

MACROGENICS INC  
Form 10-K  
March 20, 2014  
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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, 2013**

**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 001-36112**

**MACROGENICS, INC.**

**(Exact name of registrant)**

**Delaware**  
**(State of organization)**

**06-1591613**  
**(I.R.S. Employer**

**Identification Number)**

**9640 Medical Center Drive, Rockville, Maryland 20850**

**(Address of principal executive offices and zip code)**

**(301) 251-5172**

**(Registrant's telephone number)**

**Securities registered pursuant to Section 12(b) of the Act:**

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
<b>Common stock, par value \$0.01 per share</b>	<b>The NASDAQ Stock Market LLC</b>
<b>Securities registered pursuant to Section 12(g) of the Act: None</b>	

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 Exchange 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 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 is not contained herein and will not be contained, to the best of the 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 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  Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the common stock held by non-affiliates of the registrant, as of February 28, 2014, was approximately \$698,022,185. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the NASDAQ Global Select Market on February 28, 2014. For purposes of making this calculation only, the registrant has defined affiliates as including only directors and executive officers and shareholders holding greater than 10% of the common stock of the registrant as of February 28, 2014. The registrant used February 28, 2014 as the measurement date because its common stock was not publicly traded as of the last business day of its most recently completed second fiscal quarter.

The number of shares of the registrant's common stock outstanding on February 28, 2014 was 27,471,329.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of MacroGenics, Inc.'s definitive proxy statement for the 2014 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report.

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**ANNUAL REPORT ON FORM 10-K**

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**FORWARD-LOOKING STATEMENTS**

This report includes forward-looking statements within the meaning of federal securities laws. Forward-looking statements include statements that may relate to our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, financing needs and other information that is not historical information. Many of these statements appear, in particular, under the headings *Risk Factors* and *Management's Discussion and Analysis of Financial Condition and Results of Operations*. Forward-looking statements can often be identified by the use of terminology such as *subject to*, *believe*, *anticipate*, *plan*, *expect*, *intend*, *estimate*, *project*, *may*, *will*, *could*, *can*, the negatives thereof, variations thereon and similar expressions, or by discussions of strategy.

All forward-looking statements, including, without limitation, our examination of historical operating trends, are based upon our current expectations and various assumptions. We believe there is a reasonable basis for our expectations and beliefs, but they are inherently uncertain. We may not realize our expectations, and our beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements. The following uncertainties and factors, among others (including those set forth under *Risk Factors*), could affect future performance and cause actual results to differ materially from those matters expressed in or implied by forward-looking statements:

our plans to develop and commercialize our product candidates;

our ongoing and planned clinical trials;

the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;

our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

our ability to identify additional products or product candidates with significant commercial potential that are consistent with our commercial objectives;

the rate and degree of market acceptance and clinical utility of our products;

our commercialization, marketing and manufacturing capabilities and strategy;

significant competition in our industry;

costs of litigation and the failure to successfully defend lawsuits and other claims against us;

economic, political and other risks associated with our international operations;

our ability to receive research funding and achieve anticipated milestones under our collaborations;

our intellectual property position;

costs of compliance and our failure to comply with new and existing governmental regulations including, but not limited to, tax regulations;

loss or retirement of key members of management;

costs of compliance and our failure to comply with new and existing governmental regulations including, but not limited to, tax regulations;

failure to successfully execute our growth strategy, including any delays in our planned future growth; and

our failure to maintain effective internal controls.

Consequently, forward-looking statements should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. We do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.

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**PART I**

**ITEM 1. BUSINESS**

*Except as otherwise indicated herein or as the context otherwise requires, references in this annual report on Form 10-K to MacroGenics, the company, we, us and our refer to MacroGenics, Inc. and its consolidated subsidiaries. DART<sup>®</sup>, the phrase Breakthrough Biologics, Life-Changing Medicines and the MacroGenics logo are our registered trademarks. The other trademarks, trade names and service marks appearing in this report are the property of their respective owners.*

**Overview**

We are a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer and autoimmune diseases. We generate our pipeline of product candidates from our proprietary suite of next-generation antibody technology platforms, which we believe improve the performance of monoclonal antibodies and antibody-derived molecules. These product candidates, which we have identified through our understanding of disease biology and immune-mediated mechanisms, may address disease-specific challenges which are not currently being met by existing therapies. Some of these product candidates include therapeutics in the emerging field of immune oncology and are designed to promote tumor destruction by either enhancing or restoring the body's immune system to destroy cancers. We create both differentiated molecules that are directed to novel cancer targets, as well as bio-betters, which are drugs designed to improve upon marketed medicines. The combination of our technology platforms and antibody engineering expertise has allowed us to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. These collaborations provide us with funding and allow us to leverage the additional expertise of these collaborators to advance the development of our product candidates.

We have three versatile, proprietary technology platforms consisting of: (1) our Dual Affinity Re-Targeting ( DART ) platform, which enables the targeting of multiple antigens or cells by using a single molecule with an antibody-like structure, and also includes the ability to recruit any T cell in a patient's body to destroy targeted cancer cells; (2) our Fc Optimization platform, which enhances the body's immune system to mediate the killing of cancer cells through a mechanism called antibody-dependent cellular cytotoxicity ( ADCC ) in which antibodies and immune cells cooperate to destroy targets such as tumor cells; and (3) our Cancer Stem-like Cell ( CSLC ) platform, which provides a unique discovery tool to identify cancer targets shared both by tumor-initiating cells and the differentiated cancer cells derived from them. These versatile technology platforms can be applied in combination with one another to custom-design an antibody or antibody-derived molecule that is optimized to treat a specific disease.

Antibodies, which are proteins produced by specialized cells of the body's immune system usually in response to foreign substances, such as bacteria and viruses, or to cancer cells, serve as the primary resource for our product candidates. Many of our cancer product candidates are derived from our library of over 2,000 purified antibodies. Our antibodies are targeted to more than 70 different antigens, or components of the foreign substance that induce the production of antibodies, expressed on the surface of cancer cells. In addition, we continue to generate new antibodies for our library using our proprietary CSLC lines and soluble protein antigens.

We initially select a specific antibody based on its functional properties related to a disease target as well as its distribution on tissues in the body. We then utilize one or more of our technology platforms for engineering and optimizing our product candidate. We believe our approach allows us to take advantage of the enhanced properties of an engineered antibody or antibody-derived molecule to kill cancer cells and to interfere with autoimmune diseases

more effectively than a wild type, or non-engineered, monoclonal antibody. Our methods for improving the effectiveness of antibodies include the following: enhancing the body's immune system, targeting multiple antigens on the surface of the same target cell, increasing the strength of the binding of an antibody to its antigen targets, and reducing the likelihood of an unwanted immune response to the antibody or



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antibody-derived molecule. We believe our differentiated product candidates have the potential to provide new approaches to treat cancer, autoimmune disorders and other complex diseases.

We currently have two oncology product candidates in clinical development. Additionally, we have several proprietary product candidates in pre-clinical development and we expect to commence Phase 1 clinical trials on two of these product candidates in 2014. We believe the profile of our compounds provides us with the flexibility to pursue either monotherapy or combination therapy, depending on disease characteristics, current standards of care, and overall safety, tolerability, and efficacy of specific regimens.

The table below depicts the current status of our product candidates:

*Margetuximab*, also known as MGAH22, is a monoclonal antibody that targets HER2-expressing tumors, including breast, gastroesophageal, bladder and other cancers. Human epidermal growth factor receptor 2 ( HER2 ), is critical for the growth of many types of tumors. Using our Fc Optimization platform, we have engineered the constant region, or Fc region, of margetuximab to enhance the antibody's ability to kill tumor cells expressing lower levels of HER2 than that of currently approved anti-HER2 agents (such as Herceptin) and also to increase margetuximab's ability to kill tumor cells through ADCC. We designed margetuximab to benefit a large sub-group of patients, which represents 80% or more of the overall population whose Fc receptors ( FcγRs ) expressed on immune cells bind less effectively to currently available antibodies that have not been optimized by our technology. Margetuximab represents a new class of bio-betters that may potentially help larger HER2+ patient populations than those treated with current HER2 targeted drugs and drug candidates. Phase 1 data from our open-label, dose escalation trial of margetuximab presented at the June 2013 Annual Meeting of the American Society of Clinical Oncology ( ASCO ) and November 2013 Chemotherapy Foundation Symposium demonstrated anti-tumor activity had been observed at a range of doses tested, including the lowest dose level of margetuximab, even in patients who were heavily pre-treated (frequently including with other anti-HER2 agents). We currently are enrolling a Phase 2a clinical trial in metastatic breast cancer and we plan to commence a Phase 3 potential registration clinical trial in advanced gastroesophageal cancer in the second half of 2014.

*MGA271* is an Fc-optimized monoclonal antibody that targets B7-H3, a member of the B7 family of molecules which are involved in immune regulation, and is over-expressed on a wide variety of solid tumor types. Inhibition of B7 family members has been shown to have powerful anti-tumor effects in

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several solid tumor types. For example, in presentations by others at ASCO and in publications in the *New England Journal of Medicine*, complete or partial tumor regression was observed in patients with certain cancers who participated in clinical trials of antibodies targeting CTLA4, PD-1 and PD-L1, which are also members of the B7 family or their associated checkpoint receptors on T cells. We have engineered MGA271 to utilize the same Fc optimization enhancements that we incorporated in margetuximab, and to target the over-expression of B7-H3 on differentiated tumors and CSLCs, as well as on the supporting tumor vasculature and underlying tissues. MGA271 is designed to destroy all of these components of the cancer in addition to reducing its inhibitory properties on T cells. We expect to complete the first three dose expansion cohorts of a Phase 1 clinical trial by the end of 2014. We plan to initiate additional dose expansion cohorts using MGA271 as monotherapy in other tumor types in 2014, as well as combining MGA271 with other therapies for certain tumor types.

*MGD006* is a humanized DART molecule that recognizes both CD123 and CD3. CD123, the Interleukin-3 receptor alpha chain is expressed on leukemia and leukemic stem cells, but not on normal hematopoietic stem cells. T cells, which express CD3, can destroy tumor cells. In pre-clinical studies, we have demonstrated the ability of MGD006 at extremely low doses to recruit, activate, and expand T cell populations to eliminate leukemia cells. MGD006 pre-clinical data was presented at 2013 Annual Meeting of the American Society of Hematology. In February 2014, we announced that an investigational new drug ( IND ) application for MGD006 cleared the U.S. Food and Drug Administration's ( FDA's ) 30-day review period. We expect to commence a Phase 1 clinical trial of MGD006 in the second quarter of 2014.

*MGD007* is a humanized DART molecule that recognizes both the glycoprotein gpA33 and CD3. gpA33 is expressed on gastrointestinal tumors, including more than 95% of human colon cancers. We have demonstrated that this molecule is able to mediate T cell killing of gpA33-expressing cancer cells and CSLCs in pre-clinical experiments. We expect to commence a Phase 1 clinical trial of MGD007 in the second half of 2014.

We pursue a balanced approach between product candidates that we develop ourselves and those that we develop with our collaborators. Under our current strategic collaborations, we have received approximately \$129.9 million in non-equity funding through December 31, 2013. Subsequent to December 31, 2013, we earned an additional \$20.0 million under the Servier DART agreement as described below. Our collaborators include:

*Servier*. In November 2011, we entered into a collaboration agreement with Les Laboratoires Servier and Institut de Recherches Servier (collectively, *Servier* ) under which we granted Servier an option to obtain an exclusive license to develop and commercialize MGA271 in all countries other than the United States, Canada, Mexico, Japan, South Korea and India. We received a \$20.0 million option grant fee and a \$10.0 million milestone payment upon dosing the first patient in the expansion cohort of our Phase 1 clinical trial of MGA271, and may be eligible to receive up to approximately \$415.0 million in license grant fees, and clinical, development, regulatory and sales milestone payments if Servier exercises the option, obtains regulatory approval for, and successfully commercializes an MGA271 licensed product. In the event Servier exercises its option, Servier must pay a license grant fee, which we estimate to be \$30.0 million, based on the number of different indications represented within the planned Phase 1 patient population. We and Servier will share Phase 2 and Phase 3 development costs.

In September 2012, we entered into a second agreement with Servier and granted it options to obtain three separate exclusive licenses to develop and commercialize DART-based molecules, consisting of those designated by us as

MGD006 and MGD007, as well as a third DART-based molecule, in all countries other than the United States, Canada, Mexico, Japan, South Korea and India, at which time we received a \$20.0 million option grant fee. In February 2014, Servier exercised its option to develop and commercialize MGD006 in its territories for which we received a \$15.0 million license grant payment. In addition, we received a \$5.0 million milestone payment from Servier in connection with an IND application for MGD006 clearing the FDA's 30-day review period. We may be eligible to receive up to approximately \$1 billion in additional license grant fees, and clinical, development, regulatory

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and sales milestone payments if Servier exercises its two remaining options and successfully develops, obtains regulatory approval for, and commercializes a product under all three licenses, including \$5.0 million upon IND acceptance for each of MGD007 and a third DART molecule. In addition to these milestones, we and Servier will share Phase 2 and Phase 3 development costs.

Additionally, under both agreements, Servier would be obligated to pay us low double digit to mid-teen royalties on product sales in its territories.

*Gilead.* In January 2013, we entered into an agreement with Gilead Sciences, Inc. ( Gilead ) for the research, development and commercialization of up to four DART-based molecules. The time period for Gilead's exercise of one option has expired. At present, Gilead retains a license to one and options to two of the original four programs. Gilead has exclusive worldwide rights for each of these remaining programs. We received an initial \$7.5 million license grant fee for the first DART-based molecule, and are eligible to receive an additional \$7.5 million in grant fees on each of the remaining two DART-based molecules if any are selected by Gilead. We are further eligible to receive up to an additional \$20 to \$25 million in pre-clinical milestones across each of the three remaining DART programs and up to approximately \$240 to \$250 million per remaining program in additional clinical, regulatory and sales milestone payments if Gilead exercises both remaining options and achieves all of the requisite milestones under each option and license. Gilead also provides funding for our internal and external research costs under the agreement. We are also eligible to receive tiered royalties on the net sales at percentages ranging from the high-single digits to the low double digits, but less than teens, subject to reductions in specified circumstances.

*Boehringer.* In October 2010, we entered into an agreement with Boehringer Ingelheim GmbH ( Boehringer ) to discover, develop and commercialize up to ten DART-based molecules which may span multiple therapeutic areas. We granted Boehringer an exclusive worldwide, royalty-bearing, license and received an upfront payment of \$15.0 million. We subsequently received three annual maintenance payments, including a \$4.0 million payment received in the fourth quarter of 2013. Also, in the fourth quarter of 2013, Boehringer's selection of a development candidate triggered a \$5.0 million milestone payment to us under the agreement. We have the potential to earn development, regulatory and sales milestone payments that can reach up to approximately \$210.0 million for each of the DART programs under this agreement. Boehringer provides funding for our internal and external research costs and is required to pay us mid-single digit royalties on product sales. Boehringer purchased \$10.0 million of our Series D-2 Preferred Stock in January 2011.

*Pfizer.* In October 2010, we entered into a three year agreement with Pfizer, Inc. ( Pfizer ) to discover, develop and commercialize up to two DART-based molecules. We granted Pfizer a non-exclusive worldwide, royalty-bearing license and received upfront and milestone payments and funding for our internal and external research costs under the agreement. We are eligible to receive technical, development and sales milestone payments that can reach up to approximately \$210.0 million for each DART program under this agreement. Pfizer is responsible for all pre-clinical and clinical development costs for the program. In addition, Pfizer is required to pay us mid-single digit to low-teen royalties on product sales. Under this collaboration, one DART program is currently being pursued and we completed our research obligations under this program in January 2014.

We currently manufacture material for research and development efforts for all of our product candidates in-house. Drug substance for all of our clinical trials is manufactured using current good manufacturing practices ( cGMP ) at our manufacturing facility, located in Rockville, Maryland. We contract with vendors to provide fill finish manufacture of drug product. We currently have capacity to produce Phase 2 material for our antibody product candidates and all clinical and commercial material for our DART therapeutics. We intend to expand our manufacturing facility, which should enable us to increase our production capacity. In addition, we have entered into agreements with contract manufacturing organizations to supplement our clinical supply and internal capacity as we advance additional pre-clinical candidates into clinical development.

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**Our Strategy**

Our goal is to be a leader in the discovery, development and commercialization of antibody-based therapeutics for the treatment of patients with cancer, autoimmune disorders and other complex diseases.

Key elements of our strategy to achieve this goal are to:

*Rapidly and concurrently advance our clinical oncology product candidates in multiple tumor types.* We intend to pursue the fastest feasible pathways to approval and to address large, underserved markets. We are developing product candidates that we believe could address disease specific challenges which are not currently being met by existing therapies. We are currently enrolling a Phase 2a clinical trial of margetuximab in metastatic breast cancer for which we expect to have results in late 2014. We plan to commence a Phase 3 potential registration clinical trial of margetuximab in advanced gastroesophageal cancer in the second half of 2014. We are currently enrolling the dose-expansion portion of a Phase 1 clinical trial of MGA271 as a single-agent in the treatment of 45 patients with solid tumors, including: 15 patients with melanoma; 15 patients with prostate cancer and an additional group of 15 patients with other solid tumor types. Servier has indicated that it intends to evaluate MGA271 in up to 75 additional cancer patients representing additional types of cancers beginning in the first quarter of 2014. We plan to initiate additional dose expansion cohorts using MGA271 as monotherapy in other tumor types in 2014, as well as combining MGA271 with other therapies for certain tumor types. In addition, we are currently optimizing multiple DART therapeutics as candidates for clinical development. We anticipate that we will begin Phase 1 clinical trials of MGD006, our first DART candidate, in the second quarter of 2014, and MGD007, our second DART candidate, in the second half of 2014.

*Leverage collaborative relationships.* We have multiple programs in development under our collaborations and are working closely with our collaborators to advance these programs. We believe that these collaborations help to validate and rapidly advance our discovery efforts, technology platforms, and product candidates while providing significant funding to advance our pipeline and access the development and commercial expertise of our collaborators. To facilitate the capital-efficient development and commercialization of our proprietary programs, we intend to enter into additional collaboration agreements with biopharmaceutical companies. We anticipate that we would structure these collaborations in ways that would allow us to retain development and commercialization rights in key markets.

*Create new product candidates that combine the potency and target selectivity of our DART technology with small molecule and toxin conjugation technologies.* We are working with several companies to combine their proprietary linkers and drug conjugates with our monoclonal antibodies. We believe that such linkers and drug conjugates can be combined with the selective targeting properties of our DART technology. Our goal is to identify and further develop new clinical candidates, either antibody-drug conjugates ( ADCs ) or DART-drug conjugates, through these research efforts.

*Establish commercialization and marketing capabilities in the United States.* We have retained commercialization rights in the United States for our clinical stage programs as well as the three DART programs that we are developing in collaboration with Servier. We intend to build a targeted specialty sales

force and marketing capabilities in the United States to commercialize our product candidates that receive regulatory approval.

*Strengthen our leadership position in fully integrated antibody engineering and development capabilities.* We have built a powerful and fully integrated set of capabilities that are critical to our ability to discover, optimize and develop antibody-based therapeutic product candidates in a rapid and efficient manner. We intend to build on our technology platforms, methods and know-how that comprise our capabilities in order to expand our product pipeline. We intend to advance two additional oncology DART-based product candidates to IND submission and initiation of clinical testing in 2015. Our goal is to file one or more new INDs annually for the next several years.

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### **Background**

#### ***Immune System and Antibodies***

The immune system, composed of both innate and adaptive elements, defends against invading pathogens such as viruses, parasites, and bacteria, and provides surveillance against cancers. The adaptive immune system includes:

B cells, which mature into plasma cells and produce antibodies;

Helper T cells, including those that enable, or help, the B cells to produce antibodies; and

Cytotoxic T cells, which can destroy tumor cells or cells infected with viruses.

T cells and B cells (and the antibodies derived from the mature B cell) of this adaptive immune system respond to small structural differences found, for example, on a cancer cell. This normally imparts exquisite specificity on these individual immune components. As a result, billions of different structural variants can be recognized by the adaptive immune system, but each individual T cell or B cell or antibody can only bind and respond to a single structure or molecule.

As shown in the following illustration, the antibody is a Y-shaped molecule that has two identical variable regions at the tip of the arms of the antibody (Fab region), which bind to antigens, and a constant region (Fc), as its opposite end that binds to FcγRs.

#### **Monoclonal Antibody Structure**

An antibody's structure is amenable to engineering either the variable regions to improve its strength of target recognition or affinity, or the constant regions to modify its engagement and collaboration with other components of the immune system, or both. The two variable region arms naturally target the same antigen; however, they can be artificially engineered to target two different antigens, allowing the creation of a bi-specific antibody. The Fc region can bind, recruit and activate immune cells to amplify the immune response to targets bound by the variable region of the antibody molecule. The Fc region can be modified to enhance the engagement with other immune cells and increase the potency of the immune response.

Therapeutic monoclonal antibodies are typically derived from natural antibodies and are obtained from immune cells of mammals that have been immunized with a desired antigen and are all clones of the unique parent cell. The antibody's ability to bind specifically to a target or antigen is also referred to as its specificity. Using this mechanism, antibodies can tag foreign substances for attack by other immune system cells or neutralize the targets directly. In treating diseases such as cancer, researchers find antigens specific to cancer cells and create antibodies that bind those antigens to use the body's immune system to destroy these cancer cells.





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Monoclonal antibodies are often generated in mice and although they are relatively easy to generate, they can have drawbacks as targeted therapeutics. The major drawback is that a mouse monoclonal antibody is recognized by the human immune system as a foreign target and therefore, the immune system attacks the antibody, rendering it useless against its intended target. Many advances have been made to genetically engineer and humanize monoclonal antibodies. In addition, fully human antibodies can be created, which can reduce newly generated immune responses in patients treated with monoclonal antibodies.

### ***Cancer***

Cancer is a broad group of diseases in which cells divide and grow in an uncontrolled fashion, forming malignancies that can invade other parts of the body. In normal tissues, the rates of new cell growth and cell death are tightly regulated and kept in balance. In cancerous tissues, this balance is disrupted as a result of mutations, causing unregulated cell growth that leads to tumor formation and growth. While tumors can grow slowly or rapidly, the dividing cells will nevertheless accumulate and the normal organization of the tissue will become disrupted. Cancers subsequently can spread throughout the body by processes known as invasion and metastasis. Once cancer spreads to sites beyond the primary tumor, it may be incurable. Cancer cells that arise in the lymphatic system and bone marrow are referred to as hematological malignancies. Cancer cells that arise in other tissues or organs are referred to as solid tumors. Cancer can arise in virtually any part of the body, with the most common types arising in the prostate gland, breast, lung, colon and skin.

Cancer is the second leading cause of death in the United States, exceeded only by heart disease, and accounts for almost one of every four deaths. The American Cancer Society estimates that in 2013 there will be approximately 1.6 million new cases of cancer and approximately 580,000 deaths from cancer. The National Institutes of Health estimates that the direct medical cost of cancer of all types, including solid tumors, in the United States in 2010 was approximately \$125 billion and according to IMS Health the amount spent in the United States on drugs to treat cancer exceeded \$23 billion in 2011.

### ***Currently Available Cancer Treatments***

The most common methods of treating patients with cancer are surgery, radiation and drug therapy. A cancer patient often receives treatment with a combination of these methods. For patients with localized disease, surgery and radiation therapy are particularly effective. Systemic drug therapies are generally used by physicians in patients who have cancer that has spread beyond the primary site or cannot otherwise be treated through surgery. The goal of these therapies is to damage and kill cancer cells or to interfere with the molecular and cellular processes that control the development, growth and survival of cancer cells. In many cases, drug therapy entails the administration of several different drugs in combination. Over the past several decades, drug therapy has evolved from non-specific drugs that kill both healthy and cancerous cells, to drugs that target specific molecular pathways involved in cancer.

### ***Cytotoxic Chemotherapies***

The earliest approach to pharmacological cancer treatment was to develop drugs, referred to as cytotoxic drugs, which kill rapidly proliferating cancer cells through non-specific mechanisms, such as disrupting cell metabolism or causing damage to cellular components required for tumor survival and rapid growth. While these drugs have been effective in the treatment of some cancers, cytotoxic drug therapies act in an indiscriminate manner, killing healthy cells along with cancerous cells. Due to their mechanism of action, many cytotoxic drugs have a narrow dose range above which the toxicity causes unacceptable or even fatal levels of damage and below which the drugs are not effective in eradicating cancer cells.

*Targeted Therapeutics*

The next approach to pharmacological cancer treatment was to develop drugs, referred to as targeted therapeutics, including monoclonal antibodies, that target specific biological molecules in the human body that

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play a role in rapid cell growth and the spread of cancer. Included in this category are small molecule drugs as well as large molecule drugs, also known as biologics. With heightened vigilance and new diagnostic tests, targeted therapies (including monoclonal antibodies such as Herceptin, Rituxan and Avastin as well as small molecules such as Nexavar and Tarceva), have resulted in improvements in overall survival for many cancer patients.

### ***Next Generation Antibody-based Therapeutics for Cancer***

While targeted antibody therapeutics have been highly successful in treating various cancers, the therapeutic effects of many such therapies are often relatively transient. Acquired resistance to cancer therapies remains a significant clinical problem with patients frequently relapsing and the tumors metastasizing to distant organs. The significant need for improvement in the treatment of cancer through antibody-based therapies is driving the growing focus on next-generation antibody-based therapies. Opportunities to create next-generation antibody based therapeutics lie in several technology advances including: antibodies that target multiple antigens, Fc-optimization, and ADCs. Multi-specific antibodies and ADCs have the potential to increase efficacy for cancer treatments and reduce systemic toxicity. Fc optimization may enable modification of the antibody to enhance the immune system's response and augment the therapeutic potential of the antibody, and may increase its half-life, which can potentially lead to less frequent dosing (a competitive advantage for injectables) and a lower cost of goods.

### ***Growth of the Biologics Market***

Over the last 20 years, recombinant biologic therapeutic drugs, including monoclonal antibodies, the largest subclass of recombinant biologics, have had a dramatic impact on cancer therapy. The improvement of engineering technologies, efficacy and safety of biologic drugs have driven significant market growth, with worldwide sales in 2011 of \$157 billion according to data from the IMS Institute for Healthcare Informatics. Data from La Merie, a business intelligence firm, indicates that therapeutic antibody products represent approximately 52% of total biologic drug sales, with 2012 global sales of approximately \$65 billion, an increase from approximately \$22 billion in 2006. Approximately 40 antibody product candidates have been approved by the FDA and international regulatory authorities since the first approval in 1986, and the three largest selling cancer drugs are monoclonal antibodies, Rituxan, Herceptin and Avastin, which had 2012 worldwide sales of approximately \$7.1 billion, \$6.3 billion and \$6.1 billion, respectively. Today, more than 300 monoclonal antibodies are in various stages of clinical development. According to a 2010 statistical analysis by Tufts University, antibody product candidates have shown a 2.5 times higher probability of successful clinical development as compared to small-molecule drugs.

### ***Our Platforms for Creating Next-Generation Antibody-based Therapies***

We apply our understanding of disease biology, immune-mediated mechanisms and next generation antibody technologies to design highly targeted antibody-based product candidates. Our antibody-based platforms consist of: DART, Fc Optimization, and CSLCs. Through these platforms, we have designed antibody-based product candidates that have the potential to improve on standard treatments by having: (1) multi-specificities; (2) increased abilities to interact with the body's immune system to fight tumors; (3) capacity to bind more avidly to antigen targets; (4) increased potency; (5) reduced immunogenicity; or (6) the ability to target cancer cells which are resistant to standard treatments. Moreover, these technology platforms are complementary and can be combined.

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***DART Platform: Our Proprietary Approach to Engineer Multi-Specific Antibodies***

We use our DART platform to create derivatives of antibodies with the ability to bind to multiple targets instead of a single target found in traditional monoclonal antibodies. Our current DART product candidates are bi-specific. An example of a bi-specific molecule is illustrated below:

Because cancer cells have derived ways to escape the immune system, we have created DART molecules which improve upon the human immune system, by creating alternative antibody-like structures with more potent immune properties than the parent antibody molecules from which they are derived. The two variable regions of an antibody are mono-specific and are able to target only a single type structural component of an antigen. For many years, researchers have sought to create recombinant molecules that are multi-specific and capable of targeting multiple antigens or epitopes (i.e., specific part of antigen bound to the antibody) within the same molecule. The challenges in creating such molecules have been the instability of the resulting bi-specifics and their inherent short half-lives, as well as the inefficiencies in manufacturing these compounds. We believe our DART platform has overcome these engineering challenges by incorporating proprietary covalent di-sulfide linkages and particular amino acid sequences that efficiently pair the chains of the DART molecule. This results in a structure with enhanced manufacturability, long-term structural stability, and the ability to tailor the half-lives of the DARTs to their clinical needs. This engineered antibody-like protein has a very compact and stable structure and enables the targeting of multiple different antigens within a single recombinant molecule.

The DART platform has been specifically engineered to accommodate virtually any variable region sequence with predictable expression, folding, and antigen recognition. To date, we have produced over 100 different DART molecules and have completed numerous *in vitro* and *in vivo* proof-of-concept studies on most of these molecules.

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We believe our DART platform may provide a significant advantage over current biological interventions in cancer and autoimmune disorders by enabling a range of modalities, including those described below.

*Redirected T cell activation and killing.* In this version of the DART molecule, we are enabling the cancer-fighting properties of the adaptive immune system to: (1) recognize and bind to structures expressed on a cancer cell (e.g., CD123, the first specificity in the example on the right), (2) enable the recruitment of all types of cytotoxic, or cell killing, T cells, irrespective of their ability to recognize cancer cells (e.g., CD3, a common component of the T cell antigen receptor, is the second specificity in the example on the right), and (3) trigger T cell activation, expansion, and cell killing mechanisms to destroy a cancer cell. The outcome is that any of the body's T cells, in theory, could be recruited to destroy a cancer cell and thus, are not limited to the small numbers of specific T cells that are normally generated to kill a cancer cell. Furthermore, since any T cell could be recruited for this killing process, only small amounts of a DART molecule are required to trigger this potent immune response. Additionally, the compact structure of the DART protein makes it well suited for maintaining cell-to-cell contact, apparently contributing to the high level of target cell killing.

*Modulation of receptor signaling.* In another configuration of the DART molecule, we have taken advantage of the two (or more) different specificities engineered in a DART structure to bind not only to particular cells involved in autoimmune processes, such as autoimmune B cells, but also to usurp the immune checkpoint signaling pathways programmed within the cells to impede the pathogenic autoimmune responses. Our MGD010 product candidate targets both CD32B, a co-inhibitory molecule, and CD79B, part of the B cell antigen receptor complex, two proteins expressed on the immune system's B cells. Using a single DART molecule, we not only target two receptors with a single molecule, but also promote the interaction of these two receptors to interrupt the autoimmune response. This is critical because interruption of the autoimmune B cell response cannot be achieved merely by using two separate antibodies. In this particular example, the activity of CD32B on B cells is captured to curb a destructive immune response.

*Simultaneous targeting of multiple pathologic factors, such as cytokines and growth factors and their receptors.* Targeting multiple soluble proteins or receptors that are important to the perpetuation of an autoimmune disease or generation of a cancer may create therapeutic synergies within a single DART molecule. Examples of this DART include the targeting of different inflammatory cytokines, such as TNF- $\alpha$ , IL-1, and IL-6, involved in the pathogenesis of autoimmune diseases or those receptors contributing to the growth of cancers such as members of the EGFR family including EGFR1, HER2 and HER3.

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*Targeting multiple epitopes on a pathogen for enhanced neutralization and/or clearance.* Infectious agents with slightly different genetic sequences or structures may perpetuate disease. Sometimes multiple variants may infect one individual and may evade the patient's normal immune responses. Creating DARTs that eliminate multiple infectious variants of a virus or multiple toxins produced by a bacterium could be an advantage for prevention or treatment. Examples of this include targeting the major genetic and serological forms of dengue virus, the cause of a major viral disease transmitted by mosquitoes, quasi-species of HIV, or different bacterial toxins derived from pathogenic clostridium species.

In addition, we have the ability to tailor a DART molecule's valency (number of binding sites), the strength by which the binding sites attach to its targets, and its half-life in the blood circulation after delivery to a patient. Furthermore, when an Fc domain is incorporated in a DART, changes can be included that can modulate the DART's engagement with different immune cells.

We have developed proof-of-concept pre-clinical data and are developing specific product candidates using this technology, including MGD006, MGD007 and MGD010, among others. We have been able to produce DART molecules in both bacterial and mammalian expression systems.

***Fc Optimization Platform: Our Proprietary Approach to Enhance Immune-Mediated Cancer Cell Killing***

To enhance the body's immune ability, we developed our Fc Optimization platform which introduces certain mutations into the Fc region of an antibody and is able to modulate antibody interaction with immune effector cells. Such interaction enhances the body's immune ability to mediate the killing of cancer cells through ADCC.

**ADCC**

The Fc region mediates the function of certain antibodies by binding to different activating FcγRs and inhibitory FcγRs on immune effector cells found within the innate immune system. By engineering Fc regions to bind with an increased affinity to the activating FcγRs and with a reduced affinity to the inhibitory FcγRs, we have been able to impart a more effective immune response, and improve effector functions, such as ADCC. This is another example in which small changes in antibody structure can confer improvements on normal immune processes.

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We have established a proprietary platform to engineer, screen, identify and test antibodies Fc regions with customizable activity. In particular, we have licenses to use transgenic mice that express human FcγRs. These mice can be used for *in vivo* testing of antibodies that incorporate Fc domain variants, including those antibodies intended for cancer therapy.

To date, we have successfully incorporated our Fc variants in our lead product candidates, margetuximab and MGA271. We have pre-clinical data demonstrating that these Fc variants have substantially improved the antibody's therapeutic effects.

### ***Cancer Stem-like Cell Platform: Our Proprietary Approach to Discover Cancer Targets***

Our CSLC platform provides new approaches to discover and identify cancer targets that are unresponsive to current cancer therapies. Cancer stem cells represent important potential targets in oncology drug development because they are theorized to be the basis for tumor re-growth and metastasis and are refractory to much standard chemotherapy. Therefore, the ability to specifically target and destroy CSLCs could potentially address an unmet medical need in many hard-to-treat cancers today. Using our CSLC platform, we can create antibodies that target and kill CSLCs.

Building on our expertise in growing stem cells from normal tissues using proprietary media and culture conditions, we have produced CSLCs from primary human tumor tissues. These CSLCs have been generated *in vitro* from a range of solid tumors and many have demonstrated tumor growth and differentiation *in vivo*. We believe that this technology holds great promise in creating the next generation of oncology therapeutics that target both differentiated tumor cells and their precursor cells which traditionally have been resistant to conventional chemotherapy and radiation therapy.

Our strategy has been to generate CSLCs from a range of primary tumors, including those derived from the colon, lung and ovary. We analyze and characterize the CSLCs for the following: (a) ability for self-renewal, (b) ability to form tumors *in vivo* that differentiate with the expected histological characteristics, and (c) genetic and protein stem cell marker expression profiles.

To date, we have created novel antibodies that target antigens on both CSLCs and bulk differentiated tumor cells, which are derived from the CSLCs. In addition to their value for identifying potential immune-based therapeutics, other opportunities include their use in small molecule compound screening and diagnostic applications.

We have generated over 2,000 monoclonal antibodies that we have screened by immunohistochemistry ( IHC ) for lower-binding to normal, non-malignant tissues. Many of these antibodies have been characterized for binding to primary tumors and cancer cell lines and we are developing the most promising of these antibodies into product candidates. This collection of antibodies is selective for both validated and novel cancer targets.

We have utilized our CSLC technology to generate or characterize the antibodies we use in our MGA271 and MGD007 product candidates.

### **Product Candidate Pipeline**

We currently have two oncology product candidates in clinical development. Additionally, we have several proprietary product candidates in pre-clinical development and we expect to commence Phase 1 clinical trials on two of these product candidates in 2014. Further, we expect to advance two additional oncology DART-based product candidates into clinical testing in 2015.





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**Margetuximab: Fc-Optimized Antibody for HER2-expressing Solid Tumors**

*Overview*

Margetuximab ( MGAH22 ) is an Fc-optimized, monoclonal antibody that targets and binds to the HER2 protein on cancer cells and is intravenously administered in order to kill tumor cells or inhibit tumor cell growth. We are developing margetuximab as an improved, more potent, anti-HER2 treatment for a variety of HER2-expressing tumors such as breast, gastroesophageal and bladder cancer.

An important mechanism of anti-HER2 monoclonal antibody action is the mediation of ADCC. In ADCC, the anti-HER2 antibody binds to tumor cells and then recruits immune cells, such as macrophages, through their FcγRs. FcγR-mediated mechanisms play a critical part in the effectiveness of targeted tumor antibodies including anti-HER2 antibodies. Therefore, we have optimized the important Fc region of margetuximab and thereby improved the cell-killing properties of margetuximab, compared to current anti-HER2 therapies (including trastuzumab). Specifically, we increased binding to activating receptors and decreased binding to the inhibitory receptor on immune effector cells. As a result, we believe margetuximab has the potential to be effective in a much broader population than the approximately 25% of breast cancer patients treated with trastuzumab today and may overcome resistance in populations who no longer respond to trastuzumab.

The HER2 gene and receptor have an important role in normal cell growth and differentiation. When the HER2 gene has multiple copies, which is referred to as gene amplification, it results in increased HER2 protein production. This causes cells to multiply in number and grow more rapidly than normal cells, contributing to the formation of cancer. HER2 gene amplification and protein over-expression occurs in approximately 25% of women with breast cancer. The level of HER2 protein on tumors can be detected by IHC and is scored as 0, 1+, 2+ or 3+, where 3+ indicates the highest expression of HER2 positivity. Fluorescence in situ hybridization ( FISH ) testing is a method used to determine the number of HER2 gene copies that are in a tumor cell. Breast cancer patients with HER2 gene amplification and protein over-expression have a more aggressive disease, greater likelihood of recurrence, poorer prognosis, and decreased survival compared to patients with HER2-negative breast cancer. Currently, anti-HER2 therapies are only approved for treating approximately 25% of all breast cancer patients whose tumors overexpress HER2 at the 3+ level, or if 2+, when accompanied by HER2 gene amplification. As illustrated in the figure below, this population of 25% of breast cancer patients represents 60.5% of the 42% of all patients who are HER2+.

We plan to study several patient populations in which we believe margetuximab, because of its optimized structure, has the potential for particular benefit. The first populations being tested include breast and gastroesophageal cancer, but there is also potential to explore other HER2-expressing cancers such as bladder, ovarian and colon.

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We initially presented data from our Phase 1 clinical trial of margetuximab at ASCO in June 2013. We continue to explore additional intermittent dosing cohorts and expect to complete this clinical trial in 2014. We are currently enrolling an exploratory Phase 2a clinical trial in patients with metastatic breast cancer whose tumors exhibit expression of the HER2 protein at the 2+ level by IHC and lack evidence of HER2 gene amplification by FISH. We plan to initiate a Phase 3 clinical trial in patients with HER2+ gastroesophageal cancers with HER2 protein expression at the 3+ level by IHC or 2+ level by IHC with documented gene amplification by FISH that have progressed after standard first and second-line therapy. We expect to begin enrollment in this clinical trial in the second half of 2014.

### ***Current Treatments for HER2-expressing Solid Tumors***

The management of breast cancer is largely based on the stage, grade, hormone receptor status and type, and includes surgery, radiation and drug therapy. Cytotoxic chemotherapies are a mainstay of metastatic breast cancer treatment, irrespective of hormone and HER2 status. Patients who have no detectable cancer after surgery are often given additional drug treatment to prevent recurrence. This is known as adjuvant therapy. Some patients receive treatment before surgery to shrink the tumor. This is known as neoadjuvant therapy. While anti-HER2 therapies have initially been tested in patients with metastatic cancer, often as single agents, benefit has been shown in the much larger population of patients treated earlier in adjuvant and neoadjuvant settings. We expect that this paradigm will also be true for margetuximab, but in a larger population.

The management of gastroesophageal cancer is based on radical surgical resection of the tumor, which when carried out at an early stage of disease may be curative. When surgical resection of the tumor is not possible, or the tumor recurs or metastasizes, chemotherapeutic agents are utilized. The incidence of gastroesophageal cancer has been declining steadily since the 1930s, yet it remains a major cause of cancer death in the United States and a greater problem in the rest of the world. Gastroesophageal cancer is the fourth most common cancer in the world (989,000 new cases diagnosed in 2008) and the second most common cause of cancer-related death in the world. Advanced and metastatic cancers are treated with chemotherapy and radiation therapy.

Several drugs directed at HER2 have been approved for the treatment of early and advanced stage breast cancer and advanced gastroesophageal cancer. Most patients treated with existing HER2 therapies, such as trastuzumab (Herceptin), pertuzumab (Perjeta), lapatinib (Tykerb), and ado-trastuzumab emtansine (Kadcyla, also referred to as T-DM1), will either fail to respond or become resistant to continued treatment. In addition, existing HER2 therapies are not effective in the treatment of patients who do not highly over-express HER2.

### ***Potential Advantages of Margetuximab***

Margetuximab is an Fc-optimized, monoclonal antibody believed to mediate its therapeutic activity against HER2+ tumors by a combination of mechanisms including:

Modulation of the receptor signaling resulting in growth retardation or the induction of apoptosis, or cell death;

ADCC and improved binding to immune cells to enhance destruction of HER2+ tumor cells; and

Presentation of antigens by cells such as macrophages that engulf the tumor cells, digest them, and display the tumor antigens to other cells of the immune system including T cells.

FcγR mediated mechanisms play a critical part in the activity of several antibodies including anti-HER2 antibodies. FcγR sequences will differ among people and a single amino acid difference in an FcγR can significantly alter an antibody's Fc binding properties. Clinical data shows improved outcomes in metastatic breast cancer patients who have a higher binding form of an activating FcγR, CD16A, in response to treatment with chemotherapy plus trastuzumab.

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The table below shows the difference in progression-free survival between patients treated with trastuzumab who have the higher-binding form of CD16A and those who have the lower-binding form of CD16A.

Knowing that approximately 80% of subjects express the lower-binding FcγR, we specifically optimized the Fc domain of margetuximab to enhance binding to the lower-binding form of CD16A. We believe margetuximab will have greater activity than trastuzumab and may overcome resistance in populations of patients whose tumors do not respond, or no longer respond, to trastuzumab. In addition, the optimized Fc domain of margetuximab imparts reduced binding to the inhibitory FcγR, CD32B, a feature expected to further enhance the activating properties of margetuximab.

We have conducted *in vitro* and *in vivo* pre-clinical studies that support the superiority of margetuximab compared to trastuzumab. In these pre-clinical models, margetuximab exhibits enhanced anti-tumor activity against HER2-expressing tumor cell lines in *in vitro* ADCC assays and in human tumor xenograft models in human CD16A+ transgenic mice. We have also demonstrated superior effects of margetuximab over trastuzumab in *ex vivo* studies using patient samples from the Phase 1 clinical trial.

### ***Clinical Development of Margetuximab***

Based on the pre-clinical laboratory studies conducted with margetuximab, we assumed that margetuximab would have clinical benefit in patients with tumors not currently thought to be targets for trastuzumab therapy, including those whose tumors express the HER2 protein at less than 3+ levels by IHC and lack evidence of HER2 gene amplification by FISH. We also assumed that margetuximab benefits would extend to patients bearing the lower-binding form of CD16A.

#### ***Phase 2a Metastatic Breast Cancer Study***

We submitted an IND in January 2010 for margetuximab for the treatment of HER2-positive carcinomas, including breast cancer. We are currently enrolling a Phase 2a clinical trial to determine if margetuximab has sufficient activity in patients with metastatic breast cancer who are not currently considered candidates for trastuzumab therapy to further evaluate margetuximab in this patient population. We are enrolling patients with metastatic breast cancer whose tumors exhibit expression of the HER2 protein at the 2+ level by IHC and lack evidence of HER2 gene amplification by FISH. This group of patients represents an unmet medical need which

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may be addressed by margetuximab. Margetuximab will be administered as a 6 mg/kg intravenous ( IV ) solution weekly on Days 1, 8, and 15 of each 28-day cycle. If fewer than two partial or complete responses are observed in the first 21 patients evaluable for response at the first tumor re-evaluation on day 22 of cycle 2 of treatment, no additional patients will be enrolled and the trial will end. If two or more responses are observed at the first tumor re-evaluation on day 22 of cycle 2 of treatment, we will expand the clinical trial to include a total of 41 patients evaluable for response. If five or more partial or complete responses are observed in these 41 patients, then we will consider margetuximab to have adequate activity in this patient population to justify additional clinical development. We are conducting this clinical trial at six sites in the United States.

### *Anticipated Margetuximab Clinical Trials*

We plan to file a separate IND for margetuximab for the treatment of patients with HER2+ gastroesophageal cancers with HER2 protein expression at the 3+ level by IHC or 2+ level by IHC with documented gene amplification by FISH in the first quarter of 2014. We plan to commence a 425 patient, randomized Phase 3 clinical trial to evaluate the addition of margetuximab to standard cytotoxic chemotherapy (irinotecan or paclitaxel) in the third line treatment of patients with advanced gastroesophageal cancers which have progressed after standard frontline and second-line treatment of advanced disease. We have selected the clinical research organization ( CRO ) and intend to commence patient recruitment in the second half of 2014. The primary analysis will compare the overall survival of patients randomized to chemotherapy plus placebo to the overall survival of patients randomized to chemotherapy plus margetuximab.

### *Other Anticipated Phase 2 Development*

We anticipate conducting exploratory clinical trials in patients with other HER2 expressing malignancies, potentially including bladder, ovarian, endometrial, and colon cancers.

### *Phase 1 Clinical Study Results*

The Phase 1 clinical trial is an open-label, multi-dose, single-arm, dose-escalation study conducted to define the safety profile and pharmacokinetics of margetuximab and to begin to explore the antitumor activity of margetuximab in patients with refractory HER2+ tumors. We enrolled a total of 34 patients in the dose escalation (0.1 to 6.0 mg/kg) and expansion (6.0 mg/kg) phases of the trial. This patient population was heavily pre-treated with prior therapies, including 19 patients with other prior anti-HER2 therapies. In the absence of dose limiting toxicity, an additional cohort of patients was treated at the top dose. We expect to complete this clinical trial in 2014.

During the dose escalation and expansion segments of the Phase 1 clinical trial of margetuximab, a dose of 6.0 mg/kg has been well-tolerated in patients with refractory HER2+ tumors who were treated weekly for four weeks. Approximately one-third of patients received additional cycles of margetuximab treatment. Using margetuximab as a single agent, tumor response was observed even in patients who had failed prior therapies including other anti-HER2 treatment. Responses to date include:

unconfirmed partial response in one patient with mucoepidermoid carcinoma of the salivary gland treated at 1.0 mg/kg;

confirmed partial response in one patient with breast cancer treated at 3.0 mg/kg;

confirmed partial response in one patient with breast cancer treated at 6.0 mg/kg;

confirmed partial response in one patient with a gastroesophageal junction tumor treated at 6.0 mg/kg;

unconfirmed partial response in one patient with colorectal cancer at 6.0 mg/kg; and

four patients with times to progression exceeding five months.

In addition, we are exploring intermittent administration of margetuximab as a more convenient dosing regimen. In this portion of the Phase 1 clinical trial, a patient with breast cancer experienced a confirmed partial response at 10.0 mg/kg (administered every three weeks) with a time to progression currently exceeding five months.

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Evidence of activity was seen at doses as low as 0.1 mg/kg weekly, to which a patient with metastatic breast cancer whose tumor had progressed after two prior anti-HER2 therapies (trastuzumab and ado-trastuzumab emtansine) experienced stability of disease and time to progression that exceeded nine months. The maximum percent reduction (below baseline) or increase (above baseline) in the size of target tumors at any time from patients treated with different doses of margetuximab is shown below:

The most frequent adverse events observed in patients participating in the dose escalation portion of this trial were infusion reactions, which we observed in approximately 27% of patients on the day of infusion. Most of these events were mild or moderate in severity. Institution of pre-medications has reduced the incidence and severity of infusion-associated adverse events.

We assessed the *ex vivo* ADCC response of peripheral blood mononuclear cells ( PBMCs ) obtained from subjects in the dose escalation portion of this Phase 1 trial. Each patient sample was divided and exposed separately to margetuximab and trastuzumab. Margetuximab outperformed trastuzumab in *in vitro* ADCC assays, reducing the dose required to achieve equivalent cell killing and increasing total cell killing. The concentration of drug required to achieve a half maximal effect (EC<sub>50</sub>) on ADCC was much lower for margetuximab (mean 3.5 ± 1.0 ng/ml) than trastuzumab (mean 40.7 ± 17.1 ng/ml).

## **MGA271: Fc-Optimized Antibody for B7-H3-Expressing Solid Tumors**

### ***Overview***

MGA271 is a humanized, Fc enhanced, monoclonal antibody that targets B7-H3 expressing tumors and is intravenously administered in order to kill tumor cells or inhibit their growth. We are developing MGA271 to treat multiple solid tumors such as melanoma, glioblastoma, prostate cancer, and breast cancer. We believe that targeting B7-H3 using MGA271 has significant potential to treat a variety of solid tumors because it incorporates multiple complementary mechanisms of action in one molecule. These potentially include:

Enhanced ADCC through Fc Optimization;

Targeting of both CSLCs and tumor cells;

Opportunity to differentially target tumor vasculature and underlying supporting tissues; and



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Potential for enhanced anti-tumor immunity by blockade of T cell inhibition (inhibiting the inhibitor). MGA271 has been engineered to have enhanced binding to CD16A. MGA271 also exhibits reduced binding to CD32B.

We initiated a Phase 1 clinical trial of MGA271 in patients with B7-H3 tumors in August 2011. We have completed the dose escalation portion of this trial without exceeding a maximally tolerated dose. We commenced an expansion phase in the third quarter of 2013, in which we are enrolling patients and treating them at the highest dose tested during the dose escalation portion of the trial. We expect to complete the first three dose expansion cohorts of this clinical trial by the end of 2014. We plan to initiate additional dose expansion cohorts using MGA271 as monotherapy in other tumor types in 2014, as well as combining MGA271 with other therapies for certain tumor types.

**Role of B7 Family of Immune Regulators, Including B7-H3, in Cancer**

The B7 family of cell surface molecules consists of structurally related protein ligands that bind to receptors on lymphocytes and regulate immune responses. B7 homolog 3 ( B7-H3 ) is a novel member of the B7 family of immune regulatory molecules. This family of molecules is an area of interest across the pharmaceutical industry, and is being explored by companies including AstraZeneca PLC ( AstraZeneca ), Bristol-Myers Squibb Co. ( Bristol-Myers ), GlaxoSmithKline plc ( GSK ), Merck & Co. ( Merck or Merck KGaA ) and Roche. The chart below describes our understanding of various B7 immune regulator targets and current marketed products and clinical stage product candidates addressing such targets.

**B7 Immune Regulator Family**

Antigen-Presenting Cell	T Cell	Function	Product or Product Candidates
CD80 (B7-1) or CD86 (B7-2)	CTLA4	Inhibitory	Ipilimumab (marketed by Bristol-Myers) Anti-CTLA4 (AstraZeneca, Phase 2)
CD80 (B7-1) or CD86 (B7-2)	CD28	Activating	
PD-L1 (B7-H1) or PD-L2 (B7-DC)	PD1	Inhibitory	Anti-PD1 (Merck, Phase 3) Anti-PD1 (Bristol-Myers, Phase 3) Anti-PD-L1 (Bristol-Myers, Phase 2) Anti-PD-L1 (Roche, Phase 2) PD-L2/Fc fusion (GSK/AstraZeneca, Phase 1) Anti-PD1 (AstraZeneca, Phase 1) Anti-PD-L1 (Merck KGaA, Phase 1)
B7RP1 (B7-H2)	ICOS	Activating	AMG 557 (Amgen/AstraZeneca, Phase 1)
B7-H3	Unknown	Inhibitory	MGA271 (MacroGenics, Phase 1)
B7-H4	Unknown	Inhibitory	
B7-H5 (VISTA)	Unknown	Inhibitory	
B7-H6	NKp30	Activating	

In our own analysis of fixed tumor microarrays representing more than 700 samples across various tumor types including glioblastoma, thyroid, gastroesophageal, breast, pancreas, prostate, melanoma and ovarian cancers, we saw B7-H3 expression in approximately 70-99% of tumor samples, with high expression (2+ or greater by IHC) in most of these tumor types.

B7-H3 inhibits T cell activation and cytokine production. Other examples of inhibitors of T cell activation include the immune check-point regulators PD1 and CTLA4. Anti-PD1 and anti-CTLA4 (e.g., ipilimumab) antibodies have shown therapeutic effects in patients with melanoma, renal cell carcinoma, and non-small-cell lung cancer and are being tested in individuals with several other types of cancers.

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***Pre-Clinical Development of MGA271***

We have evaluated the ability of MGA271 to mediate ADCC activity across multiple cancer types expressing varying levels of B7-H3 as determined by flow cytometry. The cancer types tested included melanoma, lung cancer, prostate cancer, breast cancer, bladder cancer, and renal cancer cell lines. MGA271 mediated ADCC activity against all tumor lines that express B7-H3 at detectable levels.

MGA271 exhibited anti-tumor activity in mouse models when administered approximately one week after tumor cell implantation (as shown below), or after tumors were allowed to become fully established (approximately three weeks after implantation when tumors were approximately 300 mm<sup>3</sup> in volume).

**Anti-Tumor Efficacy of MGA271**

**in a Pre-clinical Model of Renal Cell Carcinoma**

*Cells from a renal cell carcinoma tumor line were implanted subcutaneously in immunodeficient mice that expressed the lower-binding form of human CD16A. MGA271 was administered intravenously weekly at the indicated dose levels as shown by arrows above. All dosages of MGA271, including 0.1 mg/kg, inhibited tumor growth when compared to both control groups, vehicle or IgG.*

A repeat dose Good Laboratory Practice ( GLP ) toxicology study was conducted in cynomolgus monkeys to determine the potential toxicity of MGA271. MGA271 was well tolerated when administered by IV infusion at four weekly doses of up to 150 mg/kg. The no observed adverse effect level was considered to be 150 mg/kg.

***Clinical Development of MGA271***

We expect to complete the first three dose expansion cohorts of a Phase 1 clinical trial by the end of 2014. We plan to initiate additional expansion cohorts using MGA271 as monotherapy in other tumor types in 2014, as well as combining MGA271 with other therapies for certain tumor types. We submitted an IND in March 2011 for MGA271 for the treatment of patients with refractory B7-H3-expressing tumors.

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**Table of Contents***Phase 1 Clinical Trial*

The Phase 1 trial is an open-label, multi-dose, single-arm, multi-center, dose-escalation clinical trial. This trial includes patients with B7-H3-expressing tumors, such as prostate cancer, pancreatic cancer, melanoma and ovarian cancer, and tumors whose vasculature exhibits B7-H3 expression, such as glioblastoma, renal cell carcinoma and ovarian cancer. The clinical trial began with a dose escalation segment in which patients were treated with increasing weekly doses of MGA271 from 0.01 mg/kg up to 15 mg/kg. We have not seen any dose limiting toxicity, and we initiated an expansion phase in the third quarter of 2013 at a dose of 15 mg/kg. During the expansion phase, we are recruiting an additional 15 patients to each of three cohorts that represent a distinct patient population determined by histology: 1) patients with melanoma, 2) patients with prostate cancer and 3) patients with any B7-H3 positive tumor other than melanoma or prostate cancer with the limitation of a maximum of five patients with any single histologic type such as colorectal adenocarcinoma or histologic subgroup such as sarcoma. In addition, Servier has indicated that it intends to evaluate MGA271 in up to 75 additional cancer patients representing additional types of cancers beginning in the first quarter of 2014.

We enrolled a total of 26 patients in the trial through the dose escalation portion, with 15 different types of tumors. Ten patients received additional cycles of MGA271 treatment and all have had stable disease at the first tumor re-assessment. The most frequent adverse events in the trial were mild or moderate infusion reactions.

Because anti-cancer monoclonal antibodies are target-specific, the presence of the target on tumor cells is usually required for the desired biological effect of the antibody. An IHC-based companion diagnostic for MGA271 would detect the presence of B7-H3 on the cellular membrane of tumor cells. A positive result detecting B7-H3 on the cellular surface is currently required for trial eligibility, and we expect it will be required for identification of appropriate candidates for MGA271 treatment should the product candidate be approved. We are working with two third-party vendors for the development of the companion diagnostic, and we plan to contract with a vendor for future commercialization based on the results. We plan to have a validated companion diagnostic ready for incorporation into potential Phase 3 trials and are working with a collaborator to develop it.

**MGD006: DART-Based Molecule for Acute Myeloid Leukemia***Overview*

MGD006 is a humanized DART molecule that recognizes both CD123 and CD3. We are developing MGD006 for the treatment of hematologic cancers. The primary mechanism of action of MGD006 is its ability to redirect T cells which express CD3 to kill CD123 expressing cells, such as leukemic cells. In February 2014, we announced that an IND application for MGD006 cleared the FDA's 30-day review period. We plan to initiate a Phase 1 clinical trial of MGD006 in patients with relapsed or refractory acute myeloid leukemia ( AML ) or in patients with untreated AML who are not candidates for standard induction chemotherapy in the second quarter of 2014.

*Role of CD123 in Acute Myeloid Leukemia*

CD123 has been reported to be overexpressed on malignant cells in a wide range of hematologic malignancies including AML and myelodysplastic syndrome ( MDS ). Overexpression of CD123 is associated with a poorer prognosis in AML. AML and MDS are thought to arise in and be perpetuated by a small population of leukemic stem cells ( LSCs ), which generally resist conventional chemotherapeutic agents. LSCs are characterized by high levels of CD123 expression, which is not present in the corresponding normal hematopoietic stem cell population in normal human bone marrow. CD123 is also expressed by plasmacytoid dendritic cells ( pDCs ) basophils, endothelial cells and, to a lesser extent, monocytes and eosinophils. The anti-CD123 component of MGD006 is based on a humanized

version of 7G3, a mouse monoclonal antibody directed against CD123.

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***Potential Advantages of MGD006***

As a targeted therapy for CD123-expressing cells, we believe that MGD006 will have fewer side effects than conventional chemotherapeutic agents which broadly target rapidly dividing cells including cancer cells, normal hematopoietic stem cells and certain immune cells such as activated lymphocytes.

Moreover, because CD123 is expressed on the LSCs that perpetuate this disease, MGD006 will be targeting the source of the disease, and potentially deliver more durable remissions. This would represent an advance in AML therapy, because the LSCs that sustain this disease are generally resistant to the chemotherapy which is the standard approach to disease treatment. The resistance of LSCs to chemotherapy may be due to the fact that they are a rare, relatively dormant, cell type within the leukemic cell population and, therefore, are less susceptible to the primary mechanism of action of chemotherapeutic agents.

***Pre-clinical Development of MGD006***

In November 2013, one of our academic investigators presented data from a pre-clinical study at the 55th Annual Meeting of the American Society of Hematology. The pre-clinical study investigated the ability of MGD006 to redirect T cells against CD123-positive AML blasts. Investigators demonstrated that MGD006 binds to both human CD3 and CD123 to mediate target-effector cell aggregation, T-cell activation and proliferation. MGD006 induced a dose-dependent reduction of primary AML blast survival *in vitro* and *in vivo*. Notably, a short course of treatment with MGD006 in mice engrafted with an AML patient sample induced a greater than 97% elimination of AML blasts from the peripheral blood and significant clearing from the spleen and bone marrow 6 weeks after AML cell infusion. The results of this study provide a strong rationale for the clinical development of MGD006 as a novel molecule for the treatment of patients with AML.

In our own *in vitro* experiments, we have demonstrated that MGD006 is able to mediate T cell killing of CD123-expressing cells. In an *in vitro* model of T cell-mediated killing of AML cells, addition of MGD006 led to destruction of AML cells derived from leukemia patients. Three leukemia cell lines expressing CD123 were exposed to MGD006 or a control DART protein in the presence of T cells. Dose-dependent increases in cell killing were observed following treatment with MGD006.

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In the chart below, primary AML PBMC samples were incubated with a phosphate buffered saline ( PBS ) control, a DART protein control or MGD006. Treatment with MGD006 resulted in a dose-dependent decrease in leukemic blast cell number counts.

### **AML Blasts**

We performed pilot toxicology studies in cynomolgus monkeys. Complete depletion of CD123-positive cells, an indication of activity in healthy animals, occurred at doses as low as 10 ng/kg/day. Importantly, this effect was reversible as pDCs were observed in peripheral blood a few weeks following cessation of dosing. No significant infusion reactions were observed at the lowest starting doses studied, including the pharmacologically active dose levels (10-30 ng/kg/day). Administration of MGD006 at higher doses was associated with acute infusion reactions, which typically decreased or disappeared with subsequent dosing.

### **MGD007: DART-Based Molecule for Gastrointestinal Cancers**

#### ***Overview***

MGD007 is a DART protein in which the first specificity is for the glycoprotein gpA33 and the second specificity is for CD3. MGD007 also contains an Fc domain which provides for an extended serum half-life compared to basic DARTs. gpA33 was identified through immunizations using our proprietary CSLC lines.

We are developing MGD007 as a potential therapeutic agent for the treatment of colorectal cancer. Other tumors of the gastrointestinal tract, such as pancreatic and gastroesophageal cancers, may also be potential indications for development. In a survey of normal tissues examined, the gpA33 antigen was expressed almost exclusively in the intestinal epithelium. It was present in more than 95% of human colon cancers, and in approximately 50% of gastroesophageal and pancreatic cancers. Studies by others with a radiolabeled monoclonal antibody against gpA33 demonstrated preferential binding to tumors over normal colonic mucosa.

We have conducted pre-clinical *in vitro* and *in vivo* proof-of-concept studies with MGD007 or a basic DART form of MGD007 without the Fc domain. In addition, we have completed the *in vivo* portion of a GLP toxicology study in cynomolgus monkeys. We are planning to submit an IND in 2014 and commence a Phase 1 clinical trial for MGD007 in the second half of 2014.

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### ***Pre-clinical Development of MGD007***

The results of *in vivo* experiments shown below demonstrate that a gpA33 x CD3 DART is able to mediate T cell killing of gpA33-expressing cancer cells:

*Cells from a colorectal cancer line and activated human T cells were implanted subcutaneously in immunodeficient mice. A gpA33 x CD3 DART was administered intravenously daily for four days at the time of tumor implantation. Inhibition of tumor growth was observed at all dose levels tested when compared to animals treated with a control.*

### **Other Oncology DART-Based Product Candidates**

We have an active discovery effort and we have generated multiple product candidates, which are in various stages of research and pre-clinical development. Several of these undisclosed product candidates are based on our DART technology, and are directed toward various oncology targets, both novel and validated. We intend to advance at least two of these programs to IND submission and commence Phase 1 clinical studies in 2015.

### **MGD010: DART-Based Molecule for Autoimmune Diseases**

Autoimmune diseases including rheumatoid arthritis ( RA ), Crohn s disease, systemic lupus erythematosus ( SLE ), and multiple sclerosis ( MS ), collectively affect more than 20 million people in the United States. Autoimmune disease involves self-tissue destruction by T cells and antibodies due to lack of self-tolerance. Anti-inflammatory therapies, such as TNF (tumor necrosis factor) inhibitors, have been able to improve diseases like RA; however, it has become increasingly known that, in addition to T cells, B cells play an important role in many common autoimmune and allergic disorders by initiating and amplifying the pathological disease processes. Current B cell targeted therapies either cause depletion of B cells, thus limiting their applicability due to the potential for infections (e.g., rituximab, or *Rituxan*), or exhibit a delayed onset of action and limited efficacy across patient populations (e.g., belimumab, or *Benlysta*).

To address limitations of existing B cell targeted therapies, MacroGenics has developed a novel CD32B x CD79B DART, called MGD010. In pre-clinical studies, this DART modulates the function of human B cells without B cell depletion. In normal conditions, B cells utilize CD32B as one of the key negative regulators to ensure that tolerance to self is maintained and autoimmune disease does not occur. MGD010 exploits this



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mechanism and triggers this inhibitory immune checkpoint loop. We believe this molecule preferentially blocks those B cells that are activated to produce the pathogenic antibodies that promote the autoimmune process. Studies in SLE patient B cells and humanized mouse models have demonstrated that MGD010 can block B cell activation in the absence of B cell depletion. To advance this program to the clinic, we recently performed studies in a non-human primate model with MGD010 demonstrating a favorable safety profile and pharmacological effects on targeted B cells.

In the chart below, treatment with MGD010 prolongs survival compared to a PBS control or a single dose of rituximab in a mouse model of graft-versus-host disease.

### **MGD010 in a Chronic Graft-versus-Host Disease**

#### **(Transplantation) Mouse Model**

*Immunodeficient mice administered human PBMCs by injection were treated intravenously either with MGD010 at 5.0 or 10.0 mg/kg or PBS control every four days (9 total doses) or with rituximab at 5.0 mg/kg for one dose.*

### **Teplizumab: Fc-Modified Antibody for Type 1 Diabetes**

#### ***Overview***

Teplizumab is a humanized, anti-CD3 monoclonal antibody being developed for the treatment of Type 1 Diabetes ( T1D ). Teplizumab has been engineered to alter the function of the T cells that mediate the destruction of the insulin-producing beta cells of the islets of the pancreas. Teplizumab potentially represents an advance in the treatment of T1D by addressing the underlying disorder, rather than merely using insulin replacement therapy. In 2007, we entered into a collaboration with Eli Lilly. During the clinical development of teplizumab, Eli Lilly provided financial, manufacturing, and commercial support to us while we conducted our Phase 3 clinical trials.

In June 2011, we published the results of Protégé, a Phase 3 clinical study of teplizumab in T1D, in *The Lancet* and follow-up data in *Diabetes* in 2013. The primary clinical endpoint of this trial, a composite of glycated hemoglobin ( HbA1c ), and insulin usage, was not met. HbA1c is a form of hemoglobin that reflects average plasma glucose concentration over prolonged periods of time. When T1D is poorly controlled, the glucose and consequently, HbA1c levels rise. Insulin use was measured as units used per day. Subjects were required to have a low HbA1c level (<6.5%) and low daily insulin usage (<0.5 units per day). Similar numbers of patients in the 14 day teplizumab regimen and placebo (insulin only) achieved this endpoint. Although this trial

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did not meet its primary clinical endpoint, an exploratory, post-hoc analysis suggests that teplizumab, when used in a full dose regimen, may preserve insulin production by beta cells in the pancreas, as measured by C-peptide, and increase the percentage of patients requiring very low doses of insulin compared to those on placebo. Preservation of insulin production as measured by C-peptide, relative to standard of care, is now recognized as an acceptable primary endpoint by the FDA. The findings suggest that future studies of immunotherapeutic intervention with teplizumab might have increased success in prevention of a decline in beta cell function (measured by C-peptide) and preservation of glycemic control at reduced doses of insulin, particularly in children, if intervention occurs soon after diagnosis.

Teplizumab is currently being evaluated in a Phase 2 clinical trial, called At-Risk, for the prevention or delay of onset of T1D in patients determined to be at very high risk for developing the disease. This clinical trial is being sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases ( NIDDK ). In 2011, Eli Lilly terminated its collaboration with us to develop teplizumab and pursuant to the terms of the agreement, we reacquired the commercial rights to teplizumab. We are actively seeking a collaborator for further development of teplizumab.

The At-Risk study is being conducted under an IND filed and sponsored by MacroGenics, pursuant to IND 102,629 filed in December 2009. The clinical study is being conducted by NIDDK at TrialNet clinical sites. NIDDK, in conjunction with TrialNet, prepared the clinical protocol and is responsible for training and monitoring the clinical sites. MacroGenics officially transferred these sponsor responsibilities to NIDDK in its initial IND submission. Under FDA regulations, MacroGenics remains responsible for submitting the appropriate documents to the IND, including but not limited to, IND Annual Reports, expedited reports, revised clinical protocols provided by NIDDK, and new clinical investigator information.

## **Collaborations**

We have entered into several strategic collaborations for our therapeutic programs. Our current therapeutic collaborations have provided us with approximately \$129.9 million in non-equity funding through December 31, 2013. Subsequent to December 31, 2013, we earned an additional \$20.0 million under the Servier DART agreement as described below. Key terms of our collaborations are summarized below.

### ***Servier MGA271 Agreement***

*Overview.* In November 2011, we entered into a collaboration agreement with Servier under which we granted Servier an option to obtain an exclusive license to develop and commercialize the Fc engineered antibody we designated as MGA271 and certain other Fc engineered antibodies that also bind the B7-H3 receptor, collectively referred to as the MGA271 licensed products, in all countries other than the United States, Canada, Mexico, Japan, South Korea and India. We received a \$20.0 million option grant fee and a \$10.0 million milestone payment upon dosing the first patient in the expansion cohort of our Phase 1 clinical trial of MGA271, and may be eligible to receive up to approximately \$415.0 million in license grant fees, and clinical, development, regulatory and sales milestone payments if Servier exercises the option, obtains regulatory approval for and successfully commercializes an MGA271 licensed product. In addition to these milestones, we and Servier will share Phase 2 and Phase 3 development costs. Under the agreement we are also eligible to receive royalties on the net sales of MGA271 licensed products at percentages ranging from the low double digits to the mid-teens, subject to reductions in specified circumstances. Under specific circumstances, Servier may defer payment of certain milestone payments.

*Research Plan.* Under the agreement, we are responsible for conducting research according to an agreed upon research plan during a specified research term. The activities under the research plan include the generation of data by us that the parties have agreed will be included in a data package, or MGA271 data package. We will continue conducting the current Phase 1 trial of MGA271 under the research plan. Under the agreement, Servier may conduct separate

development and clinical activities under the research plan, subject to our approval. The

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term of the research plan begins on the effective date of the agreement and ends on the earlier of November 24, 2015 or the expiration of Servier's option under the agreement. In general, during the research term, each party is responsible for the internal and external costs it incurs to conduct its activities under the research plan.

*Manufacturing.* Under the agreement we are obligated to supply cGMP produced MGA271 licensed products to supply Servier's clinical development needs for its Phase 1 and first two Phase 2 clinical trials according to a clinical supply agreement negotiated between the parties. Servier is obligated to pay for such supply of MGA271 licensed product under the clinical supply agreement at our fully burdened manufacturing cost. Prior to exercising its option, we can supply clinical material for Servier's additional needs at our discretion. If Servier exercises its option, upon its request, we are obligated to enter into negotiations to execute a commercial supply agreement for MGA271 licensed product.

*Option.* Generally, Servier may exercise its option at any time after the effective date of the agreement until ninety days after Servier's receipt of the MGA271 data package which shall include results from completed expansion cohorts from the Phase 1 clinical trial. In the event Servier exercises the option, Servier must pay a license grant fee, which we estimate to be \$30.0 million, based on the number of different indications represented within the patient population in a planned expansion cohort in our Phase 1 clinical trial of MGA271. If Servier elects not to exercise the option, it will lose all rights to develop and commercialize MGA271 licensed products and we will be entitled to develop and commercialize MGA271 licensed products throughout the world exclusively or with a third party or parties.

*License/Exclusivity.* If Servier exercises the option it will receive an exclusive license to develop and commercialize MGA271 licensed products in all countries of the world other than the United States, Canada, Mexico, Japan, South Korea and India.

In addition to Servier's exclusive right to develop and commercialize MGA271 licensed products under the agreement, there are additional obligations regarding exclusivity and noncompetition.

In addition to these provisions, in the event that we seek to grant rights to a third party to develop and/or commercialize certain DARTs that bind the B7-H3 receptor outside the United States, Servier has a right of first negotiation to obtain such rights. If Servier declines to enter negotiations or the parties fail to execute an agreement granting Servier such rights within a specified time period, subject to specified exceptions, we will have the right to enter negotiations with a third party for the same rights.

*Term and Termination.* If Servier does not exercise its option, the agreement terminates upon the expiration of the option. If Servier exercises the option, the agreement will terminate in its entirety upon the later of the expiration of the last-expiring patent related to an MGA271 licensed product, the regulatory based exclusivity period or 12 years after the first commercial sale of any MGA271 licensed product. The agreement contains customary termination rights.

***Servier DART Agreement***

*Overview.* In September 2012, we entered into a second agreement with Servier and granted it options to obtain three separate exclusive licenses to develop and commercialize DART-based molecules, consisting of those designated by us as MGD006 and MGD007, as well as a third DART molecule, collectively referred to as the DART-licensed products, in all countries other than the United States, Canada, Mexico, Japan, South Korea and India. Under the terms of the agreement, we received a \$20.0 million option grant fee. In February 2014, Servier exercised its option to develop and commercialize MGD006 in its territories for which we received a \$15.0 million license grant payment. In addition, we received a \$5.0 million milestone payment from Servier in connection with an IND application for

MGD006 clearing the FDA's 30-day review period. We may be eligible to receive up to approximately \$1 billion in additional license grant fees, and clinical, development, regulatory and sales milestone payments if Servier exercises its remaining two options and successfully develops, obtains

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regulatory approval for and commercializes a product under each license, including \$5.0 million upon IND acceptance for each of MGD007 and a third DART molecule. In addition to these milestones, we and Servier will share Phase 2 and Phase 3 development costs. Under the agreement we are also eligible to receive royalties on the net sales of DART licensed products at percentages ranging from the low double digits to the mid-teens, subject to reductions in specified circumstances.

*Research Programs.* Under the agreement, we are responsible for conducting research according to an agreed upon research plan for each option target during the specified research term. Each research plan and its activities are considered a research program. The activities under each research plan include the generation of data by us that the parties have agreed that will be included in a data package, or the Servier DART data package. With our consent, Servier may conduct separate development and clinical activities under a research plan. The research term for each research program begins on the effective date of the agreement and ends on the earlier of September 19, 2016 or the expiration of the applicable option. In general, during each research term, each party is responsible for the internal and external costs it incurs to conduct its activities under that research plan.

*Manufacturing.* Under the agreement we are obligated to negotiate a clinical supply agreement with Servier regarding the supply of cGMP produced material to supply Servier's clinical development needs for its Phase 1 and first two Phase 2 clinical trials for each DART licensed product. Servier pays for such supply of each DART licensed product under each clinical supply agreement at our fully burdened manufacturing cost. Prior to exercising one of its options, we can supply clinical material for Servier's additional needs at our discretion. If Servier exercises an option, then upon Servier's request, we are obligated to enter negotiations to execute a commercial supply agreement for DART licensed products subject to that option.

*Option.* Under the terms of the agreement, each option may be exercised by Servier within ninety days after Servier's receipt of the applicable Servier DART data package. In the event Servier exercises an option, Servier must pay a specified license grant fee for exercising that option. The respective license grant fees are \$15.0 million for the MGD006 option, which we received in February 2014, and additional amounts related to MGD007, and a remaining DART molecule, which become exercisable after a significant portion of the Phase 1 trials for each of these programs is completed. If Servier elects not to exercise an option, it will lose all rights to develop and commercialize DARTs that bind such option target and we will be entitled to develop and commercialize DARTs that bind the former option target throughout the world exclusively or with a third party or parties, subject to Servier's right of first negotiation, as described below.

*Licenses/Exclusivity.* If Servier exercises an option it will receive an exclusive license to develop and commercialize DARTs that bind to the option target for that option, and pharmaceutical products that comprise or contain such DARTs, in all countries of the world other than the United States, Canada, Mexico, Japan, South Korea and India.

In addition to Servier's exclusive right to develop and commercialize DARTs under each license, under the agreement there are additional obligations regarding exclusivity and noncompetition.

In addition to these provisions, in the event that we seek to enter into a transaction under which we would grant rights to a third party to develop and/or commercialize certain product candidates in Servier's territory that bind an option target in exchange for certain consideration, Servier has a right of first negotiation to obtain such rights. If Servier declines to enter negotiations or the parties fail to execute an agreement granting Servier such rights within a specified time period, we will have the right, subject to specified exceptions, to enter negotiations with a third party for the same rights.

*Term and Termination.* If Servier does not exercise any option, the agreement terminates upon the expiration of the last to expire option. If Servier exercises an option, the agreement will terminate in its entirety with respect to such DART licensed product upon the later of the expiration of the last-expiring patent related to a DART licensed product, the regulatory based exclusivity period or 12 years after the first commercial sale of a DART licensed product. The agreement contains customary termination rights.

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**Table of Contents*****Gilead***

*Overview.* In January 2013, we entered into an agreement with Gilead for (i) the research, development, manufacture and commercialization of DARTs that bind to a first pair of specified targets; (ii) an exclusive option for an exclusive license to research, develop, manufacture and commercialize DARTs that bind to a second pair of specified targets in North America, the European Union, Norway, Iceland, Turkey, Australia and New Zealand; and (iii) separate exclusive options for worldwide exclusive licenses to research, develop, manufacture and commercialize DARTs that bind to third and fourth pairs of targets to be subsequently identified by Gilead and accepted by us within a specified time period after the effective date of the agreement, which we collectively refer to as the Gilead licensed products. The time period for Gilead's exercise of the option to the second target pair has expired. At present, Gilead retains a license to one and options to two of the original four programs. Gilead has exclusive worldwide rights to each of these remaining programs. We received an initial \$7.5 million license grant fee for granting Gilead a license to the first target pair, and are eligible to receive an additional \$7.5 million in grant fees for each of the remaining two DART-based molecules if they are selected by Gilead, up to an additional \$20 to \$25 million in pre-clinical milestones across each of the three remaining DART programs and up to \$240 to \$250 million per remaining program in additional clinical, regulatory and sales milestones payments if Gilead exercises both remaining options and achieves all of the requisite milestones under each option and license. Under the agreement, we are also eligible to receive tiered royalties on the net sales of Gilead licensed products at percentages ranging from the high-single digits to the low double digit, but less than teen royalties subject to reductions in specified circumstances.

*Research Programs.* During specified research terms, we are responsible for conducting research according to an agreed upon research plan for each pair of targets for which Gilead exercises its option. Each research plan and its activities are considered a research program. Upon approval by the joint research committee, Gilead may conduct separate development and clinical activities under a research plan. The term of the research plan for the first target pair has already begun. The research terms of the research plans for the third and fourth target pairs can begin only after Gilead's exercise of the options for such target pairs. The term for Gilead's exercise of the option to for the second target pair has expired. Gilead has fixed time periods to exercise its options for the third and fourth target pairs and we may decline to accept Gilead's selection of the third and fourth target pairs under specified circumstances.

During each research term, Gilead will reimburse us for all internal and external costs we incur to conduct our assigned activities under that research plan, subject to specified limitations.

*Licenses.* Under the agreement, we granted Gilead an exclusive worldwide license to research, develop, manufacture and commercialize DARTs that bind to the first pair of specified targets. Upon initiation of each of the research terms for the third and fourth target pairs we will grant Gilead a worldwide exclusive license to research, develop, manufacture and commercialize DARTs that bind to the corresponding target pair. Gilead did not exercise its option with respect to the second target pair.

*Pre-clinical Milestone.* Notice by Gilead to pay the pre-clinical milestone for each target pair category must be provided to us within specified time periods. Upon providing notice to pay a pre-clinical milestone for a target pair category, Gilead will become responsible for all research, development and commercialization activities with respect to licensed products within such target pair category in Gilead's territory for such target pair license.

*Licenses.* Under the agreement, we granted Gilead an exclusive worldwide license to research, develop, manufacture and commercialize DARTs that bind to the first pair of specified targets. Upon initiation of each of the research terms for the third and fourth target pairs we will grant Gilead a worldwide exclusive license to research, develop, manufacture and commercialize DARTs that bind to the corresponding target pair. Gilead did not exercise its option with respect to the second target pair.



*Pre-clinical Milestone.* Notice by Gilead to pay the pre-clinical milestone for each target pair category must be provided to us within specified time periods. Upon providing notice to pay a pre-clinical milestone for a target

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pair category, Gilead will become responsible for all research, development and commercialization activities with respect to licensed products within such target pair category in Gilead's territory for such target pair license.

*Exclusivity.* Subject to specified exceptions, during the term of the agreement, other than with respect to the research and development activities pursuant to the agreement, we may not, directly or indirectly, research, develop, manufacture or commercialize a product that binds to both targets from any target pair category covered by the agreement in a country where Gilead has been granted a license for such target pair.

*Term and Termination.* The agreement will terminate in its entirety upon the later of the expiration of the last-expiring patent related to a Gilead licensed product, the regulatory based exclusivity period or 12 years after the first commercial sale of a Gilead licensed product. Gilead has the right to terminate the agreement at any time with respect to one or more selected target pairs or in its entirety, upon prior written notice to us. The agreement contains customary termination rights.

## ***Boehringer***

*Overview.* In October 2010 we entered into a collaboration and license agreement with Boehringer to discover, develop and commercialize up to ten DART-based molecules which span multiple therapeutic areas. Under the terms of the agreement, we granted Boehringer an exclusive, worldwide, royalty-bearing, license under our intellectual property to research, develop, and market DARTs generated under the agreement (the Boehringer licensed products) throughout the world.

Under the agreement, we received an upfront payment of \$15.0 million. We subsequently received three annual maintenance payments including one in the fourth quarter of 2013. Also, in the fourth quarter of 2013, Boehringer's selection of a development candidate triggered a \$5.0 million milestone payment to us under the agreement. We have the potential to earn development, regulatory and sales milestone payments that can reach up to approximately \$210.0 million for each of the DART programs under this agreement in the case of full commercial success of multiple DART products. Boehringer also provides funding for our internal and external research costs and is required to pay us mid-single digit royalties, on a licensed product-by-licensed product basis, on worldwide net sales, subject to reductions in specified circumstances. We have the option to co-promote certain DART products in the United States and may elect to co-fund Phase 3 clinical development in exchange for an increased royalty rate on net sales.

*Research.* Under the agreement, Boehringer is entitled to select up to ten pairs of targets for which we would generate DARTs that bind to such targets. Several of the targets were identified in the agreement. Subsequent target pairs are selected according to a process which permits us to decline to accept such target pairs under specified circumstances. During the research term of the agreement, we are responsible for generating pre-clinical DART candidates that bind the accepted target pairs and generating data according to specified criteria which will be presented to Boehringer as a data package. If Boehringer accepts a pre-clinical DART candidate it will be responsible for subsequent development and commercialization of such pre-clinical DART candidate. We have the right to co-fund a portion of the Phase 3 clinical development in exchange for an increased royalty rate. We also have the right to co-promote up to two DART products that are developed under the agreement.

*Equity Purchase.* Boehringer purchased \$10.0 million of our Series D-2 preferred stock in January 2011.

*Exclusivity.* Subject to specified exceptions, during the term of the agreement, other than with respect to Boehringer licensed products, we agreed not to research, develop or commercialize any product using our DART platform that is directed to a target covered under the agreement. Subject to specified exceptions, we further agreed not to grant any third party rights to research, develop or commercialize any product using our DART platform that is directed to a

specified number of specific targets identified in the agreement, until a specified time period or the date on which neither of the identified targets has been selected as a target subject to development and commercialization under the agreement.

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*Term and Termination.* The agreement will terminate in its entirety upon the later of the expiration of the last-expiring patent related to a Boehringer licensed product, or 12 years after the first commercial sale of a Boehringer licensed product. Boehringer has the right to terminate the agreement at any time with respect to one or more selected target pairs or in its entirety, upon prior written notice to us. However, it must maintain research efforts during a specified time period of the agreement. The agreement may also be terminated by either Boehringer or us in the event of an uncured material breach by the other party.

***Pfizer***

*Overview.* In October 2010, we entered into a research collaboration and license agreement with Pfizer. Under the agreement, we granted Pfizer a non-exclusive worldwide, royalty-bearing license and received upfront and milestone payments and funding for our internal and external research costs under the agreement. Under the terms of the agreement, we received a non-refundable, non-creditable \$5.0 million upfront fee. In addition, we are eligible to receive up to approximately \$210.0 million per Pfizer DART molecule, as defined in the agreement, in technical, development and sales milestone payments if specified net sales thresholds are reached. We are also entitled to receive royalties from Pfizer at percentages ranging from the mid-single digits to the low-teens on net sales of any Pfizer DART. Under this collaboration, one DART program is currently being pursued and we completed our research obligations under this program in January 2014.

*Research.* Under the agreement, we are obligated to construct Pfizer DARTs that bind to a first and second target identified in the agreement that are each expressed on cancer cells. During the research term of the agreement, which expired in January 2014, we conducted pre-clinical development of the Pfizer DARTs in collaboration with Pfizer according to an agreed upon research plan. Under certain circumstances, Pfizer had the right to substitute the second target during specified periods. Pfizer exercised those rights at various times during the specified periods which have now expired.

*Product Development.* Upon expiration of the research term in January 2014, Pfizer will use commercially reasonable efforts to develop and obtain regulatory approval for each Pfizer DART in both the United States and other specified countries. In addition, Pfizer will use commercially reasonable efforts to commercialize a Pfizer DART in each country where Pfizer has received regulatory approval.

*Commercialization.* Under the Agreement, Pfizer has sole responsibility and authority for commercialization of Pfizer DARTs at its sole expense.

*Manufacturing.* Pfizer has the exclusive right to manufacture Pfizer DARTs.

*License.* Under the Agreement we granted Pfizer an exclusive, worldwide license to use, develop, manufacture, and commercialize Pfizer DARTs. The license includes the right to sublicense.

*Exclusivity.* Subject to specified exceptions, until October 3, 2015, we agreed not to research, develop, commercialize, manufacture, or grant any third party rights to research, develop, commercialize, or manufacture, (i) a Pfizer DART that binds to a cancer target for which a Pfizer DART is under development in the agreement; or (ii) product candidates based on an antibody that we have supplied to serve as the basis for generating a Pfizer DART that is in development under the agreement.

*Term and Termination.* The agreement will terminate in its entirety upon the later of the expiration of the last-expiring patent related to a Pfizer DART licensed product, or 12 years after the first commercial sale of a Pfizer DART licensed product. We or Pfizer may terminate the agreement in the event of an uncured material breach by the other

party. After a specified period, Pfizer may terminate the agreement for convenience upon prior written notice to us.

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### ***Green Cross***

*Overview.* In June 2010, we entered into a Collaboration Agreement with Green Cross Corp ( Green Cross ), to grant Green Cross an exclusive license to conduct specified Phase 1 and Phase 2 trials and commercialize margetuximab in South Korea. Under the terms of the agreement, we received a non-refundable \$1.0 million upfront fee and are eligible to receive clinical, development and commercial milestone payments up to \$4.5 million if Green Cross commercializes margetuximab. We are also entitled to receive royalties ranging from the low-single digits to the low-twenties on net sales of margetuximab by Green Cross in South Korea. In addition, Green Cross purchased \$2.0 million of our Series D-2 Preferred Stock in January 2011.

*Clinical Development.* Initial development of margetuximab under the agreement is being conducted according to a Phase 1 development plan that has been agreed upon by the parties. Based upon an amendment to the agreement, Green Cross is responsible for all of its costs to conduct the Phase 1 development plan up to a specified amount and, we are responsible for all of our own costs to conduct the Phase 1 development plan.

Development of margetuximab under the agreement after completion of the Phase 1 clinical trial will be conducted according to a Phase 2 development plan. In that regard, Green Cross is obligated to use best efforts to initiate a Phase 2 clinical trial with margetuximab in South Korea within a specified period of time after the completion of the Phase 1 trial. The costs of conducting the Phase 2 trial will be the responsibility of Green Cross. After completion of the Phase 1 trial, Green Cross has the responsibility for submitting clinical trial applications to the Korea Food and Drug Administration ( KFDA ).

Green Cross shall have the option to participate in any additional studies to the extent such studies are required by the KFDA to obtain approval of margetuximab in South Korea.

*Commercialization.* Under the Agreement, Green Cross has sole responsibility and authority for commercialization of margetuximab in South Korea at its sole expense.

*Manufacturing.* We are responsible for supply of margetuximab that is used for clinical development by Green Cross in South Korea.

*License.* Under the Agreement, we granted Green Cross an exclusive license to conduct specified Phase 1 and Phase 2 trials and commercialize margetuximab in South Korea.

*Consideration.* Under the Agreement, we received a non-refundable \$1.0 million upfront fee and are eligible to receive clinical, development and commercial milestone payments up to \$4.5 million if Green Cross commercializes margetuximab. In addition, we are entitled to receive royalties which are determined by a formula that allocates the cost of commercial supply and third party royalties against net sales.

*Term and Termination.* The agreement will terminate in its entirety upon the later of the expiration of the last-expiring patent related to margetuximab, or 12 years after the first commercial sale of margetuximab in South Korea. The agreement may also be terminated by either Green Cross or us in the event of an uncured material breach by the other party. The agreement may be terminated by us immediately in the event Green Cross participates or actively assists in a legal challenge to one of the patents exclusively licensed to Green Cross under the agreement. Either party may terminate the agreement in the event of a change in control of the other party upon 30 days prior written notice to the other party.

### **Intellectual Property**

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to protect, for example, the composition of matter of our product candidates, their methods of use, the technology platforms used to generate them, related technologies and/or other aspects of the inventions that are important to our business. We also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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We plan to continue to expand our intellectual property estate by filing patent applications directed to dosage forms, methods of treatment and additional compositions created or identified from our technology platforms and ongoing development of our product candidates. Specifically, we seek patent protection in the United States and internationally for novel compositions of matter directed to aspects of the molecules, basic structures and processes for manufacturing these molecules and the use of these molecules in a variety of therapies.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary positions. We currently use multiple industry-standard patent monitoring systems to monitor new United States Patent and Trademark Office ( USPTO ) filings for any applications by third parties that may infringe on our patents. To date, we have not identified any potential infringement of our patents by third parties.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our product candidates or use of our technology platforms. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. For example, certain patents held by third parties cover Fc engineering methods and mutations in Fc regions to enhance the binding of Fc regions to Fc receptors on immune cells. Although we believe that these patents are invalid, if they cover margetuximab or MGA271 and we are unable to invalidate them, or if licenses for them are not available on commercially reasonable terms, our business could be harmed, perhaps materially.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted by the courts after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, narrowed, circumvented or invalidated by third parties.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention. We are participating in post-grant challenge proceedings, such as oppositions, that challenge the patentability of third party patents and may have to participate in such proceedings again in the future. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

The patent portfolios for our most advanced programs are summarized below.

*Margetuximab.* We own our margetuximab patent portfolio, which includes one issued patent and one pending U.S. patent application. Our issued patent relates to the composition of or methods of making or using margetuximab and covers Fc engineered HER2 binding antibodies. This patent will expire in 2025. Related Patent Cooperation Treaty ( PCT ) and national patent applications filed in a number of other countries are pending. Any patents resulting from these patent applications, if issued, will expire in 2025. Our current pending U.S. application relates to the composition of margetuximab. If issued, this patent will expire in 2029. We filed





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related PCT and national patent applications in a number of other countries. Any patents resulting from these patent applications, if issued, also will expire 2029.

Certain issued patents and pending U.S. patent applications for our Fc Optimization platform portfolio provide additional intellectual property protection for margetuximab. We own three issued patents in this portfolio, two that relate to compositions of matter and one that covers methods of use. In addition, we have four current pending U.S. patent applications relating to compositions of matter, methods of using, and methods of making. The issued patents and any patents resulting from the pending patent applications, if issued, will expire between 2024 and 2030. PCT and national patent applications filed in a number of other countries are pending. Any patents resulting from these applications, if issued, will expire on the same dates as our corresponding U.S. patents.

*MGA271.* We own our MGA271 patent portfolio. This portfolio includes two pending U.S. patent applications. One of these pending patent applications claims MGA271 variable domains that bind to the B7-H3 receptor. Both pending patent applications cover the composition of or methods of making or using MGA271. In addition, related PCT and related national patent applications are pending in several other countries. The U.S. pending patent applications and national patent applications, if issued, will expire in 2031. MGA271 is also covered by the same patents and patent applications from our Fc Optimization platform portfolio that cover margetuximab.

*MGD006.* We own our MGD006 patent portfolio. This portfolio includes two U.S. pending provisional patent applications that claims general composition of or methods of making or using MGD006. Any patents resulting from this application, if issued, will expire in 2034. We expect to file PCT and national patent applications in other countries in the future.

Three pending U.S. patent applications for our DART platform portfolio claiming compositions of matter, methods of using, methods of making also cover MGD006. These patents, if issued, will expire between 2026 and 2031. In addition, related PCT and national patent applications filed in a number of other countries are pending. Any patents resulting from these patent applications, if issued, will expire on the same dates as our corresponding U.S. patents.

*MGD010.* We own our MGD010 patent portfolio. This portfolio includes four pending U.S. patent applications. Each patent application claims compositions of matter, methods of using, and methods of making. If issued, any patents resulting from these applications will expire between 2022 and 2034. In addition, related PCT and national patent applications in a number of other countries are pending. Any patents resulting from these patent applications, if issued, will expire on the same dates as our corresponding U.S. patents.

Three pending U.S. patent applications for our DART platform portfolio claiming compositions of matter, methods of using, methods of making also cover MGD010. Any patents resulting from these U.S. patent applications will expire between 2026 and 2031. In addition, related PCT and national patent applications in a number of other countries are pending. Any patents resulting from these patent applications, if issued, will expire on the same dates as our corresponding U.S. patents.

*DART Platform.* We own our DART platform patent portfolio. This portfolio includes seven pending U.S. patent applications, each of which claims compositions of matter, methods of using, and methods of making. Patents resulting from six of these U.S. patent applications, if issued, will expire between 2026 and 2031. The remaining application, which relates to certain mutations incorporated into our DARTs, if issued, will expire in 2032. In addition, related PCT and national patent applications in a number of other countries are pending. Any patents resulting from these patent applications, if issued, will expire on the same dates as our corresponding U.S. patents. A PCT application in our DART Platform patent portfolio also relates to a particular binding component of our DARTs. Related national applications will be filed in the future.



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*Fc Optimization Platform.* We own our Fc Optimization platform patent portfolio. This portfolio includes three issued U.S. patents that cover the compositions of antibody Fc regions with certain mutations that affect their binding to Fc receptors. These patents expire in 2024. Related national patents have issued in a number of other countries or are pending. The issued patents and any patents resulting from the pending patent applications, if issued, will expire in 2024.

*Cancer Stem-like Cell Platform.* We own our cancer stem-like cell platform patent portfolio. This portfolio consists of one issued U.S. patent that will expire in 2028. Related national patents have issued in a number of other countries and will expire on the same date. In addition to patent protection, we will also rely on the use of trade secrets to protect our cancer stem-like cell platform.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

However, the term of the U.S. patents may be extended due to delays encountered during prosecution which are caused by the USPTO or by delays incurred due to compliance with FDA regulations.

### ***FDA Regulatory Review Process***

The Hatch-Waxman Act permits a patent term extension for FDA-approved drugs of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

### ***Trade Secrets***

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In many cases our confidentiality and other agreements with consultants, outside scientific collaborators, sponsored researchers and other advisors require them to assign or grant us licenses to inventions they invent as a result the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions.

Also included in our trade secrets are hybridomas which express antibodies that bind to proteins which are or may be expressed on cancerous cells, including cancer stem cells. The antibodies produced by each hybridoma

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are unique and may have properties that are absent in antibodies expressed by other hybridomas. These properties could confer advantages and capabilities to product candidates developed with antibodies that exhibit such properties. We closely control and monitor access to the hybridomas and the antibodies they produce. Before receiving such materials, our collaborators, prospective collaborators and all other parties are required to execute material transfer agreement or other agreement which contractually limit their permitted uses and dissemination of such materials. In many cases our agreements with other parties granting access to and use of our biological materials require them to assign or grant us licenses to inventions they invent as a result of their use of the materials or grant us an option to negotiate a license to use such inventions

### ***In-Licensed Intellectual Property***

We have entered into patent and know-how license agreements which grant us the right to use a certain technology related to biological manufacturing to manufacture margetuximab and MGA271. We anticipate using this technology for future product candidates. This licensor has a business dedicated to licensing this technology and we anticipate that licenses to use the technology for our future products will be available. The licenses typically include an obligation to pay an upfront payment, yearly maintenance payment and sales royalties.

We have entered into a research evaluation agreement for a technology related to biological manufacturing that we anticipate using to manufacture certain DART products. This licensor has a business dedicated to licensing this technology and we anticipate that licenses will be available to use it to manufacture quantities of the DART products for clinical and commercial uses. The licenses may include an obligation to pay an upfront payment, yearly maintenance payments, milestones and sales royalties.

In establishing our Fc Optimization platform, we entered into patent license agreements which grant us the right to use technologies to generate mutant Fc regions. The licenses include obligations to pay a yearly maintenance payment, development milestones and sales royalties on products we develop and commercialize that include mutant Fc regions generated using the patented technologies.

### **Manufacturing**

We currently have a manufacturing facility located in Rockville, Maryland. This facility has been used to manufacture all of the current clinical supply for margetuximab and MGA271 to date. We currently have capacity to produce Phase 2 material for our antibody product candidates and clinical and commercial material for our DART therapeutics. We intend to expand our capacity at this location, or possibly elsewhere. For our Phase 3 clinical trials for our antibody product candidates and for commercial sale quantities of such candidates, we anticipate that we will need to obtain additional manufacturing capacity through contract manufacturers to be able to supply the quantities required. We intend to screen multiple manufacturers to provide the drug substance for commercial purposes for some of our product candidates prior to the filing of a BLA. We currently rely on and will continue to rely on contract fill-finish service providers to fulfill our fill-finish needs for our current and future product candidates.

All of our product candidates are biologics and are manufactured in disposable bioreactors in CHO cells in accordance with cGMP. We expect to continue to develop product candidates that can be produced at our manufacturing facility and at contract manufacturing facilities.

We generate cell lines internally that serve as the source for our biologic drug substance. These cell lines are then sent to a vendor where they are expanded and banked, and are available upon our request to use in developing drug substance. All other manufacturing materials used in the production of drug substance are readily available in the ordinary course of business from a number of standard biotechnology vendors.

We generally expect to rely on third parties for the development and manufacturing of our companion diagnostics.

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### **Commercialization**

We have not yet established a sales, marketing or product distribution infrastructure because our lead product candidates are still in clinical development. We generally seek to retain commercial rights in the United States for our clinical product candidates for which we hope to receive marketing approvals and have done so to date in our collaborations other than our Boehringer, Gilead and Pfizer collaborations. We believe that it will be possible for us to access the United States oncology market through a targeted specialty sales force.

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products. We believe that such an organization will be able to address the community of oncologists who are the key specialists in treating the patient populations for which our oncology product candidates are being developed. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with thought leaders in relevant fields of medicine.

We expect that our collaborators for any companion diagnostics we may develop in the future for use with our product candidates will hold the commercial rights to these diagnostic products. We expect to coordinate closely with our diagnostic collaborators in connection with the marketing and sale of our related product candidates.

### **Competition**

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our 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 governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

There are a large number of companies developing or marketing treatments for cancer and autoimmune disorders, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, as well as biologic therapeutics that work by using next-generation antibody technology platforms to address specific cancer targets. In addition, several companies are developing therapeutics that work by targeting multiple specificities using a single recombinant molecule. Amgen is now in late-stage clinical development of cancer product candidates which work by targeting antigens both on immune effector cell populations and those expressed on certain cancer cells. In addition, other companies are developing new treatments for cancer and autoimmune diseases that enhance the Fc regions of antibodies to create more potent antibodies, including Roche and Xencor, Inc.

Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining top qualified



scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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The key competitive factors affecting the success of all of our therapeutic product candidates, if approved, are likely to be their efficacy, safety, dosing convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third party payors seeking to encourage the use of biosimilar products. Biosimilar products are expected to become available over the coming years. For example, certain HER2 biosimilar products may be approved in the U.S. prior to margetuximab. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive biosimilar products if any have been approved by then.

The most common methods of treating patients with cancer are surgery, radiation and drug therapy. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates may compete with many existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates will not be competitive with them. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third party payors.

In addition to currently marketed therapies, there are also a number of products in late stage clinical development to treat cancer. These product candidates in development may provide efficacy, safety, dosing convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our product candidates for which we obtain marketing approval.

If our lead product candidates are approved for the indications for which we are currently undertaking clinical trials, they will compete with the therapies and currently marketed drugs discussed below.

*Margetuximab.* Irrespective of HER2 status, metastatic breast cancers are often treated with cytotoxic chemotherapies such as anthracyclines and taxanes, as well as capecitabine. Advanced and metastatic cancers are treated with chemotherapy and radiation therapy. In addition, there are several approved therapies specifically indicated for the treatment of early and advanced stage breast cancer and advanced gastroesophageal cancer that are HER2+, including Herceptin, Kadcyla, Tykerb and Perjeta, and each of those drugs targets HER2+ tumors.

*MGA271.* The most common treatments for solid tumors are various chemotherapeutic agents, radiation therapy and certain targeted therapies including monoclonal antibodies such as Herceptin, Avastin, Erbitux and Vectibix, as well as small molecule agents, including, Tarceva, Sutent and Nexavar. No therapies are approved specifically for the treatment of tumors associated with the expression of B7-H3. Yervoy, which targets CTLA4, an inhibitory molecule on T cells, is currently indicated for the treatment of melanoma and marketed by Bristol-Myers. In addition, there are several antibodies in development that target other members of the B7 family or their associated checkpoint receptors. These include anti-PD1 molecules by Merck, Bristol-Myers and AstraZeneca, and anti-PD-L1 molecules by Bristol-Myers, Roche and Merck KGaA and a PD-L2 Fc fusion protein by GSK and AstraZeneca.

*MGD006.* The most common treatments for AML are various chemotherapeutic agents, radiation and stem cell transplants. No therapies are approved specifically for the treatment of AML associated with the expression of

CD123. We are aware of a monoclonal antibody currently being developed by CSL Limited which targets CD123. In addition, StemLine Therapeutics, Inc. has treated patients in a clinical trial with a recombinant protein composed of IL-3 linked to a truncated diphtheria toxin payload.

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*MGD007.* The most common treatments for gastroesophageal tumors are various chemotherapeutic agents, radiation therapy, monoclonal antibodies including Herceptin, Avastin, Erbitux, Vectibix, as well as small molecule agents. No therapies are approved specifically for the treatment of tumors associated with the expression of gpA33.

*MGD010.* Current B cell targeted therapies for autoimmune diseases include Rituxan and Arzerra for the treatment of rheumatoid arthritis and Benlysta for the treatment of SLE. In addition, several other therapies are available to reduce inflammation, including nonsteroidal anti-inflammatory drugs such as Advil and Aleve; corticosteroids such as prednisone; disease-modifying antirheumatic drugs such as methotrexate and hydroxychloroquine; immunosuppressants such as cyclosporine; and other drugs which target a variety of processes involved with inflammation such as Actemra, Kineret, Enbrel, Remicade, Humira, Simponi, Cimzia, Orencia and Xeljanz.

## **Government Regulation and Product Approval**

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

### ***FDA Approval Process***

All of our current product candidates are subject to regulation in the United States by the FDA as biological products ( biologics ). The FDA subjects biologics to extensive pre- and post-market regulation. The Public Health Service Act ( PHSA ), the Federal Food, Drug, and Cosmetic Act ( FDC Act ) and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of biologics. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending BLAs, withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, or criminal penalties.

The PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction, or spread, of communicable diseases in the United States and between states.

The process required by the FDA before a new biologic may be marketed in the United States is long, expensive, and inherently uncertain. Biologics development in the United States typically involves pre-clinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the biologic for each indication for which FDA approval is sought. Developing the data to satisfy FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the pre-clinical tests must

comply with federal regulations and requirements, including good laboratory practices. The results of pre-clinical testing are submitted to the FDA as part of an IND along with other information, including

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information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

An IND must become effective before United States clinical trials may begin. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not imposed a clinical hold, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients with the condition under investigation, all under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice ( GCP ), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board ( IRB ) for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions. The study sponsor may also suspend a clinical trial at any time on various grounds, including a determination that the subjects or patients are being exposed to an unacceptable health risk.

Clinical trials to support Biologics License Applications ( BLAs ) for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase 1, the biologics initially introduced into healthy human subjects or patients, and the biologic is tested to assess pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer treatments, initial human testing may be conducted in the intended patient population. Phase 2 usually involves trials in a limited patient population to determine the activity of the biologic for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of activity and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites. These Phase 3 clinical trials are intended to establish data sufficient to demonstrate substantial evidence of the efficacy and safety of the product to permit FDA to evaluate the overall benefit-risk relationship of the biologic and to provide adequate information for the labeling of the biologic. Trials conducted outside of the US under similar, GCP-compliant conditions in accordance with local applicable laws may also be acceptable to FDA in support of product licensing.

Sponsors of clinical trials for investigational drugs must publicly disclose certain clinical trial information, including detailed trial design and trial results in FDA public databases. These requirements are subject to specific timelines and apply to most controlled clinical trials of FDA-regulated products.

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA review and approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of all pre-clinical, clinical, and other testing and a compilation of data relating to the product s pharmacology, chemistry, manufacture, and controls and must demonstrate the safety and efficacy of the product

based on these results. The BLA must also contain extensive manufacturing information. The cost of preparing and submitting a BLA is substantial. Under federal law, the submission of most BLAs is additionally

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subject to a substantial application user fee, as well as annual product and establishment user fees, which may total several million dollars and are typically increased annually.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. Most such applications for standard review biologics are reviewed within ten months from the date the application is accepted for filing. Although FDA often meets its user fee performance goals, the FDA can extend these timelines if necessary, and FDA review may not occur on a timely basis at all. The FDA usually refers applications for novel biologics, or biologics which present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one, or more, clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic is manufactured and tested. The FDA will not approve the product unless it verifies that compliance with cGMP is satisfactory and the BLA contains data that provide substantial evidence that the biologic is safe and effective in the indication studied.

After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. The FDA approval is never guaranteed, and the FDA may refuse to approve a BLA if applicable regulatory criteria are not satisfied.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure, and potent. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. The approval for a biologic may be significantly more limited than requested in the application, including limitations on the specific diseases and dosages or the indications for use, which could restrict the commercial value of the product. The FDA may also require that certain contraindications, warnings, or precautions be included in the product labeling. In addition, as a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS or use of a companion diagnostic with a biologic can materially affect the potential market and profitability of the biologic. Moreover, product approval may require, as a condition of approval, substantial post-approval testing and surveillance to monitor the biologic's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

After a BLA is approved, the product may also be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some



products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. After approval of biologics,

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manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

### ***Fast Track***

The Fast Track program, a provision of the FDA Modernization Act of 1997, is designed to facilitate interactions between a sponsoring company and the FDA before and during submission of a BLA for an investigational agent that, alone or in combination with one or more other drugs, is intended to treat a serious or life-threatening disease or condition, and which demonstrates the potential to address an unmet medical need for that disease or condition. Under the Fast Track program, the FDA may consider reviewing portions of a marketing application before the sponsor submits the complete application if FDA determines, after a preliminary evaluation of the clinical data, that a fast track product may be effective. A Fast Track designation provides the opportunity for more frequent interactions with the FDA, and a fast track product could be eligible for priority review if supported by clinical data at the time of submission of the BLA.

### ***Biosimilars***

The Patient Protection and Affordable Care Act (Affordable Care Act) signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 ( BPCIA ). That Act created an approval pathway authorizing the FDA to approve biosimilars and interchangeable biosimilars. Biosimilars are biological products which are highly similar to a previously approved biologic product or reference product and for which there are no clinically meaningful differences between the biosimilar product and the reference product in terms of the safety, purity, and potency. For FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biosimilar and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation, which are still being worked out by the FDA. To date, no biosimilar or interchangeable biologic has been licensed under the BPCIA framework, although such approvals have occurred in Europe, and it is anticipated that FDA will approve a biosimilar in the relatively near future.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product. A biosimilar application may be filed four (4) years after the approval of the reference biologic. Although the patents for the reference biologic may be challenged by the biosimilar applicant during that time period pursuant to the BPCIA statutory patent challenge framework, no biosimilar or interchangeable product will be licensed by FDA until the end of the exclusivity period. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after first commercial marketing, (ii) 18 months after the initial application if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period. At this juncture, it is unclear whether products deemed interchangeable by FDA, in fact, will be readily substituted by pharmacies, which are governed by state pharmacy law.

***Advertising and Promotion***

Once a BLA is approved, a product will be subject to continuing post-approval regulatory requirements. For instance, FDA closely regulates the post-approval marketing and promotion of biologics, including standards and

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regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet and other social media. Failure to comply with these regulations can result in significant penalties, including the issuance of warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be precleared by the FDA, and federal and state civil and criminal investigations and prosecutions.

Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

### ***Adverse Event Reporting and GMP Compliance***

Adverse event reporting and submission of periodic reports are required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, manufacture, packaging, labeling, storage and distribution procedures must continue to conform to current cGMPs after approval. Biologics manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals, request product recalls, or impose marketing restrictions through labeling changes or product removals if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

### ***Companion Diagnostics***

The FDA regulates the sale or distribution, in interstate commerce, of medical devices, including in vitro diagnostics ( IVDs ). IVDs are a type of medical device that are intended to detect diseases, conditions, or infections, or the presence of certain genetic or other biomarkers. If safe and/or effective use of a therapeutic depends on an IVD, the FDA generally will require approval of the companion diagnostic, at the same time that the FDA approves the therapeutic. The FDA previously has required *in vitro* companion diagnostics intended to identify the patients most likely to respond to a treatment to obtain approval of a premarket approval application ( PMA ) simultaneously with approval of the biologic. A required companion diagnostic has the potential to delay approval of the biologic and create barriers to patient access.

### ***Orphan Drug***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to biologics intended to treat a rare disease or condition generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not necessarily convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first BLA applicant to receive FDA approval for a particular product to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that

product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug

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exclusivity does not prevent the FDA from approving a different biologic for the same disease or condition, or the same biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

We anticipate seeking orphan drug designation for specific indications under development with margetuximab, MGA271, MGD006 and MGD007. Such designation would be sought in those populations that are being, or will be, studied to treat a disease or condition that affects fewer than 200,000 individuals in the United States.

## ***Other Healthcare Laws and Compliance Requirements***

In the United States, our activities are potentially subject to regulation by federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments.

## ***International Regulation***

In addition to regulations in the United States, a variety of foreign regulations govern clinical trials, commercial sales, and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA approval.

## ***Pharmaceutical Coverage, Pricing, and Reimbursement***

In the United States and other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers, and other organizations. Third-party payors are increasingly examining the medical necessity and cost effectiveness of medical products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Third-party reimbursement adequate to enable us to realize an appropriate return on our investment in research and product development may not be available for our products.

## **Facilities**

Our headquarters are located in Rockville, Maryland, where we occupy office and laboratory space under a lease that expires on March 31, 2018. Our manufacturing facility is also located in Rockville under a lease with the same landlord that expires on December 31, 2014. We have an option under each lease to continue the respective lease for five years under the same terms. We also sublease office and laboratory space in South San Francisco under a lease that expires on December 31, 2018. We are seeking to sublease a substantial portion of this space.

## **Employees**

As of February 28, 2014, we had 166 full-time employees, 130 of whom were primarily engaged in research and development activities and 35 of whom had an M.D. or Ph.D. degree.

## **Legal Proceedings**

We are not currently a party to any material legal proceedings.



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**ITEM 1A. RISK FACTORS**

*Our business and results of operations are subject to numerous risks, uncertainties and other factors that you should be aware of, some of which are described below. The risks, uncertainties and other factors described below are not the only ones facing our company. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations.*

*Any of the risks, uncertainties and other factors could have a materially adverse effect on our business, financial condition or results of operations and could cause the trading price of our common stock to decline substantially.*

**Risks Related to Our Business and the Development and Commercialization of Our Product Candidates.**

*All of our product candidates are in pre-clinical or clinical development. Clinical drug development is expensive, time consuming and uncertain and we may ultimately not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.*

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration ( FDA ) and non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of a Biologics License Application ( BLA ) from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and non-U.S. regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;

restrictions on the products, manufacturers or manufacturing process;

warning letters;

civil and criminal penalties;

injunctions;

suspension or withdrawal of regulatory approvals;



product seizures, detentions or import bans;

voluntary or mandatory product recalls and publicity requirements;

total or partial suspension of production;

imposition of restrictions on operations, including costly new manufacturing requirements; and

refusal to approve pending BLAs or supplements to approved BLAs.

The FDA and foreign regulatory authorities also have substantial discretion in the drug approval process. The number of pre-clinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular drug candidate. Regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

a product candidate may not be deemed safe or effective;

the results may not confirm the positive results from earlier pre-clinical studies or clinical trials;

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regulatory agencies may not find the data from pre-clinical studies and clinical trials sufficient;

regulatory agencies might not approve or might require changes to our manufacturing processes or facilities;  
or

regulatory agencies may change their approval policies or adopt new regulations.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. These limitations may limit the size of the market for the product.

***If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to obtain regulatory approval and commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any product revenue.***

We are currently enrolling a Phase 2a clinical trial of margetuximab in patients with metastatic breast cancer and anticipate commencing a Phase 3 potential registration clinical trial of margetuximab in advanced gastroesophageal cancer in the second half of 2014. We have initiated a Phase 1 clinical trial of MGA271 that we expect to complete by the end of 2014. We expect to commence a Phase 1 clinical trial of MGD006 in the first half of 2014 and expect to commence a Phase 1 clinical trial of MGD007 in the second half of 2014. The commencement of these planned clinical trials could be substantially delayed or prevented by several factors, including:

further discussions with the FDA or other regulatory agencies regarding the scope or design of our clinical trials;

the limited number of, and competition for, suitable sites to conduct our clinical trials, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;

any delay or failure to obtain regulatory approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;

inability to obtain sufficient funds required for a clinical trial;

clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;

delay or failure to manufacture sufficient supplies of the product candidate for our clinical trials;

delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or clinical research organizations ( CROs ) the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs; and

delay or failure to obtain institutional review board ( IRB ) approval to conduct a clinical trial at a prospective site.

The completion of our clinical trials could also be substantially delayed or prevented by several factors, including:

slower than expected rates of patient recruitment and enrollment;

failure of patients to complete the clinical trial;

unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;

lack of efficacy during clinical trials;

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termination of our clinical trials by one or more clinical trial sites;

inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;

inability to monitor patients adequately during or after treatment by us and/or our CROs; and

the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing.

Changes in regulatory requirements and guidance may also occur and we may need to significantly amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us, due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;

lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;  
and

upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates.

Any failure or significant delay in completing clinical trials for our product candidates would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

***The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities.***

We currently have no products approved for sale, and we cannot guarantee that we will ever have marketable products. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or pre-clinical testing. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through initial clinical trials. Product candidates that have shown promising results in early

clinical trials may still suffer significant setbacks in subsequent registration clinical trials. Similarly, the outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in

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size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from pre-clinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial that has the potential to result in FDA or other agencies approval. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

***We use new technologies in the development of our product candidates and the FDA and other regulatory authorities have not approved products that utilize these technologies.***

Our products in development are based on new technologies, such as Fc Optimization, bi-specific DARTs and CSLCs. Given the complexity of our technologies, we intend to work closely with FDA and other regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates. It is possible that the validation process may take time and resources, require independent third-party analyses or not be accepted by the FDA and other regulatory authorities. For some of our product candidates that are based on these technology platforms, the regulatory approval path and requirements may not be clear, which could add significant delay and expense. Delays or failure to obtain regulatory approval of any of the products that we develop would adversely affect our business.

***We may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates.***

A key element of our strategy is to use and expand our technology platforms to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various cancers and autoimmune disorders, we may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect our stock price.

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

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource

allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately

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evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

***Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.***

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional pre-clinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

***We may seek fast-track designation of margetuximab and may seek fast track designation for some of our other product candidates. There is no assurance that the FDA will grant such designation and, even if it does grant fast track designation to margetuximab or one of our other product candidates, that designation may not actually lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval in the United States.***

We may seek fast-track designation of margetuximab and may seek fast track designation and review for some of our other product candidates. If a drug is intended for the treatment of a serious or life-threatening condition or disease, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Moreover, even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

***We may seek breakthrough therapy designation by the FDA for any of our product candidates but that is not assured and may not, in any event, lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval in the United States.***

We may apply for breakthrough therapy designation for some of our product candidates. The FDA is authorized to designate a product candidate as a breakthrough therapy if it finds that the product is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products designated as breakthrough therapies, interaction and communication between the FDA and the sponsor



of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

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Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

***We may be unable to obtain orphan product designation or exclusivity for some or all of our product candidates. If our competitors are able to obtain orphan product exclusivity for their products that are the same as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.***

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, FDA may designate a product candidate 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.

Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing 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 ( 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 product no longer meets the criteria for orphan drug designation or if the product 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 product 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. In the United States, even after an orphan drug is approved, the FDA can subsequently approve the same 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.

***Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.***

Although all of our product candidates have undergone or will undergo safety testing, not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved by regulatory authorities, after the approved product has been marketed. All of our product candidates are still in clinical or pre-clinical development. While our clinical trials for our initial product candidates to date have demonstrated a favorable safety profile, the results from future trials may not support this conclusion. The results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings or potential product liability claims.



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If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

regulatory authorities may require us to take our approved product off the market;

regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;

we may be subject to limitations on how we may promote the product;

sales of the product may decrease significantly;

we may be subject to litigation or product liability claims; and

our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

***Even if approved, if any of our product candidates do not achieve broad market acceptance among physicians, patients, the medical community, and third-party payors our revenue generated from their sales will be limited.***

The commercial success of our product candidates will depend upon their acceptance among physicians, patients and the medical community. The degree of market acceptance of our product candidates will depend on a number of factors, including:

limitations or warnings contained in the approved labeling for a product candidate;

changes in the standard of care for the targeted indications for any of our product candidates;

limitations in the approved clinical indications for our product candidates;

demonstrated clinical safety and efficacy compared to other products;

lack of significant adverse side effects;

sales, marketing and distribution support;

availability and extent of reimbursement from managed care plans and other third-party payors;

timing of market introduction and perceived effectiveness of competitive products;

the degree of cost-effectiveness of our product candidates;

availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;

the extent to which the product candidate is approved for inclusion on formularies of hospitals and managed care organizations;

whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular diseases;

adverse publicity about our product candidates or favorable publicity about competitive products;

convenience and ease of administration of our products; and

potential product liability claims.

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If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients and the medical community, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

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

The process of manufacturing our products is complex, highly regulated and subject to several risks, including:

The process of manufacturing biologics, such as margetuximab, MGA271, and our other product candidates, is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. 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 equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

We must comply with the FDA's current Good Manufacturing Practice (cGMP) regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of drug product for our clinical trials or the termination or hold on a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts

or seek more costly manufacturing alternatives.

***We currently have no marketing, sales or distribution infrastructure. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations, we will not be successful in commercializing our product candidates.***

We currently have no marketing, sales and distribution capabilities and we have no sales or marketing experience within our organization. If any of our product candidates are approved, we intend either to establish a

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sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, or to outsource this function to a third party. Either of these options would be expensive and time consuming. These costs may be incurred in advance of any approval of our product candidates. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

With respect to certain of our existing and future product candidates, we have entered into collaboration or other licensing arrangements with third party collaborators that have direct sales forces and established distribution systems. To the extent that we enter into additional collaboration agreements, our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.***

The life sciences industry is highly competitive and subject to rapid and significant technological change. We are currently developing therapeutics that will compete with other drugs and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products in our field before we do.

Specifically, there are a large number of companies developing or marketing treatments for cancer and autoimmune disorders, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, as well as biologic therapeutics that work by using next-generation antibody technology platforms to address specific cancer targets. In addition, several companies are developing therapeutics that work by targeting multiple specificities using a single recombinant molecule. Amgen, Inc. is in late-stage clinical development of cancer product candidates which work by targeting antigens both on immune effector cell populations and those expressed on certain cancer cells. In addition, other companies are developing new treatments for cancer and autoimmune diseases that enhance the Fc regions of antibodies to create more potent antibodies, including F. Hoffmann-La Roche Ltd. and Xencor, Inc.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient or are less expensive than any



products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our

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competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third party payors seeking to encourage the use of biosimilar products. Biosimilar products are expected to become available over the coming years. For example, certain HER2 biosimilar products may be approved prior to margetuximab. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive biosimilar products if any have been approved by then.

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act (collectively the ACA) created a new regulatory scheme authorizing the FDA to approve biosimilars. Under the ACA, a manufacturer may submit an application for licensure of a biologic product that is biosimilar to or interchangeable with a previously approved biological product or reference product. Under this new statutory scheme, an application for a biosimilar product may not be submitted to the FDA until four years following approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. Furthermore, recent legislation has proposed that the 12 year exclusivity period for each a reference product may be reduced to seven years.

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 and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

***Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that our products will be widely used.***

Even if our product candidates are approved for sale by the appropriate regulatory authorities, market acceptance and sales of these products will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will reimburse and establish payment levels. We cannot be certain that reimbursement will be available for any products that we develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act (MMA), changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs.

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our future approved products profitably. Among policy makers and payors in the United States and elsewhere, there is

significant interest in promoting changes in healthcare systems with the stated goals of

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containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of any products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

In March 2010, the ACA became law in the United States. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, any products we develop that receive regulatory approval. We also cannot predict the impact of ACA on our business or financial condition as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions, which has not yet occurred.

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

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our collaborators by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in:

decreased demand for our future approved products;

injury to our reputation;

withdrawal of clinical trial participants;

termination of clinical trial sites or entire trial programs;

increased regulatory scrutiny;

significant litigation costs;

substantial monetary awards to or costly settlement with patients or other claimants;

product recalls or a change in the indications for which they may be used;

loss of revenue;

diversion of management and scientific resources from our business operations; and

the inability to commercialize our product candidates.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

We currently hold \$15 million in product liability insurance coverage in the aggregate, with a per incident limit of \$15 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage when we begin the commercialization of our product candidates. Insurance

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coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

***Our business may become subject to economic, political, regulatory and other risks associated with international operations.***

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and collaborative and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

economic weakness, including inflation, or political instability in particular foreign economies and markets;

differing regulatory requirements for drug approvals in foreign countries;

potentially reduced protection for intellectual property rights;

difficulties in compliance with non-U.S. laws and regulations;

changes in non-U.S. regulations and customs, tariffs and trade barriers;

changes in non-U.S. currency exchange rates and currency controls;

changes in a specific country's or region's political or economic environment;

trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;

negative consequences from changes in tax laws;

compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

workforce uncertainty in countries where labor unrest is more common than in the United States;

difficulties associated with staffing and managing foreign operations, including differing labor relations;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

**Risks Related to Our Financial Position and Need for Additional Capital**

*We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.*

We are a clinical-stage biopharmaceutical company. We have incurred significant losses since our inception. As of December 31, 2013, our accumulated deficit was approximately \$175.7 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company. The net losses and negative cash flows incurred to date, together with

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expected future losses, have had, and likely will continue to have, an adverse effect on our stockholders' deficit and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. For example, our expenses could increase if we are required by the FDA to perform trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates.

To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including developing product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back, or cease our product development programs or operations.***

We are advancing our product candidates through clinical development. Developing pharmaceutical products, including conducting pre-clinical studies and clinical trials, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical trials for each indication for each of our product candidates. We will continue to require additional funding beyond what was raised in the initial public offering ( IPO ) of our common stock completed in October 2013 and the follow-on offering completed in February 2014 to complete the development and commercialization of our product candidates and to continue to advance the development of our other product candidates, and such funding may not be available on acceptable terms or at all. Although it is difficult to predict our funding requirements, based upon our current operating plan, we anticipate that our cash and cash equivalents as of December 31, 2013, combined with the net proceeds from our subsequent follow-on offering and collaboration payments we anticipate receiving, will enable us to fund the clinical development of margetuximab, MGA271, MGD006, MGD007, MGD010 and two additional pre-clinical DART-based oncology product candidates into 2017, assuming all of our collaboration programs advance as currently contemplated. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and to commercialize our product candidates.

Our future funding requirements will depend on many factors, including but not limited to:

the number and characteristics of other product candidates that we pursue;

the scope, progress, timing, cost and results of research, pre-clinical development, and clinical trials;



the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;

the costs associated with manufacturing our product candidates and establishing sales, marketing, and distribution capabilities;

our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;

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our need and ability to hire additional management, scientific, and medical personnel;

the effect of competing products that may limit market penetration of our product candidates;

our need to implement additional internal systems and infrastructure, including financial and reporting systems; and

the economic and other terms, timing of and success of our existing collaborations, and any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through a combination of public or private equity offerings, debt financings, strategic collaborations, and grant funding. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our development programs or our business operations.

***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.***

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates, or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***We have broad discretion in the use of the net proceeds from our IPO and follow-on offering and may not use them effectively.***

Our management has broad discretion to use our cash and cash equivalents to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use to fund operations, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

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

Our ability to utilize our federal net operating losses ( NOLs ) and federal tax credits is currently limited, and may be limited further, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply

if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period, which is typically three years or since the last ownership change. We are already subject to Section 382 limitations due to an acquisition we made in 2008. As of December 31, 2013, we had federal NOL carryforwards of \$103.2 million, state NOL carryforwards of \$58.4 million and research and development tax credit carryforwards of \$23.7 million available. Future changes in stock ownership may also trigger an ownership change and, consequently, another Section 382 limitation. Any

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limitation may result in expiration of a portion of the net operating loss or tax credit carryforwards before utilization which would reduce our gross deferred income tax assets and corresponding valuation allowance. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and tax credit carryforwards to reduce United States federal income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

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

*Our existing therapeutic collaborations are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.*

We have limited capabilities for drug development and do not yet have any capability for sales, marketing or distribution. We have entered into collaborations with other companies that we believe can provide such capabilities, including our collaboration and license agreements with Les Laboratoires Servier and Institut de Recherches Servier (collectively, Servier ), Gilead Sciences, Inc. ( Gilead ), Boehringer Ingelheim GmbH ( Boehringer ), Pfizer, Inc. ( Pfizer ) and Green Cross Corp. ( Green Cross ). These collaborations also have provided us with important funding for our development programs and technology platforms and we expect to receive additional funding under these collaborations in the future. Our existing therapeutic collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

collaborators may not perform their obligations as expected;

collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

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collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. For example, each of our collaboration and license agreements with Servier, Gilead, and Boehringer may be terminated for convenience upon the completion of a specified notice period.

If our therapeutic collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our technology platforms and product candidates could be delayed and we may need additional resources to develop product candidates and our technology platforms. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our program collaborators.

Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators.

For some of our product candidates, we may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our technology platforms and our business may be materially and adversely affected.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Aside from our agreement with Green Cross, subject to certain

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specified exceptions, each of our existing therapeutic collaborations contains a restriction on our engaging in activities that are the subject of the collaboration with third parties for specified periods of time.

***Independent clinical investigators and CROs that we engage to conduct our clinical trials may not devote sufficient time or attention to our clinical trials or be able to repeat their past success.***

We expect to continue to depend on independent clinical investigators and CROs to conduct our clinical trials. CROs may also assist us in the collection and analysis of data. There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. These investigators and CROs will not be our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. 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. Further, the FDA requires that we comply with standards, commonly referred to as current Good Clinical Practice ( cGCP ) for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. Failure of clinical investigators or CROs to meet their obligations to us or comply with cGCP procedures could adversely affect the clinical development of our product candidates and harm our business.

***Failure of our third party contractors to successfully develop and commercialize companion diagnostics for use with our product candidates could harm our ability to commercialize our product candidates.***

We plan to develop companion diagnostics for our product candidates where appropriate. Companion diagnostics are used to identify patients who could potentially benefit from our therapeutic product candidates. We expect that, at least in some cases, the FDA and similar regulatory authorities outside the United States may require the development and regulatory approval of a companion diagnostic as a condition to approving our product candidates. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions.

We plan to outsource the development, production and commercialization of companion diagnostics to third parties. By outsourcing these companion diagnostics to third parties, we become dependent on the efforts of our third party contractors to successfully develop and commercialize these companion diagnostics. Our contractors:

may not perform their obligations as expected;

may encounter production difficulties that could constrain the supply of the companion diagnostic;

may have difficulties gaining acceptance of the use of the companion diagnostic in the clinical community;

may not commit sufficient resources to the marketing and distribution of such product; and



may terminate their relationship with us.

If any companion diagnostic for use with one of our product candidates fails to gain market acceptance, our ability to derive revenues from sales of such product candidate could be harmed. If our third party contractors fail to commercialize such companion diagnostic, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with such product candidate or do so on commercially reasonable terms, which could adversely affect and delay the development or commercialization of such product candidate.

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*We expect to contract with third parties for the manufacture of our product candidates for clinical testing in the future and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.*

We currently have a manufacturing facility located in Rockville, Maryland. We manufacture drug substance at this facility that we use for research and development purposes and for clinical trials of our product candidates. We currently have capacity to produce Phase 2 material for our antibody product candidates and clinical and commercial material for our DART therapeutics, but our current facility will be insufficient to support our needs for our Phase 3 clinical trials for our antibody product candidates and for commercial quantities of such candidates. We do not have experience in manufacturing products at commercial scale.

We have entered into agreements with contract manufacturing organizations to supplement our clinical supply and internal capacity as we advance pre-clinical product candidates into clinical development. We expect to use third parties for the manufacture of certain of our product candidates for clinical testing, as well as for commercial manufacture of some of our product candidates that receive marketing approval and that are not manufactured by one of our third party collaborators. We plan eventually to enter into long term supply agreements with several manufacturers for commercial supplies. We may be unable to reach agreement with any of these contract manufacturers, or to identify and reach arrangements on satisfactory terms with other contract manufacturers, to manufacture any of our product candidates. Additionally, the facilities used by any contract manufacturer to manufacture any of our product candidates must be the subject of a satisfactory inspection before the FDA and other regulatory authorities approve a BLA or marketing authorization for the product candidate manufactured at that facility. We will depend on these third-party manufacturing partners for compliance with the FDA's requirements for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA and other regulatory authorities' cGMP requirements, our product candidates will not be approved or, if already approved, may be subject to recalls.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

the possibility of a breach of the manufacturing agreements by the third parties because of factors beyond our control;

the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer; and

the possibility that we may not be able to secure a manufacturer or manufacturing capacity in a timely manner and on satisfactory terms in order to meet our manufacturing needs.

Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose

potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA or any other relevant regulatory authorities.

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**Table of Contents****Risks Related to Our Intellectual Property**

*If we are unable to obtain and enforce patent protection for our product candidates and related technology, our business could be materially harmed.*

Issued patents may be challenged, narrowed, invalidated or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

Our strategy depends on our ability to identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology. Third parties may also seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the United States Patent and Trademark Office ( USPTO ) and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Outside the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, we cannot predict whether additional patents protecting our technology will issue in the United States or in foreign jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide competitive advantage. Moreover, we cannot predict whether third parties will be able to successfully obtain claims or the breadth of such claims. The allowance of broader claims may increase the incidence and cost of patent interference proceedings, opposition proceedings, and/or reexamination

proceedings, the risk of infringement litigation, and the vulnerability of the claims to challenge. On the other hand, the allowance of narrower claims does not eliminate the potential for adversarial proceedings, and may fail to provide a competitive advantage.

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Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage.

***We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.***

Even after they have issued, our patents and any patents which we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

we or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights;

third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;

third parties may initiate opposition or reexamination proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and/or licensors to participate in such proceedings to defend the validity and scope of our patents;

there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us;

the U.S. Patent and Trademark Office may initiate an interference between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our collaborators and/or licensors to participate in an interference proceeding to determine the priority of invention, which could jeopardize our patent rights; or

third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. There is a risk that a court or administrative body would decide that our patents are invalid or not infringed by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents could limit our ability to assert our patents against these or other competitors, affect our ability to receive royalties or other licensing

consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;

others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;

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we might not have been the first to make the inventions covered by patents or pending patent applications;

we might not have been the first to file patent applications for these inventions;

any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or

we may not develop additional proprietary technologies that are patentable.

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.***

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. For example, certain patents held by third parties cover Fc engineering methods and mutations in Fc regions to enhance the binding of Fc regions to Fc receptors on immune cells. Although we believe that these patents are invalid, if they cover margetuximab or MGA271 and we are unable to invalidate their patents, or if licenses for them are not available on commercially reasonable terms, our business could be harmed, perhaps materially.

Patents that we may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to any technology that we require may also materially harm our business, financial condition, and results of operations. Furthermore, we would be exposed to a threat of litigation. Invitrogen, Inc., for example, has asserted that we are required to obtain a license for use of a cell line.

In the pharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;

if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;



if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and

if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is a risk that a court would decide that we or our collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our collaborators may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an

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approved product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

The pharmaceutical and biotechnology industries have produced a significant number of patents, and 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. If we are sued for patent infringement, we would need to demonstrate that our products or 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 invalidity 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 divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

***If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.***

We are currently party to various intellectual property license agreements. These license agreements impose, and we expect that future license agreements may impose, various diligence, milestone payment, royalty, insurance and other obligations on us. For example, we have entered into patent and know-how license agreements which grant us the right to use a certain technology related to biological manufacturing to manufacture margetuximab and MGA271. These licenses typically include an obligation to pay an upfront payment, yearly maintenance payments and royalties on sales. If we fail to comply with our obligations under the licenses, the licensors may have the right to terminate their respective license agreements, in which event we might not be able to market any product that is covered by the agreements. Termination of the license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, which could adversely affect our competitive business position and harm our business.

***If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.***

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of

their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the

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individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. If such an event were to occur, it could have a material adverse effect on our business. In addition, we are responsible for the payment of patent fees for patent rights that we have licensed from other parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights.



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***If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.***

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

**Risks Related to Legal Compliance Matters**

***If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.***

Our research and development involves, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the States of Maryland and California to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, 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. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

***If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.***

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws commonly referred to as fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include false claims and anti-kickback statutes.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between

pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn

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narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. At such time, if ever, as we market any of our future approved products and these products are paid for by governmental programs, it is possible that some of our business activities could also be subject to challenge under one or more of these fraud and abuse laws.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. 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. We have adopted a code of conduct, but 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 comply with these 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, including the imposition of significant fines or other sanctions.

## **Risks Relating to Employee Matters and Managing Growth**

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

We are highly dependent on the research and development, clinical and business development expertise of Scott Koenig, M.D., Ph.D., our President and Chief Executive Officer, as well as the other members of our senior management, scientific and clinical team. Although we have entered into employment agreements with certain of our executive officers, each of them may terminate their employment with us at any time. We currently maintain \$1 million in key person insurance coverage for Dr. Koenig. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.



Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited

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number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.***

As of February 28, 2014, we had 166 full-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively with others in our industry will depend, in part, on our ability to effectively manage any future growth.

**Risks Relating to Our Common Stock**

***Our stock price may be volatile and fluctuate substantially.***

Our stock price is likely to be volatile. The stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology, and other life sciences company stocks. The volatility of pharmaceutical, biotechnology, and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common stock to fluctuate include:

results and timing of our clinical trials and clinical trials of our competitors' products;

failure or discontinuation of any of our development programs;

issues in manufacturing our product candidates or future approved products;

regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products;

competition from existing products or new products that may emerge;

developments or disputes concerning patents or other proprietary rights;

introduction of technological innovations or new commercial products by us or our competitors;

announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;

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changes in estimates or recommendations by securities analysts, if any cover our common stock;

fluctuations in the valuation of companies perceived by investors to be comparable to us;

public concern over our product candidates or any future approved products;

litigation;

future sales of our common stock;

share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

additions or departures of key personnel;

changes in the structure of health care payment systems in the United States or overseas;

failure of any of our product candidates, if approved, to achieve commercial success;

economic and other external factors or other disasters or crises;

period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;

general market conditions and market conditions for biopharmaceutical stocks; and

overall fluctuations in U.S. equity markets.

In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

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

In October 2013, we completed our IPO. Prior to the IPO, there was no public market for our common stock. Although we have completed our IPO as well as a follow-on offering and shares of our common stock are listed and trading on The NASDAQ Global Select Market, an active trading market for our shares may not be sustained. If an

active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

***Insiders have substantial control over us which could delay or prevent a change in corporate control or result in the entrenchment of management and/or the board of directors.***

As of December 31, 2013, our directors, executive officers and principal stockholders, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 78% of our outstanding common stock. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

delaying, deferring, or preventing a change in control;

entrenching our management and/or the board of directors;

impeding a merger, consolidation, takeover, or other business combination involving us; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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*We are an emerging growth company and as a result of the reduced disclosure requirements applicable to emerging growth companies, our common stock may be less attractive to investors.*

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take 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 shareholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We cannot predict whether 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. We could remain an emerging growth company until the earliest to occur of the following:

the last day of the fiscal year in which we have total annual gross revenue of \$1 billion or more;

the last day of our fiscal year following the fifth anniversary of the date of the first sale of common equity securities pursuant to the prospectus filed with the Securities and Exchange Commission on October 11, 2013;

the date on which we have issued more than \$1 billion in non-convertible debt during the previous three years; or

the date on which we are deemed to be a large accelerated filer under SEC rules and regulations.

*We incur significantly increased costs as a result of operating as a public company, and our management is required to devote substantial time to corporate governance standards.*

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, our administrative staff will be required to perform additional tasks. For example, we are in the process of adopting additional internal controls and disclosure controls and procedures. As a public company, we bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

In addition, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and related regulations implemented by the Securities and Exchange Commission and the NASDAQ Global Select Market, have increased legal and financial compliance costs that make some compliance

activities more time consuming. We cannot predict or estimate the amount of additional costs we will continue to incur or the timing of such costs. We must invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In connection with our IPO, we increased our directors' and officers' insurance coverage which will increase our insurance cost. In the future, it may be more expensive or more difficult for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members

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of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

Under the corporate governance standards of the NASDAQ Global Select Market, a majority of our board of directors and each member of our audit committee must be an independent director no later than the first anniversary of the completion of our IPO. We may encounter difficulty in attracting qualified persons to serve on our board of directors and the audit committee, and our board of directors and management may be required to divert significant time and attention and resources away from our business to identify qualified directors. If we fail to attract and retain the required number of independent directors, we may be subject to the delisting of our common stock from the NASDAQ Global Select Market.

***Provisions of our charter, bylaws, and Delaware law may make an acquisition of us or a change in our management more difficult.***

Certain provisions of our restated certificate of incorporation and amended and restated bylaws that became effective upon the completion of our IPO could discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Furthermore, since our board of directors is responsible for appointing the members of our management team, these provisions could prevent or frustrate attempts by our stockholders to replace or remove our management by making it more difficult for stockholders to replace members of our board of directors. These provisions:

allow the authorized number of directors to be changed only by resolution of our board of directors;

establish a classified board of directors, providing that not all members of the board of directors be elected at one time;

authorize our board of directors to issue without stockholder approval blank check preferred stock that, if issued, could operate as a poison pill to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;

require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;

establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings;

limit who may call stockholder meetings; and



require the approval of the holders of 75% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our restated certificate of incorporation and restated bylaws.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a prescribed period of time. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

***We do not anticipate paying cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment.***

We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses. As a result, capital appreciation, if any, of our common stock will be your sole source of gain on your investment for the foreseeable future. Investors seeking cash dividends should not invest in our common stock.

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***A significant portion of our total outstanding shares of common stock is restricted from resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. After the IPO in October 2013, we had 25,020,288 outstanding shares of common stock. This included the shares sold in the IPO, which were eligible to be resold in the public market immediately and the remaining shares that are currently restricted under securities laws or as a result of lock-up agreements but will be able to be resold upon the expiration of the lock-up agreements 180 days from the signing of the underwriting agreement in our IPO. Moreover, holders of an aggregate of 17,458,764 shares of common stock 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 also filed a registration statement on Form S-8 to register all 1,920,168 shares of common stock that we may issue under our equity compensation plans, and they therefore can be freely sold in the public market upon issuance and once vested, subject to the lock-up agreements described above.

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

As of December 31, 2013, we had options to purchase 3,200,958 shares outstanding under our equity compensation plans. We are also authorized to grant equity awards, including stock options, to our employees, directors and consultants, covering up to 1,402,459 shares of our common stock, pursuant to our equity compensation plans. We plan to register the number of shares available for issuance or subject to outstanding awards under our equity compensation plans.

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

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We cannot assure you that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

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**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

Our headquarters are located in Rockville, Maryland, where we occupy office and laboratory space under a lease that expires on March 31, 2018. Our manufacturing facility is also located in Rockville under a lease with the same landlord that expires on December 31, 2014. We have an option under each lease to continue the respective lease for five years under the same terms. We also sublease office and laboratory space in South San Francisco under a lease that expires on December 31, 2018. We are seeking to sublease a substantial portion of this space.

We believe that our properties are generally in good condition, well maintained, suitable and adequate to carry on our business. We believe our capital resources are sufficient to lease any additional facilities required to meet our expected growth needs.

**ITEM 3. LEGAL PROCEEDINGS**

In the ordinary course of business, we are involved in various legal proceedings, including, among others, patent oppositions, patent revocations, patent infringement litigation and other matters incidental to our business. We are not currently a party to any material legal proceedings.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

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**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS  
AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Information**

Our common stock has been listed on the NASDAQ Global Select Market under the symbol "MGNX" since October 10, 2013. Prior to that date, there was no public trading market for our common stock. Shares sold in our initial public offering ( "IPO" ) on October 9, 2013 were priced at \$16.00 per share.

On February 28, 2014, the closing price for our common stock as reported on the NASDAQ Global Select Market was \$35.00. The following table sets forth the high and low intra-day sale prices per share of our common stock as reported on the NASDAQ Global Select Market for the periods indicated.

	<b>High</b>	<b>Low</b>
Fourth Quarter 2013 (from October 10, 2013)	\$ 30.25	\$ 21.50

**Shareholders**

As of February 28, 2014, we had 27,471,329 shares of common stock outstanding held by approximately 192 holders of record, which include shares held by a broker, bank or other nominee. We have never declared or paid any cash dividends. We do not anticipate declaring or paying cash dividends for the foreseeable future. Instead, we will retain our earnings, if any, for the future operation and expansion of our business.

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**Performance Graph**

The following graph compares the performance of our common stock since October 9, 2013, the date of our IPO, with the performance of the NASDAQ Composite Index (U.S.) and the NASDAQ Biotechnology Index. The comparison assumes a \$100 investment on October 9, 2013 in our common stock, the stocks comprising the NASDAQ Composite Index, and the stocks comprising the NASDAQ Biotechnology Index, and assumes reinvestment of the full amount of all dividends, if any. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.

**Comparison of Cumulative Total Return**

**Among MacroGenics, Inc., the NASDAQ Composite Index and the NASDAQ Biotechnology Index**

The performance graph shall not be deemed to be incorporated by reference by means of any general statement incorporating by reference this Form 10-K into any filing under the Securities Act of 1933, as amended or the Exchange Act, except to the extent that we specifically incorporate such information by reference, and shall not otherwise be deemed filed under such acts.

**Use of Proceeds from Registered Securities**

On October 16, 2013, we completed our IPO of 5,750,000 shares of our common stock, including 750,000 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares at a public offering price of \$16.00 per share, for aggregate gross proceeds of \$92.0 million. All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-190994), which was declared effective by the Securities and Exchange Commission ( SEC ) on October 9, 2013. Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Swann LLC acted as representatives of the several underwriters. The offering commenced on October 10, 2013 and did not terminate until the sale of all of the shares offered.

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We received net proceeds from the offering of \$83.8 million, after deducting approximately \$6.4 million of underwriting discounts and commissions, and approximately \$1.9 million of offering expenses payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to our directors or officers or their associates or to persons owning 10 percent or more of our common stock.

There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on October 11, 2013. We have broad discretion in the use of the net proceeds from our initial public offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our stock.

**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA**

The consolidated statements of operations and comprehensive income (loss) data for the years ended December 31, 2013, 2012 and 2011 and the consolidated balance sheet data as of December 31, 2013 and 2012 presented below have been derived from our audited consolidated financial statements and footnotes included elsewhere herein. The consolidated balance sheet data as of December 31, 2011 has been derived from our audited consolidated financial statements which are not included herein. Historical results are not necessarily indicative of future results. The following data should be read in conjunction with Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
	<b>(in thousands, except share and per share data)</b>		
<b>Consolidated Statement of Operations and</b>			
<b>Comprehensive Income (Loss):</b>			
Total revenues	\$ 58,035	\$ 63,826	\$ 57,207
Cost and expenses:			
Research and development	46,582	45,433	41,089
General and administrative	11,087	10,188	10,869
Total costs and expenses	57,669	55,621	51,958
Income (loss) from operations	366	8,205	5,250
Other income (expense)	(627)	156	1,467
Net income (loss)	\$ (261)	\$ 8,362	\$ 6,717
Basic net income (loss) per common share	\$ (0.04)	\$ 0.00	\$ 0.00
Diluted net income (loss) per common share	\$ (0.04)	\$ 0.00	\$ 0.00
Basic weighted average number of common shares	6,847,697	1,083,276	1,025,602
Diluted weighted average number of common shares	6,847,697	1,083,276	1,025,602

	<b>As of December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
	<b>(in thousands)</b>		
<b>Consolidated Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 116,481	\$ 47,743	\$ 55,218
Total assets	125,782	53,747	62,681
Deferred revenue	27,403	44,080	54,890
Convertible preferred stock		2,947	2,947
Total stockholders' equity (deficit)	78,914	(8,237)	(17,484)

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**Table of Contents****ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion of our financial condition and results of operations should be read together with our selected consolidated financial data and the consolidated financial statements and related notes included elsewhere herein. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the section entitled Risk Factors, Forward-Looking Statements and elsewhere herein, our actual results may differ materially from those anticipated in these forward-looking statements.*

**Overview**

We are a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer and autoimmune diseases. We generate our pipeline of product candidates from our proprietary suite of next-generation antibody technology platforms which we believe improve the performance of monoclonal antibodies and antibody-derived molecules. These product candidates, which we have identified through our understanding of disease biology and immune-mediated mechanisms, may address disease-specific challenges, which are not currently being met by existing therapies. The combination of our technology platforms and antibody engineering expertise has allowed us to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. These collaborations provide us with funding and allow us to leverage the additional expertise of our collaborators to advance the development of our product candidates.

We currently have two oncology product candidates in clinical development. Additionally, we have several proprietary product candidates in pre-clinical development and we expect to commence Phase 1 clinical trials on two of these product candidates in 2014. In addition, we intend to advance two pre-clinical Dual-Affinity Re-Targeting ( DART )-based oncology product candidates to Investigational New Drug ( IND ) submission and commence Phase 1 clinical trials in 2015.

*Margetuximab*, also known as MGAH22, is an Fc-optimized monoclonal antibody that targets HER2-expressing tumors, including breast, gastroesophageal and other cancers. HER2, or human epidermal growth factor receptor 2, is critical for the growth of many types of tumors. We are currently enrolling a Phase 2a clinical trial in metastatic breast cancer and plan to commence a Phase 3 potential registration clinical trial in advanced gastroesophageal cancer in the second half of 2014.

*MGA271* is an Fc-optimized monoclonal antibody that targets B7-H3, a member of the B7 family of molecules and is over-expressed on a wide variety of solid tumor types. We expect to complete the first three dose expansion cohorts of a Phase 1 clinical trial by the end of 2014. We plan to initiate additional expansion cohorts using MGA271 as monotherapy in other tumor types in 2014, as well as combining MGA271 with other therapies for certain tumor types.

*MGD006* is a humanized DART molecule that recognizes CD123, the Interleukin-3 receptor ( IL3R ) alpha chain which is expressed on leukemia and leukemic stem cells, but not on normal hematopoietic stem cells, and CD3, which is expressed on T cells. We expect to commence a Phase 1 clinical trial in the second quarter of 2014.



*MGD007* is a humanized DART molecule that recognizes both the glycoprotein gpA33, expressed on gastrointestinal tumors, including more than 95% of human colon cancers, and CD3, which is expressed on T cells. We expect to commence a Phase 1 clinical trial in the second half of 2014.

We commenced active operations in 2000, and have since devoted substantially all of our resources to staffing our company, business planning, raising capital, developing our technology platforms, identifying potential product candidates, undertaking pre-clinical studies and conducting clinical trials. We have not generated any revenues from the sale of any products to date. We have financed our operations primarily through the private placements of convertible preferred stock, the public offerings of our common stock, collaborations,

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and government grants and contracts. From inception through December 31, 2013, we received \$151.3 million from the sale of convertible preferred stock and warrants. We raised \$85.6 million (\$83.8 million net of expenses and deferred financing costs) in October 2013 through the sale of common stock in connection with our Initial Public Offering ( IPO ) and exercise by the underwriters of their over-allotment option. We raised an additional \$77.2 million (\$76.7 million net of expenses and deferred financing costs) through a follow-on public offering of our common stock and full exercise by the underwriters of their over-allotment option in February 2014. In addition, we have received \$199.0 million of upfront, milestone and annual maintenance payments from our collaborators and have been reimbursed \$220.4 million through our collaborations and government grants and contracts. Although it is difficult to predict our funding requirements, based upon our current operating plan, we anticipate that our cash and cash equivalents as of December 31, 2013, combined with the net proceeds from our subsequent follow-on offering and collaboration payments we anticipate receiving, will enable us to fund the clinical development of margetuximab, MGA271, MGD006, MGD007, MGD010 and two additional pre-clinical DART-based oncology product candidates into 2017, assuming all of our collaboration programs advance as currently contemplated.

Through December 31, 2013, we had an accumulated deficit of \$175.7 million. Due primarily to upfront fees and milestones paid by our collaborators, we realized a profit of \$8.4 million and \$6.7 million for the years ended December 31, 2012 and 2011, respectively. We incurred a net loss of approximately \$0.3 million for the year ended December 31, 2013, primarily due to the conclusion in late 2012 of the teplizumab Protégé clinical trial-related reimbursement from Eli Lilly. We expect that over the next several years we will increase our expenditures in research and development in connection with our ongoing activities with several clinical trials.

**Strategic Collaborations and Licenses**

We have entered into several strategic collaborations which provide us with significant additional funding in order to continue development of our pipeline and to extend our technology platforms and on-going programs. Our collaborations have allowed us to speed up the progress of our on-going pre-clinical and clinical stage programs.

*Servier.* In November 2011, we entered into a collaboration agreement with Les Laboratoires Servier and Institut de Recherches Servier (collectively, Servier ) under which we granted Servier an option to obtain an exclusive license to develop and commercialize MGA271 in all countries other than the United States, Canada, Mexico, Japan, South Korea and India. We received a \$20.0 million option grant fee and a \$10.0 million milestone payment, and may be eligible to receive up to approximately \$415.0 million in license grant fees, and clinical, development, regulatory and sales milestone payments. In the event Servier exercises its option, Servier must pay a license grant fee, which we estimate to be \$30.0 million, based on the number of different indications represented within the planned Phase 1 patient population. We and Servier will share Phase 2 and Phase 3 development costs.

In September 2012, we entered into a second agreement with Servier and granted it options to obtain three separate exclusive licenses to develop and commercialize DART-based molecules, consisting of those designated by us as MGD006 and MGD007, as well as a third DART molecule, in all countries other than the United States, Canada, Mexico, Japan, South Korea and India. We received a \$20.0 million option grant fee. In addition, we will be eligible to receive up to approximately \$1 billion in additional license grant fees, and clinical, development, regulatory and sales milestone payments if Servier exercises all three of its options and successfully develops, obtains regulatory approval for, and commercializes a product under each license, including \$5.0 million upon IND acceptance for each of MGD006, MGD007 and a third DART molecule. In addition to these milestone payments, we and Servier will share Phase 2 and Phase 3 development costs.

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In February 2014, Servier exercised its option to develop and commercialize MGD006, for which we received a \$15.0 million license grant fee. We also received a \$5.0 million milestone payment from Servier in connection with the IND application for MGD006 clearing the 30-day review period by the U.S. Food and Drug Administration ( FDA )

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Additionally, under both agreements, Servier would be obligated to pay us low double digit to mid-teen royalties on product sales in its territories.

*Gilead.* In January 2013, we entered into an agreement with Gilead Sciences, Inc. ( Gilead ) for the research, development and commercialization of up to four DART-based molecules. The time period for Gilead's exercise of one option has expired. At present, Gilead retains a license to one and options to two of the original four programs. Gilead has exclusive worldwide rights for each of these remaining programs. We received an initial \$7.5 million license grant fee for the first DART-based molecule, and are eligible to receive \$7.5 million in grant fees on each of the remaining two DART-based molecules if they are selected by Gilead. We are further eligible to receive up to an additional \$20 to \$25 million in pre-clinical milestones across each of the three remaining DART programs and up to approximately \$240 to \$250 million per remaining program in additional clinical, regulatory and sales milestone payments if Gilead exercises both remaining options and achieves all of the requisite milestones under each option and license. Gilead also provides funding for our internal and external research costs under the agreement. We are also eligible to receive tiered royalties on the net sales at percentages ranging from the high-single digits to the low double digits, but less than teens, subject to reductions in specified circumstances.

*Boehringer.* In October 2010, we entered into an agreement with Boehringer Ingelheim GmbH ( Boehringer ) to discover, develop and commercialize up to ten DART-based molecules which may span multiple therapeutic areas. We granted Boehringer an exclusive worldwide, royalty-bearing license and received an upfront payment of \$15.0 million. In the fourth quarter of 2013, Boehringer nominated a bi-specific antibody therapeutic candidate generated by our DART technology for pre-clinical development. This formal selection of a development candidate triggered a \$5.0 million milestone payment to us under the agreement. We have received three annual maintenance payments, including a \$4.0 million payment in the fourth quarter of 2013. We have the potential to earn development, regulatory and sales milestone payments that can reach up to approximately \$210.0 million for each of the DART programs under this agreement. Boehringer provides funding for our internal and external research costs and is required to pay us mid-single digit royalties on product sales. From the commencement of the collaboration through December 31, 2013, we have received \$48.8 million under this agreement, including upfront, annual maintenance and milestone payments as well as research funding. In addition, Boehringer purchased \$10.0 million of our Series D-2 Preferred Stock in January 2011. This preferred stock was converted to common stock upon our IPO in October 2013.

*Pfizer.* In October 2010, we entered into a three year agreement with Pfizer, Inc. ( Pfizer ) to discover, develop and commercialize up to two DART-based molecules. We granted Pfizer a non-exclusive worldwide, royalty-bearing license and received an upfront payment of \$5.0 million and have received milestone payments and funding for our internal and external research costs under the agreement. We are eligible to receive technical, development and sales milestone payments that can reach up to approximately \$210.0 million for each DART program under this agreement. Pfizer is responsible for all pre-clinical and clinical development costs for the program. In addition, Pfizer is required to pay us mid-single digit to low-teen royalties on product sales. Under this collaboration, one DART program is currently being pursued and we completed our research obligations under this program in January 2014.

*Green Cross.* In June 2010, we entered into a collaboration agreement with Green Cross Corp. ( Green Cross ) for the development of margetuximab. We granted Green Cross an exclusive license for all indications for all pharmaceutical forms of margetuximab in South Korea. Under the terms of this agreement, we received an upfront, nonrefundable payment of \$1.0 million and are eligible to receive clinical, development and commercial milestone payments up to \$4.5 million as well as royalties ranging from the low-single digits to the low-twenties on net sales of margetuximab in South Korea. In addition, Green Cross purchased \$2.0 million of our Series D-2 Preferred Stock in January 2011. This preferred stock was converted to common stock upon our IPO in October 2013.

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### **Financial Operations Overview**

#### ***Revenues***

Our revenue consists of collaboration revenue, including amounts recognized relating to upfront nonrefundable payments for licenses or options to obtain future licenses, research and development funding and milestone payments earned under our collaboration and license agreement with our strategic collaborators, including Servier, Gilead, Boehringer, Pfizer and Green Cross. In addition, we have earned revenues through several grants and/or contracts with the U.S. government and other educational institutions on behalf of the U.S. government, primarily with respect to research and development activities related to infectious disease product candidates.

#### ***Research and Development Expense***

Research and development expenses consist of expenses incurred in performing research and development activities. These expenses include conducting pre-clinical experiments and studies, clinical trials, manufacturing efforts and regulatory filings for all product candidates, and other indirect expenses in support of our research and development activities. We capture research and development expense on a program-by-program basis for our product candidates that are in clinical development and recognize these expenses as they are incurred. The following are items we include in research and development expenses:

Employee-related expenses such as salaries and benefits;

Employee-related overhead expenses such as facilities and other allocated items;

Stock-based compensation expense to employees and consultants engaged in research and development activities;

Depreciation of laboratory equipment, computers and leasehold improvements;

Fees paid to consultants, subcontractors, clinical research organizations ( CROs ) and other third party vendors for work performed under our pre-clinical and clinical trials including but not limited to investigator grants, laboratory work and analysis, database management, statistical analysis, and other items;

Amounts paid to vendors and suppliers for laboratory supplies;

Costs related to manufacturing clinical trial materials, including vialing, packaging and testing;

License fees and other third party vendor payments related to in-licensed product candidates and technology;  
and

Costs related to compliance with regulatory requirements.

It is difficult to determine with certainty the duration and completion costs of our current or future pre-clinical programs and clinical trials of our product candidates, 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. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical trials and pre-clinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

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### ***General and Administrative Expense***

General and administrative expenses consist of salaries and related benefit costs for employees in our executive, finance, legal and intellectual property, business development, human resources and other support functions, travel expenses and other legal and professional fees.

### ***Other Income (Expense)***

Other income (expense) consists of interest income earned on our cash equivalents, offset by interest expense and other expense, including changes in the fair market value of the preferred stock warrant liability.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of financial conditions and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the balance sheets and the reported amount of the revenue and expenses recorded during the reporting period. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable. We review and evaluate these estimates on an on-going basis. These assumptions and estimates form the basis for making judgments about the carrying values of assets and liabilities and amounts that have been recorded as revenues and expenses. Actual results and experiences may differ from these estimates. The results of any material revisions would be reflected in the consolidated financial statements prospectively from the date of the change in estimate.

While a summary of significant accounting policies is described fully in Note 2 in our consolidated financial statements, we believe that the following accounting policies are the most critical to assist you in fully understanding and evaluating our financial results and any affect the estimates and judgments we used in preparing our consolidated financial statements.

### ***Revenue Recognition***

We enter into collaboration and license agreements with collaborators for the development of monoclonal antibody-based therapeutics to treat cancer and other complex diseases. The terms of these agreements contain multiple deliverables which may include (i) licenses, or options to obtain licenses, to our technological platforms, such as our Fc engineering and DART technologies, (ii) rights to future technological improvements, (iii) research and development activities to be performed on behalf of the collaborative partner or as part of the collaboration, and (iv) the manufacture of pre-clinical or clinical materials for the collaborative partner. Payments to us under these agreements may include nonrefundable license fees, option fees, exercise fees, payments for research and development activities, payments for the manufacture of pre-clinical or clinical materials, license maintenance payments, payments based upon the achievement of certain milestones and royalties on product sales. Other benefits to us from these agreements include the right to sell products resulting from the collaborative efforts of the parties in specific geographic territories. We follow the provisions of the Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ) Topic 605-25, *Revenue Recognition Multiple-Element Arrangements*, and ASC Topic 605-28, *Revenue Recognition Milestone Method*, in accounting for these agreements. In order to account for these agreements, we must identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on the achievement of certain criteria, including whether the delivered element has stand-alone value to the collaborator. The consideration received is allocated among the separate units of



accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

As of December 31, 2013, we had the following two types of agreements: 1) exclusive development and commercialization licenses to use our technology and/or certain other intellectual property to develop compounds

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against specified targets, which we refer to as exclusive licenses; and 2) option/research agreements to secure on established terms development and commercialization licenses to anticancer and other therapeutic product candidates to collaborator selected targets developed by us during an option period, which we refer to as right-to-develop agreements.

### ***Exclusive Licenses***

The deliverables under an exclusive license agreement generally include the exclusive license to our technology with respect to a specified antigen target, and may also include deliverables related to rights to future technological improvements, research and pre-clinical development activities to be performed on behalf of the collaborator. In some cases we may have an option to participate in the co-development of product candidates that result from such agreements.

Generally, exclusive license agreements contain nonrefundable terms for payments and, depending on the terms of the agreement, provide that we will (i) at the collaborator's request, provide research and pre-clinical development services at negotiated prices which are generally consistent with what other third parties would charge, (ii) earn payments upon the achievement of certain milestones, (iii) earn royalty payments, and (iv) in some cases grant us an option to participate in the development and commercialization of products that result from such agreements. Royalty rates may vary over the royalty term depending on our intellectual property rights and whether we exercise any co-development and co-commercialization rights. We may provide technical assistance and share any technology improvements with our collaborators during the term of the collaboration agreements.

We do not directly control when any collaborator will achieve milestones or become liable for royalty payments.

In determining the units of accounting, management evaluates whether the exclusive license has stand-alone value from the undelivered elements to the collaborator based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the collaborator and the availability of technology platform and product research expertise in the general marketplace. If we conclude that the license has stand-alone value and therefore will be accounted for as a separate unit of accounting, we then determine the estimated selling prices of the license and all other units of accounting based on market conditions, similar arrangements entered into by third parties, and entity-specific factors such as the terms of our previous collaboration agreements, recent pre-clinical and clinical testing results of therapeutic product candidates that use our technology platforms, our pricing practices and pricing objectives, the likelihood that technological improvements will be made, the likelihood that technological improvements made will be used by our collaborators and the nature of the research services to be performed on behalf of our collaborators and market rates for similar services.

Upfront payments on exclusive licenses are deferred if facts and circumstances dictate that the license does not have stand-alone value. Prior to the adoption of Accounting Standards Update (ASU) No. 2009-13, *Revenue Arrangements with Multiple Deliverables*, on January 1, 2011, we determined that our licenses lacked stand-alone value and were combined with other elements of the arrangement and any amounts associated with the license were deferred and amortized over a certain period, which we refer to as our period of substantial involvement. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period. Historically, our involvement with the development of a collaborator's product candidate has been significant at the early stages of development, and lessens as it progresses into clinical trials. Accordingly, we generally estimate this period of substantial involvement to begin at the inception of the collaboration agreement and conclude at the end of our substantial involvement. We reassess our periods of substantial involvement over which we amortize our upfront license fees and make adjustments as appropriate. In the event a collaborator elects to discontinue development of a specific product candidate under a single target license, but

retains its right to use our technology to develop an alternative product candidate to the same target or a target substitute, we would cease amortization of any

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remaining portion of the upfront fee until there is substantial pre-clinical activity on another product candidate and its remaining period of substantial involvement can be estimated. In the event that a single target license were to be terminated, we would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue, at the date of such termination or through the remaining substantial involvement in the wind down of the agreement.

Upfront payments on exclusive licenses may be recognized upon delivery of the license if facts and circumstances dictate that the license has stand-alone value from the undelivered elements, which generally include rights to future technological improvements, research services and the manufacture of pre-clinical and clinical materials.

We recognize revenue related to research and pre-clinical development services that represent separate units of accounting as they are performed, as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is probable. We recognize revenue related to the rights to future technological improvements over the estimated term of the applicable license.

We typically perform research activities and pre-clinical development services, including generating and engineering product candidates, on behalf of our licensees during the early evaluation and pre-clinical testing stages of drug development under our exclusive licenses. We record amounts received for research materials produced or services performed as revenue from collaborative research.

Our license agreements have milestone payments which for reporting purposes are aggregated into three categories: (i) development milestones, (ii) regulatory milestones, and (iii) sales milestones. Development milestones are typically payable when a product candidate initiates or advances into different clinical trial phases. Regulatory milestones are typically payable upon submission for marketing approval with the FDA or other countries' regulatory authorities or on receipt of actual marketing approvals for the compound or for additional indications. Sales milestones are typically payable when annual sales reach certain levels.

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) our performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Non-refundable development and regulatory milestones that are expected to be achieved as a result of our efforts during the period of substantial involvement are considered substantive and are recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive because we did not contribute effort to the achievement of such milestones are generally achieved after the period of substantial involvement and are recognized as revenue upon achievement of the milestone, as there are no undelivered elements remaining and no continuing performance obligations, assuming all other revenue recognition criteria are met.

### ***Right-to-Develop Agreements***

Our right-to-develop agreements provide collaborators with an exclusive option to obtain licenses to develop and commercialize in specified geographic territories product candidates developed by us under agreed upon research and pre-clinical development programs. The product candidates resulting from each program are

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all directed to a specific target selected by the collaborator. Under these agreements, fees may be due to us (i) at the inception of the arrangement (referred to as upfront fees or payments), (ii) the selection of a target for a program, (iii) upon the exercise of an option to acquire a development and commercialization license, referred to as exercise fee, for a program, or (iv) some combination of all of these fees.

The accounting for right-to-develop agreements is dependent on the nature of the options granted to the collaborative partner. Options are considered substantive if, at the inception of a right-to-develop agreement, we are at risk as to whether the collaborative partner will choose to exercise the options to secure development and commercialization licenses. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments imposed on the collaborator as a result of exercising the options.

For right-to-develop agreements where the options to secure development and commercialization licenses to a product program are considered substantive, we do not consider the development and commercialization licenses to be a deliverable at the inception of the agreement. For those right-to-develop agreements entered into prior to the adoption of ASU No. 2009-13 where the options to secure development and commercialization licenses are considered substantive, we have deferred the upfront payments received and recognize this revenue over the period during which the collaborator could elect to exercise options for development and commercialization licenses. These periods are specific to each collaboration agreement. If a collaborator selects a target for a product program, any substantive option fee is deferred and recognized over the life of the option, generally 12 months. If a collaborator exercises an option and acquires a development and commercialization license to a product program, we attribute the exercise fee to the development and commercialization license.

Upon exercise of an option to acquire a development and commercialization license, we would also attribute any remaining deferred option fee, in addition to the consideration received for the license upon exercise of the option, to the development and commercialization license. We then apply the multiple-element revenue recognition criteria to the development and commercialization license and other deliverables, if any, to determine the appropriate revenue recognition method. This method is consistent with our accounting policy for upfront payments on exclusive licenses (discussed above). In the event a right-to-develop agreement were to be terminated, we would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue, at the date of such termination.

For right-to-develop agreements where the options to secure development and commercialization licenses to product programs are not considered substantive, we consider the development and commercialization licenses to be a deliverable at the inception of the agreement and apply the multiple-element revenue recognition criteria to determine the appropriate revenue recognition. All of our right-to-develop agreements have been determined to contain substantive options. We do not directly control when any collaborator will exercise its options for development and commercialization licenses.

***Research and Development Expense and related Accrued Expenses***

As part of the process of preparing our consolidated financial statements, we may be required to estimate accrued expenses. In order to obtain reasonable estimates, we review open contracts and purchase orders. In addition, we communicate with applicable personnel in order to identify services that have been performed, but for which we have not yet been invoiced. In most cases, our vendors provide us with monthly invoices in arrears for services performed. We confirm our estimates with these vendors and make adjustments as needed. The following are examples of our accrued expenses:

Fees paid to CROs for services performed on clinical trials;

Fees paid to investigate sites for performance on clinical trials; and

Fees paid for professional services.

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Expenses related to clinical trials performed by our CROs are dependent on the successful enrollment of patients. These expenses can vary from site to site and contract to contract. We base our estimated accruals on the time period over which the services are to be performed and the level of effort to be expended in each period based on the estimated enrollment of patients in each trial. We will adjust accordingly should the estimates vary from the actual expenses. However, we do not anticipate that our payment of actual expenses will differ materially from our estimates.

***Income Taxes***

Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more-likely-than-not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the largest amount that is more than 50% likely to be realized upon ultimate settlement. Our policy is to record interest and penalties related to uncertain tax positions as a component of income tax expense.

We recorded net deferred tax assets of \$79.4 million as of December 31, 2013, which have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily comprised of federal and state tax net operating loss ( NOL ) carryforwards and research and development tax credit carryforwards. As of December 31, 2013, we had federal NOL carryforwards of \$104.8 million, state NOL carryforwards of \$60.3 million and research and development tax credit carryforwards of \$23.7 million available. The federal NOL carryforwards will begin to expire at various dates starting in 2023. We are already subject to Section 382 limitations due to an acquisition we made in 2008. Future changes in stock ownership may also trigger an ownership change and, consequently, another Section 382 limitation. Any limitation may result in expiration of a portion of the net operating loss or tax credit carryforwards before utilization which would reduce our gross deferred income tax assets and corresponding valuation allowance. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and tax credit carryforwards to reduce United States federal income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

***Stock-Based Compensation***

We recognize stock-based compensation expense in accordance with the provisions of ASC Topic 718, *Compensation - Stock Compensation*. The fair value of stock-based payments is estimated, on the date of grant, using a Black-Scholes model. The resulting fair value is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the option. The use of a Black-Scholes model requires us to apply judgment and make assumptions and estimates that include the following:

*Fair Value of Common Stock* Before our entry into the public market on October 10, 2013, our Board of Directors determined the fair value of the common stock. The Board of Directors made determinations of fair value based, in part, upon contemporaneous valuations to determine fair value. The contemporaneous valuations were performed in accordance with applicable methodologies, approaches and assumptions of the technical practice-aid issued by the American Institute of Certified Public Accountants Practice Aid entitled



*Valuation of Privately-Held Company Equity Securities Issued as Compensation.*

*Expected Volatility* Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. As we do not yet have sufficient history of our own volatility, we have identified several public

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entities of similar size, complexity and stage of development and calculate the historical volatility using the volatility of these companies.

*Expected Dividend Yield* We have never declared or paid dividends and have no plans to do so in the foreseeable future.

*Risk-Free Interest Rate* This is the U.S. Treasury rate for the week of each option grant during the year, having a term that most closely resembles the expected life of the option.

*Expected Term* This is the period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of ten years and we have estimated the expected life of the option term to be seven years. We use a simplified method to calculate the average expected term.

*Expected Forfeiture Rate* The forfeiture rate is the estimated percentage of options granted that is expected to be forfeited or canceled on an annual basis before becoming fully vested. We estimate the forfeiture rate based on turnover data with further consideration given to the class of the employees to whom the options were granted.

**Results of Operations for the Years Ended December 31, 2013 and 2012****Research and Development Revenue**

The following represents a comparison of our research and development revenue for the years ended December 31, 2013 and 2012:

	Year Ended December 31,		Increase/(Decrease)	
	2013	2012		
	(dollars in millions)			
Revenue from collaborative research	\$ 56.7	\$ 59.6	\$ (2.9)	(5)%
Grant revenue	1.3	4.2	(2.9)	(69)%
<b>Total revenue</b>	<b>\$ 58.0</b>	<b>\$ 63.8</b>	<b>\$ (5.8)</b>	<b>(9)%</b>

The decrease in collaboration revenue of \$2.9 million for the year ended December 31, 2013 compared to 2012 is primarily due to the conclusion of teplizumab clinical trial-related reimbursement revenue from our former collaborator, Eli Lilly. Aside from reimbursing us for the continued monitoring expense of one on-going trial, Eli Lilly's participation in the development of teplizumab concluded in the first quarter of 2013. This decrease is partially offset by the receipt of a \$10.0 million milestone payment under our agreement with Servier, a \$5.0 million milestone payment from Boehringer, and the addition of our collaboration with Gilead.

Grant revenue decreased in the year ended December 31, 2013 compared to 2012 due primarily to the completion of grants to study H5N1 influenza virus, small pox and West Nile virus.



**Table of Contents*****Research and Development Expense***

The following represents a comparison of our research and development expense for the years ended December 31, 2013 and 2012:

	<b>Year Ended December 31,</b>		<b>Increase/(Decrease)</b>	
	<b>2013</b>	<b>2012</b>		
	<b>(dollars in millions)</b>			
Margetuximab	\$ 6.2	\$ 6.1	\$ 0.1	2%
MGA271	7.1	6.7	0.4	6%
DART-based product candidates	25.7	12.0	13.7	114%
Teplizumab	2.0	14.6	(12.6)	(86)%
Other discovery and pre-clinical programs, collectively	5.6	6.0	(0.4)	(7)%
<b>Total research and development expense</b>	<b>\$ 46.6</b>	<b>\$ 45.4</b>	<b>\$ 1.2</b>	<b>3%</b>

During the year ended December 31, 2013 our research and development expense increased by \$1.2 million compared to 2012 due to an increase in spending on DART-based product candidates, offset by the reduction in spending on teplizumab-related clinical development as we ended trial enrollment and began closing down the trials.

***General and Administrative Expense***

The following represents a comparison of our general and administrative expense for the years ended December 31, 2013 and 2012:

	<b>Year Ended</b>		<b>Increase/(Decrease)</b>	
	<b>December 31,</b>	<b>2012</b>		
	<b>2013</b>	<b>2012</b>	<b>(dollars in millions)</b>	
General and administrative expense	\$ 11.1	\$ 10.2	\$ 0.9	9%

General and administrative expense increased for the year ended December 31, 2013 by \$0.9 million compared to 2012 primarily due to an increase in professional fees and other costs associated with preparations for public company operations.

***Other Income (Expense)***

The change to other expense of \$626,813 for the year ended December 31, 2013 from other income of \$156,445 for the year ended December 31, 2012 is primarily due to the change in the fair market value of the preferred stock warrant liability (which was settled in connection with the Company's IPO).

**Results of Operations for the Years Ended December 31, 2012 and 2011*****Research and Development Revenue***

The following represents a comparison of our research and development revenue for the years ended December 31, 2012 and 2011:

	<b>Year Ended December 31,</b>		<b>Increase/(Decrease)</b>	
	<b>2012</b>	<b>2011</b>		
	<b>(dollars in millions)</b>			
Revenue from collaborative research	\$ 59.6	\$ 47.0	\$ 12.6	27%
Grant revenue	4.2	10.2	(6.0)	(59)%
<b>Total revenue</b>	<b>\$ 63.8</b>	<b>\$ 57.2</b>	<b>\$ 6.7</b>	<b>12%</b>

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The increase in collaboration revenue of \$12.6 million for the year ended December 31, 2012 compared to 2011 is primarily due to two Servier collaborations, one of which was signed in late 2011 and one which was signed in late 2012. Grant revenue decreased as our contract with the U.S. government to develop a monoclonal antibody for the treatment of West Nile Virus ended in September 2011.

***Research and Development Expense***

The following represents a comparison of our research and development expense for the years ended December 31, 2012 and 2011:

	<b>Year Ended December 31,</b>		<b>Increase/(Decrease)</b>	
	<b>2012</b>	<b>2011</b>	<b>(dollars in millions)</b>	
Margetuximab	\$ 6.1	\$ 6.3	\$ (0.2)	(3)%
MGA271	6.7	5.1	1.6	31%
DART-based product candidates	12.0	7.3	4.7	64%
Teplizumab	14.6	8.8	5.8	66%
Other discovery and pre-clinical programs, collectively	6.0	13.6	(7.6)	(56)%
<b>Total research and development expense</b>	<b>\$ 45.4</b>	<b>\$ 41.1</b>	<b>\$ 4.3</b>	<b>10%</b>

Expenditures in research and development increased by \$4.3 million overall during the year ended December 31, 2012 compared to 2011. This was due to the following:

Increased spending in support of the MGA271 Phase 1 clinical trial;

Increased spending on toxicology related studies and increased efforts on our DART-based product candidates as a result of additional collaborations; and

Despite ceasing enrollment on teplizumab-related clinical trials, we continued to follow the patients for an additional 18 months and closed down the trials in late 2012.

These increases were partially offset by:

Completion of our contract with the U.S. government to study West Nile Virus that resulted in a reduction in spending; and

Reduced spending on our Cancer Stem-like Cell ( CSLC ) efforts.

***General and Administrative Expense***

The following represents a comparison of our general and administrative expense for the years ended December 31, 2012 and 2011:

	<b>Year Ended December 31,</b>		<b>Increase/(Decrease)</b>	
	<b>2012</b>	<b>2011</b>		
	<b>(dollars in millions)</b>			
General and administrative expense	\$ 10.2	\$ 10.9	\$ (0.7)	(6)%

The decrease in general and administrative expense of \$0.7 million is due primarily to reduced patent filing and related legal expense, which was partially offset by an increase in the amount of bonuses paid in the year ended December 31, 2012. Additionally, we realized a savings from the consolidation of personnel from three to two facilities in Rockville, Maryland.

**Table of Contents*****Other Income (Expense)***

The decrease in other income of \$1.3 million for the year ended December 31, 2012 compared to the year ended December 31, 2011 is primarily due to the change in the fair market value of the preferred stock warrant liability.

***Cash Flows***

The following table represents a summary of our cash flows for the years ended December 31, 2013, 2012 and 2011:

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
	<b>(dollars in millions)</b>		
<b>Net cash provided by (used in):</b>			
Operating activities	\$ (14.2)	\$ (6.6)	\$ 6.8
Investing activities	(3.0)	(0.9)	(0.5)
Financing activities	85.9	0.0	12.1
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>\$ 68.7</b>	<b>\$ (7.5)</b>	<b>\$ 18.4</b>

***Operating Activities***

Net cash used in operating activities reflects, among other things, the amounts used to run our clinical trials and pre-clinical activities, including toxicology studies. The difference between net cash used in operating activities during the year ended December 31, 2013 and 2012 was primarily due to less teplizumab clinical trial-related reimbursement revenue from our former collaborator, Eli Lilly, and higher general and administrative expenses, offset by receipt of a \$10.0 million milestone from Servier and a \$5.0 million milestone from Boehringer. The difference between 2012 and 2011 was primarily due to upfront fees received from our collaborators.

***Investing Activities***

Net cash used in investing activities in each of the years ended December 31, 2013, 2012, and 2011 is primarily due to the acquisition of additional lab equipment needed to further our research and development activities.

***Financing Activities***

Net cash provided by financing activities for the year ended December 31, 2013 includes net proceeds from our IPO and cash from stock option exercises. Net cash provided by financing activities for the year ended December 31, 2011 includes net proceeds from the issuance of preferred stock.

**Liquidity and Capital Resources**

Since our inception through December 31, 2013, we have raised an aggregate of \$654.5 million to fund our operations. Of this total amount, we have received \$151.3 million from the sale of convertible preferred stock and warrants, \$364.7 million from our collaborators, including payments in the form of upfront, milestone and annual maintenance payments and reimbursement for research and development services performed, \$83.8 million from our



IPO and \$54.7 million from government grants and contracts. As of December 31, 2013, we had \$116.5 million in cash and cash equivalents.

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On October 16, 2013, we completed the IPO of our common stock, which resulted in the sale of 5,750,000 shares, including all additional shares available to cover over-allotments, at a price of \$16.00 per share. We raised \$85.6 million (\$83.8 million net of expenses and deferred financing costs). In connection with the closing of the IPO, all of our outstanding convertible preferred stock automatically converted to common stock at various ratios as disclosed in Note 4 to the financial statements.

On February 18, 2014, we completed a follow-on public offering of our common stock, in which we sold 1,800,000 shares of common stock, at a price of \$36.50 per share. Additionally, the underwriters of the offering exercised the full amount of their over-allotment option resulting in the sale of an additional 450,000 shares of our common stock at a price of \$36.50 per share. We received net proceeds of \$76.7 million from the offering, net of underwriting discounts and commissions and other estimated offering expenses.

In addition to our existing cash and cash equivalents, we expect to continue to receive additional reimbursement from our collaborators for research and development services rendered, additional milestone, opt-in and annual license maintenance payments and grant revenue. However, our ability to receive these milestone payments is dependent upon our ability to achieve certain levels of research and development activities and is therefore uncertain at this time.

**Funding Requirements**

We have not generated any revenue from product sales to date and do not expect to do so until such time as we obtain regulatory approval of and commercialize one or more of our product candidates. As we are currently in the clinical trial stage of development, it will be some time before we expect to achieve this and it is uncertain that we ever will. We expect that we will continue to increase our operating expenses in connection with ongoing as well as additional clinical trials and pre-clinical development of product candidates in our pipeline. We expect to continue our collaboration arrangements and will look for additional collaboration opportunities. We also expect to continue our efforts to pursue additional grants and contracts from the U.S. government in order to further our research and development. Although it is difficult to predict our funding requirements, based upon our current operating plan, we anticipate that our existing cash and cash equivalents as of December 31, 2013, combined with the net proceeds from our subsequent follow-on offering and collaboration payments we anticipate receiving, will enable us to fund the clinical development of margetuximab, MGA271, MGD006, MGD007, MGD010 and two additional pre-clinical DART-based oncology product candidates into 2017, assuming all of our collaboration programs advance as currently contemplated.

**Contractual Obligations and Contingent Liabilities**

The following table represents future minimum operating lease payments under non-cancelable operating leases as of December 31, 2013:

	Total	Less than 1 year	1 to 3 years (in millions)	3 to 5 years	More than 5 years
Operating Leases	\$ 16.7	\$ 3.7	\$ 6.7	\$ 6.3	\$

Our current obligations and contingent liabilities are limited to the operating leases at our three facilities, including two in Rockville, Maryland and one in South San Francisco, California.

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In connection with an Asset Purchase Agreement with Tolerance Therapeutics, Inc. ( Tolerance ) entered into in June 2005, we may be required to give Tolerance additional consideration as follows: (i) a maximum of \$10.9 million if certain milestones are met, including the initiation of Phase 3 trials and the filing of various regulatory product license applications; (ii) 36,135 shares of our common stock; and (iii) royalty payments between 1.75% and 4.0% of net sales of products acquired from or patented by Tolerance or other product fees earned by us.

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In July 2008, we acquired Raven Biotechnologies ( Raven ). The Raven purchase agreement provides for certain contingent payments that are based on the achievement of development and commercialization activities for product candidates derived from the acquired Raven technology. We are required to make a onetime payment of \$5.0 million to the former Raven stockholders upon the initiation of patient dosing in the first Phase 2 clinical trial of any product derived from the Raven cancer stem cell program. No payment shall be made if the Phase 2 trial start date has not occurred on or before July 15, 2018. Other consideration includes a percentage of revenue (excluding consideration for research and development, equity and certain cost reimbursements) we may receive for each license of a product candidate derived from the Raven cancer stem cell program. The revenue percentage in each case is based upon the execution date of the subject license. No consideration is owed for licenses executed after July 16, 2018. There is additional contingent consideration of one time payments of \$8.0 million and \$12.0 million, which depend upon the achievement of a specified level of sales of a product derived from the Raven cancer stem cell program. At our sole discretion, each payment can be made in cash, common stock or a combination thereof.

The contractual obligations table does not include any potential future payments we may be required to make under our Asset Purchase Agreement with Tolerance or the purchase agreement with Raven. Due to the uncertainty of the achievement and timing of the events requiring payment under that agreement, the amounts to be paid by us are not fixed or determinable at this time.

## **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, as defined under the rules and regulations of the Securities and Exchange Commission.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our primary objective when considering our investment activities is to preserve capital in order to fund our operations. As of December 31, 2013, we had cash and cash equivalents of \$116.5 million, of which \$26.0 million was invested in money market funds and the remainder was in our corporate operating account. Our primary exposure to market risk is related to changes in interest rates and our current investment policy is to invest principally in deposits and securities issued by the U.S. government and its agencies and money market instruments. We do not believe that our cash and cash equivalents have significant risk.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by this item is set forth on pages F-1 F-32.

## **ITEM 9. CHANGES AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **Disclosure Controls and Procedures**

Our management, including our principal executive and principal financial officers, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2013. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in this annual report on Form 10-K has been appropriately recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, to allow timely

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decisions regarding required disclosure. Based on that evaluation, our principal executive and principal financial officers have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

### **Changes in Internal Control**

Our management, including our principal executive and principal financial officers, has evaluated any changes in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2013, and has concluded that there was no change that occurred during the quarterly period ended December 31, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **Management Report on Internal Control over Financial Reporting**

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

pertain to the management of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2013. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (COSO) in Internal Control-Integrated Framework.

Based on our assessment, management believes that, as of December 31, 2013, the Company's internal control over financial reporting is effective based on those criteria.

**ITEM 9B. OTHER INFORMATION**

None.

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**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

We incorporate herein by reference the relevant information concerning directors, executive officers and corporate governance to be included in our definitive proxy statement for the 2014 annual meeting of stockholders (the 2014 Proxy Statement ).

**ITEM 11. EXECUTIVE COMPENSATION**

We incorporate herein by reference the relevant information concerning executive compensation to be included in the 2014 Proxy Statement.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

We incorporate herein by reference the relevant information concerning security ownership of certain beneficial owners and management to be included in the 2014 Proxy Statement.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

We incorporate herein by reference the relevant information concerning certain other relationships and related transactions to be included in the 2014 Proxy Statement.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

We incorporate herein by reference the relevant information concerning principal accounting fees and services to be included in the 2014 Proxy Statement.



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**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Consolidated Financial Statements:

Report of Ernst & Young LLP, Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations and Comprehensive Income (Loss)	F-4
Consolidated Statements of Stockholders' Equity	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits

The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately following our consolidated financial statements. The Exhibit Index is incorporated herein by reference.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized:

MACROGENICS, INC.

By: /s/ Scott Koenig  
Scott Koenig, M.D., Ph.D.

*President and CEO and Director*

Pursuant to the requirements of the Securities Act of 1934, as amended, this Report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Scott Koenig	President and CEO and Director	March 20,
Scott Koenig, M.D., Ph.D.	(Principal Executive Officer)	2014
/s/ James Karrels	Vice President, Chief Financial	
James Karrels	Officer and Secretary (Principal	March 20,
	Financial Officer)	2014
/s/ Lynn Cilinski	Vice President, Controller and	
Lynn Cilinski	Treasurer (Principal Accounting	March 20,
	Officer)	2014
/s/ Paulo Costa		March 20,
Paulo Costa	Director	2014
/s/ Matthew Fust		March 20,
Matthew Fust	Director	2014
/s/ Kenneth Galbraith		March 20,
Kenneth Galbraith	Director	2014
/s/ Edward Hurwitz		March 20,
Edward Hurwitz	Director	2014

/s/ Eran Nadav, Ph.D.		
Eran Nadav, Ph.D.	Director	March 20, 2014
/s/ Arnold Oronsky, Ph.D.		
Arnold Oronsky, Ph.D.	Director	March 20, 2014
/s/ David Stump, M.D.		
David Stump, M.D.	Director	March 20, 2014

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**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	Page Number
<u>Report of Ernst &amp; Young LLP, Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets at December 31, 2013 and 2012</u>	F-3
<u>Consolidated Statements of Operations and Comprehensive Income (Loss) for the years ended December 31, 2013, 2012 and 2011</u>	F-4
<u>Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2013, 2012 and 2011</u>	F-5
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

MacroGenics, Inc.

We have audited the accompanying consolidated balance sheets of MacroGenics, Inc. as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2013. 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 audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of MacroGenics, Inc. at December 31, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

McLean, Virginia

March 20, 2014

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## MACROGENICS, INC.

## CONSOLIDATED BALANCE SHEETS

	December 31,	
	2013	2012
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 116,481,409	\$ 47,743,155
Accounts receivable	2,004,019	2,046,219
Prepaid expenses	971,705	137,634
Total current assets	119,457,133	49,927,008
Restricted cash	404,850	404,850
Property and equipment, net	5,035,232	3,267,796
Other assets	885,166	147,246
Total assets	\$ 125,782,381	\$ 53,746,900
<b>Liabilities and stockholders equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 3,169,034	\$ 3,739,125
Accrued expenses	3,583,552	1,237,025
Lease exit liability current	1,438,742	628,768
Deferred revenue current	20,267,323	24,123,176
Other liabilities current	362,920	
Total current liabilities	28,821,571	29,728,094
Lease exit liability, net of current portion	8,006,428	9,445,171
Deferred rent liability	2,904,227	2,801,653
Preferred stock warrant liability		52,947
Deferred revenue, net of current portion	7,135,687	19,956,343
Total liabilities	46,867,913	61,984,208
Stockholders equity (deficit):		
Series A-1 convertible preferred stock, \$0.01 par value 26,874,792 shares authorized, issued and outstanding at December 31, 2012 with an aggregate liquidation preference of \$27,000,000; no shares outstanding at December 31, 2013		268,748
Series A-2 convertible preferred stock, \$0.01 par value 7,364,582 shares authorized, issued and outstanding at December 31, 2012 with an aggregate liquidation preference of \$7,000,000; no shares outstanding at December 31, 2013		73,646
Series B convertible preferred stock, \$0.01 par value 71,401,237 shares authorized, issued and outstanding at December 31, 2012 with an aggregate liquidation preference of \$31,000,000; no shares outstanding at December 31,		714,012

2013		
Series C convertible preferred stock, \$0.01 par value 110,952,217 shares authorized, issued and outstanding at December 31, 2012 with an aggregate liquidation preference of \$45,000,000; no shares outstanding at December 31, 2013		1,109,522
Series D-1 convertible preferred stock, \$0.01 par value 30,000,000 shares authorized, 14,446,227 shares issued and outstanding at December 31, 2012 with an aggregate liquidation preference of \$9,400,000; no shares outstanding at December 31, 2013		144,462
Series D-2 convertible preferred stock, \$0.01 par value 75,000,000 shares authorized, 63,681,176 shares issued and outstanding at December 31, 2012 with an aggregate liquidation preference of \$41,500,000; no shares outstanding at December 31, 2013		636,812
Common stock, \$0.01 par value 125,000,000 shares authorized and 25,177,597 shares outstanding at December 31, 2013; 425,000,000 shares authorized and 1,098,914 shares outstanding at December 31, 2012	251,775	10,989
Treasury stock, at cost; 14,381 shares at December 31, 2013 and December 31, 2012	(57,742)	(57,742)
Additional paid-in capital	254,453,673	164,334,646
Accumulated deficit	(175,733,238)	(175,472,403)
Total stockholders' equity (deficit)	78,914,468	(8,237,308)
Total liabilities and stockholders' equity (deficit)	\$ 125,782,381	\$ 53,746,900

*See accompanying notes.*

**Table of Contents****MACROGENICS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)**

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
<b>Revenues:</b>			
Revenue from collaborative research	\$ 56,753,123	\$ 59,645,819	\$ 47,054,397
Grant revenue	1,281,545	4,180,279	10,152,969
<b>Total revenues</b>	<b>58,034,668</b>	<b>63,826,098</b>	<b>57,207,366</b>
<b>Costs and expenses:</b>			
Research and development	46,581,930	45,432,894	41,088,899
General and administrative	11,086,759	10,187,894	10,868,791
<b>Total costs and expenses</b>	<b>57,668,689</b>	<b>55,620,788</b>	<b>51,957,690</b>
<b>Income (loss) from operations</b>	<b>365,979</b>	<b>8,205,310</b>	<b>5,249,676</b>
Other income (expense)	(626,814)	156,445	1,467,444
<b>Net comprehensive income (loss)</b>	<b>\$ (260,835)</b>	<b>\$ 8,361,755</b>	<b>\$ 6,717,120</b>
Basic net income (loss) per common share	\$ (0.04)	\$ 0.00	\$ 0.00
Diluted net income (loss) per common share	\$ (0.04)	\$ 0.00	\$ 0.00
Basic weighted average number of common shares	6,847,697	1,083,276	1,025,602
Diluted weighted average number of common shares	6,847,697	1,083,276	1,025,602

*See accompanying notes.*



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## MACROGENICS, INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Series D-2 Convertible Preferred Stock		Common Stock	
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
401,237	\$ 714,012	110,952,217	\$ 1,109,522	14,446,227	\$ 144,462	45,253,788	\$ 452,538	1,000,681	\$ 10,000
						18,427,388	184,274	48,349	483,490
401,237	714,012	110,952,217	1,109,522	14,446,227	144,462	63,681,176	636,812	1,049,030	10,483,490
								49,884	498,840
401,237	714,012	110,952,217	1,109,522	14,446,227	144,462	63,681,176	636,812	1,098,914	10,982,330
								5,750,000	57,500,000
401,237	(714,012)	(110,952,217)	(1,109,522)	(14,446,227)	(144,462)	(63,681,176)	(636,812)	17,060,634	170,633,000

1,268,049 12,6

\$ \$ \$ \$ 25,177,597 \$ 251,7

*See accompanying notes.*

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**Table of Contents****MACROGENICS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
<b>Operating activities</b>			
Net income (loss)	\$ (260,835)	\$ 8,361,755	\$ 6,717,120
Adjustments to reconcile net income to net cash provided by (used in) operating activities:			
Depreciation expense	1,193,340	959,930	1,147,300
Share-based compensation	862,162	838,395	2,347,439
Fair value adjustment of warrant liability	626,349	(150,695)	(1,459,435)
Changes in operating assets and liabilities:			
Accounts receivable	42,200	1,351,650	12,551,066
Prepaid expenses	(834,071)	(91,160)	76,876
Restricted cash		177,321	(513)
Other assets	(375,000)	780	(133,782)
Accounts payable	(570,091)	(7,312,331)	(10,271,048)
Accrued expenses	2,346,527	185,200	272,988
Lease exit liability	(628,769)	(533,560)	(447,019)
Deferred revenue	(16,676,509)	(10,810,089)	(4,275,976)
Deferred rent	102,574	440,815	232,324
Net cash (used in) provided by operating activities	(14,172,123)	(6,581,989)	6,757,340
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(2,960,776)	(940,043)	(500,213)
Net cash used in investing activities	(2,960,776)	(940,043)	(500,213)
<b>Cash flows from financing activities</b>			
Proceeds from issuance of preferred stock			12,014,816
Proceeds from issuance of common stock, net of offering costs	85,871,153	46,826	70,400
Net cash provided by financing activities	85,871,153	46,826	12,085,216
Net change in cash and cash equivalents	68,738,254	(7,475,206)	18,342,343
Cash and cash equivalents at beginning of period	47,743,155	55,218,361	36,876,018
Cash and cash equivalents at end of period	\$ 116,481,409	\$ 47,743,155	\$ 55,218,361
<b>Noncash financing activities:</b>			
Conversion of preferred stock	\$ 2,947,202	\$	\$
<i>See accompanying notes.</i>			



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**MACROGENICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Nature of Operations**

MacroGenics, Inc. (the Company) was incorporated in Delaware on August 14, 2000. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer and autoimmune diseases. The Company generates its pipeline of product candidates from its proprietary suite of next-generation antibody technology platforms which it believes improve the performance of monoclonal antibodies and antibody-derived molecules. These product candidates, which the Company has identified through its understanding of disease biology and immune-mediated mechanisms, may address disease-specific challenges which are not currently being met by existing therapies. The Company creates both differentiated molecules that are directed to novel cancer targets, as well as bio-betters which are drugs designed to improve upon marketed medicines.

On October 16, 2013, the Company completed an initial public offering (IPO) of its common stock, which resulted in the sale of 5,750,000 shares, including all additional shares available to cover over-allotments, at a price of \$16.00 per share. The Company received net proceeds before expenses from the IPO of \$85.6 million after deducting underwriting discounts and commissions paid by the Company.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation and Principles of Consolidation***

The consolidated financial statements include the accounts of MacroGenics, Inc. and its wholly owned subsidiary, MacroGenics West, Inc. All intercompany accounts and transactions have been eliminated in consolidation. The Company currently operates in one operating segment. Operating segments are defined as components of an enterprise about which separate discrete information is available for the chief operating decision maker, or decision making group, in deciding how to allocate resources and assessing performance. The Company views its operations and manages its business in one segment, which is developing monoclonal antibody-based therapeutics for cancer, autoimmune and infectious diseases.

***Use of Estimates***

The preparation of the financial statements in accordance with generally accepted accounting principles (GAAP) requires the Company to make estimates and judgments in certain circumstances that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. In preparing these consolidated financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, fair values of assets, convertible preferred stock and common stock, preferred stock warrant liability, income taxes, pre-clinical study and clinical trial accruals and other contingencies. Management bases its estimates on historical experience or on various other assumptions that it believes to be reasonable under the circumstances. Actual results could differ from these estimates.

In addition, prior to the Company's IPO in October 2013, the Company utilized estimates and assumptions in determining the fair value of its common stock. The Company granted stock options at exercise prices not less than the fair value of its common stock as determined by the Board of Directors, with input from management.

Management used contemporaneous valuations in estimating the fair value of its common stock. The board of directors determined the estimated fair value of the common stock based on a number of objective and subjective factors, including external market considerations affecting the biotechnology industry and the historic prices at which the Company sold shares of its preferred stock.

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**MACROGENICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

***Cash and Cash Equivalents***

The Company considers all investments in highly liquid financial instruments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents consist of certificates of deposit and investments in money market funds with commercial banks and financial institutions. Cash equivalents are stated at amortized cost, plus accrued interest, which approximates fair value.

***Accounts Receivable***

Accounts receivable that management has the intent and ability to collect are reported in the consolidated balance sheets at outstanding amounts, less an allowance for doubtful accounts. The Company writes off uncollectible receivables when the likelihood of collection is remote.

The Company evaluates the collectability of accounts receivable on a regular basis. The allowance, if any, is based upon various factors including the financial condition and payment history of customers, an overall review of collections experience on other accounts and economic factors or events expected to affect future collections experience. No allowance was recorded as of December 31, 2013 or 2012, as the Company has a history of collecting on all outstanding accounts.

***Restricted Cash***

The Company is required to maintain certificates of deposit that serve as collateral for various operating leases and corporate credit card accounts. Amounts classified as restricted cash on the consolidated balance sheets are \$404,850 at December 31, 2013 and 2012.

***Fair Value of Financial Instruments***

The fair market values of the financial instruments included in the financial statements, which include cash equivalents and money market accounts, approximate their carrying values at December 31, 2013 and 2012, due to their short-term maturities. The Company accounts for recurring and non-recurring fair value measurements in accordance with the Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ) 820, *Fair Value Measurements and Disclosures* ( ASC 820 ). ASC 820 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value, and requires expanded disclosures about fair value measurements. The ASC 820 hierarchy ranks the quality of reliability of inputs, or assumptions, used in the determination of fair value and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.

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Level 2 Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models, such as interest rates and yield curves that can be corroborated by observable market data.

Level 3 Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgments to be made by a reporting entity e.g., determining an appropriate adjustment to a discount factor for illiquidity associated with a given security.

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Table of Contents**MACROGENICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the ASC 820 hierarchy.

Financial assets and liabilities subject to fair value measurements were as follows:

**Fair Value Measurements at December 31, 2013**

		<b>Quoted Prices in Active Markets for Identical Assets Level 1</b>			<b>Significant Other Observable Inputs Level 2</b>	<b>Significant Unobservable Inputs Level 3</b>
	<b>Total</b>					
<b>Assets:</b>						
Cash and cash equivalents	\$ 90,434,435	\$ 90,434,435		\$	\$	
Money market funds	26,046,974	26,046,974				
Restricted cash	404,850	404,850				
<b>Total Assets</b>	<b>\$ 116,886,259</b>	<b>\$ 116,886,259</b>		<b>\$</b>	<b>\$</b>	

**Fair Value Measurements at December 31, 2012**

		<b>Quoted Prices in Active Markets for Identical Assets Level 1</b>			<b>Significant Other Observable Inputs Level 2</b>	<b>Significant Unobservable Inputs Level 3</b>
	<b>Total</b>					
<b>Assets:</b>						
Cash and cash equivalents	\$ 18,695,197	\$ 18,695,197		\$	\$	
Money market funds	29,047,958	29,047,958				
Restricted cash	404,850	404,850				
<b>Total Assets</b>	<b>\$ 48,148,005</b>	<b>\$ 48,148,005</b>		<b>\$</b>	<b>\$</b>	
<b>Liabilities:</b>						
	\$ (52,947)	\$		\$	\$ (52,947)	

Preferred stock warrant  
liability

As of December 31, 2012, the Company transferred its money market funds from Level 2 to Level 1 because the inputs are now based upon a quoted market price.

The Company's Level 1 securities primarily consist of restricted cash, cash equivalents and money market funds. The Company determines the estimated fair value for its Level 1 securities using quoted (unadjusted) prices for identical assets or liabilities in active markets.

The Company determines the estimated fair value for its Level 2 securities using the following methods: quoted prices for similar assets/liabilities in active markets, inputs other than quoted prices that are observable for the asset/liability (e.g., interest rates, yield curves volatilities, default rates, etc.) and inputs that are derived principally from or corroborated by other observable market data.

Table of Contents**MACROGENICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The following table provides a rollforward of the Company's preferred stock warrant liability, which was the only financial instrument measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as defined in ASC 820:

Balance at December 31, 2012	\$ (52,947)
Total unrealized gains (losses) included in earnings	(626,349)
Settlement of preferred stock warrants	679,296
Balance at December 31, 2013	\$

In order to estimate the fair value of the preferred stock purchase warrants, the business enterprise value was established based on a discounted cash flow model (income approach). The Company utilized an option pricing method to value the shares using a contingent claims analysis, which applies a series of call options whose inputs reflect the liquidation preferences and conversion behavior of the different classes of equity. After the equity value of the business enterprise was determined, the total equity value is allocated to the various equity instruments such as preferred stock, stock options and preferred stock purchase warrants. Key management estimates relate to the time period to liquidation and conversion behavior of a particular class of stockholders. The business enterprise value includes assumptions related to product approval, market penetration and costs to develop the product. Significant changes to these assumptions would result in increases/decreases to the fair value of the outstanding warrants.

The total unrealized gains (losses) on the preferred stock warrants included in earnings is included as a component of other income (expense) in the consolidated statement of operations and comprehensive income. Immediately prior to the Company's IPO in October 2013, all the preferred stock warrants were exercised and converted into shares of Series D-2 preferred stock, which were subsequently converted to common stock.

***Concentration of Credit Risk***

Substantially all of the Company's cash and cash equivalents are maintained with major financial institutions in the United States. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, and accounts receivable. The counterparties are various corporations, financial institutions and government agencies of high credit standing.

For the years ended December 31, 2013, 2012 and 2011, all of the Company's grant revenue was related to contracts and research grants received from U.S. government agencies. Collaborations with Les Laboratoires Servier and Institut de Recherches Servier (collectively, Servier), Boehringer Ingelheim GmbH (Boehringer), Gilead Sciences, Inc. (Gilead), Pfizer, Inc. (Pfizer) and Eli Lilly & Co. (Eli Lilly) account for all other revenue. All outstanding receivables are due from the Company's collaborators and U.S. government agencies.

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**Table of Contents****MACROGENICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The following table represents the percentage of all significant revenue earned in the periods indicated:

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Servier	51.6%	17.3%	
Boehringer	24.8%	18.4%	15.6%
Gilead	13.8%		
Pfizer	6.0%	8.7%	10.8%
Government Agencies	2.2%	6.5%	17.7%
Eli Lilly	1.4%	48.9%	54.0%

The following table represents the percentage of all significant accounts receivable:

	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
Gilead	53.4%	
Pfizer.	12.3%	45.4%
Boehringer	12.2%	18.0%
Eli Lilly	7.0%	28.2%
Servier	6.4%	
Government Agencies	4.6%	8.4%

***Property and Equipment***

Property and equipment are stated at cost. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred. Depreciation is computed using the straight-line method over the following estimated useful lives:

Computer equipment	3 years
Software	3 years
Furniture	10 years
Laboratory and office equipment	5 years
Leasehold improvements	Shorter of lease term or useful life

***Impairment of Long-Lived Assets***

The Company assesses the recoverability of its long-lived assets in accordance with the provisions of ASC 360, *Property, Plant and Equipment*. ASC 360 requires that long-lived assets be reviewed for impairment whenever events

or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset or asset group. If carrying value exceeds the sum of undiscounted cash flows, the Company then determines the fair value of the underlying asset group. Any impairment to be recognized is measured by the amount by which the carrying amount of the asset group exceeds the estimated fair value of the asset group. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less costs to sell. As of December 31, 2013 and 2012, the Company determined that there were no impaired assets and had no assets held-for-sale.

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**Table of Contents****MACROGENICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS*****Income Taxes***

Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more-likely-than-not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the largest amount that is more than 50% likely to be realized upon ultimate settlement. The Company's policy is to record interest and penalties related to uncertain tax positions as a component of income tax expense.

***Revenues******Revenue Recognition***

The Company enters into collaboration and license agreements with collaborators for the development of monoclonal antibody-based therapeutics to treat cancer and other complex diseases. The terms of these agreements contain multiple deliverables which may include (i) licenses, or options to obtain licenses, to the Company's technological platforms, such as its Fc Optimization and Dual-Affinity Re-Targeting ( DART ) technologies, (ii) rights to future technological improvements, (iii) research and development activities to be performed on behalf of the collaborator or as part of the collaboration, and (iv) the manufacture of pre-clinical or clinical materials for the collaborator. Payments to the Company under these agreements may include nonrefundable license fees, option fees, exercise fees, payments for research and development activities, payments for the manufacture of pre-clinical or clinical materials, license maintenance payments, payments based upon the achievement of certain milestones and royalties on product sales. Other benefits to the Company of these agreements include the right to sell products resulting from the collaborative efforts of the parties in specific geographic territories. The Company follows the provisions of the FASB ASC Topic 605-25, *Revenue Recognition - Multiple-Element Arrangements*, and ASC Topic 605-28, *Revenue Recognition - Milestone Method*, in accounting for these agreements. In order to account for these agreements, the Company must identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on the achievement of certain criteria, including whether the delivered element has stand-alone value to the collaborator. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

For the periods presented, the Company had the following two types of agreements with the parties identified below: 1) exclusive development and commercialization licenses to use the Company's technology and/or certain other intellectual property to develop compounds against specified targets (referred to herein as exclusive licenses); and 2) Option/research agreements to secure on established terms, development and commercialization licenses to anticancer and other therapeutic product candidates to collaborator selected targets developed by the Company during an option period (referred to herein as right-to-develop agreements).

There are no performance, cancellation, termination or refund provisions in any of the arrangements that contain material financial consequences to the Company.

*Exclusive Licenses*

The deliverables under an exclusive license agreement generally include the exclusive license to the Company's DART technology with respect to a specified antigen target, and may also include deliverables



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related to rights to future technological improvements, research and pre-clinical development activities to be performed on behalf of the collaborator. In some cases the Company may have an option to participate in the co-development of product candidates that result from such agreements.

Generally, exclusive license agreements contain nonrefundable terms for payments and, depending on the terms of the agreement, provide that the Company will (i) at the collaborator's request, provide research and pre-clinical development services at negotiated prices which are generally consistent with what other third parties would charge, (ii) earn payments upon the achievement of certain milestones, (iii) earn royalty payments, and (iv) in some cases grant the Company an option to participate in the development and commercialization of products that result from such agreements. Royalty rates may vary over the royalty term depending on the Company's intellectual property rights and whether the Company exercises any co-development and co-commercialization rights. The Company may provide technical assistance and share any technology improvements with its collaborators during the term of the collaboration agreements.

The Company does not directly control when any collaborator will achieve milestones or become liable for royalty payments.

In determining the units of accounting, management evaluates whether the exclusive license has stand-alone value from the undelivered elements to the collaborator based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research and development capabilities of the partner and the availability of technology platform and product research expertise in the general marketplace. If the Company concludes that the license has stand-alone value and therefore will be accounted for as a separate unit of accounting, the Company then determines the estimated selling prices of the license and all other units of accounting based on market conditions, similar arrangements entered into by third parties, and entity-specific factors such as the terms of the Company's previous collaboration agreements, recent pre-clinical and clinical testing results of therapeutic product candidates that use the Company's technology platforms, the Company's pricing practices and pricing objectives, the likelihood that technological improvements will be made, the likelihood that technological improvements made will be used by the Company's collaborators and the nature of the research services to be performed on behalf of its collaborators and market rates for similar services.

Upfront payments on exclusive licenses are deferred if facts and circumstances dictate that the license does not have stand-alone value. Prior to the adoption of Accounting Standards Update (ASU) No. 2009-13, *Revenue Arrangements with Multiple Deliverables*, on January 1, 2011, the Company determined that its licenses lacked stand-alone value because it did not have vendor-specific objective evidence of selling price (VSOE), and were combined with other elements of the arrangement and any amounts associated with the license were deferred and amortized over a certain period, which the Company refers to as the Company's period of substantial involvement. In making the determination of the length of the period over which to defer revenue for contracts entered into prior to the adoption of ASU No. 2009-13, significant judgment and estimation is used by the Company and can have an impact on the amount of revenue recognized in a given period. Historically, the Company's involvement with the development of a collaborator's product candidate has been significant at the early stages of development, and lessens as it progresses into clinical trials. Accordingly, the Company generally estimates this period of substantial involvement to begin at the inception of the collaboration agreement and conclude at the end of the Company's substantial involvement. ASU

No. 2009-13 amends the criteria for separating and allocating consideration in a multiple element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual value method. The selling prices of deliverables under an arrangement may be derived using third-party evidence ( TPE ), or a best estimate of selling price ( BESP ), if VSOE is not available. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the license agreement was sold on a standalone basis.

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Establishing BEBP involves management's judgment and considers multiple factors, including market conditions and company-specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating the BEBP, management considers whether changes in key assumptions used to determine the BEBP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially within the Company's control. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element and revenue is accordingly recognized as each element is delivered. Management exercises significant judgment in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting, the Company evaluated whether the exclusive license had standalone value to the collaborator based on consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination included the research and development capabilities of the collaborator and the availability of relevant research expertise in the marketplace. In addition, the Company considered whether or not (i) the collaborator could use the license for its intended purpose without the receipt of the remaining deliverables, (ii) the value of the license was dependent on the undelivered items and (iii) the collaborator or other vendors could provide the undelivered items.

The Company reassesses its periods of substantial involvement over which the Company amortizes its upfront license fees and makes adjustments as appropriate. In the event a collaborator elects to discontinue development of a specific product candidate under a single target license, but retains its right to use the Company's technology to develop an alternative product candidate to the same target or a target substitute, the Company would cease amortization of any remaining portion of the upfront fee until there is substantial pre-clinical activity on another product candidate and its remaining period of substantial involvement can be estimated. In the event that a single target license were to be terminated, the Company would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue, at the date of such termination or through the remaining substantial involvement in the wind down of the agreement.

Upfront payments on exclusive licenses may be recognized upon delivery of the license if facts and circumstances dictate that the license has stand-alone value from the undelivered elements, which generally include rights to future technological improvements, research services and the manufacture of pre-clinical and clinical materials.

The Company recognizes revenue related to research and pre-clinical development services that represent separate units of accounting as they are performed, as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is probable. The Company recognizes revenue related to the rights to future technological improvements over the estimated term of the applicable license.

The Company typically performs research activities and pre-clinical development services, including generating and engineering product candidates, on behalf of its licensees during the early evaluation and pre-clinical testing stages of drug development under its exclusive licenses. The Company records amounts received for research materials produced or services performed as revenue from collaborative research.

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The Company's license agreements have milestone payments which for reporting purposes are aggregated into three categories: (i) development milestones, (ii) regulatory milestones, and (iii) sales milestones. Development milestones are typically payable when a product candidate initiates or advances into different clinical trial phases. Regulatory milestones are typically payable upon submission for marketing approval with the U.S. Food and Drug Administration (FDA) or other countries' regulatory authorities or on receipt of actual marketing approvals for the compound or for additional indications. Sales milestones are typically payable when annual sales reach certain levels.

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Non-refundable development and regulatory milestones that are expected to be achieved as a result of the Company's efforts during the period of substantial involvement are considered substantive and are recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive because the Company does not contribute effort to the achievement of such milestones are generally achieved after the period of substantial involvement and are recognized as revenue upon achievement of the milestone, as there are no undelivered elements remaining and no continuing performance obligations, assuming all other revenue recognition criteria are met.

*Right-to-Develop Agreements*

The Company's right-to-develop agreements provide collaborators with an exclusive option to obtain licenses to develop and commercialize in specified geographic territories product candidates developed by the Company under agreed upon research and pre-clinical development product programs. The product candidates resulting from each program are all directed to a specific target selected by the collaborator. Under these agreements, fees may be due to the Company (i) at the inception of the arrangement (referred to as upfront fees or payments), (ii) the selection of a target for a program, (iii) upon the exercise of an option to acquire a development and commercialization license (referred to as exercise fees or payments earned) for a program, or (iv) some combination of all of these fees.

The accounting for right-to-develop agreements is dependent on the nature of the options granted to the collaborator. Options are considered substantive if, at the inception of a right-to-develop agreement, the Company is at risk as to whether the collaborator will choose to exercise the options to secure development and commercialization licenses. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments imposed on

the collaborator as a result of exercising the options.

For right-to-develop agreements where the options to secure development and commercialization licenses to a product program are considered substantive, the Company does not consider the development and commercialization licenses to be a deliverable at the inception of the agreement. For those right-to-develop

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agreements entered into prior to the adoption of ASU No. 2009-13 where the options to secure development and commercialization licenses are considered substantive, the Company has deferred the upfront payments received and recognizes this revenue over the period during which the collaborator could elect to exercise options for development and commercialization licenses. These periods are specific to each collaboration agreement. If a collaborator selects a target for a product program, any substantive option fee is deferred and recognized over the life of the option, generally 12 months. Subsequent to the adoption of ASU No. 2009-13, the Company's evaluation of whether the option is substantive is consistent with pre-adoption of ASU No. 2009-13. How the Company determines the selling price of the option is the only difference between pre and post adoption of ASU No. 2009-13. Post adoption of ASU No. 2009-13, the selling prices of deliverables under an arrangement may be derived using TPE or a BESP, if VSOE is not available. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the right-to-develop agreement was sold on a standalone basis. Establishing BESP involves management's judgment and considers multiple factors, including market conditions and company-specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the right-to-develop agreement. In validating the BESP, management considers whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially within the Company's control. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element and revenue is accordingly recognized as each element is delivered. Management exercises significant judgment in determining whether a deliverable is a separate unit of accounting.

If a collaborator exercises an option and acquires a development and commercialization license to a product program, the Company attributes the exercise fee to the development and commercialization license. The Company determines the selling price of the option license, upon exercise, through management's best estimate. Management's determination of selling price includes such factors as stage of development, market potential and cash flow models used during the negotiation with the collaborator. Through December 31, 2013, none of our collaboration partners had exercised an option. However, one of our collaboration partners did elect to exercise an option in February 2014. See Note 13 for additional information.

Upon exercise of an option to acquire a development and commercialization license, the Company would also attribute any remaining deferred option fee, in addition to the consideration received for the license upon exercise of the option, to the development and commercialization license. The Company then applies the multiple-element revenue recognition criteria to the development and commercialization license and other deliverables, if any, to determine the appropriate revenue recognition method. This model is consistent with the Company's accounting policy for upfront payments on exclusive licenses (discussed above). In the event a right-to-develop agreement were to be terminated, the Company would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue, at the date of such termination. The Company's right-to-develop agreements have been determined to contain substantive options.

For right-to-develop agreements where the options to secure development and commercialization licenses to product programs are not considered substantive, the Company considers the development and commercialization licenses to be a deliverable at the inception of the agreement and applies the multiple-element revenue recognition criteria to determine the appropriate revenue recognition. The Company does not directly control when any collaborator will exercise its options for development and commercialization licenses.

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***Research and Development Costs***

Research and development expenditures are expensed as incurred. Research and development costs primarily consist of employee related expenses, including salaries and benefits, expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct the Company's clinical trials, the cost of acquiring and manufacturing clinical trial materials and other allocated expenses, license fees for and milestone payments related to in-licensed products and technologies, stock-based compensation expense, and costs associated with non-clinical activities and regulatory approvals.

***Comprehensive Income (Loss)***

Effective January 1, 2012, the Company adopted ASU 2011-05, *Presentation of Comprehensive Income*, which amended ASC Topic 220, *Comprehensive Income* (ASU 2011-05). The amendments in ASU 2011-05 require the presentation of the comprehensive income (loss) and its components as part of the consolidated financial statements. Comprehensive income (loss) is comprised of the net income (loss) and other changes in equity that are excluded from net income (loss). Comprehensive income (loss) equals net income (loss) for the years ended December 31, 2013, 2012 and 2011.

***Stock-based Compensation***

Stock-based payments are accounted for in accordance with the provisions of ASC 718, *Compensation - Stock Compensation*. The fair value of stock-based payments is estimated, on the date of grant, using the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option.

For all time-vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. Recognition of stock-based compensation expense is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period.

The Company utilizes the Black-Scholes model for estimating fair value of its stock options granted. Option valuation models, including the Black-Scholes model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

***Net Income (Loss) Per Share***

Basic income (loss) per common share is determined by dividing income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted income (loss) per share is computed by dividing the earnings (loss) attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company's stock option grants, potential Employee Stock

Purchase Plan awards and warrants and the if-converted method is used to determine the dilutive effect of the Company's preferred stock.

Prior to the Company's initial public offering, net income (loss) per share was calculated under the two-class method under which all earnings (distributed and undistributed) are allocated to each class of common stock and participating securities based on their respective rights to receive dividends. In the event that the Board

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of Directors declared a dividend payable in cash or other property on the then-outstanding shares of common stock, the holders of the Series A-1, A-2, B, C, D, and D-2 convertible preferred stock would be entitled to receive the amount of dividends per share of preferred stock that would be payable on the largest number of whole shares of common stock into which each share of preferred stock could then be converted. Therefore, the Series A-1, A-2, B, C, D and D-2 are participating securities. All of the outstanding shares of Series A-1, A-2, B, C, D, and D-2 convertible preferred stock converted to common stock upon the consummation of the Company's IPO.

Basic and diluted income (loss) per common share is computed as follows:

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Net income (loss)	\$ (260,835)	\$ 8,361,755	\$ 6,717,120
Less: undistributed earnings allocated to participating securities		(8,361,755)	(6,717,120)
Net income (loss) allocable to common shares	\$ (260,835)	\$	\$
Basic weighted average common shares outstanding	6,847,697	1,083,276	1,025,602
Basic income (loss) per common share	\$ (0.04)	\$ 0.00	\$ 0.00
Net income (loss)	\$ (260,835)	\$ 8,361,755	\$ 6,717,120
Less: undistributed earnings allocated to participating securities and other add-backs to net income (loss)		(8,361,755)	(6,717,120)
Net income (loss) allocable to common shares	\$ (260,835)	\$	\$
Basic weighted average common shares outstanding	6,847,697	1,083,276	1,025,602
Effect of dilutive securities			
Diluted weighted average common shares outstanding	6,847,697	1,083,276	1,025,602
Diluted income (loss) per common share	\$ (0.04)	\$ 0.00	\$ 0.00

The following common stock equivalents were excluded from the calculation of diluted net income (loss) per share because their effect would be anti-dilutive:

**Year Ended December 31,**

	<b>2013</b>	<b>2012</b>	<b>2011</b>
Series A-1 Preferred Stock		2,156,114	2,156,114
Series A-2 Preferred Stock		392,274	392,274
Series B Preferred Stock		4,336,037	4,336,037
Series C Preferred Stock		5,909,906	5,909,906
Series D Preferred Stock		769,468	769,468
Series D-2 Preferred Stock		3,391,991	3,391,991
Effect of Converted Preferred Stock	13,189,920		
Warrants to purchase Series D-2 Preferred Stock		180,784	180,784
Stock Options	2,313,970	3,249,702	2,885,417

***Recently Issued Accounting Standards Adopted***

In July 2013, the FASB issued ASU No. 2013-11, which amended ASC Topic 740 regarding presentation of an unrecognized tax benefit when a net operating loss ( NOL ) carryforward, a similar tax loss, or a tax credit

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carryforward exists. The amendments in ASU No. 2013-11 require an entity to present an unrecognized tax benefit as a reduction of a deferred tax asset for an NOL carryforward, or similar tax loss or tax credit carryforward, rather than as a liability when (1) the uncertain tax position would reduce the NOL or other carryforward under the tax law of the applicable jurisdiction and (2) the entity intends to use the deferred tax asset for that purpose. The ASU does not require new recurring disclosures. This amendment is effective prospectively for fiscal years beginning after December 15, 2013. The Company does not believe this amendment will have a material impact on its financial statements.

The Company has evaluated all ASUs through the date the consolidated financials were issued and believes that the adoption of these will not have a material impact on the Company's consolidated financial statements.

**3. Property and Equipment**

Property and equipment consists of the following:

	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
Computer equipment	\$ 2,379,254	\$ 2,003,706
Software	1,477,416	1,323,081
Furniture	599,650	599,650
Lab equipment	11,166,619	8,747,790
Office equipment	51,360	51,360
Leasehold improvements	4,893,770	4,881,706
Property and equipment	20,568,069	17,607,293
Less accumulated depreciation	(15,532,837)	(14,339,497)
Property and equipment, net	\$ 5,035,232	\$ 3,267,796

Depreciation expense for the years ended December 31, 2013, 2012 and 2011 was \$1.2 million, \$1.0 million and \$1.1 million, respectively.

**4. Stockholders' Equity (Deficit)**

During 2002 and 2003, the Company issued a total of 34,239,374 shares of Series A-1 and Series A-2 convertible preferred stock ( Series A preferred stock ) for \$1.00 per share resulting in net proceeds of approximately \$34.0 million.

On October 12, 2004, the Company entered into a series of transactions raising \$30.3 million, net of related offering costs of approximately \$238,000, from the sale of 71,401,237 shares of its Series B convertible preferred stock ( Series B preferred stock ). In connection with the Series B preferred stock offering, 13,604,016 shares of common stock were

allocated to holders of Series A-1 preferred stock as an anti-dilution measure.

On May 16, 2006, the Company raised \$44.9 million, net of related offering costs of \$101,246, from the sale of 110,952,217 shares of its Series C convertible preferred stock ( Series C preferred stock ). In connection with the Series C preferred stock offering, 10,003,300 shares of common stock were allocated to holders of Series B preferred stock as an anti-dilution measure.

On July 16, 2008, the Company issued 12,466,039 shares of its Series D convertible preferred stock ( Series D preferred stock ) in exchange for all of the outstanding capital stock and convertible notes payable of

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Raven Biotechnologies, Inc. ( Raven ). Subsequently, in March 2011 a settlement was reached with the former Raven stockholders bringing the total Series D preferred stock issued in connection with the Raven acquisition to 14,446,227 shares.

On September 19, 2008, the Company raised \$24.8 million, net of related offering costs of \$156,788, from the sale of 38,337,678 shares of its Series D-2 convertible preferred stock ( Series D-2 preferred stock ). The Company also issued preferred stock warrants for the purchase of 2,875,327 shares of Series D-2 preferred stock. The preferred stock warrants were exercisable at any time prior to September 2018, but expired upon an IPO, and had a stated exercise price of \$0.65 per warrant. On May 16, 2010, the Company exercised a put notice to Eli Lilly in accordance with the Series D-2 preferred stock purchase agreement, resulting in the issuance of 6,916,110 shares of Series D-2 preferred stock and a warrant to purchase 518,708 additional shares of Series D-2 preferred stock. On January 11, 2011, the Company raised gross proceeds of \$12.0 million from the sale of 18,427,388 shares of its Series D-2 preferred stock. Issuance costs associated with the sale were not material.

Due to certain provisions in the Series D-2 convertible preferred stock warrant agreement, these warrants were required to be classified as a liability. Management believed that the circumstances requiring cash settlement of the award were remote. The Series D-2 preferred stock warrant liability was recorded at fair value and has been adjusted to fair value at the end of each reporting period using the Option-Pricing Method, with changes in value recorded as Other income (expense) in the accompanying consolidated statements of operations and comprehensive income (loss). Prior to the Company's IPO in October 2013, all the preferred stock warrants were exercised and subsequently were converted into shares of common stock in connection with the IPO.

Dividends were noncumulative and accrued on the Series A-1, Series A-2, Series B, Series C, Series D and Series D-2 preferred stock at a rate of \$0.08, \$0.0341, \$0.0324 and \$0.0522 per annum, respectively, and were payable when and as declared by the Board of Directors. Dividends had to be declared so that the Series A, Series B, Series C and Series D preferred stock were paid in like-kind and participated equally to those of the Series D-2 preferred and common stock. No dividends had been declared prior to the conversion of the preferred stock to common stock in connection with the IPO.

The Company's Series A-1, Series A-2, Series B, Series C, Series D and Series D-2 preferred stock were initially convertible into 1.506, 1.00, 1.14, 1.00, 1.00 and 1.00 shares, respectively, of common stock at the option of the holder. The conversion ratio of certain series of preferred stock was subject to change in the event specified dilutive transactions occurred, which included the Company's IPO. There were no anti-dilution protections for the Series A-2 preferred stock and no adjustment to the Series A-1 preferred stock conversion price was to be made if a common stock issuance was at a price per share greater than the conversion price of the Series C preferred stock. Upon consummation of the Company's IPO in October 2013, all outstanding shares of preferred stock automatically converted to shares of the Company's common stock at the applicable conversion ratios then in effect. The conversion price was \$12.39, \$18.77, \$6.95, \$7.70, \$12.20 and \$12.20 for each share of Series A-1, A-2, Series B, Series C, Series D and Series D-2 convertible preferred stock, respectively.

On October 16, 2013, the Company completed its IPO, in which 5,000,000 shares of the Company's common stock were sold at a price of \$16.00 per share. Additionally, the underwriters of the Company's IPO exercised the full

amount of their over-allotment option resulting in the sale of an additional 750,000 shares of the Company's common stock at a price of \$16.00 per share. The Company received net proceeds of \$83.8 million from the IPO, net of underwriting discounts and commissions and other offering expenses. Upon consummation of the IPO, all outstanding shares of preferred stock automatically converted to common stock at the applicable conversion ratios then in effect.



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In connection with preparing for its IPO in October 2013, the Company's Board of Directors and stockholders approved a 1-for-18.7739 reverse stock split of the Company's common stock. The reverse stock split became effective on September 26, 2013. All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. In addition, in September 2013, the Company's Board of Directors and stockholders approved an amendment of the Company's certificate of incorporation to, among other things, change the definition of a designated public offering to remove the per share price requirement. The amended and restated certificate of incorporation also changed the authorized number of shares of common stock from 425,000,000 to 125,000,000, and authorized 5,000,000 shares of undesignated preferred stock with a par value of \$0.01 per share. There were no shares of undesignated preferred stock issued or outstanding as of December 31, 2013.

**5. Shared-Based Payments*****Stock Option Plan***

The Company's 2000 Stock Option and Incentive Plan ( 2000 Plan ) allowed for the grant of awards in respect of an aggregate of 130,725 shares, which was increased to 150,297 shares, of the Company's common stock in the form of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock and restricted stock units and other performance awards. As of December 31, 2013, under the 2000 Plan, there were options to purchase an aggregate of 23,657 shares of common stock outstanding at a weighted average exercise price of \$0.83 per share. The 2000 Plan has expired, and no further awards may be issued under the plan. Any shares of common stock subject to awards under the 2000 Plan that expire, terminate, or are otherwise surrendered, canceled, forfeited or repurchased without having been fully exercised, or resulting in any common stock being issued, will become available for issuance under the 2013 Stock Incentive Plan ( 2013 Plan ) up to a specified number of shares.

Effective February 2003, the Company implemented the 2003 Equity Incentive Plan ( 2003 Plan ), and it was amended and approved by the Company's stockholders in 2005. The 2003 Plan originally allowed for the grant of awards in respect of an aggregate of 2,051,644 shares of the Company's common stock. Between 2006 and 2010 the maximum number of shares of common stock authorized to be issued by the Company under the 2003 Plan was increased by 1,739,116 shares to 3,790,760. During the year ended December 31, 2012, the maximum number of shares of common stock authorized to be issued by the Company under the 2003 Plan was increased by 545,970 shares to 4,336,730. Stock options granted under the 2003 Plan may be either incentive stock options as defined by the Internal Revenue Code ( IRC ), or non-qualified stock options.

As of December 31, 2013, under the 2003 Plan, there were options to purchase an aggregate of 2,559,011 shares of common stock outstanding at a weighted average exercise price of \$1.52 per share. Upon the completion of the IPO, the 2003 Plan was terminated, and no further awards may be issued under the plan. Any shares of common stock subject to awards under the 2003 Plan that expire, terminate, or are otherwise surrendered, canceled, forfeited or repurchased without having been fully exercised, or resulting in any common stock being issued, will become available for issuance under the 2013 Plan, up to a specified number of shares.

In October 2013, the Company implemented the 2013 Plan. The 2013 Plan provides for the grant of stock options and other stock-based awards, as well as cash-based performance awards. The aggregate number of shares of common stock initially available for issuance pursuant to awards under the 2013 Plan is 1,960,168 shares. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each year from January 1, 2014 through and including January 1, 2023, by the lesser of (a) 1,960,168 shares, (b) 4.0% of the total number of shares of common stock outstanding on December 31 of the

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preceding calendar year, or (c) the number of shares of common stock determined by the Board of Directors. All of the shares available for issuance under the 2013 Plan are eligible for issuance pursuant to the exercise of incentive stock options. If an option expires or terminates for any reason without having been fully exercised, if any shares of restricted stock are forfeited, or if any award terminates, expires or is settled without all or a portion of the shares of common stock covered by the award being issued, such shares are available for the grant of additional awards. However, any shares that are withheld (or delivered) to pay withholding taxes or to pay the exercise price of an option are not available for the grant of additional awards. As of December 31, 2013, under the 2013 Plan, there were options to purchase an aggregate of 618,290 shares of common stock outstanding at a weighted average exercise price of \$19.06 per share.

***Stock Option Exchange***

On March 16, 2011 ( Exchange Date ), the Company modified certain outstanding options with exercise prices of \$1.88 and \$4.69 ( Original Options ). These Original Options were canceled and replaced with options having an exercise price of \$0.94 ( Replacement Options ), reflecting the current fair market value of the Company's common stock on the Exchange Date. Original Options submitted for exchange were replaced on a one-for-one basis with Replacement Options. Additionally, the Replacement Options retain all terms and conditions of the Original Options except for the reduction to the exercise price as described above.

Total compensation associated with the Replacement Options consisted of the grant-date fair value of the Original Options for which the requisite service period is expected to be rendered (or has already been rendered) at the Exchange Date, plus the incremental cost associated with the modification of terms. The incremental compensation expense was measured as the excess of the fair value of the Replacement Options over the fair value of the Original Options re-measured as of the Exchange Date. A total of 1,921,894 Original Options were exchanged for Replacement Options.

The following stock-based compensation amounts were recognized for the periods indicated:

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Research and development	\$ 507,142	\$ 471,809	\$ 1,018,935
General and administrative	355,020	366,586	1,328,504
<b>Total stock-based compensation expense</b>	<b>\$ 862,162</b>	<b>\$ 838,395</b>	<b>\$ 2,347,439</b>

***Employee Stock Options***

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model using the assumptions in the following table:

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Expected dividend yield	0%	0%	0%
Expected volatility	53% - 67%	51%	62%
Risk-free interest rate	1.24% - 2.19%	1.18%	1.35%
Expected term.	7 years	7 years	7 years
Expected forfeiture rate	5.06% - 5.57%	5.57%	5.58%

**Expected Dividend Yield** The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

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**Expected Volatility** Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. As the Company does not yet have sufficient history of its own volatility, the Company has identified several public entities of similar size, complexity and stage of development and calculates historical volatility using the volatility of these companies.

**Risk-Free Interest Rate** This is the U.S. Treasury rate for the week of each option grant during the year, having a term that most closely resembles the expected life of the option.

**Expected Term** This is the period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of ten years. The Company estimates the expected life of the option term to be seven years. The Company uses a simplified method to calculate the average expected term.

**Expected Forfeiture Rate** The forfeiture rate is the estimated percentage of options granted that is expected to be forfeited or canceled on an annual basis before becoming fully vested. The Company estimates the forfeiture rate based on turnover data with further consideration given to the class of the employees to whom the options were granted.

Equity instruments issued to non-employees are accounted for under the provisions of ASC 505-50, *Equity Based Payments to Non-Employees*. Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed.

The following table summarizes stock option activity for 2013:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2012	3,249,541	\$ 0.94	7.3	
Granted	1,307,101	10.70		
Exercised	(1,268,049)	0.85		
Forfeited or expired	(87,635)	1.11		
Outstanding, December 31, 2013	3,200,958	4.90	6.9	\$ 67,532
December 31, 2013:				
Exercisable	1,688,251	0.94	4.8	42,311
Vested and expected to vest	3,022,948	4.64	6.8	64,574

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During 2013, 2012 and 2011 the Company issued 1,268,049, 863,176 and 49,883 shares of common stock, respectively, in conjunction with stock option exercises. The Company received cash proceeds from the exercise of these stock options of approximately \$1.1 million, \$46,826 and \$53,225 during 2013, 2012 and 2011, respectively.

The weighted-average grant-date fair value of options granted during 2013, 2012 and 2011 was \$6.91, \$0.94 and \$0.94 per share, respectively. The total intrinsic value of options exercised during 2013, 2012 and 2011 was approximately \$5.4 million, \$271,929 and \$102,418, respectively. The total fair value of stock options which vested during 2013, 2012 and 2011 was \$487,603, \$879,024 and \$1,108,107, respectively. As of December 31, 2013, the total unrecognized compensation expense related to non-vested stock options, net of related forfeiture estimates, was \$7.6 million, which the Company expects to recognize over a weighted-average period of approximately four years.

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For the years ended December 31, 2013, 2012 and 2011 there was no current provision for federal or state income taxes due to the taxable losses which resulted or use of legacy NOL carryforwards.

The significant components of the Company's deferred tax assets (liabilities) were as follows:

	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Deferred income tax assets:</b>		
Federal U.S. net operating loss carryforward	\$ 36,561,195	\$ 35,330,167
State net operating loss carryforward	3,315,514	3,521,722
Research and development credit, net	3,785,612	2,777,899
Orphan drug credit, net	19,883,076	19,039,613
Deferred rent	5,132,458	5,218,002
Deferred revenue	8,216,695	9,379,064
Depreciation	1,438,477	1,247,772
Other	1,438,870	1,575,782
Gross deferred income tax assets	79,771,897	78,090,021
Valuation allowance	(79,376,945)	(78,090,021)
Net deferred income tax assets	394,952	
<b>Deferred income tax liabilities:</b>		
Other	(394,952)	
Gross deferred income tax liabilities	(394,952)	
Net deferred income tax asset/(liability)	\$	\$

The Company recognizes valuation allowances to reduce deferred tax assets to the amount that is more likely than not to be realized. In assessing the likelihood of realization, management considers (i) future reversals of existing taxable temporary differences; (ii) future taxable income exclusive of reversing temporary difference and carryforwards; (iii) taxable income in prior carryback years if carryback is permitted under applicable tax law; and (iv) tax planning strategies. The Company's net deferred income tax asset is not more likely than not to be utilized due to the lack of sufficient sources of future taxable income and cumulative book losses which have resulted over the years. The net increase in the valuation allowance in 2013 is due to the fact the Company generated research and development and orphan drug credits and NOL carryforwards which increased the net deferred tax asset. The increase in the credits and NOL carryforwards were offset by the decrease in deferred revenue and resulted in a net current year increase to the valuation allowance.

The Company has reported book losses from inception through December 31, 2010. The NOL carryforwards of approximately \$104.8 million for U.S. federal and approximately \$60.3 million for state will expire in various years beginning in 2023 through 2033. In addition, the Company has U.S. federal tax credits of \$23.7 million which will expire in various years beginning in 2020 through 2033.

The use of the Company's U.S. federal NOL and tax credit carryforwards in future years are restricted due to changes in the Company's ownership and tax attributes acquired by the Company in a purchase. As of December 31, 2013, \$8.5 million of the Company's NOLs are limited for use over the years 2014 - 2027 in which a range of such amounts could be utilized on an annual basis of \$0.2 million to \$1.4 million. The remaining \$96.3 million of NOLs is not limited and can be offset against future taxable income. Additionally,



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approximately \$1.8 million of NOLs will be recognized as a benefit through additional-paid-in-capital when realized. Further, despite the NOL and credit carryforwards, the Company may have a future tax liability due to an alternative minimum tax or state tax requirements in which net operating losses do not exist.

The reconciliation of the reported estimated income tax benefit to the amount that would result by applying the U.S. federal statutory tax rate to the net income is as follows:

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
United States federal tax at statutory rate	\$ (91,293)	\$ 2,926,615	\$ 2,350,992
State taxes (net of federal benefit)	609,476	1,460,289	1,480,185
Deferred income tax adjustments	(855,130)	(512,375)	
Deferred state blended rate adjustments	(344,178)		
Research credit, net	(225,605)		
Orphan drug credit, net	(843,463)	(4,895,671)	(7,056,607)
Other permanent items	2,931	7,627	4,696
Equity-based compensation	241,467	279,165	725,811
Fair value adjustment of preferred stock warrant liability	218,872	(52,743)	(496,208)
Change in valuation allowance	1,286,923	787,093	2,991,131
Income tax expense/(benefit)	\$	\$	\$

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

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Beginning balance	\$ 1,592,357	\$ 1,533,986	\$ 1,246,025
Increases/(decreases) for current year tax positions	115,502	58,371	287,961
Increases/(decreases) for prior year tax positions			
Decreases as a result of expiration of statute of limitations			
Ending balance	\$ 1,707,859	\$ 1,592,357	\$ 1,533,986

As of December 31, 2013 and 2012, of the total gross unrecognized tax benefits, approximately \$1.2 million and \$1.1 million would favorably impact the Company's effective income tax rate, respectively. Although, due to the Company's determination that the deferred income tax asset would not more likely than not be realized, a valuation allowance would be recorded, therefore, zero net impact would result within the Company's effective income tax rate. The Company's uncertain income tax position liability has been recorded to deferred income taxes to offset the tax attribute carryforward amounts.

For the years ended December 31, 2013, 2012 and 2011, the Company has not recognized any interest or penalties related to the uncertain income tax positions due to the fact such position is related to tax attribute carryforwards which have not yet been utilized. The Company does not expect its unrecognized income tax position to significantly decrease within the next twelve months.

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The Company's U.S. Federal and state income tax returns from 2001 to 2012 remain subject to examination by the tax authorities. The Company's 2001 through 2009 years remain open for examination, even though the statute of limitations has expired, due to the net operating losses and credits carried forward for use in prospective years.

**7. Lease Exit Liability**

On July 16, 2008, the Company acquired Raven Biotechnologies, Inc. ( Raven ), a private South San Francisco-based company focused on the development of monoclonal antibody therapeutics for treating cancer. Raven was considered a development-stage enterprise as defined in ASC 915, *Development Stage Entities*. In connection with the acquisition, the Company issued 12,466,039 shares of its Series D convertible preferred stock in exchange for all of the outstanding capital stock and convertible notes payable of Raven.

The Company undertook restructuring activities related to the acquisition of Raven. These restructuring activities included reductions in staffing levels and the intended exit of leased facilities. All severance-related payments were completed in the year ended December 31, 2009.

In connection with these restructuring activities, as part of the cost of acquisition, the Company established a restructuring liability attributed to an existing operating lease. The terms of the operating lease extend through 2018.

Changes in the lease exit liability are as follows:

Accrual balance at December 31, 2011	\$10,607,499
Principal payments	(533,560)
Accrual balance at December 31, 2012	10,073,939
Principal payments	(628,769)
Accrual balance at December 31, 2013	\$9,445,170

Future principal payments to be made under the lease agreement for the next five years and thereafter as of December 31, 2013 are as follows:

2014	\$ 1,438,742
2015	1,641,905
2016	1,866,031
2017	2,113,118
2018	2,385,374
Thereafter	

\$ 9,445,170

The purchase agreement provides for a specified total of certain contingent milestones that are based on the achievement of certain product sales derived from the acquired Raven technology. Also, a onetime payment of \$5.0 million will be made to the Raven stockholders upon the initiation of patient dosing in the first Phase 2 clinical trial of any product derived from the Raven Cancer Stem Cell Program. No payment shall be made if the Phase 2 trial start date has not occurred on or before July 15, 2018. Other consideration includes a percentage of revenue (excluding consideration for research and development and equity) received by the Company for license of a product derived from the Raven Cancer Stem Cell Program and a onetime payment ranging from \$8.0 million to \$12.0 million dependent upon a specified level of sales of products derived from the Raven Cancer Stem Cell Program.

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The contingent consideration will be accounted for as additional purchase price and recorded as incremental in-process research and development expense when it is deemed probable that the contingencies will be attained. No additional amounts have been recorded during the years ended December 31, 2013, 2012 and 2011.

**8. Collaboration and License Agreements**

***Servier***

In November 2011, the Company entered into a right-to-develop collaboration agreement with Servier for the development and commercialization of MGA271 in all countries other than the United States, Canada, Mexico, Japan, South Korea and India.

Upon execution of the agreement, Servier made a nonrefundable payment of \$20.0 million to the Company. The Company is eligible to receive up to \$30.0 million in license grant fees, \$47.0 million in clinical milestone payments, \$140.0 million in regulatory milestone payments and \$208.0 million in sales milestone payments if Servier exercises the option, obtains regulatory approval for and successfully commercializes MGA271. The Company concluded that the license grant fees are not deliverables at the inception of the arrangement. The Company has determined that each potential future clinical, development and regulatory milestone is substantive. Although sales milestones are not considered substantive, they are still recognized upon achievement of the milestone (assuming all other revenue recognition criteria have been met) because there are no undelivered elements that would preclude revenue recognition at that time. In the event Servier exercises its option to continue development of MGA271, Servier must pay a license grant fee. Under this agreement, Servier would be obligated to pay the Company from low double digit to mid-teen royalties on product sales in its territories.

The Company has evaluated the research collaboration agreement with Servier and has determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company concluded that the option is substantive and that the license fees for this option is not a deliverable at the inception of the arrangement as there is considerable uncertainty that the option would be exercised and the additional fee to be paid upon exercise of the option represents its estimated selling price (i.e. no substantial discount was given). The Company's substantive performance obligations under this research collaboration include an exclusivity clause to its technology, technical, scientific and intellectual property support to the research plan during the first year of the agreement and participation on an executive committee and a research and development committee. The Company determined that these performance obligations represent a single unit of accounting, since the license does not have stand-alone value to Servier without the Company's technical expertise and committee participation. As such, the initial upfront payment was deferred and is being recognized ratably over the initial 27-month period, which represents the expected period of development and the Company's participation on the research and development committee. The Company further concluded that each potential future clinical, development and regulatory milestone is substantive.

During the years ended December 31, 2013, 2012 and 2011 the Company recognized revenue of \$21.3 million, \$9.1 million and 0.9 million, respectively, under this agreement. Revenue recognized in the year ended December 31, 2013 included a \$10.0 million substantive milestone payment received upon dosing the first patient in a Phase 1 dose expansion cohort trial of MGA271.

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At December 31, 2013, \$0.9 million of revenue remained deferred under this agreement, all of which was included in current liabilities. At December 31, 2012, \$10.0 million of revenue was deferred under this agreement, \$9.1 million of which was included in current liabilities and \$0.9 million of which was included in long-term liabilities.

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In September 2012, the Company entered into a second right-to-develop collaboration agreement with Servier and granted it options to obtain three separate exclusive licenses to develop and commercialize DART-based molecules, consisting of those designated by the Company as MGD006 and MGD007, as well as a third DART molecule, in all countries other than the United States, Canada, Mexico, Japan, South Korea and India.

Upon execution of the agreement, Servier made a nonrefundable payment of \$20.0 million to the Company. In addition, the Company will be eligible to receive up to \$65.0 million in license grant fees, \$98.0 million in clinical milestone payments, including \$5.0 million upon IND acceptance for each of MGD006, MGD007 and a third DART molecule, \$300.0 million in regulatory milestone payments and \$630.0 million in sales milestone payments if Servier exercises all of the options and successfully develops, obtains regulatory approval for, and commercializes a product under each license. In addition to these milestones, the Company and Servier will share Phase 2 and Phase 3 development costs. The Company has determined that each potential future clinical, development and regulatory milestone is substantive. Although sales milestones are not considered substantive, they are still recognized upon achievement of the milestone (assuming all other revenue recognition criteria have been met) because there are no undelivered elements that would preclude revenue recognition at that time. Under this agreement, Servier would be obligated to pay the Company between high-single digit and mid-teen royalties on net product sales in its territories.

The Company has evaluated the research collaboration agreement with Servier and has determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company concluded that each option is substantive and that the license fees for each option are not deliverables at the inception of the arrangement and were not issued with a substantial discount. The Company's substantive performance obligations under this research collaboration include an exclusivity clause to its technology, technical, scientific and intellectual property support to the research plan during the first year of the agreement and participation on an executive committee and a research and development committee. The Company determined that the performance obligations with respect to the pre-clinical development represent a single unit of accounting, since the license does not have stand-alone value to Servier without the Company's technical expertise and committee participation. As such, the initial up front license payment was deferred and is being recognized ratably over the initial 29-month period, which represents the expected development period. The Company further concluded that each potential future clinical, development and regulatory milestone is substantive.

During the years ended December 31, 2013 and 2012 the Company recognized revenue of \$8.6 million, and \$2.0 million, respectively. No milestones have been recognized under this agreement during the years ended December 31, 2013 and 2012.

At December 31, 2013, \$9.4 million of revenue was deferred under this agreement, \$8.6 million of which was included in current liabilities and \$0.8 million of which was included in long-term liabilities. At December 31, 2012, \$18.0 million of revenue was deferred under this agreement, \$8.6 million of which was included in current liabilities and \$9.4 million of which was included in long-term liabilities.

In February 2014, Servier exercised its exclusive option to develop and commercialize MGD006. As a result of the exercise, the Company received a \$15.0 million payment from Servier for its license to develop and commercialize MGD006 in its territories. In addition, the Company received a \$5.0 million payment from Servier upon the

achievement of a clinical milestone related to the IND application for MGD006 clearing the 30-day review period by the FDA.

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***Gilead***

In January 2013, the Company entered into an agreement with Gilead for the research, development and commercialization of up to four DART-based molecules. The time period for Gilead's exercise of one option has expired. At present, Gilead retains a license to one and options to two of the original four programs. Gilead has exclusive worldwide rights for each of these remaining programs.

The Company received an initial \$7.5 million license grant fee for the first DART-based molecule, and is eligible to receive additional license grant fees of \$7.5 million on each of the remaining two DART-based molecules if they are selected by Gilead. The Company is further eligible to receive up to an additional \$20 to \$25 million in pre-clinical milestones across each of the three remaining DART programs and up to approximately \$240 to \$250 million per remaining program in additional clinical, regulatory and sales milestones if Gilead exercises both remaining options and achieves all of the requisite milestones under each option and license. The Company has determined that the other licenses are conditional deliverables, which are substantive options that were not granted with a substantial discount. The Company has determined that each potential future clinical, development and regulatory milestone is substantive. Although sales milestones are not considered substantive, they are still recognized upon achievement of the milestone (assuming all other revenue recognition criteria have been met) because there are no undelivered elements that would preclude revenue recognition at that time. Gilead also provides funding for the Company's internal and external research costs under the agreement. Additionally, Gilead would be obligated to pay the Company high single digit to low double digit, but less than teen royalties on product sales.

The Company has evaluated the research collaboration agreement with Gilead and has determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under this research collaboration include a license to its technology and research and development services. The Company concluded that the deliverables do not have stand alone value and therefore, represent a combined single unit of accounting. Due to the lack of standalone value for the license and research and development services, the combined unit of accounting (the upfront payment and the expected research and development reimbursements) is being recognized ratably over a period of 21 months, which represents the expected development period.

The Company and Gilead have also agreed to establish a joint research committee to facilitate the governance and oversight of the parties' activities under the agreements. Management considered whether participation on the joint committee may be a deliverable and determined that it was not a deliverable. Had management considered participation on the joint committee as a deliverable, it would not have had a material impact on the accounting for the arrangement.

The Company recognized revenues of approximately \$8.0 million under this agreement for the year ended December 31, 2013. No milestones have been achieved under this agreement.

At December 31, 2013, \$3.6 million of revenue was deferred under this agreement, all of which was included in current liabilities.

***Boehringer***

In October 2010 the Company entered into a collaboration and license agreement with Boehringer to discover, develop and commercialize up to ten DART-based molecules which span multiple therapeutic areas. Under the terms of the agreement, the Company granted Boehringer an exclusive, worldwide, royalty-bearing, license under its intellectual property to research, develop, and market DARTs generated under the agreement throughout the world.

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Upon execution of the agreement, the Company received an upfront payment of \$15.0 million. The Company subsequently received three annual maintenance payments including one in the fourth quarter of 2013. These maintenance payments are being recognized over the estimated period of development. The Company has the potential to earn milestone payments of approximately \$41.0 million related to pre-clinical and clinical development, \$89.0 million related to regulatory milestones and \$83.0 million related to sales milestones for each of the DART programs under this agreement in the case of full commercial success of multiple DART products. The Company has determined that each potential future clinical, development and regulatory milestone is substantive. Although sales milestones are not considered substantive, they are still recognized upon achievement of the milestone (assuming all other revenue recognition criteria have been met) because there are no undelivered elements that would preclude revenue recognition at that time. Boehringer also provides funding for the Company's internal and external research costs and is required to pay the Company mid-single digit royalties on product sales. In November 2013, Boehringer nominated a bi-specific antibody therapeutic candidate generated by the Company's DART technology for pre-clinical development. This formal selection of a development candidate triggered a \$5.0 million milestone payment to the Company. From the commencement of the collaboration through December 31, 2013, the Company has received \$48.8 million under this agreement, including upfront, annual maintenance and milestone payments as well as research funding. In addition, Boehringer purchased \$10.0 million of the Company's Series D-2 Preferred Stock in January 2011. This preferred stock was converted to common stock upon the Company's IPO in October 2013.

The Company determined that the deliverables under the Boehringer agreement include the license, the research and development services to be performed by the Company, and the co-promotion/manufacturing services. The Company concluded that the co-promotional activities were optional and were subject to further negotiation upon reaching regulatory approval. As such, the co-promotional period is not included in the expected obligation period to perform services.

The Company concluded that the undelivered element of research and development services had fair value. The Company concluded that the license does not have value on a standalone basis (e.g. absent the provision of the research and development services) and therefore does not represent a separate unit of accounting. The Company concluded that because the drug candidate has not yet been developed, the license is of no value to Boehringer without the ensuing research and development activities using the DART technology, which is proprietary to the Company. Likewise, Boehringer could not sell the license to another party (without the Company agreeing to provide the research and development activities for the other party).

Therefore, the upfront license fee and research and development services were treated as a combined unit of account and recognized over the expected obligation period associated with the research and development services through September 2015, which represents the estimated period of development.

The Company and Boehringer have also agreed to establish a joint research committee to facilitate the governance and oversight of the parties' activities under the agreements. Management considered whether participation on the joint committee may be a deliverable and determined that it was not a deliverable. However, had management considered participation on the joint committee as a deliverable, it would not have had a material impact on the accounting for the arrangement as the period of participation in this committee matched the obligation period for the research and development services.

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There have been no material modifications to this agreement since the adoption of ASU 2009-13 on January 1, 2011.

The Company recognized revenues of approximately \$14.4 million, \$11.7 million and \$8.9 million during the years ended December 31, 2013, 2012 and 2011, respectively. Revenue recognized in the years ended

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**MACROGENICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2013 and 2012 included milestone payments of \$5.0 million and \$2.0 million, respectively, for the achievement of clinical milestones. No milestones were achieved in the year ended December 31, 2011. At December 31, 2013, \$12.8 million of revenue was deferred under this agreement, \$7.0 million of which was included in current liabilities and \$5.8 million of which was included in long-term liabilities. At December 31, 2012, \$14.0 million of revenue was deferred under this agreement, \$5.0 million of which was included in current liabilities and \$9.0 million of which was included in long-term liabilities.

***Pfizer***

In October 2010, the Company entered into a three year agreement with Pfizer to discover, develop and commercialize up to two DART-based molecules. The Company granted Pfizer a non-exclusive worldwide, royalty-bearing license and received an upfront payment of \$5.0 million and has received milestone payments and funding for the Company's internal and external research costs under the agreement.

The Company is eligible to receive milestone payments of approximately \$17.0 million related to pre-clinical and clinical development and \$195.0 million related to commercialization and sales milestones for each DART program under this agreement. The Company has determined that each potential future technical and development milestone is substantive. Although sales milestones are not considered substantive, they are still recognized upon achievement of the milestone (assuming all other revenue recognition criteria have been met) because there are no undelivered elements that would preclude revenue recognition at that time. Pfizer is responsible for all pre-clinical and clinical development costs for the program. In addition, Pfizer is required to pay the Company mid-single digit to low-teen royalties on product sales. Under this collaboration, one DART program is currently being pursued and the Company completed its research obligations under this program in January 2014.

The Company has evaluated the research collaboration agreement with Pfizer and has determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under this research collaboration include an exclusive license to its technology, research and development services and manufacturing services. The Company concluded that the manufacturing services were optional and were subject to further negotiation upon reaching regulatory approval. As such, the manufacturing services are not included in the expected obligation period to perform services.

The Company determined that it had fair value of the undelivered element of the research and development services. However, the Company concluded that the license does not have value on a standalone basis (e.g. absent the provision of the research and development services) and therefore does not represent a separate unit of accounting. Facts that were considered included the development of the candidate noting that because the drug candidate has not yet been developed, the license is of no value to Pfizer without the ensuing research and development activities using the DART technology, which is proprietary to the Company. Likewise, Pfizer could not sell the license to another party (without the Company agreeing to provide the research and development activities for the other party).

Therefore, the upfront license fee and research and development services were treated as a combined unit of accounting and recognized over the expected obligation period associated with the research and development services through January 2014, which represents the estimated period of development.

The \$5.0 million upfront payment received by the Company is non-refundable; therefore, there is no right of return for the license. The Company recognizes revenue associated with this non-refundable up-front license fee through the expected obligation period associated with the research and development services, which ended in January 2014.

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**MACROGENICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The Company and Pfizer have also agreed to establish a joint research committee to facilitate the governance and oversight of the parties' activities under the agreements. Management considered whether participation on the joint committee may be a deliverable and determined that it was not a deliverable because it is a participating right and not an obligation of the Company. However, had management considered participation on the joint committee as a deliverable, it would not have had a material impact on the accounting for the arrangement.

There have been no material modifications to this agreement since the adoption of ASU 2009-13 on January 1, 2011.

The Company recognized revenues of approximately \$3.5 million, \$5.5 million and \$5.2 million during the years ended December 31, 2013, 2012 and 2011, respectively. Included in the 2012 revenues are milestone payments totaling \$500,000. No additional milestones have been achieved under this agreement through December 31, 2013.

At December 31, 2013 and 2012, \$7,291 and \$1.3 million of revenue was deferred under this agreement, respectively, all of which was included in current liabilities.

***Green Cross***

In June 2010, the Company entered into a collaboration agreement with Green Cross for the development of the Company's anti-HER2 antibody known as MGAH22, or margetuximab. This arrangement grants Green Cross an exclusive license to conduct specified Phase 1 and Phase 2 clinical trials and commercialize margetuximab in South Korea.

Upon execution of the agreement, Green Cross made a nonrefundable payment of \$1.0 million to the Company. The Company is eligible to receive clinical development and commercial milestone payments of up to \$4.5 million. The Company has determined that each potential clinical development and commercial milestone is substantive. The Company is also entitled to receive royalties on net sales of margetuximab in South Korea. The Company and Green Cross have formed a joint steering committee to coordinate and oversee activities on which the companies collaborate under the agreement.

The Company has evaluated the collaboration agreement with Green Cross and has determined that it is a revenue arrangement with multiple deliverables or performance obligations. The Company's substantive performance obligations under this agreement include an exclusive license to its technologies and participation in a joint steering committee. The Company concluded that the license does not have value on a standalone basis and therefore does not represent a separate unit of accounting. Likewise, Green Cross could not sell the license to another party.

The \$1.0 million upfront payment received by the Company is non-refundable; as such, there is no right of return for the license. Therefore, the upfront license fee and participation on the joint steering committee were treated as a combined unit of accounting and will be recognized over the term of the agreement through June 2020.

There have been no material modifications to this agreement since the adoption of ASU 2009-13 on January 1, 2011.

The Company recognized revenues of approximately \$100,000 under this agreement during each of the three years ended December 31, 2013. No milestones were achieved under this agreement during the three years ended December 31, 2013.

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**MACROGENICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

At December 31, 2013, \$650,000 of revenue was deferred under this agreement, \$100,000 of which was included in current liabilities and \$550,000 of which was included in long-term liabilities. At December 31, 2012, \$750,000 of revenue was deferred under this agreement, \$100,000 of which was included in current liabilities and \$650,000 of which was included in long-term liabilities.

***Eli Lilly***

In October 2007, the Company entered into an exclusive license and collaboration agreement (together, the Agreements) with Eli Lilly to jointly develop and commercialize teplizumab, a humanized anti-CD3 monoclonal antibody. As part of the Agreements, Eli Lilly acquired the exclusive rights to the molecule.

Upon execution of the Agreements, Eli Lilly made a nonrefundable payment of \$41.0 million to the Company. In May 2008, Eli Lilly paid the Company a milestone payment of \$50.0 million and in May 2010, Eli Lilly paid an additional milestone of \$5.0 million.

On October 28, 2010, Lilly notified the Company of its decision to terminate the agreement after review of one year of clinical data from the Protégé trial in Type 1 diabetes patients treated with teplizumab. Such data failed to support the primary efficacy end point in the study. In February 2011, the Company reacquired the commercial rights to the molecule from Eli Lilly. During the year ended December 31, 2012, Eli Lilly satisfied its obligation related to the cost of monitoring patients under the Protégé and Encore trials. The Company's obligations continued through September 2012, which represented the follow up period for enrolled patients and the Company's final reporting of the trial's results. There is no additional clinical trial activity under the Eli Lilly Agreements as it relates to such trials. However, Eli Lilly continues to reimburse the Company for monitoring patients in one currently active trial.

During the years ended December 2013, 2012 and 2011, the Company recognized revenue of \$0.8 million, \$31.2 million and \$30.9 million, respectively, under this agreement. No milestones were achieved under this agreement during the three years ended December 31, 2013.

**9. Commitments and Contingencies**

***Operating Leases***

The Company leases office and laboratory space in Rockville, Maryland under a lease that expires on March 31, 2018, and leases a manufacturing facility in Rockville under a lease that expires on December 31, 2014. The Company has an option under each lease to continue the respective lease for five years under the same terms. The Company also subleases office and laboratory space in South San Francisco under a lease that expires on December 31, 2018. All of the leases contain rent escalation clauses. For financial reporting purposes, rent expense is charged to operations on a straight-line basis over the term of the lease. As of December 31, 2013 and 2012, the Company had recorded a deferred rent liability of \$2.9 million and \$2.8 million, respectively. Rent expense for the years ended December 31, 2013, 2012 and 2011 was \$2.7 million, \$2.7 million and \$2.9 million, respectively.



**Table of Contents****MACROGENICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Future minimum lease payments under noncancelable operating leases at December 31, 2013 are as follows:

2014	\$ 3,651,421
2015	3,310,884
2016	3,410,210
2017	3,512,517
2018	2,780,398
Thereafter	
	\$ 16,665,430

**10. Product Milestone Payments and Royalty Agreements**

In connection with an Asset Purchase Agreement with Tolerance Therapeutics, Inc. ( Tolerance ) entered into during June 2005, the Company may be required to issue Tolerance additional consideration as follows: (i) \$10,950,000 if certain milestones are met, including the initiation of Phase 3 trials and filing of various regulatory product license applications; (ii) 36,135 shares of common stock; and (iii) royalty payments between 1.75% and 4.0% of net sales of products acquired from or patented by Tolerance or other product fees earned by the Company. Any additional consideration required to be paid under the Asset Purchase Agreement will be recorded as research and development expense when incurred. No payments related to the additional consideration have occurred during the three years ended December 31, 2013. Additionally, certain agreements require the Company to pay royalties. Currently, the Company is not obligated to pay royalties, as no revenue from product sales is being generated by the Company.

**11. Employee Benefit Plan**

On September 25, 2002, the Company established the MacroGenics 401(k) Plan (the Plan ) for its employees under Section 401(k) of the IRC. Under this Plan, all employees at least 21 years of age are eligible to participate in the Plan, starting on the first day of each month. Employees may contribute up to 100% of their salary, subject to government maximums.

Employees are 100% vested in their contributions to the Plan. The Company's contribution to the Plan, as determined by the Board of Directors, is discretionary. The Company's contributions to the Plan totaled \$252,930, \$225,195 and \$217,097 for the years ended December 31, 2013, 2012 and 2011, respectively.

**12. Quarterly Financial Information (unaudited)**

**1<sup>st</sup> Quarter    2<sup>nd</sup> Quarter    3<sup>rd</sup> Quarter    4<sup>th</sup> Quarter**  
**(in thousands, except per share data)**

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<b>2013</b>				
Revenue	\$ 10,598	\$ 12,299	\$ 20,232	\$ 14,906
Net income (loss)	(3,366)	(294)	6,604	(3,205)
Net income (loss) per share, basic	\$ (2.93)	\$ (0.24)	\$ 0.14	\$ (0.14)
Net income (loss) per share, diluted	\$ (2.93)	\$ (0.24)	\$ 0.01	\$ (0.14)

<b>2012</b>				
Revenue	\$ 20,510	\$ 17,435	\$ 16,082	\$ 9,799
Net income (loss)	4,320	3,546	2,601	(2,105)
Net income (loss) per share, basic	\$ 0.00	\$ 0.00	\$ 0.00	\$ (1.92)
Net income (loss) per share, diluted	\$ 0.00	\$ 0.00	\$ 0.00	\$ (1.92)

Annual net income (loss) per share includes the effects of income allocated to participating securities.

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**MACROGENICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**13. Subsequent Events**

In February 2014, Servier exercised its exclusive option to develop and commercialize MGD006. Servier will gain exclusive development and commercial rights in all countries outside of the U.S., Canada, Mexico, Japan, South Korea and India. In those countries, the Company will retain development and commercialization rights. As a result of the exercise, the Company received a \$15.0 million payment from Servier. In addition, the IND application for MGD006 has cleared the 30-day review period by the FDA, triggering an additional \$5.0 million payment to the Company by Servier.

In February 2014, the Company completed a follow-on equity offering, in which the Company sold 1.8 million shares of its common stock at a price of \$36.50 per share. Additionally, the underwriters of the offering exercised the full amount of their over-allotment option resulting in the sale of an additional 450,000 shares of the Company's common stock at a price of \$36.50 per share. The Company received net proceeds of \$76.7 million from this offering, net of underwriting discounts and commissions and other estimated offering expenses.

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation of Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (001-36112) filed on October 18, 2013)
3.2	Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.4 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
3.3	Certificate of Correction to the Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K (001-36112) filed on October 18, 2013)
4.1*	Fifth Amended and Restated Registration Rights Agreement by and among the Company, the Founders, and the Investors, dated February 3, 2014
4.2	Specimen Stock Certificate (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 9, 2013)
10.1+	Company 2000 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
10.2+	Form of Incentive Stock Option Agreement under 2000 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
10.3+	Company 2003 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
10.4+	Form of Incentive Stock Option Agreement under 2003 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
10.5+	Company 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.6+	Form of Incentive Stock Option Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.7+	Form of Nonstatutory Stock Option Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.8	Lease Agreement by and between Red Gate III LLC and the Company, dated May 31, 2011 (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
10.9	Amendment to Lease Agreement by and between Red Gate III LLC and the Company, dated March 26, 2013 (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 (File No.

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333-190994) filed by the Company on September 4, 2013)

- 10.10 Lease Agreement by and between W. M. Rickman Construction Co. LLC and the Company, dated December 2, 2004 (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
- 10.11 Amendment to Lease Agreement by and between W. M. Rickman Construction Co. LLC and the Company, dated January 31, 2006 (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)

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- 10.12 Second Amendment to Lease Agreement by and between W. M. Rickman Construction Co. LLC and the Company, dated June 1, 2011 (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
- 10.13 Sublease Agreement by and between Amgen SF, LLC and Raven biotechnologies, Inc., dated November 21, 2006 (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
- 10.14 Form of Indemnification Agreement (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
- 10.15 Collaboration and License Agreement by and between Boehringer Ingelheim International GmbH and the Company, dated October 18, 2010 (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 4, 2013)
- 10.16 License Agreement by and between the Company and Gilead Sciences, Inc., dated January 3, 2013 (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 4, 2013)
- 10.16.1 First Amendment to License Agreement by and between the Company and Gilead Sciences, Inc., dated October 1, 2013 (incorporated by reference to Exhibit 10.16.1 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 4, 2013)
- 10.17 Collaboration Agreement by and between the Company and Green Cross Corp., dated June 30, 2010 (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 4, 2013)
- 10.18 First Amendment to Collaboration Agreement by and between the Company and Green Cross Corp., dated January 19, 2011 (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
- 10.19 Second Amendment to Collaboration Agreement by and between the Company and Green Cross Corp., dated December 13, 2012 (incorporated by reference to Exhibit 10.19 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
- 10.20 Option for a License Agreement by and between the Company and Les Laboratoires Servier and Institut de Recherches Servier, dated September 19, 2012 (incorporated by reference to Exhibit 10.20 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 4, 2013)
- 10.21 Option for a License Agreement by and between the Company and Les Laboratoires Servier and Institut de Recherches Servier, dated November 24, 2011 (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 4, 2013)
- 10.22 Research Collaboration and License Agreement by and between Pfizer Inc. and the Company, dated October 13, 2010 (incorporated by reference to Exhibit 10.22 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 4, 2013)
- 10.23 Amendment No. 1 to Research Collaboration and License Agreement by and between Pfizer Inc. and the Company, dated August 9, 2012 (incorporated by reference to Exhibit 10.23 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
- 10.24 Amendment No. 2 to Research Collaboration and License Agreement by and between Pfizer Inc. and the Company, effective October 13, 2013 (incorporated by reference to Exhibit 10.24 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 20, 2013)



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10.25+	Form of Employment Agreement between the Company and Scott Koenig, M.D., Ph.D. (incorporated by reference to Exhibit 10.25 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.26+	2013 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.27 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.27+*	Form of Employment Agreement between the Company and James Karrels
21.1	Subsidiaries of Company (incorporated by reference to Exhibit 21.1 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
23.1	Consent of Ernst & Young, LLP, Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a) Certification of Principal Executive Officer
31.2	Rule 13a-14(a) Certification of Principal Financial Officer
32.1	Section 1350 Certification of Principal Executive Officer
32.2	Section 1350 Certification of Principal Financial Officer
101.INS**	XBRL Instance Document
101.SCH**	XBRL Schema Document
101.CAL**	XBRL Calculation Linkbase Document
101.DEF**	XBRL Definition Linkbase Document
101.LAB**	XBRL Labels Linkbase Document
101.PRE**	XBRL Presentation Linkbase Document

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment granted by the SEC.

+ Indicates management contract or compensatory plan.

\* Previously filed.

\*\* In accordance with Regulation S-T, the XBRL-related information in Exhibit 101 to this Annual Report on Form 10-K shall be deemed to be furnished and not filed .