or SOT;

develop CMV-CTL based on existing clinical proof of concept data in refractory CMV infection after HCT;

continue development of WT1-CTL and collaborate with MSK in the discovery and development of additional T-cell programs; and

leverage our relationships and experience to in-license or acquire additional product candidates for development.

Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled **Risk Factors** immediately following this prospectus summary. Some of these risks are:

we have a limited operating history on which to assess our business, have generated no revenues, have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future;

we expect that we will need to raise additional financing to achieve our product candidate development, regulatory approval and commercialization goals;

we are very early in our product candidate development efforts and are heavily dependent on the regulatory approval and successful commercialization of our product candidates;

our T-cell product candidates represent new therapeutic approaches that present significant challenges;

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we rely on third parties to conduct our preclinical studies and clinical trials;

we have no experience manufacturing our product candidates on a large clinical or commercial scale and are dependent on third parties to conduct such manufacturing;

our commercial success depends on attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of dialysis and cancer centers;

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if we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, we may not be able to compete effectively; and

our future success depends in part upon our ability to retain members of our executive management team and to attract, retain and motivate other qualified personnel.

Corporate Information

We were incorporated in August 2012 in Delaware. Our principal executive offices are located at 701 Gateway Blvd., Suite 200, South San Francisco, California 94080 and our telephone number is (650) 278-8930. Our website address is www.atarabio.com. Information contained on or accessible through our website is not a part of this prospectus and should not be relied upon in determining whether to make an investment decision.

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, and therefore we may take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or 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 any golden parachute payments. We may take advantage of these exemptions until we are no longer an emerging growth company. We will remain an emerging growth company 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 nonconvertible debt securities; and (4) the date on which we are deemed to be a large accelerated filer as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We have chosen to irrevocably opt out of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards.

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The Offering

Common stock offered by Atara \$125,000,000 of shares

Option to purchase additional shares of common stock \$18,750,000 of shares

Common stock to be outstanding after this offering shares, assuming a public offering price of \$52.62 per share, the last reported sale price of our common stock on The Nasdaq Global Select Market on June 26, 2015.

Use of proceeds We estimate that our net proceeds from this offering will be approximately \$ million, or approximately \$ million if the underwriters' option to purchase additional shares of our common stock is exercised in full, after deducting underwriting discounts and commissions and estimated offering expenses.

We intend to use the net proceeds from this offering, along with our other capital resources, primarily (1) to complete our planned confirmatory Phase 2 clinical trial of PINTA 745, (2) to continue our initial Phase 1 clinical study of STM 434, (3) to continue the ongoing and planned studies and trials with our T-cell product candidates and (4) to continue to expand and advance our clinical and preclinical pipeline for working capital and for other general corporate purposes and to potentially acquire or license other product candidates, businesses or technologies, although we have no present commitments for any such acquisitions or licenses. See Use of Proceeds for additional information.

Risk factors See Risk Factors beginning on page 12 and the other information included in, or incorporated by reference into, this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.

Nasdaq Global Select Market symbol ATRA

The number of shares of common stock to be outstanding after this offering is based on 24,360,247 shares of our common stock outstanding as of March 31, 2015, and excludes the following:

906,391 shares of common stock issuable upon settlement of restricted stock units, or RSUs, outstanding as of March 31, 2015;

1,314,635 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2015 with a weighted average exercise price of \$19.61 per share;

2,046,541 shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan, or 2014 Plan as of March 31, 2015;

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432,898 shares of common stock reserved for issuance under our 2014 Employee Stock Purchase Plan, or our ESPP, as of March 31, 2015; and

any future automatic increases in the number of shares of common stock reserved for issuance under our 2014 Plan or ESPP.

In addition, unless we specifically state otherwise, all information in this prospectus assumes no exercise of the underwriters' option to purchase up to an additional \$18,750,000 of shares of common stock from us.

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The following tables summarize our consolidated and combined financial data. You should read this summary consolidated and combined financial data together with the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K and our Quarterly Report on Form 10-Q, our consolidated and combined financial statements and related notes, each of which is incorporated by reference in this prospectus.

We have derived the summary combined statement of operations data for the years ended December 31, 2013 and 2014 from our audited consolidated and combined financial statements. We have derived the summary consolidated and combined statements of operations data for the three months ended March 31, 2014 and 2015 and our consolidated balance sheet data as of March 31, 2015 from our unaudited interim consolidated and combined financial statements. The unaudited interim consolidated and combined financial statements have been prepared on the same basis as the audited consolidated and combined financial statements and reflect, in the opinion of management, all adjustments of a normal, recurring nature that are necessary for a fair presentation of the unaudited interim consolidated and combined financial statements. Our historical results are not necessarily indicative of the results that should be expected in the future, and our interim results are not necessarily indicative of the results that should be expected for the full year or any other period.

	Year ended December 31, 20132014		Three months ended March 31, 20142015	
	(In thousands, except per share information)			
Consolidated and Combined Statements of Income Data				
Operating Expenses:				
Research and development	\$ 4,306	\$ 14,380	\$ 2,981	\$ 5,767
Research and development costs paid to Amgen	553	1,066		
General and administrative	3,756	12,710	4,096	3,544
Total operating expenses	8,615	28,156	7,077	9,311
Loss from operations	(8,615)	(28,156)	(7,077)	(9,311)
Interest and other income	12	125	6	153
Loss before provision for income taxes	(8,603)	(28,031)	(7,071)	(9,158)
Provision (benefit) for income taxes	170	(25)	(22)	2
Net loss	\$ (8,773)	\$ (28,006)	\$ (7,049)	\$ (9,160)
Comprehensive loss	\$ (8,773)	\$ (28,106)	\$ (7,060)	\$ (9,078)
Basic and diluted net loss per common share ⁽¹⁾	\$ (9.08)	\$ (5.62)	\$ (5.58)	\$ (0.42)

(1) Periods presented prior to our October 2014 initial public offering do not give effect to the automatic conversion of our preferred stock into common stock upon the closing of our initial public offering.

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	As of March 31, 2015	
	Actual	As Adjusted ⁽¹⁾
(In thousands)		
<i>Consolidated and Combined Balance Sheet Data</i>		
Cash, cash equivalents and investments	\$ 166,696	\$
Working capital	\$ 166,177	\$
Total assets	\$ 169,817	\$
Total stockholders' equity	\$ 166,094	\$

- (1) The as adjusted column reflects the sale of _____ shares of our common stock in this offering, at the assumed public offering price of \$ _____ per share, the last reported sale price of our common stock on The Nasdaq Global Select Market on _____, 2015, after deducting underwriting discounts and commissions and estimated offering expenses. The as adjusted column does not reflect our \$4.5 million obligation to MSK, incurred in June 2015 in connection with the exercise of our option to license certain T-cell product candidates from MSK.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and all of the other information included and incorporated by reference in this prospectus before investing in our common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. If any of the following risks materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Financial Results and Capital Needs

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

We are a clinical-stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from product sales to date, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. For the year ended December 31, 2014 and the three months ended March 31, 2015, we reported a net loss of \$28.0 million and \$9.2 million, respectively, and we had an accumulated deficit of \$50.0 million at March 31, 2015.

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

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

Our company was formed in August 2012. Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights and conducting product development activities for our product candidates. We have not yet demonstrated our ability to successfully complete any Phase 2 or Phase 3 clinical trials, obtain regulatory approval, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization for any of our product candidates. In addition, the adoptive immunotherapy technology underlying our T-cell product candidates, EBV-CTL,

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CMV-CTL and WT1-CTL, is new and largely unproven. Any predictions about our future success, performance or viability, particularly in view of the rapidly evolving cancer immunotherapy field, may not be as accurate as they could be if we had a longer operating history or approved products on the market.

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

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

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

successfully complete development activities, including the necessary clinical trials;

complete and submit biologics license applications, or 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;

develop manufacturing and distribution processes for our novel T-cell product candidates;

obtain commercial quantities of our products at acceptable cost levels;

achieve market acceptance of our products, if any;

attract, hire and retain qualified personnel;

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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.

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

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

We expect to expend substantial resources for the foreseeable future continuing the clinical development and manufacturing of PINTA 745, STM 434, EBV-CTL, CMV-CTL and WT1-CTL and the advancement and expansion of our preclinical research pipeline, including ATA 842. These expenditures will include costs associated with research and development, potentially acquiring new product candidates or technologies, conducting preclinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. Under the terms of our license agreements with Amgen and MSK, we are obligated to make an upfront payment to MSK of \$4.5 million and additional milestone payments of up to \$86.0 million to Amgen and up to \$33.0 million to MSK with respect to the three licensed clinical stage T-cell programs upon the achievement of certain development, regulatory approval or commercial milestones. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our 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;

- 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.

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Based on our current operating plan, we believe that our existing cash and cash equivalents and short-term investments, together with the net proceeds from this offering, will be sufficient to fund our projected operating requirements through the second half of 2018. As of March 31, 2015, we had cash and cash equivalents and short-term investments of \$166.7 million. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We do not have any committed external source of funds. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

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

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

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

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, or NOL, 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, or the Code, if over a rolling three-year period, the cumulative change in our ownership exceeds 50% (as determined under applicable Treasury regulations), our ability to utilize our US NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset future taxable income or taxes may be limited. We 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, including potential changes in connection with this offering. 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.

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Risks Related to the Development of Our Product Candidates

We are very early in our development efforts and have only five 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. We have five product candidates, PINTA 745, STM 434, EBV-CTL, CMV-CTL and WT1-CTL, in clinical development. All of our other product candidates are currently in preclinical development. We have invested substantially all of our efforts and financial resources in identifying and developing potential product candidates and conducting preclinical studies, clinical trials and manufacturing activities. Our ability to generate revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

completion of preclinical studies and clinical trials with positive results;

receipt of regulatory approvals from applicable authorities;

obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;

making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;

develop manufacturing and distribution processes for our novel T-cell product candidates;

manufacturing products at an acceptable cost;

launching commercial sales of our product candidates, if 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

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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 product candidates.

We do not have any products that have gained regulatory approval. Currently, our only clinical-stage product candidates are PINTA 745, EBV-CTL and CMV-CTL, which are in Phase 2 clinical trials, and STM 434 and WT1-CTL, which are in Phase 1 clinical studies. 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;

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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.

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

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

obtaining regulatory approval from the FDA and other regulatory authorities, which have very limited experience with the commercial development of T-cell therapies;

developing and deploying consistent and reliable processes for procuring blood from consenting third-party donors, isolating T-cells from the blood of such donors, activating the isolated T-cells against a specific antigen, characterizing and storing the resulting activated T-cells for future therapeutic use, selecting and delivering an appropriate partially HLA matched cell line from among the available T-cell lines, and finally infusing these activated T-cells into patients;

utilizing these product candidates in combination with other therapies, which may increase the risk of adverse side effects;

educating medical personnel regarding the potential side effect profile of each of our product candidates;

developing processes for the safe administration of these products, including long-term follow-up for all patients who receive these product candidates;

sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process these product candidates;

developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;

establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities; and

developing therapies for types of diseases beyond those initially addressed by our current product candidates.

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

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

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The results of preclinical testing or earlier clinical studies are not necessarily predictive of future results. Our existing product candidates in clinical studies or trials, 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 studies or trials. Despite the results reported in earlier preclinical studies or clinical studies or 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, STM 434, EBV-CTL, CMV-CTL or WT1-CTL or any of our other product candidates in any particular jurisdiction. For example, our EBV-CTL, CMV-CTL and WT1-CTL product candidates have only been evaluated in single-center studies under investigator-sponsored INDs held by MSK, and the findings may not be reproducible in multi-center studies conducted under commercially-sponsored INDs. In addition, the Phase 2 clinical trials with EBV-CTL enrolled a heterogeneous group of patients with a variety of EBV-associated malignancies, including but not limited to EBV-LPD after HCT and EBV-LPD after SOT. These Phase 2 studies were not prospectively designed to evaluate the efficacy of EBV-CTL in the treatment of a single disease state for which we may later seek approval. Efficacy data from prospectively designed studies may differ significantly from those obtained from retrospective subgroup analyses. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials.

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and clinical 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 study or trial design that we are able to execute;

delay or failure in obtaining authorization to commence a study or trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a study or trial;

delay or failure in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study or trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study or trial sites;

delay or failure in obtaining institutional review board, or IRB, approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical study or trial at each site;

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withdrawal of clinical study or trial sites from our clinical studies or trials or the ineligibility of a site to participate in our clinical studies or trials;

delay or failure in recruiting and enrolling suitable subjects to participate in a study or trial;

delay or failure in subjects completing a study or trial or returning for post-treatment follow-up;

clinical sites and investigators deviating from trial protocol, failing to conduct the study or trial in accordance with regulatory requirements, or dropping out of a study or trial;

inability to identify and maintain a sufficient number of study or trial sites, many of which may already be engaged in other clinical study or trial programs, including some that may be for the same indication;

failure of our third-party clinical study or trial managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data;

delay or failure in adding new study or 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 a study or 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 studies or 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 studies or trials;

lack of adequate funding to continue a study or trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or

changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical study or trial.

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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 study or trial, the design of the clinical study or trial, ability to obtain and maintain patient consents, risk that enrolled subjects will drop out before completion, competing clinical studies or trials and clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. We may not be able to initiate or continue to support clinical trials of PINTA 745, EBV-CTL or CMV-CTL or clinical studies for STM 434 or WT1-CTL 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 or trials could become too expensive to

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complete. We rely on CROs, other vendors and clinical study or trial sites to ensure the proper and timely conduct of our clinical studies and 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 study or trial of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical studies or 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 studies or trials for the product candidates we have licensed from Amgen or MSK may also decrease the period of commercial exclusivity under our corresponding product candidate license from Amgen or MSK. In addition, many of the factors that could cause a delay in the commencement or completion of clinical studies or 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.

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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. In addition, we may seek orphan drug status for EBV-CTL in rituximab refractory EBV-LPD after HCT, for EBV-CTL in EBV-LPD after SOT, for CMV-CTL in refractory CMV infection after HCT and for WT1-CTL in AML and multiple myeloma.

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 European Medicines Agency, or 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.

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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 contract manufacturing organizations, or 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 fetal or embryonic 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 current good manufacturing practices, or cGMP, current Good Clinical Practices, or GCP, good tissue practices, or GTPs, 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.

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Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of the Department of Health and Human Services, or HHS, state attorneys general, members of Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities. 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 and MSK. We are in the process of planning for 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 and MSK. Our CMOs will need to conduct significant development work to prepare each of our product candidates for studies, trials and commercial readiness.

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

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