Immune Design Corp.
Form 10-K
March 31, 2015
Table of Contents

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

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2014
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number: 001-36561

IMMUNE DESIGN CORP.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	26-2007174 (I.R.S. Employer Identification Number)
1616 Eastlake Ave. E., Suite 310 Seattle, Washington (address of principal executive officers)	98102 (Zip code)

(206) 682-0645
(Registrant's telephone number, including area code)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	NASDAQ Global Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ¨ No x
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 x 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 (§232.405 of this chapter) 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. x

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	x (Do not check if a smaller reporting company)	Smaller reporting company	¨

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

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

As of March 20, 2015, the registrant had 16,979,688 shares of common stock, par value $0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement, or the Proxy Statement, for the 2015 Annual Meeting of Stockholders of the registrant are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2014.

Table of Contents

TABLE OF CONTENTS

In this report, unless otherwise stated or as the context otherwise requires, references to “Immune Design,” “the Company,” “we,” “us,” “our” and similar references refer to Immune Design Corp. The Immune Design logo, "IMDZVex", “ZVex” and “GLAAS” are our unregistered trademarks. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “esti “predicts,” “potential,” “intends” or “continue,” or the negative of these terms or other comparable terminology. Forward-looking statements include, but are not limited to, statements about:

- our estimates regarding our expenses, use of proceeds, future revenues, anticipated capital requirements and our needs for additional financing;
- the implementation of our business model and strategic plans for our business and technology;
- the timing of the commencement, progress and receipt of data from any of our preclinical and clinical trials;
- the expected results of any clinical trial and the impact on the likelihood or timing of any regulatory approval;
- the scope of protection we establish and maintain for intellectual property rights covering our technology;
- the timing or likelihood of regulatory filings and approvals;
- the timing and outcome of any current or future litigation;
- developments relating to our competitors and our industry; and
- our expectations regarding licensing, acquisitions and strategic operations.

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

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, after the date of this report, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

This report also contains estimates, projections and other information concerning our industry, the market and our business. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. We obtained the industry, market and competitive position data in this report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties.

Table of Contents

PART I

Item 1. Business

Overview

We are a clinical stage immunotherapy company with next-generation in vivo approaches designed to enable the body's immune system to fight disease. We have engineered our technologies to activate the immune system's natural ability to create tumor-specific cytotoxic T cells to fight cancer. We are developing multiple product candidates from our two discovery platforms, ZVex™ and GLAAS™, which we believe have the potential to treat a broad patient population either as individual therapies or in combination with other immuno-oncology mechanisms of action. Our primary product candidates, CMB305 and G100, utilize multiple immuno-oncology approaches and, we believe, address the shortcomings of existing therapies. The following is our product development pipeline based on our ZVex and GLAAS platforms:

CMB305 is a prime-boost approach, in which an agent called LV305 from our ZVex platform is dosed sequentially with a second agent from our GLAAS platform, G305. Both LV305 and G305 completed dosing in separate Phase 1 dose escalation trials with no serious adverse events. Importantly, we believe the initial safety and immunogenicity data from these two trials support the commencement of CMB305 trials. After the FDA allowed our IND for CMB305, we began dosing in a Phase 1 dose-escalation clinical trial in the first quarter of 2015 for the treatment of four solid tumor types. We expect initial data to be available from the dose-escalation portion of this study in the second half of 2015.

G100 was developed from the GLAAS platform and we are currently enrolling patients with Merkel cell carcinoma, or MCC, or sarcoma in two separate Phase 1 clinical trials. We commenced the MCC trial in January 2014 and expect it to be completed in the second quarter of 2015. We previously disclosed that one of our initial patients treated had a complete response in the first loco-regional tumor treated with G100. Since that time, we have observed additional evidence of clinical efficacy. While we believe these responses may be related to treatment with G100, the results from our Phase 1 clinical trial are not yet final, and we cannot be certain that this is the case or that these, or any other future responses observed, will be durable. The sarcoma study commenced in November 2014 via an investigator-sponsored study at the Fred Hutchinson Cancer Research Center, or FHCRC, which we expect to complete by year-end 2015. We intend to further develop G100 in a Phase 1 trial in non-Hodgkin Lymphoma to begin in the second quarter of 2015.

For each of the ongoing clinical trials, although the data may be available as of a given date, we may elect to announce the results at an appropriate medical meeting.

Because of its prime-boost approach, we believe CMB305 should be more effective than either of its components, LV305 or G305, alone. Although we currently intend to focus our development efforts on CMB305 and G100, in December 2014, we dosed the first patient in an expansion trial of LV305 at the highest dose studied in the Phase 1 dose escalation study. The expansion trial is designed to study the same four tumor types studied in the CMB305 Phase 1 trial, and will explore the use of LV305 with a checkpoint inhibitor in melanoma patients who have an inadequate response to anti-PD1 therapy. We expect data from the expansion trial to be available by the end of 2015. After reviewing the data from those trials, we may elect to separately develop LV305.

We believe our approach to fighting cancer is the first of its kind. We utilize ZVex and GLAAS to develop product candidates that work in vivo and are designed to create and expand diverse armies of immune cells, known as cytotoxic T lymphocytes, or CTLs, to fight tumors. An in vivo approach is preferred because it addresses both the cumbersome administration and the need for patient customization inherent in ex vivo approaches, such as engineered CD8 T cells. The fundamental discoveries underlying ZVex originated with one of our founders, Nobel laureate David Baltimore, Ph.D. Dr. Baltimore and his colleagues theorized that a lentivirus, which is a virus that works in immune cells such as dendritic cells, or DCs, could be engineered to selectively deliver the specific genetic information of a tumor marker, called an antigen, directly to DCs in the skin. The expression of this antigen would trigger an immune response of CTLs to eliminate the tumor. GLAAS, in comparison, is a highly potent synthetic stimulator of a specific cellular receptor called TLR4 that is present in DCs. Activation of DCs through TLR4 can safely trigger an anti-tumor immune response and synergize with CTLs generated by ZVex for what we believe will be a greater degree of tumor

killing than either approach alone.

1

Table of Contents

While our primary focus is immuno-oncology, we believe that our platforms also have therapeutic potential in infectious disease, allergy and autoimmune disease.

ZVex and GLAAS: Complementary and Productive Product Discovery Platforms

ZVex is a discovery platform that uses a first-in-class vector to generate product candidates designed to create CTLs in vivo. A primary function of CTLs is the selective recognition and subsequent destruction of tumor cells. The ZVex vector is a delivery system based on a re-engineered virus to carry the genetic information of a tumor antigen safely and selectively to DCs in the skin. DCs are the most important immune cells to target because they initiate the specific immune response that generates CTLs to kill the tumor. When ZVex-based product candidates are injected into a cancer patient, the vector is designed to interact only with these DCs, delivering the tumor antigen in the form of RNA. The DC then processes the RNA into a protein, splits it and presents the protein fragments outside of the cell to neighboring resting CD8 T cells, which are precursors to CTLs. When a CD8 T cell is presented with a new antigen protein fragment by the DC, it becomes activated and starts dividing, creating millions of CTLs that will kill tumor cells bearing that same specific tumor antigen. ZVex product candidates have the potential to carry the genetic material of different tumor antigens and, as a result, can target multiple types of cancers.

GLAAS, which stands for GLA Adjuvant Systems, is a discovery platform that also works in vivo and is based on a small synthetic molecule called GLA, which stands for glucopyranosyl lipid A. GLA selectively binds to the TLR4 receptor and causes potent activation of the DC. When GLA is accompanied by a tumor antigen and injected into a patient, the combination is taken up by DCs and leads to the production and expansion of immune cells called CD4 T helper lymphocytes. Similar to CTLs, these CD4 T cells will be specific to the tumor antigen taken up by the DC, but unlike CTLs, they generally cannot kill antigen-bearing tumor cells. They do, however, play a key role in boosting the anti-tumor immune response by: (1) expanding the number and function of existing CTLs that are specific to the same tumor antigen; and (2) providing help to other immune cells, including B lymphocytes that produce antibodies and natural killer, or NK, cells that are also important in the overall anti-tumor immune response. We therefore believe that product candidates containing GLAAS with a tumor antigen will be effective in amplifying the anti-tumor activity of CTLs, as well as other beneficial anti-tumor mechanisms. Like ZVex, GLAAS product candidates have the potential to target multiple types of cancers.

The combination of ZVex and GLAAS synergize to yield a more potent immune response called a heterologous prime-boost. ZVex primes the immune system by triggering the generation of CTLs, while GLAAS, by activation of CD4 T cells, boosts the immune response by expanding and enhancing the function of CTLs and other anti-tumor

Table of Contents

immune mechanisms. We are also studying a different combination of both platforms in a "prime-pull" strategy where ZVex primes the immune system and GLAAS 'pulls' CTLs to the tumor via intra-tumoral injection. We believe that these combinations of different technologies result in first-in-class and best-in-class approaches that generate and expand CTLs and recruit them to the tumor. The following data from an in vivo rodent model illustrate the effect on antigen-specific CTL generation when combining ZVex and GLAAS platforms in a prime-boost. When used alone, the ZVex agent increased the CTLs from 0.05% to 3.16%, and when in combination with GLAAS, the percentage of antigen-specific CTLs in the rodents increased to 15.7%.

The Immune Design Approaches

Immuno-oncology broadly refers to the modulation of the immune system to eradicate tumor cells and is often colloquially divided into two categories: “create and expand” the anti-tumor immune response, and “remove the brakes” placed on the immune response by the tumor’s defenses. Our platforms focus on the “create and expand” category and are designed to generate strong, tumor-specific CTLs in vivo while addressing many of the shortcomings of previous approaches. Our platforms can generate individual product candidates, such as LV305 and G100, or product candidates administered in sequence, such as CMB305. Additionally, our platforms can be combined with other immuno-oncology therapeutic mechanisms such as checkpoint inhibitors from the "remove the brakes" category, which we believe will generate a greater immune response.

We are targeting tumors using two different strategies that we refer to as the Specific Antigen and Endogenous Antigen, or intra-tumoral Immune Activation, approaches. Under the Specific Antigen approach, our product candidates contain a selected antigen enabling the immune system to recognize and kill the tumor cells expressing the same antigen. LV305 and CMB305 are examples of this approach. Under the Endogenous Antigen approach, our GLAAS-based immuno-oncology product candidate, G100, is not designed to target a specific tumor antigen. Instead, we believe that when administered with mechanisms that kill, or lyse, tumor cells, our GLAAS-based product candidates will cause DCs near the lysed tumor to activate and capture the wide range of released endogenous tumor antigens. We believe this will trigger a broad immune response against those newly-encountered tumor antigens.

CMB305, our primary product candidate being developed under the Specific Antigen approach, targets the tumor antigen NY-ESO-1. We have selected NY-ESO-1 because it is highly expressed in a number of tumors, but the immune system rarely mounts an effective immune response against it. Additionally, its safety has been evaluated by others in numerous clinical trials. We are conducting Phase 1 clinical trials of CMB305 and its component agent, LV305, in patients with solid tumors, including both rare tumors, such as synovial sarcoma, and higher-incidence tumors such as lung, ovarian and melanoma. We have chosen synovial sarcoma because of its high NY-ESO-1 expression profile. In addition, synovial sarcoma is an orphan disease. If we are able to obtain orphan drug designation from the FDA for any of our Specific Antigen approach product candidates for synovial sarcoma, we may be able to obtain certain benefits such as research tax credits, grant funding, and the potential for seven years of marketing exclusivity under certain circumstances. LV305 completed dosing of its Phase 1 dose-escalation

Table of Contents

clinical trial with no evidence of safety concerns and, importantly, demonstrated immunogenicity data we believe supports progressing development of CMB305. Although we are focused on CMB305 as the primary product candidate in the Specific Antigen approach, we are also exploring the potential of LV305 as a single therapy and, in December 2014, we dosed the first patient in an expansion trial at the highest dose studied in the Phase 1 dose escalation trial. The expansion trial will treat patients with any of four solid tumor types and include the exploration of LV305 with an anti-PD1 checkpoint inhibitor in melanoma patients who have had an inadequate response to anti-PD1, with the completion of dosing scheduled for the second half of 2015. We expect safety and immunogenicity data from the LV305 Phase 1 dose escalation and expansion trials to be available by the end of the first quarter and in the second half of 2015, respectively. Because we believe CMB305, the prime boost of LV305 and G305, should be the most potent therapy under our current Specific Antigen approach, we are planning to focus our development on this product candidate and progress it into more advanced clinical studies, while preserving the ability to separately develop LV305. We believe the initial safety and immunogenicity data from the LV305 and G305 trials support the development of CMB305, and after the FDA allowed our IND for CMB305, we began dosing our first patient in a Phase 1 dose-escalation clinical trial for the treatment of four solid tumor types in the first quarter of 2015, with initial data expected to be available in the second half of 2015. Finally, although we believe G305 may be an effective therapy with patients who have pre-existing but insufficient immune responses prior to treatment, we do not intend to develop it as a stand-alone product.

G100 is our first product candidate being developed under our Endogenous Antigen, or intra-tumoral Immune Activation, approach and is currently being evaluated in two Phase 1 clinical trials. The first trial is evaluating intra-tumoral injection of G100 in patients with either loco-regional or metastatic Merkel cell carcinoma, or MCC, an orphan disease. We previously disclosed that one of our initial patients treated had a complete response in the first loco-regional tumor treated with G100. Since that time, we have observed additional evidence of clinical efficacy. While we believe these responses may be related to treatment with G100, the results from our Phase 1 clinical trial are not yet final, and we cannot be certain that this is the case or that these or any future responses observed will be durable. We intend to follow these patients to determine the safety of G100 and the durability of these responses. We began enrolling patients in January 2014 and expect this trial to be completed in the second quarter of 2015. We are also studying G100 in combination with radiation therapy in sarcoma patients in an investigator-sponsored study at the FHCRC. The FHCRC began enrolling patients in November 2014, and we expect the trial to be completed by the end of 2015. In the second quarter of 2015, we intend to initiate a Phase 1 trial of G100 with local radiation for the treatment of patients with a type of non-Hodgkin lymphoma.

We were incorporated under the laws of the State of Delaware in February 2008. Since inception, we have focused our efforts on the research and development of in vivo immunotherapy treatments. Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents as of December 31, 2014 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. Our future capital requirements will depend on many factors including those discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors—Risks Related to Our Financial Position and Capital Needs—We will require additional capital to finance our operations, which may not be available to us on acceptable terms, if at all. As a result, we may not complete the development and commercialization of our product candidates or develop new product candidates.”

Our Strategy

Develop product candidates to treat a broad patient population. We believe our product candidates should benefit a wide range of patients because they are designed to create tumor-killing CTLs, could potentially kill any tumor, and have utility as both individual and multiple combination therapies.

Rapidly advance first-in-class immuno-oncology product candidates through clinical development. We intend to continue to execute a focused clinical development plan that takes selected in vivo product candidates through approval. We are initially focused on indications with a significant unmet need in targeted patient populations. We intend to focus our development efforts on CMB305 and G100, while preserving the ability to separately develop LV305.

Leverage our platforms' ability to address multiple tumor types to build a robust product pipeline. Our ZVex and GLAAS platforms allow us to select different tumor antigens and create separate therapies for potentially any tumor type. We believe this ability, and the capacity of our vectors to simultaneously express antigens and immuno-regulatory molecules, will be a driver of our future growth beyond the current product candidates.

Table of Contents

Selectively monetize non-oncology indications, while retaining optionality for internal development. Both ZVex and GLAAS also have potential application in infectious disease, allergy and autoimmune disease. We have licensed the right to use GLAAS in specific infectious disease and allergy indications to large pharmaceutical companies. These collaborations provide us with both near- and long-term potential revenue and external validation of our technology.

Establish infrastructure and capabilities to support the future commercialization of our products. Our management team has extensive experience commercializing pharmaceutical products and as our product candidates advance, we intend to add the appropriate additional regulatory and commercial expertise to maximize the potential for successful product launches and franchise management. In certain instances, we will seek partners to maximize the commercial potential of our product candidates.

Immunotherapy and the Application of Our Platforms

Brief Overview of Immunotherapy

Immunotherapy is the treatment of disease via use of the immune system, which can be achieved by inducing, enhancing or suppressing an immune response. Immunotherapies currently play an increasingly large role in treating conditions such as cancer, chronic infectious diseases, autoimmune diseases and allergic diseases.

The main function of the immune system is to discriminate between “self” and “non-self.” Under normal conditions, the immune system is geared to eliminate non-self molecules, such as foreign proteins, sugars and lipids. Cancer cells thrive, in part, because they trick the immune system into recognizing them as self, even if they express foreign proteins called antigens. Tumor-associated antigens result from a variety of cancer-related mechanisms such as genetic mutations or changes in protein behavior. When the immune system does not recognize tumor-associated antigens, this failure is called immune tolerance. We believe breaking immune tolerance is an important aspect for most immuno-oncology-based therapeutics because it will enable the immune system to recognize tumor antigens as non-self and lead to tumor destruction by CTLs. Another mechanism the tumors may use to evade the immune system is the up-regulation of molecules that fend off an immune response against the tumor. This tumor-induced mechanism can be overcome by administering products called immune checkpoint inhibitors. Several checkpoint inhibitors are currently in clinical trials, and two have been approved by the FDA.

Chronic infectious diseases, such as hepatitis B and C, are also a result of a dysfunctional immune system because viral antigens can escape immune recognition. Immunotherapy also has significant therapeutic potential in the context of allergic diseases because allergies are the result of an immune system shift towards recognizing environmental or food antigens as non-self. Our technologies also have potential therapeutic utility in infectious disease, allergy and autoimmune disease.

Mechanisms and Limitations of Immuno-Oncology Modalities

There are multiple in vivo and ex vivo approaches designed to “create and expand” the anti-tumor immune response and “remove the brakes” placed on the immune response by the tumor’s defenses.

Removing the Brakes: Checkpoint Inhibitors

Checkpoint inhibitors are designed to attack the defenses a tumor has against the immune system. We believe the efficacy of this approach depends on the existence of a CTL response against the tumor once those defenses are removed. However, some patients’ immune systems do not recognize the tumor and therefore do not generate CTLs necessary to kill the tumor. If cancer immunotherapy is to become a therapy of choice to eradicate tumors, each patient will need a strong engine to generate tumor-specific CTLs and the ability to neutralize or overcome any suppressive mechanism that a specific tumor is creating to fend off the CTLs.

Creating and Expanding an Immune Response: Ex Vivo Modalities

Engineered CD8 T Cells - In these approaches, naïve resting CD8 T lymphocytes are isolated from the blood of cancer patients, manipulated in the laboratory and infused back into the patient. These approaches have produced potent anti-tumor responses, but are hampered by the risk of severe toxicity, limited scope of antigen recognition and cumbersome ex vivo procedures.

Dendritic Cell Vaccines - This ex vivo group of approaches involves isolating DCs from the blood of cancer patients, activating them in the laboratory and administering them to the patient with the hope that the DCs will trigger an immune response against tumor cells. Although this approach has resulted in one FDA approved product, its manufacturing and handling are cumbersome.

5

Table of Contents

Creating and Expanding an Immune Response: In Vivo Modalities

Protein Vaccines - Many historical protein vaccine approaches rely on injecting either full-length or fragments of a tumor antigen protein into a cancer patient. These methods have often elicited an insufficient immune response. Full-length proteins are preferable to fragments, but full-length proteins may also require a second agent, called an immune adjuvant, to elicit a sufficient immune response. Adjuvants are designed to generate a better immune response but are historically non-specific and only marginally immunogenic. Importantly, this approach triggers an immune response characterized by antigen-specific antibodies and CD4 T cells, but not CTLs that are essential for killing cancer cells.

Oncolytic Viruses - Oncolytic viruses are rapidly and aggressively replicating viruses that, when injected intra-tumorally in accessible tumors such as melanoma skin lesions, preferentially lyse tumor cells instead of normal host cells. This lysis releases endogenous tumor antigens from the dying tumor cells, which may activate surrounding DCs that absorb the released antigens and trigger a broad immune response against a large number of tumor antigens. This approach holds promise but based on clinical trials conducted by third parties, may require combination with another modality to reach appropriate efficacy.

Delivery of Genomic Tumor Antigens - We believe delivering tumor antigens in their genomic form via viral vectors is the best way to generate CTLs if the DC can capture the vector and process the genomic information efficiently. However, vectors used to date have had significant limitations:

- some of these vectors are replicative, meaning that they act like a live virus that infects a large variety of non-DC cells, causing disease;
- patients with previous exposure to the virus from which the vector was derived may have neutralizing antibodies; and
- none of these vectors were designed to selectively target and work effectively inside of DCs.

ZVex is designed to overcome these limitations of other viral vectors, while taking advantage of the superior CTL-generating property of this approach.

The Immune Design Difference

We believe there has been a shift in the immuno-oncology paradigm due to a better understanding of why previous immunotherapy approaches have failed to trigger an effective anti-tumor immune response. We have focused on designing and developing cutting-edge discovery platforms and product strategies for effective cancer immunotherapies that take into consideration the limitations of other approaches.

Our novel in vivo cancer immunotherapies are designed for superior generation and expansion of CTLs to kill tumors. We believe a robust set of CTLs may, by itself or in combination with other therapies, lead to a meaningful clinical benefit for cancer patients. In the development of our discovery platforms and product candidates, we have considered not only historical weaknesses in different modalities, but also areas for improvement in light of more recent therapeutic approaches.

The Difference in Discovery

ZVex is a vector system partially derived from a lentivirus that is used to transfer the genetic information of foreign antigens to DCs in vivo in order to induce a tumor antigen-specific CTL response. ZVex has a variety of features to increase its safety and efficacy. We believe ZVex is superior to other lentiviral approaches and previous efforts attempting to deliver foreign genetic information to generate an immune response for the following reasons:

- Selectivity for dendritic cells, by design. DCs are the best immune cells to generate the maximum CTL response when loaded with a foreign antigen. Lentiviruses, the backbone of ZVex, are known to be highly functional in DCs. We have engineered selectivity into our vector by coating the lentiviral particle with an envelope of another virus called Sindbis. Sindbis is naturally selective for a receptor only found on DCs, called DC-SIGN. As a result, our vectors will only bind to DCs, significantly reducing the risk of interacting with non-DCs. We believe that vectors being used by others in clinical trials lack this selectivity.

Table of Contents

Capacity for substantial genetic payload. Our ZVex vector contains sufficient space for two or more antigens. This allows for the concomitant expression of two or more tumor antigens, or of a tumor antigen and an immune stimulatory molecule such as a single-chain checkpoint inhibitor antibody. Consequently, we believe ZVex may be used not only for antigen expression and positive immune response, such as in oncology indications, but also to dampen an immune response such as in autoimmune indications.

No prior immunity to ZVex. Because of the rarity of the Sindbis virus, humans in developed countries have a low prevalence of immunity against it. This lack of pre-existing immunity allows for multiple administrations of ZVex products, increasing the likelihood of a greater therapeutic benefit. This addresses one of the problems observed with other vectors, where a high level of antibodies against such vectors exist broadly in the population.

Integration deficiency. Lentiviruses are known for their natural capability to integrate within the genome of their host cell, notably DCs. However, we have engineered the vector to make it integration-deficient and thereby safer for patients. By making changes in the molecular sequence of the lentiviral vector, including the deletion of more HIV-specific sequences from its genome than comparable lentiviral vectors, and making functional changes in the enzyme that carries out the integration, the capacity of the vector to integrate its genetic material into that of the host cell is reduced approximately 1,000-fold from that of lentiviruses that are currently being used in the clinic. To our knowledge, the ZVex platform is the only integration-deficient lentiviral vector platform being developed for oncology indications.

Platform to generate product candidates for multiple indications. Each ZVex vector combined with the genetic payload of choice results in a distinct product candidate that can target different diseases. Although we are leveraging NY-ESO-1 as our initial tumor antigen, subsequent product candidates may contain the RNA for one or more antigens as well as checkpoint inhibitors. We believe these future product candidates would target a completely different set of tumors.

Potential for multiple vector platforms. ZVex is designed to deliver its payload to a specific type of DC. However, we can alter the cells targeted by our vectors to enable interaction with cells other than just DCs by using alternative envelopes, creating the potential for platforms beyond ZVex.

We have generated a significant amount of in vitro and in vivo preclinical data to support ZVex, including (1) generation of up to 15% of all CD8s specific to the desired antigen, which is up to several-fold higher than observed with many other vector systems, (2) establishment of a strong dose-CTL-response correlation in tumor models as evidence of our mechanism of action, (3) the ability to dose repeatedly, resulting in boosting of CD8 T cells and increased efficacy, and (4) the ability to break immune tolerance, an important component of immuno-oncology.

GLAAS is based on a fully synthetic molecule similar to lipid A, called GLA, which is short for glucopyranosyl lipid A. Lipid A is a natural substance that occurs in the cell wall of certain bacteria and has strong immune-stimulating properties because of its interaction with toll-like receptor 4, or TLR4. DCs are the most potent antigen-presenting cells and have TLR4 receptors on their surface, the activation of which has several important aspects:

- a strong immune response whereby DCs are activated and can express antigens, as well as secrete a number of inflammatory cytokines that lead to the activation of immune cells, in particular naive CD4 and CD8 T cells;
- overcoming the immunosuppressive tumor microenvironment by activating DCs, T cells and NK cells;
- when accompanied by an antigen in protein form, generation of a strong, antigen-specific adaptive immune response characterized by Th 1-type CD4 T cells; and
- reversal of an allergic immune response to a state of attenuated immune reactivity towards the allergen.

We own or control rights to multiple formulations of GLA, two of which have been administered by us and others to over 1,000 subjects. The combination of a selected antigen with a formulation of choice makes GLAAS a potentially broad platform for a wide range of therapeutic applications.

Table of Contents

The Difference of Our Immuno-Oncology Product Candidates

We have designed our product candidates to be different from current and traditional immuno-oncology products in the following ways:

Focus on CTLs - Earlier therapeutic efforts to generate an immune response against a tumor antigen either did not directly focus on CTL generation or used sub-optimal mechanisms. We are focused on directly generating a robust initial CTL population as well as memory CTLs, which are important for long-term immune surveillance. If CTL generation and expansion can be complemented by other mechanisms, such as the induction of CD4 T cells as part of the same immune response against the tumor, we expect the specific CTL response to be more robust.

Select and Administer Tumor Antigens Effectively - An increasing number of tumor antigens have been identified in recent years, and some have been validated as targets for active immunotherapy by balancing their expression in tumor cells versus healthy tissues. If the goal of the therapy is to generate the maximum CTL response, the antigen should be delivered in the form of DNA or RNA exclusively to DCs so the DC can express the full-length protein and present the peptide fragments to CD8 T lymphocytes. However, if CD4 T cell and antibody production is the goal, delivering an already expressed protein should be effective. Moreover, complementing the administered protein antigen with a molecular adjuvant such as the TLR4 agonist in GLAAS should enhance its immunogenicity.

Administer the Therapy In Vivo - We believe a product that can be used safely when delivered in vivo via simple injection will be preferable to the cumbersome processes involved with ex vivo manipulation of immune cells. Moreover, all ex vivo approaches are highly customized to each patient, whereas in vivo approaches can be applicable to a large number of patients.

Implement a Prime-Boost Strategy - While a CTL-generating product can be sufficient alone, combining it with other immune drivers using a heterologous prime-boost can enhance CTL generation and trigger other mechanisms to augment the immune response. Heterologous prime-boost regimens have to date been mainly explored in the field of HIV vaccines, where they were shown to increase and broaden both T cell and antibody responses. We have evidence from several preclinical experiments that the administration of an antigen-specific ZVex vector when followed by, or in some cases preceded by, administration of the same recombinant protein with GLAAS, results in dramatically enhanced CD8 T cell responses.

Leverage Combination Therapies - It is our view that the future of immuno-oncology treatment is combination therapy, and we have designed our approaches to potentially combine with multiple other immuno-oncology mechanisms. Based on clinical trials in limited tumor types conducted to date, we believe that many, if not most, patients are immunologically tolerant to the tumor and lack an immune response. Therefore, these patients will receive little or no clinical benefit from checkpoint inhibitors unless a strong immune response is triggered. We therefore believe the combination of a CTL-generating approach with a checkpoint inhibitor is likely to provide significant therapeutic benefit.

Cause Antigen Spreading - Tumor destruction mediated by a strong CTL response against one tumor antigen can release other antigens present in the tumor cell. DCs then consume these new antigens, leading to additional immune responses. We believe a GLAAS product candidate will boost this second wave of CTLs generated against multiple distinct tumor antigens not present in the initial therapy, thereby enhancing the breadth of the immune response. This process is termed “antigen spreading” and is associated with increased efficacy of the immunotherapy. We anticipate potential antigen spreading to occur in both our heterologous prime-boost and Endogenous Antigen approaches in patients.

Our Approaches to Treating Cancer

Our immuno-oncology product candidates are being developed in two separate approaches: Specific Antigen and Endogenous Antigen.

Specific Antigen

The Specific Antigen approach uses selected antigens that are also present in the patient’s tumor so the immune system will be educated to recognize the tumor antigen and kill tumor cells expressing it. ZVex products carry RNA of a chosen antigen, whereas GLAAS products are accompanied by a full-length protein of the same antigen. We have generated a significant amount of preclinical data illustrating the desirable qualities of this approach. The following graph illustrates the ability of ZVex to generate an immune response against a self protein in an in vivo rodent tumor

model, demonstrating the ability of ZVex to overcome immune tolerance.

Table of Contents

For our first product candidates, we have chosen a tumor-associated antigen named NY-ESO-1 that is expressed in a large number of solid and liquid tumors in varying degrees. Our first two clinical programs under this approach from ZVex and GLAAS are LV305 and G305, respectively. LV305 delivers the RNA for NY-ESO-1, while G305 consists of a specific formulation of GLA and the full-length NY-ESO-1 protein. We are administering LV305 and G305 in sequence to become CMB305, a heterologous prime-boost therapy. Although G305 may be an effective therapy with patients who have insufficient immune responses prior to treatment, we do not intend to develop it as a stand-alone product. We believe it is more effective dosed sequentially with LV305 as a prime-boost therapy. Because we believe CMB305 will be more effective than either technology alone, we intend to focus our development efforts on CMB305 and G100, while preserving the ability to separately develop LV305.

For our future product candidates, we plan to investigate, among other things, potential antigen targets from virally-caused tumors with known tumor antigens. Approximately 12% of human cancers may be caused by viruses, including human papillomavirus or hepatitis B virus. In the event the viral proteins interacting with the cell and inducing its malignant transformation are known and are immunogenic, they may qualify as future targets for our Specific Antigen approach.

Endogenous Antigen/Intra-tumoral Immune Activation

Unlike the Specific Antigen approach, the Endogenous Antigen - or intra-tumoral immune activation - approach does not require a selected tumor antigen present in the cancer. It instead relies on endogenous tumor antigens released during tumor lysis by treatments such as chemotherapy or local radiation. Neighboring GLAAS-activated DCs then capture the diverse set of released antigens and generate a broad and varied immune response. Because local radiation is an effective way to cause tumor cell lysis in accessible tumors, we plan initially to evaluate tumors that are accessible to both local radiation and intra-tumoral administration of GLAAS.

G100 is our first Endogenous Antigen product candidate being evaluated in two Phase 1 clinical trials in patients with Merkel cell carcinoma, or MCC, and sarcoma, both accessible tumors. We previously disclosed that one of our initial patients treated in the MCC trial has a complete response in the first loco-regional tumor treated with G100. Since then, we have observed additional evidence of clinical efficacy. While we believe these responses may be related to treatment with G100, the results from our Phase 1 clinical trial are not yet final, and we cannot be certain that this is the case or that these or any future responses observed will be durable. We intend to follow these patients to determine the safety of G100 and the durability of these responses.

A Broad Footprint in Immuno-Oncology

We believe that cancer patients soon will be stratified pre-immune therapy into those with low or no CTL responses against their tumor versus those with good CTL responses. It is anticipated that many patients will fall into the first category, especially those with genetically stable, and hence less immunogenic, tumors. Because we believe our technologies should be broadly applicable across tumor types, patients in the larger group needing a CTL response would be candidates for immunotherapy with either ZVex, ZVex/GLAAS or intra-tumoral GLAAS (G100).

The larger group of patients without a strong, pre-existing CTL response is also not expected to benefit from checkpoint inhibitors alone. We believe our technologies have the potential to convert this group into a robust CTL response-type group and enable them to respond to checkpoint inhibitors.

In addition, there may also be an opportunity to combine our approaches with other immuno-oncology mechanisms, such as engineered T cells, to extend the duration of the T cell response or "pull" T cells to the tumor.

Table of Contents

Therapeutic Applications Outside Oncology

Beyond oncology, our technologies also offer several promising applications in the fields of infectious diseases, allergy and autoimmune disease.

Infectious Diseases

For certain infectious diseases, no effective preventive vaccines are available, and existing vaccines against common pathogens often show suboptimal efficacy, particularly in the elderly. In addition, most vaccines against highly variable pathogens offer only narrow protection against certain variants, which is a serious problem in certain indications such as pandemic influenza. Also, chronic infectious diseases exist where the immune system is tolerized to foreign infectious disease antigens and cannot eliminate an established infection. Chronic infectious diseases constitute important medical needs worldwide, with HIV and hepatitis B as examples.

Historically, antigens have been used with sub-optimal immune adjuvants and have mainly focused on generating antibodies, which have been limited by low affinity and a narrow spectrum of activity. We believe using a novel molecular adjuvant like GLA combined with infectious diseases antigens will boost pre-existing T cells and trigger a broad antibody response, allowing for diverse antigen recognition. To date, GLA has been studied in human clinical trials involving over 1,000 subjects. The results of these trials we have reviewed to date support the finding of increased magnitude and breadth of the antibody response. With respect to chronic infectious diseases, we believe that either a ZVex product alone, or the sequential dosing of ZVex and GLAAS in a heterologous prime-boost setting, may help the immune system to overcome the tolerizing effects of these infections and eradicate them.

We have a preclinical vaccine program called G103 to treat herpes simplex virus type 2, or HSV2. G103 consists of several recombinantly expressed proteins adjuvanted with a specific formulation of GLA. In October 2014, we announced a collaboration with Sanofi Pasteur, the vaccines division of Sanofi, to develop G103 along with additional assets contributed by us and Sanofi Pasteur. In addition to the G103 program, we have granted several licenses under the GLAAS platform to partners developing a range of infectious disease vaccines.

Allergy

We believe allergy represents an exciting area for the application of GLAAS. Allergies to pollen or food often occur because of aberrant immune reactions, which are characterized by helper T cells producing signals that induce other immune cells to cause the allergy symptoms. We have a large set of preclinical data demonstrating that certain formulations of GLAAS, when given prophylactically or therapeutically with or without the allergen, can shift the responses in a way that results in significant protection from allergy symptoms. In essence, the immune system can be taught to redirect the T cells to respond in better ways. In August 2014, we announced a licensing agreement with Sanofi pursuant to which we granted Sanofi the right to use the GLAAS platform to develop therapeutics to treat a selected food allergy.

Autoimmune Disease

In autoimmune diseases, the immune system has lost its tolerance for certain self-antigens and attacks normal cells and tissues in the body. We believe this process may be reversed by instructing DCs to tolerize antigen-specific T cells, using ZVex.

Table of Contents

Our Clinical Programs

Our oncology clinical-stage product candidates are depicted in the following diagram:

Although LV305 and G305 could have potential therapeutic benefit as single therapies, we plan to evaluate LV305 administered sequentially with G305 as CMB305. In addition, although we believe CMB305 should be more effective than LV305 alone, we are preserving the ability to separately develop LV305.

- LV305 - Conducted pursuant to an Investigational New Drug, or IND, application, which was filed by us in December 2013.
- G305 - Conducted pursuant to an IND application, which was filed by us in July 2013.
- CMB305 - Conducted pursuant to an IND application, which was filed by us in October 2014
- G100 Merkel Cell Carcinoma - Conducted pursuant to an IND application, which was filed by us in August 2013.
- G100 + XRT Sarcoma IST - IND filed by FHCRC
- G100 + XRT NHL - To be conducted under our IND application for G100.

Cancer is characterized by abnormal cells that grow and proliferate, forming masses called tumors. Under certain circumstances, these proliferating cells can metastasize throughout the body and produce deposits of tumor cells in distant sites. To be effective, cancer therapies must eliminate or control the growth of the cancer. Generally, foreign antigens trigger an immune response that results in the removal of disease-causing agents from the body. Cancer cells frequently display antigens that are unique to the tumor. However, the immune system may not have learned to distinguish between tumor cells and normal cells and, thus, may be unable to mount a strong anti-cancer response. Tumors also have various defense mechanisms that can prevent the immune system from recognizing their antigens and mounting an effective immune response.

The following table sets forth the 2014 incidence rate of the tumor types we are exploring in our current Phase 1 clinical trials using the Specific Antigen approach, all of which tumors express NY-ESO-1, in varying degrees:

TUMOR TYPE	Projected New Cases in 2014 (US)
Lung & Bronchus	224,210
Ovarian	21,980
Melanoma	76,100
Soft Tissue Sarcoma	12,020

We plan to test our therapies in two types of sarcoma, called synovial sarcoma and myxoid round cell liposarcoma. Synovial sarcoma is a rare form of cancer in the joints with a five-year and ten-year survival for people with large tumors or metastatic disease of less than 25% and 15%, respectively. Myxoid round cell liposarcoma is a rare malignant tumor that most often occurs in the deep-seated soft tissues of the extremities. At least 80% of patients with synovial sarcoma or myxoid round cell liposarcoma express the NY-ESO-1 protein.

Merkel cell carcinoma and follicular non-Hodgkin lymphoma, or NHL, are the initial tumor targets in our trials using the Endogenous Antigen approach, which uses G100 injected directly into the tumor to stimulate a local and systemic response. We are also studying G100 in combination with radiation in patients with sarcoma via an investigator-sponsored trial at the FHCRC. The low incidence rates of NHL and MCC qualifies each as an orphan disease, and if we are able to obtain orphan drug designation from the FDA for G100 for NHL or MCC, we may be

Table of Contents

able to obtain certain benefits such as research tax credits and grant funding. Either disease could be an ideal setting to show that G100 can provide clinical benefit and may provide separate registration paths.

Oncology Product Candidates and Development Strategy

Specific Antigen Approach

Our Specific Antigen approach is based on the observation that human tumor cells make a variety of antigens that are not found in normal tissues. We conducted an extensive search to choose NY-ESO-1. This protein is found in many types of cancer, and we believe it is an attractive target for cancer immunotherapy due to its frequent expression in tumors and its immunogenic potential. Among the antigens selected by the National Cancer Institute as the best targets for immunotherapy, only NY-ESO-1 and one other antigen have been shown to be tumor-specific.

LV305 (the Prime in CMB305's "Prime Boost")

LV305 utilizes the Specific Antigen approach to activate the immune system against a tumor by generating CTLs against the specific tumor-associated antigen. As a ZVex-based product, LV305 is highly specific for DCs, unable to replicate and impaired in its integration capacity. LV305 is engineered to selectively activate CTLs without inducing CTL exhaustion, and with an improved safety profile. In the preclinical efficacy model below, LV305 reduced tumor burden of an NY-ESO-1 expressing tumor, and produced a material increase in antigen-specific CD8s, both in a dose-dependent manner.

The upper left figure illustrates the results of mice being injected intravenously with rodent tumor cells expressing NY-ESO-1. This resulted in the formation of 100-150 lung metastases per animal (black dots). Three days after the injection of the tumor cells, the mice were injected with (i) a sterile buffer solution, (ii) a single dose of ZVex expressing a non-tumor antigen or (ii) a single dose of LV305, in either a low, medium or high dose. The injections had a strong therapeutic effect and reduced the number of lung nodules in a statistically significant manner at each of three different dose levels tested. The p-values in the figure express the statistical significance level of the difference of lung nodules in treated mice versus mice receiving the control. A p-value <0.05 is considered statistically significant, so all three p-values obtained are highly significant. The upper right figure shows the CD8 T-cell responses in normal mice immunized with (i) a sterile buffer solution, (ii) a single dose of ZVex expressing a non-tumor antigen or (iii) a single dose of LV305, in either a low, medium or high dose. The bars show the NY-ESO-1 specific CD8 T-cell responses measured in the rodent spleens and expressed as percentage of all CD8 T-cells in the spleen. As depicted above, there was a linear dose-response of CD8 T-cells in relation to the level of LV305 doses administered. The T-cells were further analyzed for expression of three different cytokines, IL-2, IFNg, TNFa and combinations thereof, as represented by the shaded boxes in the image on the right. T-cells expressing two or more cytokines are called polyfunctional, which is indicative of a more robust and effective T-cell response. As can be seen, the T-cells induced by LV305 are polyfunctional. The lower left figure shows the result of the experiment performed as above, but with the modification that in two groups of mice either CD8 T cells or CD4 T cells were depleted in vivo prior to immunization (denoted as anti-CD8 or anti-CD4 on the x-axis). In non-depleted mice, a high dose of LV305 conferred nearly complete protection, whereas the same dose resulted in significantly reduced protection in the CD8 depleted mice. This demonstrates clearly that CD8 T cells induced by LV305 mediate protection in this tumor model. As can be seen, depletion of CD4 T cells also reduced protection, albeit to a lesser extent, confirming our view of the important contribution of CD4 T cells to CD8 T cell mediated tumor control. The lower right figure depicts a control experiment showing that CD8 and CD4 T cell depletion in normal mice prior to immunization with LV305 resulted in the absence or reduction of CD8 T cell responses, respectively.

Table of Contents

We have completed dosing in a Phase 1 clinical study to evaluate the safety of escalating doses of LV305 in vivo in a defined patient population with solid tumors expressing the NY-ESO-1 tumor antigen. The patients must have had locally advanced, recurrent, or metastatic cancer in any of five tumor types: breast cancer, melanoma, non-small cell lung cancer, or NSCLC, ovarian cancer or sarcoma. When available we take post-treatment tumor biopsies to assist in clarifying the mechanisms that may be mediating a treatment effect, such as the generation of NY-ESO-1 specific CTLs. Clinical benefit will be evaluated by analyzing tumor responses and progression through short and long-term follow-up via clinical and radiological assessments. A preliminary assessment of effectiveness will be done by expanding cohorts of patients with specific tumor types at the highest dose of LV305. We believe that initial data from this study have demonstrated an acceptable safety profile and sufficient immunogenicity to warrant, in combination with G305, development of CMB305. Because we believe the prime-boost approach of CMB305 should be more effective than either LV305 or G305 alone, we intend to focus development efforts on CMB305 as the primary Specific Antigen product candidate. However, in December 2014, we dosed the first patient in an expansion trial of LV305 at the highest dose studied in the Phase 1 dose escalation. The expansion trial is designed to study the same four tumor types studied in the CMB305 Phase 1 trial, and will explore the use of LV305 with a checkpoint inhibitor in melanoma patients who have an inadequate response to anti-PD1 therapy. We expect data from the expansion trial to be available by the end of 2015. After reviewing the data from those trials, we may elect to separately develop LV305. Although we expect safety and immunogenicity data from the dose-escalation portion of the LV305 Phase 1 clinical trial to be available in the first quarter of 2015, we do not anticipate releasing any preliminary data prior to the completion of the trial, and although the data may be available as of a given date, we may elect to announce the results at an appropriate medical meeting.

G305 (the Boost in CMB305's "Prime Boost")

G305 is an agent from the GLAAS platform that is designed to enhance our Specific Antigen approach as part of CMB305. A Phase-1 study evaluated increasing doses of a specific formulation of GLA combined with recombinant, full length NY-ESO-1 protein. A full-length tumor antigen contains all of the possible antigenic components that can be recognized by the immune system to trigger a broad immune response. The G305 clinical trial evaluated safety, immunogenicity, and the preliminary indications of efficacy in small groups of NY-ESO-1-positive patients who had the same types of cancers as in the LV305 study. Different formulations of GLA have been tested with or without antigens by us and others in over 1,000 human subjects. These agents have demonstrated an ability to trigger a strong immune response against the antigen formulated with the GLA molecule. In addition, the NY-ESO-1 protein has been administered to over 2,800 subjects in clinical trials conducted by others and was generally well-tolerated, with no identified material safety signals.

While G305 could have potential therapeutic benefit as a monotherapy to a subpopulation of patients who have pre-existing NY-ESO-1-specific CTLs, our current plan is to evaluate G305 with LV305 in a heterologous prime-boost as CMB305. We commenced the Phase 1 clinical trial of G305 in November 2013 and completed dosing in October 2014. We do not anticipate releasing any preliminary data prior to the completion of the trial, and although the data may be available as of a given date, we may elect to announce the results at an appropriate medical meeting

CMB305

We believe that prime-boost therapies are an optimal way to trigger a robust immune response. This is particularly true when distinct, but complementary, parts of the immune response are stimulated. Based on our preclinical studies and their predicted mechanisms of action when given as a prime-boost, we expect the sequential dosing of LV305 and G305 - called CMB305 - to have synergistic effects and induce a stronger anti-tumor CTL response. In addition to increasing the magnitude of the CTL response, we expect this approach to generate memory CTLs and therefore long-term immune surveillance, as well as enhance other immune anti-tumor mechanisms.

Because each of LV305 and G305 have demonstrated an acceptable safety profile and, we believe, sufficient immunogenicity as individual agents, we plan to evaluate CMB305 at the maximum tolerated dose of LV305 given as a prime-boost with G305. Our Phase 1 clinical trial will evaluate safety, immunogenicity and preliminary indications of efficacy in patients with four tumor types, with safety and immunogenicity data expected to be available in the second half of 2015. The FDA has cleared the IND, and we began dosing in the first quarter of 2015 patients who

have had an inadequate response or unacceptable toxicity with one or more previous cancer therapies. We also intend to commence Phase 1 expansion studies studying additional patients in each of the four tumor types, all of which should inform a Phase 2 clinical trial intended to open during the second half of 2015 in a lower incidence tumor with significant unmet need that we believe may qualify for orphan designation.

Table of Contents

In all of these Specific Antigen trials, we will be collecting blood and tumor samples to measure CTL generation against NY-ESO-1 and to determine epitope mapping, antigen spreading and T cell receptor repertoire.

Endogenous Antigen Approach (Intra-tumoral Immune Activation)

G100

We are evaluating our first product candidate from our Endogenous Antigen approach, G100, in a Phase 1 clinical trial in patients with MCC. MCC is a rare and aggressive type of skin cancer associated with a polyomavirus infection and UV exposure. The majority of patients present with localized disease in the skin, although the disease can readily spread to regional and distant sites. The accessibility of most MCC tumors makes them ideal for intra-tumoral dosing and obtaining skin lesion biopsies to determine changes in the tumor microenvironment following G100 treatment. This Phase 1 trial commenced in January 2014 and is designed to evaluate the safety, immunogenicity and preliminary indications of efficacy of administered intra-tumorally in MCC patients with either loco-regional or metastatic disease. We previously disclosed that one of our initial patients had a complete response in the first loco-regional tumor treated with G100. Since then, we have observed additional evidence of clinical efficacy. While we believe the responses we observed may be related to treatment with G100, we cannot be certain that this is the case, that we will observe any additional complete or partial responses, or that these or any future responses observed will be durable. We intend to follow these patients to determine the safety of G100 and durability of these responses.

We are also developing G100 for the treatment of other types of tumors where preclinical data suggests there may be ideal opportunities for the Endogenous Antigen approach. A sarcoma clinical study commenced in November 2014 via an investigator-sponsored study at the Fred Hutchinson Cancer Research Center, or FHCRC, which we expect to complete by year-end 2015. We also plan to initiate a study in the second quarter of 2015 that will combine G100 and radiation in non-Hodgkin lymphoma. Both are being conducted to evaluate the local immune environment, as well as the effect on distant tumors. We do not anticipate releasing any preliminary data prior to the completion of these trials, and although the data may be available as of a given date, we may elect to announce the results at an appropriate medical meeting.

Infectious Diseases and Allergy Immunotherapy Programs

Although our primary focus is on the development of cancer immunotherapies, we are also establishing partnerships with third parties to develop potential therapies for non-oncology diseases. The following chart details our existing infectious disease programs and collaborations:

Manufacturing

Overview

We are establishing manufacturing processes and supply agreements for all of the components used in our product candidates to support ongoing and planned clinical trials. These include the components for LV305 and bulk and formulated GLA for CMB305 and G100. We rely on third-party contract manufacturing organizations, or CMOs, to produce our product candidates for clinical use and currently do not own or operate manufacturing facilities. We require that our CMOs produce bulk drug substances and finished drug products in accordance with current Good Manufacturing Practices, or cGMPs, and all other applicable laws and regulations. We may continue to rely on CMOs to develop and manufacture our products for commercial sale. We maintain agreements with potential and existing manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

Table of Contents

LV305

We have contracts with third-party manufacturers to produce the vector, final drug product and fill-finish. Release and stability testing is done through a combination of in-house testing and contractual agreements with our CMOs. Our new contract manufacturer, to which we recently transitioned all of the manufacturing of our lentiviral vectors, has only recently begun to manufacture LV305.

GLA

Manufacturing for the GLAAS platform generally encompasses both the synthesis of bulk GLA, its formulations and the fill-finish of formulated GLA. We have established a supply chain for bulk GLA and two types of formulated GLA: GLA stable emulsion, also called GLA-SE, and GLA aqueous formulation, also called GLA-AF.

The synthetic process for the manufacture of bulk GLA is a trade secret and we retain control and ownership of the process. Our CMOs also perform release and stability testing on the bulk GLA. The scale of the GLA synthetic manufacturing process is adequate to support commercial production for our product candidates.

We have also contracted with a CMO to formulate and fill-finish our GLA-SE drug product. We have manufactured multiple lots in support of Phase 1 and 2 clinical trials. The formulation process utilizes technology that is readily scalable to support commercial manufacturing of our product candidates. Release and stability testing on the GLA-SE drug product is contracted to several CMOs.

Intellectual Property

Overview

Our intellectual property strategy is to protect our technologies by filing multiple patent applications and obtaining patent rights both in the United States and in foreign countries that we consider important to our current and future business. In addition, we have acquired and will seek to acquire, as needed or desired, intellectual property rights of others through assignment or license to complement and enhance our portfolio of patent rights. We also rely upon trade secrets, know-how and continuing technological innovations to develop and maintain our competitive position.

Patents

ZVex

We are the owner or exclusive licensee to proprietary patent positions related to our ZVex platform. Our patent portfolio includes a patent family licensed from the California Institute of Technology, or Caltech, and is directed to our dendritic cell targeting lentiviral vector platform technology. This patent family includes patents granted domestically and in Europe, Australia, Japan and South Africa and has granted claims that include composition of matter claims to our lentiviral vector and packaging cells as well as methods of using our lentiviral vector to elicit an immune response against a target antigen of interest and methods of preparing our lentiviral vector.

Our patent portfolio also includes two patent families solely owned by us, directed to improvements to the lentiviral vector and methods of making the lentiviral vector, with patents granted domestically and in various countries including in Europe, Australia and New Zealand. The granted patents include composition of matter claims to our lentiviral vector, a lentiviral vector packaging system, methods of using our lentiviral vectors to induce an immune response to an antigen and methods of making lentiviral vector particles.

We also license one patent family from the University of North Carolina at Chapel Hill, or UNC Chapel Hill, directed to a specific component of our lentiviral vectors, with patent applications pending in the United States, Europe and Japan.

Together, we own or license seven issued U.S. patents, nine granted foreign patents and numerous pending U.S. and foreign patent applications. We also own pending U.S. and foreign patent applications directed to methods using our lentiviral vectors in combination with our GLAAS platform.

Granted patents directed to our lentiviral vectors have expiration dates ranging from 2027 to 2032, not giving effect to any potential extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The 20-year projected expiration dates for our pending patent applications range from 2027 to 2034, not giving effect to any potential extensions and assuming payment of all associated fees.

Table of Contents

GLAAS

We license rights to four granted U.S. patents and several granted foreign patents from the Infectious Disease Research Institute, or IDRI. We own two granted U.S. patents and own or license numerous patent applications in the United States and abroad directed to our GLAAS platform. The patents licensed from IDRI include patents in the United States, Europe, Australia, China, Japan and Hong Kong. Key patents and pending applications in our portfolio are directed to vaccine compositions and uses of compositions containing GLA in a variety of disease indications including cancer, infectious diseases and allergy. The issued IDRI patents in the United States and granted IDRI foreign patents are directed to any antigen-containing vaccine formulations containing GLA, medical uses of the formulations to generate antigen-specific immune response for cancer, infectious disease and autoimmune disease antigens and medical uses for generating an immune response by administering pharmaceutical compositions containing GLA. We also own or license pending U.S. and foreign patent applications directed to G103.

Our granted patents directed to GLA will expire in 2027, with one U.S. patent that will expire in early 2028 due to expected patent term adjustment, not giving effect to any potential extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The 20-year projected expiration dates for our pending patent applications range from 2027 to 2035, not giving effect to any potential extensions and assuming payment of all associated fees.

We require employees, consultants, advisors and collaborators to enter into agreements with appropriate confidentiality and intellectual property provisions standard for the industry.

Licensing Agreements

We have in-licensed intellectual property related to our discovery platform technologies, including the following:

Exclusive License Agreement with Caltech

In January 2009, we entered into an exclusive license agreement with Caltech, pursuant to which we obtained a worldwide, exclusive license under certain patent rights directed to the production of DC-targeted therapeutic and prophylactic immunization strategies, with the right to sublicense. We also received a time-limited option to expand the field of use to include human cancer applications, which we exercised in September 2009. Additionally, we have a non-exclusive, sub-licensable worldwide license to unpatented know-how related to the licensed patents. Under the license agreement, we are obligated to use diligent commercial efforts to develop and commercialize licensed products and to make them available to the developing world.

In partial consideration for the patent rights licensed to us under the license agreement, we issued shares of our common stock to Caltech. We are obligated to pay Caltech a low single-digit percentage royalty on net sales of licensed products, subject to a non-material annual minimum, as well as a mid single-digit to low double-digit percentage share of any payments that we receive from sub-licensees, which percentage depends on the stage of development when the sublicense was granted. We are also obligated to pay Caltech up to an aggregate of $1.6 million in additional payments based on the achievement of certain development and regulatory milestones. Our royalty obligations continue for the life of the relevant licensed patent rights. Currently, we expect that the last-to-expire licensed patent in the United States will expire in 2027.

Our license agreement with Caltech will remain in effect until the later of the expiration of the last-to-expire licensed patent rights or the end of our payment obligations under the license agreement. Either party may terminate the license agreement in the event of the other party’s uncured material breach or certain insolvency events.

Exclusive License Agreement with UNC Chapel Hill

In January 2013, we entered into a non-exclusive license agreement with UNC Chapel Hill, pursuant to which we obtained a worldwide, sub-licensable, non-exclusive license to certain modified retroviral vectors, including a license under all patent rights owned or controlled by UNC Chapel Hill covering such vectors. In January 2015, we exercised an option to obtain an exclusive license under these patent rights. Under the license agreement, we are obligated to use commercially reasonable efforts to diligently pursue the development and commercialization of licensed products, and we are required to meet certain performance milestones relating to the development of licensed products.

Through December 31, 2014, we have paid to UNC Chapel Hill an aggregate of $0.1 million, consisting of a license-issue fee, an annual renewal fee, a fee for the extension of the option period and reimbursement of patent

16

Table of Contents

expenses relating to the licensed patent rights. We will owe UNC Chapel Hill one or more non-material milestone payments upon the occurrence of certain events relating to the development or regulatory approval of licensed products. We are also obligated to pay UNC Chapel Hill non-material annual renewal fees, a low double-digit percentage share of any payments that we receive from sub-licensees, and a low single-digit royalty on net sales of licensed products by us or our sub-licensees. Our royalty obligations continue for the life of the licensed patent rights, on a product-by-product and country-by-country basis, and in any event will cease upon termination or expiration of the license agreement. Currently, we expect that the last-to-expire licensed patent in the United States will expire in 2028.

Our license agreement with UNC Chapel Hill will expire upon the expiration of the last-to-expire licensed patent rights, or, if no patents issue from the licensed patent rights, in January 2028. We may terminate the license agreement at any time upon advance written notice to UNC Chapel Hill. UNC Chapel Hill may terminate the license agreement in the event of our uncured material breach or if we become insolvent, and either party may terminate the license agreement for uncured fraud, willful misconduct, or illegal conduct of the other party.

Amended and Restated License Agreement with the Infectious Disease Research Institute

In November 2010, we entered into an amended and restated license agreement with IDRI, pursuant to which we obtained licenses under certain patent rights and know-how relating to synthetic TLR4 agonists, including products containing GLA. The patent rights licensed under this agreement are directed to GLA and other synthetic TLR4 agonists, compositions that include these molecules, and methods of using these compositions to elicit or enhance an immune response. The licensed patent rights cover all of our GLAAS platform products. The licenses granted to us under the license agreement are generally exclusive and worldwide and generally extend to the treatment, prevention or diagnosis of any disease or condition. However, IDRI has retained all rights with respect to certain infectious diseases found predominantly in low-income countries and we have no rights to use the licensed technology for these diseases. Also, for certain specific territories, indications, and/or a narrow subset of synthetic TLR4 agonist-containing products, our rights are more limited. For example, we have non-exclusive rights to use GLA for the treatment, prevention, or diagnosis of HIV and streptococcus pneumonia, and in certain low income countries, we have non-exclusive rights with respect to a narrow set of other specific infectious diseases. For two narrow categories of other synthetic TLR4 agonists, our rights are both non-exclusive and limited to cancer and specific infectious diseases, including infectious diseases within our core focus. Under the license agreement, we are obligated to use commercially reasonable efforts to develop and commercialize licensed products to which we have exclusive rights. We and IDRI are not permitted to sell or transfer GLA outside our respective exclusive fields.

Through December 31, 2014, we have paid IDRI an aggregate of $1.9 million in upfront and annual fees, sublicensing fees and financial support of continuing research on GLA to IDRI, and issued shares of our common stock to IDRI. We are obligated to pay IDRI up to $2.4 million in additional payments based on the achievement of certain developmental and regulatory milestones for the first GLA product, and up to $1.3 million in additional payments based on the achievement of certain developmental and regulatory milestones for each subsequent GLA product. Lower milestone payments apply to territories, indications, and/or synthetic TLR4 agonist where our rights are not exclusive. We are obligated to pay IDRI a low single-digit royalty on net sales of licensed products that varies according to the indication, as well as a percentage share of any payments that we receive from sub-licensees, ranging from the low double-digits to the middle single-digits. Our royalty obligations continue for the life of the relevant licensed patents or 12 years after the first commercial sale of a licensed product, whichever is longer. Currently, we expect that the last-to-expire licensed patent in the United States will expire in 2028.

Our license agreement with IDRI will remain in effect until the expiration of our payment obligations under the license agreement. We may terminate the license agreement at any time with advance written notice. IDRI may terminate the license agreement if we challenge any of the licensed patents. Either party may terminate the license agreement for the other party’s uncured material breach or upon certain insolvency events.

Collaboration Agreements

Exclusive License Agreements with MedImmune

In October 2010, we entered into three separate license agreements with MedImmune LLC, or MedImmune, pursuant to which we granted MedImmune a worldwide, sub-licensable, exclusive license use GLA to develop and sell

vaccines in three different infectious disease indications. Two of the three agreements remain in full force and effect, and the rights granted under the third have returned to us. Under the license agreements, MedImmune is obligated to use commercially reasonable efforts to develop and obtain regulatory approval for a licensed product in certain markets, and to market and sell licensed products in any country where it obtains regulatory approval.

Table of Contents

Through December 31, 2014, MedImmune has paid us an aggregate of $5.5 million in upfront payments under the license agreements. Under each license agreement, MedImmune is obligated to make additional aggregate payments of $62.9 million to $75.0 million, depending on the infectious disease indication, based on achievement of certain development, regulatory and commercial milestones for the licensed indication. MedImmune is also obligated to pay us a low double-digit percentage share of non-royalty payments that it receives from sub-licensees and a mid single-digit royalty on net sales of licensed products, which royalty is subject to reduction under certain circumstances. Under our license agreement with IDRI, we are obligated to share with IDRI a percentage of payments received from third-party licensees, including MedImmune. MedImmune's royalty obligations will continue, on a country-by-country basis, for at least 10 years after the first commercial sale of the first licensed product in the applicable country and will continue on a country-by-country and product-by-product basis, for the life of the licensed patents that cover the sale of the applicable product in the applicable country.

Each of our license agreements with MedImmune will remain in effect until the later of October 2060 or the expiration of MedImmune's payment obligations. MedImmune may terminate any of the license agreements at any time with advance written notice. We or MedImmune may terminate any of the license agreements in case of the other party's uncured material breach or upon certain insolvency events.

Exclusive License Agreement with Sanofi

In August 2014, we granted Sanofi an exclusive license to use the GLAAS platform to discover, develop and commercialize products to treat a selected food allergy. We received an undisclosed upfront payment and are eligible to receive development and commercialization milestones totaling US $168.0 million, as well as tiered royalties on sales of approved products.

Collaboration Agreement with Sanofi Pasteur

In October 2014, we entered into a collaboration for the development of a herpes simplex virus, or HSV, immune therapy with Sanofi Pasteur, the vaccines division of Sanofi. We and Sanofi Pasteur each contributed product candidates to the collaboration: Sanofi Pasteur contributed HSV-529, a clinical-stage, replication-defective HSV vaccine product candidate, and we contributed G103, our preclinical trivalent vaccine product candidate. The collaboration will explore the potential of various combinations of agents, including leveraging our GLAAS platform, with the goal to select the best potential immune therapy for patients. We will develop the products jointly through Phase 2 clinical trials, at which point Sanofi Pasteur intends to continue development of the most promising candidate and be responsible for commercialization. Sanofi Pasteur will bear the costs of all preclinical and clinical development, and we will provide a specific formulation of GLA from the GLAAS platform at our cost through Phase 2 studies. We are eligible to receive future milestone and royalty payments on any product developed from the collaboration.

Competition

The biotechnology and pharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our product candidates, technology, knowledge and experience provide us with competitive advantages, we face competition from established and emerging pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our product candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our product candidates. Our competitors may also obtain FDA or other regulatory approval for their product candidates 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.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being

concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining 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.

Table of Contents

Government Regulation and Product Approval

In the United States, the FDA regulates our current product candidates as biological drug products, or biologics, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and related regulations. Biologics are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable United States regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial actions. These actions could include the suspension or termination of clinical trials by the FDA or an Institutional Review Board, or IRB, the FDA's refusal to approve pending applications or supplements, revocation of a biologics license, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, civil penalties or criminal prosecution. Any administrative or judicial action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of biologics. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, purity, potency, labeling, storage, distribution, record keeping and reporting, approval, import and export, advertising and promotion and post-market surveillance of our products.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of any future product candidates or approval of product or manufacturing changes, new disease indications, or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Biologics Marketing Approval

The process required by the FDA before biologics may be marketed in the United States generally involves nonclinical laboratory and animal tests; submission of an IND application, which must become effective before clinical trials may begin; adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic for its intended use or uses; pre-approval inspection of manufacturing facilities and clinical trial sites; and FDA approval of a BLA, which must occur before a biologic can be marketed or sold.

The testing and approval process requires substantial time and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Our planned clinical trials for our product candidates may not begin or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory approval to commence a study;
- reaching agreement with third-party clinical trial sites and their subsequent performance in conducting accurate and reliable studies on a timely basis;
- obtaining institutional review board approval to conduct a study at a prospective site; and
- recruiting patients to participate in a study; and
- supply of the investigational product and related materials.

Before testing any compound in human subjects, a company must develop extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Animal studies must be performed in compliance with the FDA's Good Laboratory Practice, or GLP, regulations and the United States Department of Agriculture's Animal Welfare Act and related regulations.

Prior to commencing the first clinical trial in humans, an initial IND application must be submitted to the FDA. A company must submit preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in humans. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA within the 30-day time period raises concerns or questions about the conduct of the clinical trial and places the trial on clinical hold. In such case, the IND application sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. A separate submission to the existing IND must be made for each successive clinical trial to be conducted during product development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the protocol and informed consent for any clinical trial before it commences at that site. Informed consent must also be obtained

19

Table of Contents

from each study subject. Regulatory authorities, an IRB, a data safety monitoring board or the trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk.

A study sponsor is also required to submit to NIH for public posting on NIH's clinical trial website, details about certain active clinical trials and clinical trial results. For purposes of developing product candidates for BLA approval, human clinical trials are typically conducted in phases that may overlap:

Phase 1—the investigational biologic is initially given to healthy human subjects or patients and tested for safety, dosage tolerance, reactivity, absorption, metabolism, distribution and excretion. These studies may also gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational products may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

Phase 2—studies are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to assess the efficacy of the investigational product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

Phase 3—when Phase 2 evaluations demonstrate that a dosage range of the investigational product may be effective and may have an acceptable safety profile, and provide sufficient information for the design of Phase 3 clinical trials, Phase 3 clinical trials are undertaken to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for product approval by the FDA.

All of these trials must be conducted in accordance with Good Clinical Practice, or GCP, requirements in order for the data to be considered reliable for regulatory purposes.

Government regulation may delay or prevent marketing of product candidates for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approvals for any future product candidates on a timely basis, if at all. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

The Biologic License Application Approval Process

In order to obtain approval to market a biologic in the United States, a BLA must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational product for the proposed indication. Each BLA submission requires a substantial user fee payment unless a waiver or exemption applies. The application includes all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators.

The FDA will initially review the BLA for completeness before it accepts it for filing. Under the FDA's procedures, the agency 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 the application is sufficiently complete to permit substantive review. After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, which includes determining whether it is effective for its intended use, and whether the product is being manufactured in accordance with cGMP, to assure and preserve the product's identity, strength, quality, potency and purity. The FDA may refer applications for novel products or products that 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 and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

20

Table of Contents

During the approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biologic. A REMS may include various elements depending on what the FDA considers necessary for the safe use of the drug. These elements may range from a medication guide or patient package insert to limitations on who may prescribe or dispense the biologic. If the FDA concludes that a REMS is needed, the BLA sponsor must submit a proposed REMS and the FDA will not approve the BLA without a REMS that the agency has determined is acceptable.

Certain applications for approval must include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug or biological product in relevant pediatric populations. The FDA may waive or defer the requirement for a pediatric assessment, either at the Company's request or by the agency's initiative.

The Orphan Drug Act provides incentives for the development of drugs and biological products intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States. If a sponsor demonstrates that a drug or biologic is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug or biologic that is approved for the orphan designated indication is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity.

For investigational products that are intended to treat serious diseases, certain mechanisms may expedite the FDA approval process. For example, FDA may grant Priority Review designation to a product that could provide significant improvement in the treatment, diagnosis, or prevention of a serious condition. Priority Review sets the target date for FDA action on the application at six months from the FDA's filing of the BLA, rather than the standard 10 months. Priority review designation does not, however, change the scientific or medical standard for approval or the quality of evidence necessary to support approval. Another potential approach is Fast Track designation, which a sponsor can request at any time during the development process to facilitate development and expedite review of a product intended to treat a serious condition and fill an unmet medical need. Fast Track designation involves early and frequent communication between the FDA and the sponsor, which often leads to earlier approval. Breakthrough Therapy designation is another approach that is intended to expedite development and review of a product that is intended to treat a serious condition and where preliminary clinical evidence indicates that the product may demonstrate substantial improvement over available therapy on a clinically significant endpoint. Like Fast Track designation, Breakthrough Therapy designation provides a sponsor with the opportunity to obtain early and intensive guidance from FDA for an efficient drug development program.

After the FDA completes its initial review of a BLA, it will either communicate to the sponsor that it will approve the product, or issue a complete response letter to communicate that it will not approve the BLA in its current form and to inform the sponsor of changes that the sponsor must make or additional clinical, nonclinical or manufacturing data that must be received before the FDA can approve the application, with no implication regarding the ultimate approvability of the application. If a complete response letter is issued, the sponsor may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure compliance with GCP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine that the data generated by the clinical site should be excluded from analyses provided in the BLA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process for a biologic requires substantial time, effort and financial resources and this process may take several years to complete. Data obtained from clinical activities are not always conclusive and may

be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

Table of Contents

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 clinical trials may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA has express statutory authority to require sponsors to conduct post-market studies to specifically address safety issues identified by the agency.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of a REMs, restrictions on distribution, or post-marketing study requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

FDA Post-Approval Requirements

Any products manufactured or distributed by us or on our behalf pursuant to FDA approvals are subject to continuing regulation by the FDA, including requirements for record-keeping, reporting of adverse experiences with the biologic, submitting annual reports, and reporting biological product deviations. Manufacturers are required to register their facilities with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and certain state agencies for compliance with cGMP standards, which impose certain quality processes, manufacturing controls and documentation requirements upon us and our third-party manufacturers in order to ensure that the product is safe, has the identity and strength, and meets the quality, purity and potency characteristics that it purports to have. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, refuse to approve any BLA or other application, force us to recall a drug from distribution, shut down manufacturing operations or withdraw approval of the BLA for that biologic. Noncompliance with cGMP or other requirements can result in issuance of warning letters, civil and criminal penalties, seizures, and injunctive action.

The FDA and other federal and state agencies closely regulate the labeling, marketing and promotion of biologics. While doctors may prescribe any product approved by the FDA for any use, a company can only make claims about a product that are consistent with its FDA approval, and the Company is allowed to market a drug only for the particular use approved by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, untitled or warning letters, corrective advertising requirements, injunctions, potential civil and criminal penalties, criminal prosecution, and agreements with governmental agencies that materially restrict the manner in which a company promotes or distributes drug products. Government regulators, including the Department of Justice and the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities, recently have increased their scrutiny of the promotion and marketing of drugs.

Finally, post-approval modifications to a licensed biological product, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical or clinical trials, to be submitted in a new or supplemental BLA, which would require FDA review and approval.

Biologics Price Competition and Innovation Act of 2009

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the Public Health Service Act to create a new licensure framework for biosimilar products, or biosimiliars, which could ultimately subject our biological product candidates to competition from biosimiliars. Under the BPCIA, a manufacturer may submit an abbreviated application for licensure of a biologic that is “biosimilar to” an already licensed biologic, or reference product. This abbreviated approval pathway is intended to permit a biosimilar to come to market more quickly and less expensively, by relying to some extent on the FDA’s previous review and approval of the reference biologic to which the proposed product is biosimilar. Previously, there had been no regulatory approval pathway for such biosimilar products.

Under the BPCIA, a biosimilar sponsor's ability to seek or obtain approval through the abbreviated pathway is limited by periods of exclusivity granted to the sponsor of the reference product. No biosimilar application may be accepted by the FDA for review until four years after the date of approval of the reference product, and no such

Table of Contents

application, once accepted, may receive final approval until 12 years after that same date. Once approved, biosimilar products likely would compete with, and in some circumstances may be deemed under the law to be "interchangeable with", the previously approved reference product.

On March 6, 2015, the FDA approved the first biosimilar, Zarxio (filgrastim-sndz), a leukocyte growth factor which referenced Amgen's filgrastim product, Neupogen. Because Neupogen was approved in 1991, Amgen had no remaining exclusivity. In contrast, the twelve-year marketing exclusivity and four-year data exclusivity provided to innovator products will be available for each of our biological product candidates, running from the date of each such product's first licensure.

Coverage and Reimbursement

In both domestic and foreign markets, sales of any product candidates for which we may receive regulatory approval will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include governmental healthcare programs, such as Medicare and Medicaid, private health insurers and managed care organizations and other entities. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is granted, the reimbursement rates paid for covered products might not be adequate. Even if favorable coverage status and adequate reimbursement rates are attained, less favorable coverage policies and reimbursement rates may be implemented in the future. The marketability of any products for which we may receive regulatory approval for commercial sale may suffer if governmental healthcare programs and other third-party payors fail to provide coverage and adequate reimbursement to allow us to sell such products on a competitive and profitable basis. For example, under these circumstances, physicians may limit how much or under what circumstances they will prescribe or administer, and patients may decline to purchase, such products. This, in turn, could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

The market for any product candidates for which we may receive regulatory approval will depend significantly on the degree to which these products are listed on third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included on such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our product candidates will be considered cost-effective by third-party payors. This process could delay the market acceptance of any product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

Other Healthcare Laws

In the United States, the research, manufacturing, distribution, marketing, sale and promotion of drug products and medical devices are subject to numerous regulations by various federal, state and local authorities in addition to the FDA, including but not limited to, the U.S. Department of Health and Human Services, or HHS, and its various divisions, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS. These regulations are enforced by various federal, state and local authorities, including but not limited to, the U.S. Department of Justice, state Attorneys General, state Medicaid Fraud Control Units, HHS' various enforcement divisions, including but not limited to, the Office of Inspector General, the Office for Human Research Protections, or OHRP, and the Office of Research Integrity and other state and local government agencies. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

We are subject to complex laws pertaining to healthcare “fraud and abuse,” including, but not limited to, the federal Anti-Kickback Statute, the federal False Claims Act, the Federal Physician Payment Sunshine Act and other state and federal laws.

Table of Contents

The Federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good or service for which payment may be made under federal health care programs such as the Medicare and Medicaid 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. Violations of the Federal Anti-Kickback Statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. The Federal Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 and subsequent legislation, or collectively, the Healthcare Reform Act or PPACA, among other things, amends the intent requirement of the Federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions; however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. The Federal False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment, or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim. Several pharmaceutical and other healthcare companies have faced enforcement actions under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, also may implicate the Federal False Claims Act. Federal False Claims Act violations may result in imprisonment, criminal fines, civil monetary damages and penalties and exclusion from participation in federal healthcare programs. The majority of U.S. states also have statutes or regulations similar to the Federal Anti-Kickback Statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs. A number of states have Anti-Kickback Statutes that apply regardless of the payor. In addition, the Federal Physician Payment Sunshine Act requires extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data. The system for reporting is called Open Payments and applies to pharmaceutical companies. Last year was the first year for reporting under the Open Payments system. Failure to comply with the reporting obligations may result in civil monetary penalties.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing related activities including the provision of gifts, meals, or other items to certain health care providers. In addition, some states require pharmaceutical companies to implement compliance programs or marketing codes.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal or state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant criminal and civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private “qui tam” actions brought by individual whistleblowers in the name of the government, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Table of Contents

Affordable Care Act

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, even if they are approved for sale. 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 containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical and medical device industries have been a particular focus of these efforts and have been significantly affected by major legislative initiatives.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, was enacted, which includes measures that have or will significantly change health care delivery and financing by both governmental and private insurers. Among the provisions of the Affordable Care Act of importance to the pharmaceutical and medical device industries are the following:

The Affordable Care Act increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, from 15.1% to 23.1% and from 11% to 13% of the average manufacturer price, or AMP, for most branded and generic drugs and biologic agents, respectively. The Affordable Care Act also added a new rebate calculation for “line extensions” (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products and potentially impacted manufacturers’ Medicaid Drug Rebate liability by modifying the statutory definition of AMP. The Affordable Care Act also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations as of 2010 and by expanding the population potentially eligible for Medicaid drug benefits, to be phased-in by 2014. Effective in 2010, the Affordable Care Act expanded the types of entities eligible to receive discounted pricing through the 340B drug pricing program. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

The Affordable Care Act imposes a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., “donut hole”) as a condition for the manufacturers’ outpatient drugs to be covered under Medicare Part D.

The Affordable Care Act imposes an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications. The Affordable Care Act expanded healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, and added new government investigative powers, and enhanced penalties for noncompliance.

The Affordable Care Act establishes the Physician Payment Sunshine Act (as referenced above) which now requires pharmaceutical and medical device manufacturers to track and report annually certain financial arrangements with physicians and teaching hospitals, as defined in the Affordable Care Act and its implementing regulations, including reporting any “payments or other transfers of value” made or distributed to such entities, and it requires applicable manufacturers and applicable group purchasing organizations to report annually any ownership and investment interests held by physicians and certain other healthcare providers and their immediate family members by the 90th day of each calendar year.

The Affordable Care Act added a new requirement to annually report drug samples that manufacturers and distributors provide to physicians.

New Patient-Centered Outcomes Research Institute was established pursuant to the Affordable Care Act to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.

The Affordable Care Act created the Independent Payment Advisory Board which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could

Table of Contents

result in reduced payments for prescription drugs. Under certain circumstances, these recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings.

The Affordable Care Act established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

In 2012, the Supreme Court of the United States heard challenges to the constitutionality of certain provisions of the Affordable Care Act. The Supreme Court's decision upheld most of the Affordable Care Act. However, the Supreme Court struck down a provision in the Affordable Care Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state's current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court's ruling, it is unclear whether states will expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and whether there will be more uninsured patients in 2015 than anticipated when Congress passed the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there will be fewer insured patients overall. The reduction in the number of insured patients could impact our sales, business and financial condition.

In early 2015, the Supreme Court of the United States heard a case in which it will decide whether the federal government has the authority to make subsidies available to millions of Americans who buy health insurance on federal Exchanges. The outcome of this case could adversely affect the ability of enrollees to continue their insurance coverage and consequently may affect the insurance coverage to certain individuals for the Company's products. A decision is expected in June.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees

As of December 31, 2014, we had 33 full-time employees and three part-time employees. Of these employees, 24 were primarily engaged in research and development activities and 13 have a M.D. or a Ph.D. degree. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Available Information

Our website address is www.immunedesign.com. We make available on our website, free of charge, our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D. C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov. The information found on our website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

Table of Contents

Item 1A. Risk Factors.

This Annual Report on Form 10-K contains forward-looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our common stock. You should carefully consider these risk factors, together with all of the other information included in this Annual Report on Form 10-K as well as our other publicly available filings with the SEC.

Risks Related to Our Financial Position and Capital Needs

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

We are a clinical-stage biotechnology company with a limited operating history. Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain regulatory approval or become commercially viable. We have no products approved for commercial sale and have generated only limited revenue to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since our inception in 2008. For the years ended December 31, 2014, 2013 and 2012, we reported a net loss of $34.2 million, $16.0 million and $10.8 million, respectively. As of December 31, 2014, we had an accumulated deficit of $90.8 million.

We expect to continue to incur significant 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. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues, if any. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We currently have limited revenues and may never achieve or maintain profitability.

To date, we have only generated limited revenues from sales of GLA and such revenues have not been sufficient to cover our operating expenses. Our ability to generate significant product revenue and become profitable depends upon our ability to successfully commercialize our current product candidates or any other future product candidates. We do not anticipate generating revenue from the sale of our current or future product candidates for the foreseeable future. Our ability to generate significant product revenue from our current or future product candidates also depends on a number of additional factors, including but not limited to our ability to:

- successfully complete the research and clinical development of and receive regulatory approval for current and future product candidates, including those of our licensees for the use of GLA in specific indications;
- launch, commercialize and achieve market acceptance of our current and future product candidates for which we obtain marketing approval, if any, and if launched independently, successfully establish a sales, marketing and distribution infrastructure;
- establish and maintain supplier and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- establish, maintain and protect our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biotechnology product development, including that our product candidates may not achieve the clinical endpoints of applicable trials, we are unable to predict the timing or amount of increased expenses, and if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide to or are required by the FDA or foreign regulatory authorities to perform additional studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs

associated with launching and commercializing these products.

Table of Contents

Even if we generate revenues from the sale of any of our product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable and subsequently do not sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce our operations or even shut down.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms, if at all. As a result, we may not complete the development and commercialization of our product candidates or develop new product candidates.

Development of our product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities. Our future capital requirements will depend on many factors, including, among others:

the scope, rate of progress, results and costs of our clinical trials, preclinical studies and other research and development activities;

the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;

the cost, timing and outcomes of regulatory proceedings, including FDA review of any Biologics License Application, or BLA, we file;

payments required with respect to development milestones we achieve under our in-licensing agreements;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;

the costs associated with commercializing our product candidates, if they receive regulatory approval;

the cost and timing of developing our ability to establish sales and marketing capabilities;

the costs of current or future litigation or judgments;

competing technological efforts and market developments;

changes in our existing research relationships;

our ability to establish collaborative arrangements to the extent necessary;

revenues received from any existing or future products; and

payments received under any current or future strategic partnerships.

We anticipate that we will continue to generate significant losses for the next several years as we incur expenses to complete our clinical trial programs for our product candidates, build commercial capabilities, develop our product pipeline and expand our corporate infrastructure. We believe that our existing cash and cash equivalents, will allow us to fund our operating plan for at least the next 12 months. However, our operating plan may change as a result of factors currently unknown to us.

There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. Actual research and development costs could substantially exceed budgeted amounts.

We may never be able to generate a sufficient amount of product revenue to cover our expenses. To finance our operations, we expect to seek additional funding through public or private equity or debt financings, collaborations or licenses, capital lease transactions or other available financing transactions. However, we cannot be certain that additional financing will be available on acceptable terms, if at all. Moreover, in the event that additional funds are obtained through arrangements with collaborative partners, such arrangements may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves. Our failure to obtain adequate financing when needed and on acceptable terms could force us to delay, reduce the scope of or eliminate one or more of our research or development programs.

Table of Contents

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

Until we can generate a sufficient amount of revenue from our product candidates, if ever, we expect to finance future cash needs through public or private equity or debt offerings or from other sources. Additional capital may not be available on reasonable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders and increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

We plan to use potential future operating losses and our federal and state net operating loss, or NOL, carryforwards to offset taxable income from revenue generated from operations or corporate collaborations. However, our ability to use NOL carryforwards could be limited as a result of issuance of equity securities.

We plan to use our current year operating losses to offset taxable income from any revenue generated from operations or corporate collaborations. To the extent that our taxable income exceeds any current year operating losses, we plan to use our NOL carryforwards to offset income that would otherwise be taxable. However, under the Tax Reform Act of 1986, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three-year period. As a result, our use of federal NOL carryforwards could be limited by the provisions of Section 382 of the U.S. Internal Revenue Code of 1986, as amended, depending upon the timing and amount of additional equity securities that we issue. In addition, we have not performed an analysis of limitations, and we may have experienced an ownership change under Section 382 as a result of past financings. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow.

Risks Related to Our Business and Industry

We are subject to litigation that could interrupt the supply of our drug candidates, delay our clinical trials and future clinical development and materially harm our business.

In September 2013, Henogen, the manufacturer of some of our lentiviral vectors, was sued in Belgium by one of its customers, TheraVectys SA, or TVS, who claimed that the manufacturer had breached its exclusive contract with TVS by producing lentiviral vectors for us. While we were not named in the suit in Belgium, we voluntarily intervened in that proceeding to protect our rights. In addition, TVS subsequently filed a complaint against us in the United States District Court for the District of Delaware, alleging tortious interference, unfair competition and misappropriation of trade secrets. In April 2014, TVS filed a Notice of Voluntary Dismissal without prejudice for this suit. As a result of the action in Belgium, Henogen was temporarily enjoined from producing or delivering the lentiviral vectors we need for our ZVex platform-based product candidates. This injunction was lifted by the Belgian court in October 2013.

In October 2013, Henogen filed an action in the Commercial Court of Paris against TVS. We were not a party to this action. In April 2014, the Commercial Court of Paris rendered a decision in which it dismissed all claims raised by Henogen, determined that Henogen had breached the agreement with TVS and, among other things, ordered Henogen to comply with the exclusivity provision of the agreement. It is our understanding that Henogen and TVS have reached a settlement agreement pertaining to this matter.

On or about July 24, 2014, shortly after our Registration Statement on Form S-1 was declared effective by the SEC for our initial public offering, TVS filed a new complaint against us in the Chancery Court of the State of Delaware, alleging facts substantially similar to the prior complaint. In addition, the complaint further alleges that we obtained shipments of lentiviral vectors for vaccines from Henogen and are conducting clinical trials with these lentiviral vectors. The complaint asserts four counts for relief: tortious interference with contractual relationship, unfair competition, misappropriation of trade secrets, and unjust enrichment; claimed damages were not specified. The complaint also requested injunctive relief enjoining us from using lentiviral vectors developed or produced by Henogen, using any other materials or information obtained by Henogen, and citing to the FDA or otherwise relying

on any clinical trials using lentiviral vector vaccines developed or produced by Henogen.

Table of Contents

On or about July 24, 2014, TVS also filed a motion for expedited proceedings in support of an anticipated motion for preliminary injunction. On August 8, 2014 the court granted TVS' motion for expedited proceedings and set a hearing date in mid-November 2014 for TVS' anticipated motion for preliminary injunction. In September 2014, TVS filed a motion to postpone the hearing date and delay the proceedings it previously sought to expedite. The court granted the motion and set a new date for the hearing. On or about December 15, 2014, TVS filed a motion for a preliminary injunction seeking, among other things, to enjoin us from making any use of lentiviral vectors pending final resolution of the litigation. A hearing was held on TVS's motion in January 2015.

By order dated March 9, 2015, the Chancery Court denied TVS' motion for a preliminary injunction. The court has not yet made any final determination on the merits of the lawsuit, which will be determined at a full trial which we expect will occur prior to the end of the third quarter of 2015. We cannot predict the outcome of any trial on the merits. The Chancery Court ruled that TVS had not established a reasonable probability of success on the merits of most, but not all, of its claims. If we receive an adverse judgment, we could be subject to the payment of damages, which could have a material adverse effect on our financial position and results of operations. In addition, the Chancery Court could enter injunctive or other equitable relief of unknown scope, which could delay or prevent further development of LV305 or other product candidates from our ZVex platform.

We have transitioned the manufacture of our lentiviral vectors to a new manufacturer to mitigate the risk of future supply interruptions. However, in the event we are unable to use any lentiviral vectors manufactured from our new manufacturer or any future manufacturer or the clinical data from the ongoing Phase 1 trial of LV305, prevented from conducting any new clinical trials using lentiviral vectors or otherwise prevented from developing, using or producing products using lentiviral vectors as a result of an injunction ordered by the Delaware Chancery Court after a trial on the merits or any other legal proceeding, the development of LV305 or any other product candidates from our ZVex platform could be substantially delayed and our business could be harmed. We also cannot be certain that TVS will not bring separate actions against us or our current or any future contract manufacturer which we may use to produce lentiviral vectors. Any such litigation could lead to delays in manufacturing doses of, or developing, LV305 or other products candidates from our ZVex platform.

Ongoing legal proceedings with TheraVectys SA are time consuming and expensive and constitute a significant distraction to management, which could adversely affect our ability to execute on our business plan and have a material adverse effect on our business.

TVS is simultaneously pursuing its legal proceeding against us in the Chancery Court of the State of Delaware and a separate patent opposition proceeding at the EPO. While we did not initiate these proceedings, we are obligated to vigorously defend the company and protect our intellectual property. Litigation is expensive, particularly given the multiple jurisdictions and actions brought by TVS. The costs of defending these actions and protecting our rights will have a materially adverse effect on our results of operations through at least 2015. In addition, managing these actions is time consuming and results in significant distraction of management and operational resources, which could have a material adverse effect on our ability to execute on our business plan.

Our product candidates are in early stages of development. We cannot predict if we will receive regulatory approval to commercialize our product candidates.

All of our product candidates are in early stages of development, including product candidates that are in Phase 1 clinical development, and they will require extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by FDA, or whether any BLA will be approved upon review.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. If our clinical results are not successful, we may terminate the clinical trials for a product candidate and abandon any further research or testing of the product candidate. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

If our product candidates fail to meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them.

Our product candidates may not prove to be safe and efficacious in clinical trials and may not meet all of the applicable regulatory requirements needed to receive regulatory approval. For example, while we have observed a complete response in a patient with a loco-regional Merkel cell tumor treated with G100 in an ongoing Phase 1 clinical trial, the results from our Phase 1 clinical trial are not yet final, and we cannot assure you that G100 will be

Table of Contents

efficacious in clinical trials, that the complete response was a result of being treated with G100 or that any response will be durable.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required may vary depending on factors such as, the product candidate, the condition being evaluated, results of the previous trial and regulations or guidance applicable to any particular product candidate. The design of our clinical trials is based on many assumptions about the expected effect of our product candidates, and if those assumptions prove incorrect, the clinical trials may not demonstrate the safety or efficacy of our product candidates. Preliminary results may not be confirmed upon full analysis of the detailed results of a trial, and prior clinical trial program designs and results may not be predictive of future clinical trial designs or results. Product candidates in later stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints. If our product candidates fail to meet the necessary safety or efficacy endpoints, we may not be able to receive regulatory approval.

If we experience delays in clinical testing, we will be delayed in commercializing our product candidates, our costs may increase and our business may be harmed.

We have not completed all the clinical trials necessary to support an application with the FDA for approval to market any of our product candidates. Our current and future clinical trials may be delayed or terminated as a result of many factors, including:

efforts by TVS to slow down our clinical development, including through the entry of a permanent injunction or other equitable relief by the Chancery Court of Delaware after a trial on the merits in our ongoing litigation with TVS;

delays in, or failure to obtain, approval from institutional review boards, or IRBs, or ethics committees, or ECs, or institutional biosafety committees, to begin clinical trials at study sites;

imposition of a clinical hold by the FDA or other regulatory authorities, or a decision by the FDA, other regulatory authorities, IRBs, ECs, or recommendation by a data safety monitoring board, to suspend or terminate clinical trials at any time for safety issues or for any other reason;

delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;

deviations from the trial protocol by clinical trial sites and investigators, or failure to conduct the trial in accordance with regulatory requirements;

failure of third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;

delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;

for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected patients;

delays in having patients complete participation in a trial or return for post-treatment follow-up;

delays caused by patients dropping out of a trial due to side effects, disease progression or other reasons;

slow patient enrollment because of the perceived risk of contracting HIV because the viral vector we use in LV305 and CMB305 was constructed from genetic sequences, some of which were derived from HIV;

withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or

changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

Any inability of us or our partners to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenues or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

Table of Contents

If we encounter difficulties enrolling patients in our clinical trials, our clinical trials could be delayed or otherwise adversely affected.

We may not be able to enroll a sufficient number of patients or those with required or desired characteristics to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- the nature and size of the patient population;
- the number and location of clinical sites we enroll;
- competition with other companies for clinical sites or patients;
- design of the trial protocol;
- eligibility criteria for the study in question;
- slow patient enrollment because of the perceived risk of contracting HIV because the viral vector we use in LV305 and CMB305 was constructed from genetic sequences, some of which were derived from HIV;
- ability to obtain and maintain patient consents; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

Our product candidates may cause undesirable side effects or have other properties that could prevent their regulatory approval, limit the commercial scope of their approved uses, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In such an event, we could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- we may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- the FDA or other regulatory authorities may issue safety alerts, "Dear Healthcare Provider" letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of a Risk Evaluation and Mitigation Strategy, or REMS, or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose other implementation requirements on us;
- regulatory authorities may require that we conduct post-marketing studies;

Table of Contents

we could be sued and held liable for harm caused to subjects or patients; and
our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or otherwise materially harm the commercial prospects for the product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We may be required to suspend, repeat, redesign or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's current Good Clinical Practices, or cGCP, or other applicable foreign government guidelines. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies, IRBs and ECs at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable current Good Manufacturing Practices, or cGMP. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than current therapies; or
- the quality or stability of the product candidate may fall below acceptable standards.

Our ZVex platform is novel, which may raise new regulatory issues that could delay or make regulatory approval of our product ZVex candidates more difficult.

The process of obtaining required FDA and other regulatory approvals, including foreign approvals, is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Because our ZVex platform is novel, regulatory agencies lack experience with product candidates such as LV305 and CMB305, which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our ZVex product candidates.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.

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

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

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials' endpoints to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

Table of Contents

disagreement with our interpretation of data from preclinical studies or clinical trials;
the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals for those jurisdictions and comply with their numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, if regulatory approval for any of our product candidates is granted, it may be later withdrawn. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in countries outside of the United States may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

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

Even if we obtain regulatory approval for a product candidate, it will be subject to ongoing regulation by the FDA and comparable foreign regulatory authorities, including requirements governing the manufacture, quality control, further development, labeling, packaging, tracking, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The FDA and comparable foreign regulatory authorities continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may, among other measures, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated

severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we or the manufacturing facilities for

Table of Contents

our product candidates, if approved, fail to comply with applicable regulatory requirements, a regulatory agency may:

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

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

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved, or off-label, uses, may be subject to enforcement letters, inquiries and investigations, as well as civil and criminal sanctions. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval in their respective jurisdictions.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to administrative, civil and criminal penalties, damages, monetary fines, disgorgement, individual imprisonment, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, curtailment or restructuring of our operations and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include, but are not limited to, the federal civil False Claims Act, which allows any individual to bring a lawsuit against an individual or entity, including a pharmaceutical or biopharmaceutical company on behalf of the federal government alleging the knowing submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment or approval by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual initiating the lawsuit will share in any fines or settlement funds. These False Claims Act lawsuits against pharmaceutical and biopharmaceutical companies have increased significantly in number and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices, including promoting off-label drug uses involving fines in excess of $1.0 billion. This growth in litigation has increased the risk that a pharmaceutical or biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation, which have a material adverse effect on our business, financial condition and results of operations. Promotion prior to marketing approval or for off-label uses may also give rise to criminal prosecution in the European Union.

The FDA's and other applicable government agencies' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval, and thus the sale and promotion, of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Table of Contents

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. Our commercial success also depends on coverage and adequate reimbursement and pricing of our product candidates by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

the efficacy and safety profile as demonstrated in clinical trials;
the timing of market introduction of the product candidate as well as competitive products;
the clinical indications for which the product candidate is approved;
acceptance of the product candidate as a safe and effective treatment by physicians, clinics and patients;
the potential and perceived advantages of product candidates over alternative treatments;
the perceived risk of contracting HIV because the viral vector we use in LV305 and CMB305 was constructed from genetic sequences, some of which were derived from HIV;
the cost of treatment in relation to alternative treatments;
the availability of coverage and adequate reimbursement and pricing by third-party payors, including government payors and the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors;
the willingness of the target patient population to try new therapies based on new technologies and of physicians to prescribe these therapies;
the strength of marketing and distribution support;
relative convenience and ease of administration;
the frequency and severity of adverse events;
the effectiveness of sales and marketing efforts; and
unfavorable publicity relating to the product candidate.

Our competitors may develop and market products that are less expensive, more effective, safer or reach the market sooner than our product candidates, which may diminish or eliminate the commercial success of any products we may commercialize.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Table of Contents

Although there is only one approved in vivo immuno-oncology therapy, there are numerous currently approved therapies to treat cancer. Many of these approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. This may make it difficult for us to differentiate our products from currently approved therapies, which may adversely impact our business strategy. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to commercialize any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to establish, maintain and protect intellectual property rights related to our product candidates;
- the ability to manufacture commercial quantities of any of our product candidates that receive regulatory approval; and
- acceptance of any of our product candidates that receive regulatory approval by physicians and other healthcare providers.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

We may encounter delays in our clinical enrollment or other unforeseen challenges because the viral vector used in LV305 and CMB305 was constructed from genetic sequences, some of which were derived from HIV.

The viral vector in our LV305 and CMB305 product candidates was constructed from many genetic sequences, some of which were derived from HIV. While the vector will not cause an HIV infection, patients may test positive for HIV under certain screening tests and perceive the use of our product candidates as putting themselves at risk of contracting HIV. We disclose the origination of the vector in the consent forms used in our trial enrollments, which may cause patients to be deterred from enrolling in our trials resulting in delays in the enrollment for our clinical trials. Furthermore, we may encounter other difficulties, such as lack of market adoption of any commercialized product candidate, due to the public's negative perception of the risk of contracting HIV.

We will need to develop or acquire additional capabilities in order to commercialize any product candidates that obtain regulatory approval, and we may encounter unexpected costs or difficulties in doing so.

We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have no experience in preparing applications for marketing approval, commercial-scale manufacturing, managing of large-scale information technology systems or managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources. To do this effectively, we must:

- train, manage and motivate a growing employee base;
- accurately forecast demand for our products; and
- expand existing operational, financial and management information systems.

Table of Contents

We plan to conduct process development activities to support late stage development and commercialization activities and seek approval of our product candidates. Should we not receive timely approval of our production process, our ability to produce the immunotherapy products following regulatory approval for sale could be delayed, which would further delay the period of time when we would be able to generate revenues from the sale of such products, if we are even able to generate revenues at all.

We have no internal sales or marketing capability and may rely on alliances with others possessing such capabilities to commercialize our products successfully.

We intend to market our product candidates, if and when such product candidates are approved by the FDA or comparable foreign regulatory authorities, either directly or through other strategic alliances and distribution arrangements with third parties. There can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on advantageous terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional expense. If we are unable to enter into such arrangements on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. Depending on the nature of the third party relationship, we may have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. If we are not successful in commercializing our product candidates, 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 depend on key personnel for our continued operations and future success and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the immuno-oncology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Many of the other biopharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates and our business will be limited.

Even if we commercialize a product candidate, it or any other product candidates that we develop may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to commercialize any product candidates successfully will depend in part on the extent to which coverage and adequate reimbursement for our product candidates will be available from government health administration authorities, private health insurers and other organizations. The laws that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

Current and future legislation may increase the difficulty and cost for us to commercialize our drug candidates and affect the prices we may obtain.

In the United States and many foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of enacted or proposed legislative and regulatory changes affecting the healthcare system and pharmaceutical

and biopharmaceutical industries that could, among other things, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the Affordable Care Act. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program

Table of Contents

by increasing the minimum rebate for both branded and generic drugs, effective the first quarter of 2010 and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices. This could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The Affordable Care Act further created a separate AMP for certain categories of drugs generally provided in non-retail outpatient settings. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization, and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. Also effective in 2010, the Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing, although, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs used in orphan indications. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase. The Affordable Care Act also imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Furthermore, as of 2011, this law changed the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to certain eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D. Additionally, the Affordable Care Act created a new licensure framework for follow-on biologic products. The Affordable Care Act also created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with providing funding for such research. Additionally, the Affordable Care Act created the Independent Payment Advisory Board, which has the authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law, even if Congress does not act on the recommendation. Furthermore, the Affordable Care Act established a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, as described in more detail below. Notably, a significant number of provisions are not yet, or have only recently become, effective.

Many of the details regarding the implementation of the Affordable Care Act are yet to be determined, and at this time, it remains unclear the full effect that the Affordable Care Act would have on our business. In particular, there is uncertainty surrounding the applicability of the biosimilars provisions under the Affordable Care Act to our product candidates. FDA's implementation of the biosimilars provisions is at an early stage. Depending on how FDA's regulation of biosimilars evolves, we may be required to change our current strategies.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2%, starting in 2013. The Bipartisan Budget Act of 2013, enacted on December 26, 2013, and Public Law 113-82, enacted on February 15, 2014, expanded sequestration through fiscal year 2024. These cuts will occur unless Congress repeals or amends the reductions in future legislation. Continuation of sequestration or enactment of other reductions in Medicare reimbursement for drugs could affect our ability to achieve a profit on any candidate products that are approved for marketing.

Moreover, the recently enacted Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding drug products to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the

manufacturers' products are appropriately licensed. Further, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or that are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. In the European Union the Falsified Medicines Directive imposes similar requirements which are expected to add materially to product costs.

Table of Contents

In addition to federal reforms, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenues. In addition, legislation has been introduced that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and exert downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate sufficient revenue, attain profitability or successfully commercialize our products. The full impact of these new laws, as well as laws and other reform measures that may be proposed and adopted in the future, remains uncertain, but may continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs, which could have a material adverse effect on our business operations.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates.

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

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

While we currently hold $5.0 million in trial liability insurance coverage, this may not adequately cover all liabilities that we may incur. We also may not be able to maintain insurance coverage at a reasonable cost or in an amount

40

Table of Contents

adequate to satisfy any liability that may arise in the future. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition.

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

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal false claims laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, also imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the Physician Payment Sunshine Act (federal Open Payments program), created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to the U.S. Department of Health and Human Services ownership and investment interests held by physicians (as defined above) and their immediate family members;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers;
- state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers;
- state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and

41

Table of Contents

state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

Risks Related to our Dependence on Third Parties

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with budgets and other financial obligations or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates in a timely or cost-effective manner.

We rely, and expect to continue to rely, on third-party CROs to conduct our clinical trials. Because we do not conduct our own clinical trials, we must rely on the efforts of others and cannot always control or accurately predict the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not anticipate significantly increasing our personnel in the foreseeable future and therefore, expect to continue to rely on third parties to conduct our future clinical trials. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become prohibitively expensive, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

We currently depend on third parties for the development and commercialization of five of our non-cancer treatment product candidates.

We have entered into exclusive licenses and development agreements with MedImmune pursuant to which we have granted MedImmune exclusive licenses to develop and commercialize product candidates relating to certain infectious diseases. We also have entered into an exclusive license agreement with Sanofi for use of our GLAAS discovery platform to develop therapeutic agents to treat a selected food allergy and a collaboration agreement with Sanofi Pasteur for the development of a herpes simplex virus immune therapy. We cannot control whether or not these partners will devote sufficient time and resources to the ongoing clinical and preclinical programs or whether these partners will fulfill their obligations under the agreements. The product candidates developed pursuant to these agreements may not be scientifically, medically or commercially successful.

In addition, we could be adversely affected by:

- our partners' failure to timely perform their obligations under our agreements;
- our partners' failure to timely or fully develop or effectively commercialize the product candidates; and
- a material contractual dispute between us and our partners.

Any of the foregoing could adversely impact the likelihood and timing of any milestone or royalty payments we are eligible to receive from MedImmune, Sanofi or Sanofi Pasteur and could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline.

We may not succeed in establishing and maintaining additional development collaborations, which could adversely affect our ability to develop and commercialize product candidates.

In addition to our current agreements with MedImmune, Sanofi and Sanofi Pasteur, a part of our strategy is to enter into additional product development collaborations in the future, including collaborations with major biotechnology or

pharmaceutical companies. We face significant competition in seeking appropriate development partners and the

Table of Contents

negotiation process is time-consuming and complex. Moreover, we may not succeed in our efforts to establish a development collaboration or other alternative arrangements for any of our other existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish new development collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such development collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing.

Moreover, if we fail to establish and maintain additional development collaborations related to our product candidates:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly, and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and
- we will bear all of the risk related to the development of any such product candidates.

If we enter into one or more collaborations, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to unfavorable terms.

Any future collaborations we enter into could subject us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of our product candidates;
- collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- collaborators may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- collaborators may experience financial difficulties;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

We have no manufacturing capacity and anticipate continued reliance on third-party manufacturers for the development and commercialization of our products.

Table of Contents

We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates. We have limited experience in manufacturing our product candidates, and we lack the resources and the capabilities to do so on a clinical or commercial scale. We do not intend to develop facilities for the manufacture of products for clinical trials or commercial purposes in the foreseeable future. We rely on third-party manufacturers to produce bulk drug substance and formulated drug products as well as fill-finish required for our clinical trials. We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners, to manufacture commercial quantities of our product candidates. We do not have a long-term commercial supply arrangement in place with any of our contract manufacturers. If we need to identify additional manufacturers, we may experience delay and additional cost. We have not secured commercial supply agreements with any contract manufacturers and can give no assurance that we will enter commercial supply agreements with any contract manufacturers on favorable terms or at all.

Our contract manufacturers' failure to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury or death, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. Our existing manufacturers and any future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business. In the event of a natural disaster, business failure, strike or other difficulty, we may be unable to replace a third-party manufacturer in a timely manner and the production of our product candidates would be interrupted, resulting in delays and additional costs.

Manufacturers have limited or no experience producing our product candidates and may not produce our vectors and product candidates at the quality, quantities and timing needed to support clinical trials or commercialization.

The components of our product candidates are difficult to make. No manufacturer currently has the experience or ability to produce our vectors and product candidates at commercial levels. In addition, the manufacturer of LV305 has only recently begun to manufacture LV305. Our contract manufacturing organizations, or CMO, may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds, which could delay our clinical trials.

The manufacturing process for the full length NY-ESO-1 protein in CMB305 is difficult and we currently obtain the protein from a single source. If we utilize an alternative source, we may be required to demonstrate comparability of the drug product before releasing the product for clinical use. The loss of our current supplier could result in manufacturing delays for the component substitution, and we may need to accept changes in terms or price from our existing supplier in order to avoid such delays.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

Our success depends in significant part on our and our licensor's and licensees' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties rights to patent portfolios. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, and other licenses may not give us such rights.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors or licensees fail to establish, maintain or protect such patents and other intellectual property rights, such

rights may be reduced or eliminated. If our licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

Table of Contents

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' or licensees' patent rights are highly uncertain. Our and our licensors' or licensees' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors or licensees to narrow the scope of the claims of our or our licensors' or licensees' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We may be required to disclaim part or all of the term of certain patents or part or all of the term of certain patent applications.

There are no assurances that our patent counsel, lawyers or advisors have given us correct advice or counsel. Opinions from such patent counsel or lawyers may not be correct or based on incomplete facts. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our or our licensee's patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. Our and our licensors' or licensees' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. However, the applicable authorities, including the U.S. Patent and Trademark Office, or USPTO, and FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world is prohibitively expensive, and our or our current or future licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Moreover, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. In addition, even where patent protection is obtained, third-party competitors may challenge our patent claims

in the various patent offices. For example, in February 2013, a third party filed an opposition at the European Patent Office, or EPO, requesting revocation of European Patent No. 2068918 directed to GLA formulations and uses. This patent is licensed to us by the Infectious Disease Research Institute, or IDRI, and is an important part of our proprietary position for GLA in Europe. We are vigorously defending the grant of this patent, however the final outcome of the proceedings is uncertain and will likely not be known for several years. We cannot be certain that this patent will be maintained by the EPO. Moreover, it is possible that the patent will be maintained, but in a limited scope, and we cannot predict if such a scope would adequately cover our products.

Table of Contents

Revocation of this patent, or maintenance of an amended patent with inadequate coverage could impair our ability to prevent competition from third parties in Europe, which could have an adverse impact on our business.

The laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, some of our patents relate to treatment methods or dosing regimens that are not considered patentable subject matter in some foreign countries. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in countries outside the United States, or from selling or importing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our and our licensors' proprietary rights generally. Proceedings to enforce our and our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly and our and our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. Certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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

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

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect

the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties

Table of Contents

and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could have a material adverse effect on our business and financial condition.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, 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 and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

Third parties may infringe our or our licensors' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights, to protect our or our licensors' or collaborators' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensors or collaborators to challenge the validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. Accordingly, despite our or our licensors' or collaborators' efforts, we or our licensors or collaborators may not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue for various reasons, including on the grounds that our or our licensors' or collaborators' patents do not cover the technology in question. An adverse result in any litigation proceeding could result in one or more of our or our licensors' or collaborators' patents being invalidated, held unenforceable or interpreted narrowly.

Third-party preissuance submission of prior art to the USPTO, or opposition, derivation, reexamination, inter partes review or interference proceedings, or other preissuance or post-grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators may be instituted with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome of a third-party challenge to our owned or licensed patents or patent applications could include a determination of unpatentability, invalidity or a narrowing amendment to our patents. An unfavorable outcome in an interference proceeding that awards our patent claims to a third party could require us or our licensors or collaborators to cease using related technology. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or

proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent.

For example, in February 2013, a third party filed an opposition at the EPO, requesting revocation of European Patent No. 2068918 directed to GLA formulations and uses. We licensed this patent from IDRI. We are vigorously

Table of Contents

defending the grant of this patent. This patent is an important part of our proprietary position for GLA in Europe. The final outcome of the proceedings is uncertain and will likely not be known for several years.

An unfavorable outcome could require us or our licensors, collaborators or suppliers to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors, collaborators or suppliers a license on commercially reasonable terms or at all. Even if we or our licensors, collaborators or suppliers obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors, collaborators or suppliers. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business.

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

If we breach the agreements under which third parties have licensed intellectual property rights to us, we could lose the ability to use certain of our technologies or continue the development and commercialization of our product candidates.

Our commercial success depends upon our ability to identify, test, develop, manufacture, market and sell product candidates and use our and our licensors' or collaborators' proprietary technologies without infringing the proprietary rights of third parties. Pursuant to the license agreement with IDRI, we obtained licensing rights to certain GLA technologies, which we utilize in the development of our GLA product candidates. Similarly, under our licenses with Caltech and UNC Chapel Hill, we obtained rights to certain patents which we utilize in the development of our ZVex based product candidates. If we fail to comply with the obligations under the license agreements, including a material breach by us, certain insolvency events or failure to diligently pursue the development of products, the other party may have the right to terminate the license agreements. In addition, IDRI may terminate our licenses in the event we challenge the validity, enforceability or scope of any patent licensed to us by IDRI. In the event one of these licenses is terminated, we will not be able to develop, manufacture, market or sell any product candidate that is covered by the license agreement. Such an occurrence would adversely affect our ability to continue to develop our current product candidates as well as potential future product candidates. Termination of any of these licenses or reduction or elimination of our rights under any license agreement may result in our having to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under the license agreement, including our rights to intellectual property or technology important to our development programs.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. For example, we are currently defending against a lawsuit initiated by TVS claiming, among other things, that we misappropriated TVS' trade secrets. While we intend to vigorously defend against these claims and we believe TVS has not established a reasonable likelihood of success on the merits with respect to these claims, we cannot guarantee the outcome in a trial on the merits.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defending against claims of misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or

Table of Contents

products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Risks Related to Ownership of Our Common Stock

The market price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been and is likely to continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this report, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors’ products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our officers, directors or their affiliated funds or our other stockholders;
- changes in the structure of healthcare payment systems;

Table of Contents

market conditions in the pharmaceutical and biotechnology sectors;
rumors or new announcements by third parties, including competitors; and
general economic, industry and market conditions.

In addition, the stock market in general, and The NASDAQ Global Market, or NASDAQ, and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and material adverse impact on the market price of our common stock.

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

As of March 20, 2015, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 74% of our voting stock. These stockholders may have the ability to control us through this ownership position and be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We are an "emerging growth company" as defined in the JOBS Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not "emerging growth companies" including:

the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
the "say on pay" provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Protection Act, or Dodd-Frank Act, and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer;
the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and instead provide a reduced level of disclosure concerning executive compensation; and
any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We may take advantage of these exemptions until we are no longer an "emerging growth company." We would cease to be an "emerging growth company" upon the earliest of: (i) the first fiscal year following the fifth anniversary of our initial public offering in July 2014; (ii) the first fiscal year after our annual gross revenues are $1.0 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities; or (iv) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700.0 million as of the end of the second quarter of that fiscal year.

We currently take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an “emerging growth company.” For example, we have irrevocably elected

Table of Contents

not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an "emerging growth company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we may 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 and may decline.

We are incurring significant increased costs as a result of operating as a public company, and our management devotes substantial time to meet compliance obligations.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act as well as rules subsequently implemented by the SEC and NASDAQ, that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. In addition, on July 21, 2010, the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. The requirements of these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel will need to devote a substantial amount of time to these new compliance initiatives.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 20, 2015, we had 16,979,688 shares of common stock outstanding, of which 12,545,371 shares of our common stock are considered restricted as a result of securities laws or held by our affiliates with restrictions on trade. The remaining shares may be sold by our stockholders in the public market at any time without restriction.

Table of Contents

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

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

- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our headquarters, where we have office and research and development laboratory space, is in Seattle, Washington, where we sublease 11,000 square feet of space pursuant to a sublease that expires in November 2016, with an option to extend for one additional month. We also lease a 9,640 square foot facility in South San Francisco, California, which is comprised of office space. This lease expires in January 2020, with an option to extend the lease for an additional five years. We believe that our existing facilities are sufficient for our current needs.

Item 3. Legal Proceedings

TheraVectys SA v. Immune Design Corp.

In October 2013, TheraVectys SA, or TVS, a French biotechnology company, filed a complaint against us in the United States District Court for the District of Delaware. TVS alleged that it had entered into a contractual relationship with Henogen SA, or Henogen, in 2010 with respect to the production of lentiviral vector vaccines for TVS. Henogen is a contract manufacturing organization with which we contracted for the manufacture of our LV305 product candidate. TVS alleged that its contractual relationship with Henogen contained an exclusivity provision limiting Henogen's ability to participate in the manufacturing process of a vaccine based on lentiviral DNA Flap vectors for third parties, as well as a provision preventing Henogen from sharing or using certain TVS confidential technology for manufacturing processes developed by TVS with or for the benefit of others. TVS alleged that we entered into a contractual relationship with Henogen in 2012 to manufacture lentiviral vectors for vaccines, which TVS contends interfered with its contract with Henogen and resulted in the use of certain TVS confidential information and trade secrets. The complaint asserted three counts for relief: tortious interference with contractual relationship, unfair competition and misappropriation of trade secrets. TVS did not specify its claimed damages,

52

Table of Contents

other than to assert that they exceed $75,000. TVS also requested in its complaint injunctive relief enjoining us from importing, receiving possessing or using lentiviral vector vaccines developed or produced by Henogen, but never filed a motion seeking injunctive relief. The parties entered into several stipulations extending the deadline for us to respond to the complaint. On or about April 7, 2014, TVS filed a Notice of Voluntary Dismissal without prejudice of this lawsuit.

On or about July 24, 2014, shortly after our Registration Statement on Form S-1 was declared effective by the SEC for our initial public offering, TVS filed a new complaint against us in the Chancery Court of the State of Delaware, alleging facts substantially similar to the prior complaint. In addition, the complaint further alleges that we obtained shipments of lentiviral vectors for vaccines from Henogen and are conducting clinical trials with these lentiviral vectors. The complaint asserts four counts for relief: tortious interference with contractual relationship, unfair competition, misappropriation of trade secrets, and unjust enrichment; claimed damages were not specified. The complaint also requested injunctive relief enjoining us from using lentiviral vectors developed or produced by Henogen, using any other materials or information obtained by Henogen, and citing to the FDA or otherwise relying on any clinical trials using lentiviral vector vaccines developed or produced by Henogen.

On or about July 24, 2014, TVS also filed a motion for expedited proceedings in support of an anticipated motion for preliminary injunction. On August 8, 2014 the court granted TVS' motion for expedited proceedings and set a hearing date in mid-November 2014 for TVS' anticipated motion for preliminary injunction. In September 2014, TVS filed a motion to postpone the hearing date and delay the proceedings it previously sought to expedite. The court granted the motion and set a new date for the hearing. On or about December 15, 2014, TVS filed a motion for a preliminary injunction seeking, among other things, to enjoin us from making any use of lentiviral vectors pending final resolution of the litigation. A hearing was held on TVS's motion in January 2015.

By order dated March 9, 2015, the Chancery Court denied TVS' motion for a preliminary injunction. The court has not yet made any final determination on the merits of the lawsuit, which will be determined at a full trial which we expect will occur prior to the end of the third quarter of 2015. We intend to continue to vigorously defend this lawsuit.

European Patent Oppositions

In February 2013, a third party filed an opposition at the European Patent Office, or EPO, requesting revocation of European Patent No. 2068918 directed to GLA formulations and uses. This patent is owned by Infectious Disease Research Institute and under license to us. We are vigorously defending the grant of this patent, with a reply to the opposition brief having been filed on September 27, 2013. No date for an oral hearing has yet been set. This patent is an important part of our proprietary position for GLA in Europe. The final outcome of the proceedings is uncertain and will likely not be known for several years.

In October 2014, TVS filed an opposition at the EPO requesting revocation of European Patent No. 2456786 directed at improvements to our lentiviral vector. This opposition is not substantively related to the ongoing Delaware lawsuit previously disclosed, and to our knowledge, TVS is not using the technology claimed in this patent. We intend to vigorously defend the grant of this patent, and in light of other European patents and patent applications directed to our lentiviral platform technology, we do not believe the validity of this patent will have a material effect on the scope of our patent protection in Europe.

Item 4. Mine Safety Disclosures.

Not applicable.

Table of Contents

PART II

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

Market Information

Our common stock has been listed on The NASDAQ Global Market under the symbol “IMDZ” since July 24, 2014. Prior to July 24, 2014, there was no public trading market for our common stock. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market:

	High	Low
Year Ended December 31, 2014:		
Third Quarter (from July 24, 2014)	$19.05	$11.51
Fourth Quarter	$40.13	$17.05

As of March 20, 2015, we had 16,979,688 shares of common stock outstanding held by approximately 27 stockholders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Table of Contents

Stock Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since July 24, 2014, which is the date our common stock first began trading on the NASDAQ Global Market, to two indices: the NASDAQ Composite Index and the Russell 2000 Index. The stockholder return shown in the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

$100 investment in stock or index	July 24, 2014	September 30, 2014	December 31, 2014
IMDZ (IMDZ)	$100.00	$146.56	$255.44
NASDAQ Composite Index (IXIC)	$100.00	$100.48	$105.90
Russell 2000 Index (^RUT)	$100.00	$95.28	$104.19

Recent Sales of Unregistered Securities

In 2014, we issued an aggregate of 2,328 unregistered shares upon the exercise of stock options issued pursuant to our 2008 Equity Incentive Plan. The issuances of such shares were exempt from the registration requirements of the Securities Act pursuant to Section 3(b) and Rule 701 promulgated thereunder as transactions pursuant to a compensatory benefit plan, as provided under Rule 701.

In July 2014, immediately prior to the closing of our initial public offering, warrants issued to 5 accredited investors to purchase approximately 978,592 shares of our common stock at an exercise price of $8.175 per share automatically net exercised into 311,923 shares of common stock. In July 2014, immediately prior to the closing of our initial public offering, warrants issued to 3 accredited investors to purchase approximately 996,940 shares of common stock were exercised for proceeds of $8.1 million in cash at an exercise price of $8.175 per share. The issuances of such shares were exempt from the registration requirements of the Securities Act in reliance on Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering.

Initial Public Offering

Use of Proceeds

In July 2014, we completed an initial public offering (the IPO) of 5,000,000 shares of common stock at a price of $12.00 per share. In August 2014, we sold an additional 410,564 shares of common stock directly to our underwriters when they exercised portions of their over-allotment option on two separate occasions at $12.00 per share. We received net proceeds of $57.8 million (inclusive of the exercise of the over-allotment option) after deducting underwriting discounts and commissions and offering expenses totaling $7.1 million.

Table of Contents

None of the expenses associated with the IPO were paid to directors, officers, or persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries. Jefferies LLC and Leerink Partners LLC acted as joint book-running managers, and Wells Fargo Securities, LLC acted as co-manager for the offering.

Shares of our common stock began trading on the NASDAQ Global Market on July 24, 2014. The shares were registered under the Securities Act on Registration Statement on Form S-1 (Registration No. 333-196979), which was declared effective by the SEC on July 23, 2014.

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus dated July 24, 2014, filed with the SEC pursuant to Rule 424(b)(4) pursuant to the Securities Act of 1933, as amended. As of December 31, 2014 we have used approximately $10.7 million of the net offering proceeds primarily to fund clinical development of our product candidates, litigation, legal and administration expenses to fund the growth of our operations.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Table of Contents

Item 6. Selected Financial Data.

You should read the following selected financial data together with the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this report and our financial statements and the accompanying notes included elsewhere in this report.

We have derived the statements of operations data for the years ended December 31, 2014, 2013 and 2012 and the balance sheet data as of December 31, 2014, 2013 and 2012 from our audited financial statements, included elsewhere in this report. Our historical results for any prior period are not necessarily indicative of results to be expected for the full year or in any future period.

	YEARS ENDED DECEMBER 31,		
	2014	2013	2012
	(in thousands, except share and per share amounts)		
Statements of Operations Data:			
Total revenues	$6,433	$1,599	$2,960
Operating expenses:			
Cost of product sales	638	669	1,518
Research and development	22,746	11,554	8,604
General and administrative	12,927	4,433	3,713
Total operating expenses	36,311	16,656	13,835
Loss from operations	(29,878)	(15,057)	(10,875)
Interest and other income (expense)	4	37	35
Change in fair value of convertible preferred stock warrant liability	(4,277)	(955)	—
Net loss attributable to common stockholders	$(34,151)	$(15,975)	$(10,840)
Basic and diluted net loss per share attributable to common stockholders(1)	$(4.56)	$(43.48)	$(30.43)
Weighted-average shares used to compute basic and diluted net loss per share attributable to common stockholders(1)	7,494,790	367,437	356,215

(1) See Note 3 of our financial statements included elsewhere herein for an explanation of the method used to compute basic and diluted net loss per share of common stock and the weighted-average number of shares used in computation of the per share amounts.

	AS OF DECEMBER 31,		
	2014	2013	2012
	(in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	$75,354	$30,387	$12,762
Working capital	66,035	28,695	11,068
Total assets	78,383	30,965	14,252
Convertible preferred stock warrant liability	—	3,336	—
Convertible preferred stock	—	81,394	51,726
Total stockholders' equity (deficit)	66,346	(55,834)	(40,120)

Table of Contents

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, future financial performance, expense levels and liquidity sources, includes forward-looking statements that involve risks and uncertainties. You should read the “Risk Factors” section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage immunotherapy company with next-generation in vivo approaches designed to enable the body’s immune system to fight disease. We have engineered our technologies to activate the immune system’s natural ability to create tumor-specific cytotoxic T cells and fight cancer. We are developing multiple product candidates from our two discovery platforms, ZVex™ and GLAAS™, which we believe have the potential to treat a broad patient population. Our product candidates, LV305, CMB305 and G100, utilize multiple immuno-oncology approaches and, we believe, address the shortcomings of existing therapies. LV305 and G100 are in Phase 1 clinical trials and we expect to initiate a Phase 1 clinical trial for CMB305 by the end of the year. CMB305 combines our two platforms in a prime-boost approach that we believe should be more effective than either LV305 or G305 alone. Although we plan to focus our development efforts on CMB305 and G100, we plan to conduct a small exploratory trial to compare LV305 and CMB305 in the same tumor types. After reviewing those data, we may elect to separately develop LV305.

We have devoted substantially all of our resources since inception to our drug development efforts, including undertaking clinical trials of our product candidates, development of our ZVex and GLAAS discovery platforms, conducting preclinical studies, protecting our intellectual property and providing general and administrative support to our product development activities. To date, we have funded our operations primarily through proceeds from the issuance of our stock, payments received under license and collaboration agreements and GLA product sales. From inception in February 2008 through December 31, 2014, we have raised or earned a total of $164.6 million in cash, including:

$150.3 million from the sale and conversion of common stock, convertible preferred stock and warrants;

$10.8 million from the licensing of our technology; and

$3.5 million from GLA product sales and contract research services.

Our net loss was $34.2 million, $16.0 million and $10.8 million for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, we had an accumulated deficit of $90.8 million. We have incurred net losses to date and we expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will significantly increase as we:

complete our current and planned Phase 1 clinical trials;

advance clinical development of CMB305 and G100 into Phase 2 clinical studies;

perform additional process development for our product candidates, including initial commercial scale up efforts;

seek regulatory approvals for our product candidates, if any, that successfully complete clinical trials;

establish a sales, marketing and distribution infrastructure to commercialize and market products for which we obtain regulatory approval;

maintain, expand and protect our intellectual property portfolio;

continue research and development efforts to build our pipeline beyond the current product candidates;

hire additional clinical, quality control, scientific and management personnel; and

add operational and financial personnel to support our product development efforts and operational support applicable to operating as a public company.

We do not expect to generate significant revenue unless and until we successfully complete development of, obtain marketing approval for and commercialize our product candidates, either alone or in collaboration with third parties.

58

Table of Contents

We expect these activities will take a number of years and our success in these efforts is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to the regulatory approval and commercialization of any of our product candidates. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operating activities through public or private equity or debt financings, collaborations or licenses, capital lease transactions or other available financing transactions. However, we may be unable to raise additional funds through these or other means when needed, on favorable terms or at all.

Financial Overview

Revenue

Collaboration and Licensing Revenue

We derive our revenue from collaboration and licensing agreements and the sale of products associated with material transfer, collaboration and GLA supply agreements. We have recognized $6.4 million, $1.6 million and $3.0 million in revenue in 2014, 2013 and 2012, respectively. We may generate revenue in the future from payments from future license or collaboration agreements, product sales or government contracts and grants. We expect that any revenue we generate will fluctuate from quarter to quarter.

In August 2014, we entered into an agreement with Sanofi under which we granted Sanofi an exclusive license for use of our GLAAS platform to discover, develop and commercialize products to treat an undisclosed food allergy. Upon execution of the agreement, we received a $3.5 million upfront payment, recognized as revenue during the year ended December 31, 2014. The agreement provides for additional payments based upon the attainment of certain development and commercialization milestones, and tiered royalties on sales of approved products.

In October 2010, we entered into three separate license agreements with MedImmune pursuant to which we granted MedImmune a worldwide, sublicensable, exclusive license to use GLA to develop and sell vaccines in three different infectious disease indications. MedImmune paid us upfront payments under the license agreements in 2010. Under each license agreement, MedImmune is obligated to make additional payments based on the achievement of certain developmental, regulatory and commercial milestones for the licensed indication. For the year ended December 31, 2014, we received milestone payments of $1.0 million associated with the license agreements. MedImmune is also obligated to pay us a low double-digit percentage share of any non-royalty payments that it receives from sublicensees and mid single-digit royalty payments on net sales of licensed products, which royalty is subject to reduction under certain circumstances.

From time to time, we also enter into non-exclusive license arrangements, material transfer agreements or option agreements with respect to GLA in specified non-oncology indications. The parties with whom we contract are in certain cases obligated to make additional payments based on achievement of milestones.

In October 2014, we entered into a collaboration with Sanofi Pasteur for the development of a Herpes Simplex Virus, or HSV, immune therapy. Sanofi Pasteur and Immune Design will each contribute product candidates to the collaboration: Sanofi Pasteur will contribute HSV-529, a clinical-stage replication-defective HSV vaccine product candidate, and Immune Design will contribute G103, our preclinical trivalent vaccine product candidate. The collaboration will explore the potential of various combinations of agents, including leveraging Immune Design's GLAAS platform, with the goal to select the best potential immune therapy for patients. Each company will develop the products jointly through Phase 2 clinical trials, at which point Sanofi Pasteur intends to continue development of the most promising candidate and be responsible for commercialization. Sanofi Pasteur will bear the costs of all preclinical and clinical development, with Immune Design providing a specific formulation of GLA from the GLAAS platform at its cost through Phase 2 studies. Immune Design will be eligible to receive future milestone and royalty payments on any product developed from the collaboration. For the year ended 2014, we recognized $1.1 million in other, net revenue associated with payments received by Sanofi for development costs incurred to date for our development of G103.

GLA Product Sales

We sell formulations of GLA to selected companies for use in ongoing preclinical studies and clinical trials. All revenues associated with the sale of GLA supplied by us are reported as GLA product sales with the applicable costs reported under cost of product sales. In 2014, 2013, and 2012 we recognized approximately $0.9 million, $0.9 million and $1.9 million in revenues, respectively, and $0.6 million, $0.7 million and $1.5 million in cost of GLA product

sales, respectively, through these arrangements.

Table of Contents

Research and Development Expenses

We focus our resources on our internal and collaborative research and development activities, including the conduct of preclinical studies, product development, activities related to regulatory filings for our product candidates and clinical trials. We recognize our research and development expenses as they are incurred.

We account for research and development costs on a program-by-program basis. The table below summarizes our direct research and development expenses for the periods indicated. Our direct research and development expenses consist principally of external costs, such as fees paid to CMOs, CROs, consultants, clinical trial sites and for contract research services. We typically use our employee and infrastructure resources across multiple research and development programs, and therefore do not allocate salaries, stock-based compensation, employee benefit or other indirect costs related to our research and development to specific product candidates. Those expenses are included in "Indirect research and development expense by type" in the table below:

	YEARS ENDED DECEMBER 31,		
	2014	2013	2012
	(in thousands)		
Direct research and development expense by platform:			
ZVex	$7,934	$4,370	$2,889
GLAAS	6,685	2,269	800
G103	999	—	—
Other	115	216	1,014
Total direct research and development program expense	15,733	6,855	4,703
Indirect research and development expense by type:			
Personnel related costs	5,538	3,294	2,309
Research and development supplies and services	741	818	1,241
Allocated facility, equipment, travel and other expense	734	587	351
Total indirect research and development expense	7,013	4,699	3,901
Total research and development expense	$22,746	$11,554	$8,604

We plan to increase our research and development expenses for the foreseeable future as we continue to develop our product candidates. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our product candidates or the period in which material net cash, if any, from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

the scope, rate of progress, expense and results of our ongoing and additional clinical trials that we may conduct;
the scope, rate of progress and expense of process development;
other research activities; and
the timing of regulatory approvals.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance, information technology and human resources functions. Other significant general and administrative expenses include professional fees for accounting and legal services, expenses associated with obtaining and maintaining patents and other intellectual property and allocation of facilities costs.

We expect that our general and administrative expenses will increase as we continue to expand infrastructure to support operating as a public company. These increases will likely include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel and increased fees for directors, outside consultants, lawyers and accountants. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to public companies.

60

Table of Contents

Interest and other income

Interest and other income consists of interest income earned on our cash and cash equivalents, and marketable securities and the gain or loss on the disposal of property and equipment, if any.

Change in Fair Value of Convertible Preferred Stock Warrant Liability

In October 2013, in connection with the issuance of the Series C convertible preferred stock, we issued fully exercisable warrants for the purchase of 1,975,532 shares of our Series C convertible preferred stock at an exercise price of $8.175 per share. The warrants were recorded at fair value at issuance, at each subsequent reporting date, and immediately prior to their exercise in July 2014. Immediately prior to the closing of our Initial Public Offering, or IPO, the preferred stock warrants were exercised in full and the preferred shares issued upon exercise were automatically converted to common stock upon the closing of our initial public offering, or IPO; accordingly, we no longer record a related periodic fair value adjustment.

Results of Operations

Comparison of Years Ended December 31, 2014 and 2013

The following table summarizes our results of operations for the years ended December 31, 2014 and 2013:

	TWELVE MONTHS ENDED DECEMBER 31,		INCREASE/ DECREASE
	2014	2013	
	(in thousands)		
Total revenues	$6,433	$1,599	$4,834
Operating expenses:			
Cost of product sales	638	669	(31)
Research and development	22,746	11,554	11,192
General and administrative	12,927	4,433	8,494
Total operating expenses	36,311	16,656	19,655
Loss from operations	(29,878)	(15,057)	(14,821)
Interest and other income	4	37	(33)
Change in fair value of convertible preferred stock warrant liability	(4,277)	(955)	(3,322)
Net loss attributable to common stockholders	$(34,151)	$(15,975)	$(18,176)

Total Revenues and Cost of Product Sales

Revenues increased by $4.8 million to $6.4 million in 2014 from $1.6 million in 2013. This increase was primarily due to a $3.8 million increase in licensing revenue derived from our GLAAS licensing agreements with Sanofi and MedImmune to develop therapeutic agents using GLA and a $1.1 million increase in collaboration revenue recorded from our Sanofi Pasteur G103 HSV collaboration. There was no material change in 2014 from 2013 in product sales and the associated cost of product sales.

Research and Development Expenses

Our research and development expenses increased by $11.2 million to $22.7 million in 2014 from $11.6 million in 2013. This increase was primarily attributable to an increase of $5.9 million to support LV305, G305 and G103 product development and manufacturing, a $2.2 million increase in clinical costs to support the G100, G305 and LV305 Phase 1 clinical trials, and a $2.3 million increase in personnel-related expenses as a result of growth in research and development headcount to support our programs and a $0.8 million increase in licensing and other research and development expenses.

General and Administrative Expenses

Our general and administrative expenses increased by $8.5 million to $12.9 million in 2014 from $4.4 million in 2013. The increase was primarily attributable to a $5.2 million increase in litigation support costs, a $1.2 million increase in professional services to support operating as a public company and a $2.1 million increase in personnel-related and facilities expenses, primarily related to an increase in administrative headcount to support the growth and expansion of our business.

Change in Fair Value of Convertible Preferred Stock Warrant Liability

The increase in fair value of the convertible preferred stock warrant liability was driven by an increase in the valuation of our stock. There were no warrants outstanding as of December 31, 2014.

Table of Contents

Comparison of Fiscal Years Ended December 31, 2013 and 2012

The following table summarizes the results of our operations for the years ended December 31, 2013 and 2012:

	YEARS ENDED DECEMBER 31,		INCREASE/ DECREASE
	2013	2012	
	(in thousands)		
Total revenues	$1,599	$2,960	$(1,361)
Operating expenses:			
Cost of product sales	669	1,518	(849)
Research and development	11,554	8,604	2,950
General and administrative	4,433	3,713	720
Total operating expenses	16,656	13,835	2,821
Loss from operations	(15,057)	(10,875)	(4,182)
Interest and other income	37	35	2
Change in fair value of convertible preferred stock warrant liability	(955)	—	(955)
Net loss attributable to common stockholders	$(15,975)	$(10,840)	$(5,135)

Total Revenue and Cost of Product Sales

Revenues decreased by $1.4 million to $1.6 million in 2013 from $3.0 million in 2012. The decrease was primarily attributable to a $1.0 million decrease as a result of fewer GLA sales and a $0.4 million decrease in licensing revenue and other revenue attributable to a research collaboration that completed in 2012. The $0.8 million decrease in the cost of product sales was the result of the decrease in GLA sales.

Research and Development Expenses

Our research and development expenses increased by $3.0 million to $11.6 million in 2013 from $8.6 million in 2012. The increase was primarily attributable to an increase of $1.4 million in contract manufacturing and development to support the LV305 Phase 1 clinical trial, an increase of $0.9 million of clinical costs to support the start of G100 and G305 Phase 1 clinical trials and a $0.7 million increase in personnel-related expenses as a result of growth in research and development headcount to support clinical development.

General and Administrative Expenses

Our general and administrative expenses increased by $0.7 million to $4.4 million in 2013 from $3.7 million in 2012. The increase was primarily attributable to the $0.6 million increase in professional service fees in support of our patent portfolio and a $0.1 million increase in personnel-related expenses and facilities, primarily related to an increase in administrative headcount to support the growth and expansion of our business.

Change in Fair Value of Convertible Preferred Stock Warrant Liability

The $1.0 million decrease in other income is from the revaluation of the convertible preferred stock warrant liability which was driven by an increase in the valuation of our common stock. There were no 2013 warrants outstanding during 2012.

Liquidity and Capital Resources

Since our inception through December 31, 2014, we have raised a total of $164.6 million in cash, including $150.3 million from the sale of our common stock, convertible preferred stock and warrants and the exercise of the warrants in connection with our IPO, $10.8 million from the licensing of our technology and $3.5 million primarily from GLA sales and contract research services.

In July 2014, we completed our IPO of 5,000,000 shares of our common stock, at a price of $12.00 per share. In August 2014, we sold an additional 410,564 shares of common stock directly to our underwriters when they exercised a portion of their over-allotment at $12.00 per share. We received net proceeds of $57.8 million (inclusive of the exercise of the over-allotment) after deducting underwriting discounts and commissions and offering expenses. In connection with the closing of the IPO, all outstanding shares of convertible preferred stock automatically converted into 9,769,422 shares of common stock. In July 2014, prior to the completion of the IPO, warrants to purchase 996,940 shares of common stock were exercised for $8.1 million in cash and resulted in the issuance of an additional 996,940 shares of common stock. Immediately prior to the closing of the IPO, warrants to purchase 978,592 shares

were automatically net exercised, resulting in an issuance of an additional 311,923 shares of common stock. The significant number of shares issued in July 2014 is expected to impact the year-over-year comparability of our net loss per share calculations through the third quarter of 2015. As of December 31, 2014, we had cash and cash equivalents totaling $75.4 million.

Table of Contents

In addition to our existing cash and cash equivalents, we are eligible to receive research and development funding and to earn milestone and other contingent payments for the achievement of defined collaboration objectives and certain development, regulatory and commercial milestones and royalty payments under our collaboration agreements. Our ability to earn these milestone and contingent payments and the timing of achieving these milestones is primarily dependent upon the outcome of our collaborators' research and development activities and is uncertain at this time.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical and preclinical research and development services, including manufacturing, laboratory and related supplies, legal, patent and other regulatory expenses and general overhead costs. We believe our use of CROs and contract manufacturers provides us with flexibility in managing our spending and limits our cost commitments.

Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, that we can generate substantial product revenues, we expect to finance our cash needs through collaboration arrangements and, if necessary, equity or debt financings. Except for any obligations of our collaborators to reimburse us for research and development expenses or to make milestone or royalty payments under our agreements with them, we do not have any committed external source of liquidity. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents as of December 31, 2014 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of developing products and testing them in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our clinical trials, preclinical studies and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings, including FDA review of any Biologics License Application, or BLA, we file;
- payments required with respect to development milestones we achieve under our in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- the costs of current or future litigation or judgments;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish collaborative arrangements to the extent necessary;
- revenues received from any existing or future products; and
- payments received under any current or future strategic partnerships.

Table of Contents

Cash Flows

The following is a summary of cash flows for the years ended December 31, 2014, 2013 and 2012:

	YEARS ENDED DECEMBER 31,		
	2014	2013	2012
	(in thousands)		
Net cash used in operating activities	$(20,669)	$(14,298)	$(9,578)
Net cash used in investing activities	(344)	(132)	(294)
Net cash provided by financing activities	65,980	32,055	10,626

Net Cash Used in Operating Activities

Net cash used in operating activities was $20.7 million for the year ended December 31, 2014 and consisted of our net loss of $34.2 million offset by non-cash charges of $0.2 million for depreciation and amortization, $1.3 million for stock-based compensation expense, and a $4.3 million non-cash loss for the revaluation of convertible preferred stock warrant liabilities. The net change in operating assets and liabilities was $7.7 million.

Net cash used in operating activities was $14.3 million for the year ended December 31, 2013 and consisted of our net loss of $16.0 million offset by non-cash charges of $0.4 million for depreciation and amortization, $0.3 million for stock-based compensation expense, and a $1.0 million non-cash loss for the revaluation of convertible preferred stock warrant liabilities.

Net cash used in operating activities was $9.6 million for the year ended December 31, 2012 and consisted of our net loss of $10.8 million offset by non-cash charges of $0.5 million for depreciation and amortization and $0.2 million for stock-based compensation expense. The net change in operating assets and liabilities was $0.5 million.

Net Cash Used in Investing Activities

Net cash used in investing activities was $0.3 million, $0.1 million, and $0.3 million for the years ended December 31, 2014, 2013, and 2012 and primarily relates to the purchase of property and equipment, primarily lab equipment to support research and development efforts.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $66.0 million for the year ended December 31, 2014 and consisted primarily of $57.8 million in net proceeds from the IPO and $8.1 million from the cash exercise of the preferred stock warrants.

Net cash provided by financing activities was $32.1 million for the year ended December 31, 2013. In October 2013, we sold approximately 4 million shares of our Series C convertible preferred stock and approximately 2 million of our 2013 warrants for net proceeds of $32.1 million, of which $2.4 million was allocated to the 2013 warrants.

Net cash provided by financing activities was $10.6 million for the year ended December 31, 2012. In November 2012, we sold shares of Series B convertible preferred stock for net proceeds of $10.6 million.

Contractual Obligations and Contingent Liabilities

The following summarizes our significant contractual obligations as of December 31, 2014:

CONTRACTUAL OBLIGATIONS	TOTAL	LESS THAN 1 YEAR	1 TO 3 YEARS	3 TO 5 YEARS	MORE THAN 5 YEARS
	(in thousands)				
Operating leases [1]	$2,579	$718	$1,074	$755	$32
Total obligations	$2,579	$718	$1,074	$755	$32

(1) Represents future minimum lease payments under non-cancelable operating leases in effect as of December 31, 2014, for our facilities in Seattle, Washington and South San Francisco, California. The minimum lease payments above do not include common area maintenance charges or real estate taxes. Additionally, we were required to provide a $121,000 letter of credit as a security deposit on one of our leases, of which no funds had been drawn down as of December 31, 2014. See Note 9 for further discussion of lease terms.

The contractual obligations table above does not include any potential future milestone payments to third parties as part of certain collaboration and licensing agreements, which could total up to $2.4 million in aggregate payments for

the first licensed GLA product we develop, up to $1.3 million in aggregate payments for each subsequent

Table of Contents

licensed GLA product we develop and up to $1.9 million in aggregate payments for ZVex products we develop. It also does not include any potential future royalty payments we may be required to make under our licensing agreements as described in Note 10 to our financial statements appearing elsewhere in this report.

Payments under these agreements are not included in the above contractual obligations table due to the uncertainty of the occurrence of the events requiring payment under these agreements, including our share of potential future milestone and royalty payments. These payments generally become due and payable only upon achievement of certain clinical development, regulatory or commercial milestones.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing at the end of this report, we believe that the following accounting policies are the most critical to fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

We derive our revenue from collaboration and licensing agreements and the sale of products associated with material transfer, collaboration and GLA supply agreements.

Licensing fees are recognized when the amounts are earned and determinable during the applicable period. We recognize up-front nonrefundable license fees when due under contractual agreements and when we do not have a continuing obligation to provide services related to the agreement. Revenue associated with nonrefundable up-front license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected term of our continued involvement in the research and development process. Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved, and the milestone payments are due and collectible. If not deemed substantive, we recognize such milestones as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process.

Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable, (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value. Payments received in advance of work performed are recorded as deferred revenue.

Certain agreements from which we derive our revenue include multiple deliverables. We recognize the revenue of each deliverable at fair value, determined to be the estimated selling price in cases where neither vendor-specific objective evidence nor third-party evidence is available.

Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price to the customer is fixed or determinable; and (4) collectability is reasonably assured. The evaluation of these revenue recognition criteria requires significant management judgment. For instance, we use judgment to assess collectability based on factors such as the customer's creditworthiness and past collection history, if applicable. If we determine that collection of a payment is not reasonably assured, revenue recognition is deferred until receipt of payment. We also use judgment to assess whether a price is fixed or determinable including but not limited to, reviewing contractual terms and conditions related to

payment terms.

Table of Contents

Revenue from product sales of GLA is recognized when the risk of loss has passed to the customer or deferred until such time that risk of loss has passed. All revenues associated from the sale of GLA supplied by us are reported under product sales with the applicable costs reported under cost of product sales. Product sales consist of the direct costs associated with the manufacture and formulation of GLA, including costs to purchase raw materials, third-party contract manufacturing costs, assay testing and ongoing product stability testing.

Accrued Liabilities

Accrued liabilities represent accrued compensation including vacation accruals, unearned revenue and accrued expenses. As part of the process of preparing our financial statements, we are required to estimate our accrued professional services and research and development expenses. This process involves reviewing contracts and vendor agreements, communicating with our applicable personnel to identify services that have been performed on our behalf. We estimate the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us.

We base our expenses related to contract manufacturing and clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple contract manufacturing organizations and clinical research organizations that conduct and manage supply and clinical studies on our behalf. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. To date, we have not experienced any significant adjustments to our estimates.

Convertible Preferred Stock Warrant Liability

We accounted for the warrants issued in 2013 in accordance with Accounting Standards Codification, or ASC, Topic 480-10, Distinguishing Liabilities from Equity, which requires that a financial instrument, other than an outstanding share, that, at inception, includes an obligation to repurchase the issuer’s equity shares regardless of the timing or likelihood of the redemption, shall be classified as a liability. We measure the fair value of the warrant liability based on the fair value of the warrants which we determine based on an allocation of our enterprise value to all classes of equity and preferred stock, including the warrants. In valuing the 2013 warrants, we utilized the income method approach in combination with a Monte Carlo simulation, which is a method that evaluates many possible value outcomes to establish the expected value of an asset. This methodology allows the modeling of securities with complex terms, such as the 2013 warrants, where path dependency, floors, caps, triggers, changes of control and down round financing provisions can be taken into account. In each reporting period, we recorded any change in fair value of the warrants as a non-operating gain or loss in our statements of operations.

The estimated fair value of warrants accounted for as liabilities was determined on the issuance date and were subsequently remeasured to fair value at each reporting date. The following Monte Carlo option pricing model assumptions were used:

Upon the issuance in October 2013 of our Series C convertible preferred stock, we used the following input assumptions to estimate fair value: equity value of the entity, different conversion prices for different scenarios, time to maturity of 1.7 to 2.0 years under the different exercise scenarios, volatility of 82% and a risk free interest rate of 0.3%.

For December 31, 2013, we used the following input assumptions to estimate fair value: equity value of the entity, different conversion prices for different scenarios, time to maturity of 1.2 to 1.7 years under the different exercise scenarios, volatility of 82% and risk free interest rate of 0.3%.

In July 2014, immediately prior to the closing of the IPO all of our convertible preferred stock warrants were exercised. As of the exercise date, we used our IPO price to estimate the fair value of the warrants. Upon exercise of the warrants, the convertible preferred stock warrant liability was reclassified to stockholders' equity (deficit). See note 8 for additional discussion of the warrant exercise.

66

Table of Contents

The following table shows the reconciliation of the convertible preferred stock warrant liability measured and recorded at fair value on a recurring basis (in thousands):

	ESTIMATED FAIR VALUE
Balance as of January 1, 2013	$—
Fair value at issuance of convertible preferred stock warrant liability (October 16, 2013)	2,381
Change in fair value of convertible preferred stock warrant liability	955
Balance as of December 31, 2013	3,336
Change in fair value of convertible preferred stock warrant liability	4,277
Conversion and exercise of preferred stock warrant into shares of common stock	(7,613)
Balance as of December 31, 2014	$—

Stock-Based Compensation

In accordance with ASC 718, Stock Compensation, we determine the fair value of stock options and other stock-based compensation issued to employees as of the grant date. We recognize the fair value of stock-based compensation as compensation expense over the requisite service period, which is the vesting period. We also record stock options and other stock-based compensation issued to non-employees at their fair value as of the grant date. We then periodically remeasure the awards to reflect the current fair value at each reporting period and recognize expense over the related service period.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in our statements of operations as follows:

	YEARS ENDED DECEMBER 31,		
	2014	2013	2012
Employee:			
Research and development	$421	$40	$30
General and administrative	703	111	75
Non-Employee:			
Research and development	216	39	43
General and administrative	4	65	96
Total stock-based compensation expense	$1,344	$255	$244

We calculate the fair value of stock-based compensation awards using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the use of subjective assumptions, including the expected term of the stock options, stock price volatility, risk free interest rate and the fair value of the underlying common stock on the date of grant. We used the following assumptions in the model:

We determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant.

The expected term represents the period that the stock-based awards are expected to be outstanding. Our historical option exercise experience does not provide a reasonable basis upon which to estimate an expected term because of a lack of sufficient data. Therefore we estimate the expected term by using the “simplified method,” which calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

Table of Contents

We do not have sufficient history to estimate the volatility of our common stock price. We calculate expected volatility based on reported data for selected, reasonably similar publicly traded companies for which the historical information is available. For the purpose of identifying peer companies, we consider characteristics such as industry, stage of development, market capitalization, risk profile, length of trading history and similar vesting terms. We plan to continue to use the guideline peer group volatility information until the historical volatility of our common stock is relevant to measure expected volatility for future option grants.

The assumed dividend yield is based on our expectation of not paying dividends in the foreseeable future.

The assumptions that we used in the Black-Scholes option pricing model are set forth below:

	YEARS ENDED DECEMBER 31,		
	2014	2013	2012
Weighted-average estimated fair value	$9.32	$2.31	$0.97
Risk-free interest rate	1.54% - 2.16%	0.97% - 1.99%	0.93% - 1.19%
Expected term of options (in years)	5.50 - 6.75	5.45 - 6.08	5.85 - 6.07
Expected stock price volatility	90% - 93%	90%	90%
Expected dividend yield	—%	—%	—%

The amount of stock-based compensation expense we recognize during a period is based on the value of the portion of the awards that we expect to ultimately vest. We estimate forfeitures for employee grants at the time of grant, and revise the estimates, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Ultimately, the actual expense recognized over the vesting period will only represent those options that vest. Changes in the estimated forfeiture rate can have a significant impact on our stock-based compensation expense as the cumulative effect of adjusting the rate is recognized in the period the forfeiture estimate is changed. For instance, if a revised forfeiture rate is lower than the previously estimated forfeiture rate, we make an adjustment that will result in an increase to the stock-based compensation expense recognized in our financial statements. To date, our forfeitures have been immaterial.

Prior to our IPO, our board of directors periodically determined the per share fair value of our common stock at various dates using valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, also known as the Practice Aid. We performed these valuations contemporaneously as of December 31, 2012, October 16, 2013 and March 31, 2014. For financial reporting purposes, we also performed a retrospective valuation on December 31, 2013. Upon the completion of our IPO, the fair value of our common stock has been determined by the trading value of our common stock on NASDAQ.

In conducting the private company valuations, our board of directors, with input from management and independent third-party valuation specialists, considered objective and subjective factors that we believed to be relevant for each valuation conducted, including our best estimate of our business condition, prospects and operating performance at each valuation date. Within the valuations performed, we used a range of factors, assumptions and methodologies. The significant factors included:

the rights, preferences and privileges of our convertible preferred stock as compared to those of our common stock, including the liquidation preferences of our convertible preferred stock;

our results of operations, financial position and the status of research and development efforts;

the lack of liquidity of our common stock as a private company;

our stage of development and business strategy and the material risks related to our business and industry;

the likelihood of achieving a liquidity event for the holders of our common stock and stock options, such as a sale of our company given prevailing market conditions;

Table of Contents

- the achievement of corporate objectives, including entering into collaboration and license agreements, and the likelihood of entering into such agreements;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the life sciences and biotechnology industry sectors;
- the state of the IPO market for similarly situated privately held biotechnology companies;
- general U.S. economic conditions; and
- our most recent valuations prepared in accordance with methodologies outlined in the Practice Aid.

The dates of our valuations have not always coincided with the dates of our stock-based compensation grants. Our board of directors granted all options at exercise prices per share not less than the per share fair value of our common stock underlying those options on the grant date.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an “emerging growth company” until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.0 billion or more, (b) the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering in July 2014, (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates and concentration of credit risk. As of December 31, 2014, we had cash and cash equivalents of $75.4 million consisting of bank deposits and interest-bearing money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities. Additionally, our cash balances deposited in a bank in the United States may be in excess of insured levels.

We contract with contract manufacturers internationally. Transactions with these providers are predominantly settled in U.S. dollars and, therefore, we believe that we have only minimal exposure to foreign currency exchange risks. We do not hedge against foreign currency risks.

Item 8. Financial Statements and Supplementary Data.

69

Table of Contents

The financial statements required by this Item 8 are set forth beginning at page F-1 of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2014, Management, including our President and Chief Executive Officer and Vice President, Finance and Administration, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), as of the end of the period covered by this report. Based upon the evaluation, our President and Chief Executive Officer and Vice President, Finance and Administration concluded that the disclosure controls and procedures were effective to ensure that information required to be disclosed in the reports we file and submit under the Securities Exchange Act of 1934, as amended, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including our President and Chief Executive Officer and Vice President, Finance and Administration, as appropriate to allow timely discussion regarding required disclosure.

Management’s Annual Report on Internal Control Over Financial Reporting

This report does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies. Additionally, our auditors will not be required to formally opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an “emerging growth company” as defined in the JOBS Act as we have taken advantage of the exemptions available to us through the JOBS Act.

Changes in Internal Control Over Financial Reporting

There have been no significant changes in our internal control over financial reporting during our most recent fiscal quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Table of Contents

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Executive Compensation," "Director Compensation" and "Committees of the Board of Directors - Compensation Committee Interlocks and Insider Participation" in our Proxy Statement.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans" in our Proxy Statement.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled "Transactions with Related Persons" and "Election of Directors" in our Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to the information set forth in the section titled "Ratification of Appointment of Independent Registered Public Accounting Firm" in our Proxy Statement.

Table of Contents

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The financial statements schedules and exhibits filed as part of this Annual Report on Form 10-K are as follows:

(1) Financial Statements

Reference is made to the financial statements included in Item 8 of Part II hereof.

(2) Financial Statement Schedules

All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(3) Exhibits

The exhibits required to be filed as part of this report are listed in the Exhibit List attached hereto and are incorporated herein by reference.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, as amended, the registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

IMMUNE DESIGN CORP.
(Registrant)

Date: March 31, 2015

/s/ Carlos Paya, M.D., Ph.D.
Carlos Paya, M.D., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 31, 2015

/s/ Paul Rickey
Paul Rickey
Vice President, Finance and Administration
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Carlos Paya, M.D., Ph.D. and Stephen Brady, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Table of Contents

Pursuant to the requirements of the Securities Exchange 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.

SIGNATURE	TITLE	DATE
/s/ Carlos Paya, M.D., Ph.D. Carlos Paya, M.D., Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2015
/s/ Paul Rickey Paul Rickey	Vice President, Finance and Administration (Principal Accounting Officer and Principal Financial Officer)	March 31, 2015
/s/ Ed Penhoet, Ph.D. Ed Penhoet, Ph.D.	Chairman of the Board	March 31, 2015
/s/ Brian Atwood Brian Atwood	Director	March 31, 2015
/s/ David Baltimore, Ph.D. David Baltimore, Ph.D.	Director	March 31, 2015
/s/ Franklin Berger Franklin Berger	Director	March 31, 2015
/s/ William Ringo William Ringo	Director	March 31, 2015
/s/ Lewis Coleman Lewis Coleman	Director	March 31, 2015
/s/ Peter Svennilson Peter Svennilson	Director	March 31, 2015

Table of Contents

IMMUNE DESIGN CORP
INDEX TO FINANCIAL STATEMENTS

Table of Contents

IMMUNE DESIGN CORP
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Immune Design Corp.

We have audited the accompanying balance sheets of Immune Design Corp. (the "Company") as of December 31, 2014 and 2013, and the related statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2014. 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 financial position of the Company at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP
Seattle, Washington
March 31, 2015

Table of Contents

IMMUNE DESIGN CORP
BALANCE SHEETS
(in thousands, except share and per share amounts)

	DECEMBER 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$75,354	$30,387
Accounts receivable	1,970	87
Inventory	25	17
Prepaid expenses	633	179
Total current assets	77,982	30,670
Property and equipment, net	401	295
Total assets	$78,383	$30,965
Liabilities, convertible preferred stock, and stockholders' equity		
Current liabilities:		
Accounts payable	$6,903	$866
Accrued liabilities	5,001	1,082
Deferred rent, current	43	27
Total current liabilities	11,947	1,975
Other noncurrent liabilities	90	94
Convertible preferred stock warrant liability	—	3,336
Commitments and contingencies		
Convertible preferred stock, $0.001 par value per share; 10,000,000 and 12,882,593 shares authorized at December 31, 2014 and 2013, respectively; zero and 9,769,422 shares issued and outstanding at December 31, 2014 and 2013, respectively; liquidation preference of zero and $84,300 at December 31, 2014 and 2013, respectively	—	81,394
Stockholders' equity (deficit):		
Common stock, $0.001 par value per share; 100,000,000 and 15,045,871 shares authorized at December 31, 2014 and 2013, respectively; 16,878,817 and 369,460 shares issued and outstanding at December 31, 2014 and 2013, respectively	17	3
Additional paid-in capital	157,092	775
Accumulated deficit	(90,763)	(56,612)
Total stockholders' equity (deficit)	66,346	(55,834)
Total liabilities, convertible preferred stock and stockholders' equity	$78,383	$30,965

The accompanying notes are an integral part of these financial statements.

Table of Contents

IMMUNE DESIGN CORP
STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	YEARS ENDED DECEMBER 31,		
	2014	2013	2012
Revenues:			
Licensing revenue	$4,500	$729	$876
Product sales	881	870	1,877
Other, net	1,052	—	207
Total revenues	6,433	1,599	2,960
Operating expenses:			
Cost of product sales	638	669	1,518
Research and development	22,746	11,554	8,604
General and administrative	12,927	4,433	3,713
Total operating expenses	36,311	16,656	13,835
Loss from operations	(29,878)	(15,057)	(10,875)
Interest and other income	4	37	35
Change in fair value of convertible preferred stock warrant liability	(4,277)	(955)	—
Net loss attributable to common stockholders	$(34,151)	$(15,975)	$(10,840)
Basic and diluted net loss per share attributable to common stockholders	$(4.56)	$(43.48)	$(30.43)
Weighted-average shares used to compute basic and diluted net loss per share attributable to common stockholders	7,494,790	367,437	356,215

The accompanying notes are an integral part of these financial statements.

Table of Contents

IMMUNE DESIGN CORP
STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share and per share amounts)

	CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' (DEFICIT) EQUITY
	SHARES	AMOUNT	SHARES	AMOUNT			
Balance, December 31, 2011	4,688,191	$41,111	349,051	$3	$ 259	$ (29,797)	$ (29,535)
Issuance of Series B convertible preferred stock for cash at $9.41 per share, net of issuance costs of $10	1,130,165	10,615	—	—	—	—	—
Exercise of stock options	—	—	11,910	—	11	—	11
Stock-based compensation	—	—	—	—	244	—	244
Net loss	—	—	—	—	—	(10,840)	(10,840)
Balance, December 31, 2012	5,818,356	51,726	360,961	3	514	(40,637)	(40,120)
Issuance of Series C convertible preferred stock for cash at $8.18 per share, net of issuance costs of $251	3,951,066	29,668	—	—	—	—	—
Exercise of stock options	—	—	8,499	—	6	—	6
Stock-based compensation	—	—	—	—	255	—	255
Net loss	—	—	—	—	—	(15,975)	(15,975)
Balance, December 31, 2013	9,769,422	81,394	369,460	3	775	(56,612)	(55,834)
Issuance of common stock at $12.00 per share upon completion of IPO, net of offering costs of $7,100	—	—	5,410,564	5	57,802	—	57,807
Conversion of convertible preferred stock to common stock	(9,769,422)	(81,394)	9,769,422	10	81,384	—	81,394
Issuance of common stock upon cash and net exercise of warrants for $12.00 per share	—	—	1,308,863	1	8,149	—	8,150
	—	—	—	—	7,613	—	7,613

Conversion of preferred stock warrant liability to additional paid-in capital	—	—	—	—	2	—	—
Reverse stock split true-up	—	—	—	(2)	2	—	—
Exercise of stock options	—	—	20,508	—	23	—	23
Stock-based compensation	—	—	—	—	1,344	—	1,344
Net loss	—	—	—	—	—	(34,151)	(34,151)
Balance, December 31, 2014	—	$—	16,878,817	$17	$ 157,092	$ (90,763)	$ 66,346

The accompanying notes are an integral part of these financial statements.

Table of Contents

IMMUNE DESIGN CORP
STATEMENTS OF CASH FLOWS
(in thousands)

	YEARS ENDED DECEMBER 31,		
	2014	2013	2012
Operating activities			
Net loss	$(34,151)	$(15,975)	$(10,840)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	238	407	548
Stock-based compensation expense	1,344	255	244
Revaluation of convertible preferred stock warrant liability	4,277	955	—
Other	—	94	23
Changes in operating assets and liabilities:			
Accounts receivable	(1,883)	426	(452)
Inventory	(8)	109	(252)
Prepaid expenses	(454)	8	152
Accounts payable	6,037	(213)	504
Accrued liabilities	3,955	(453)	623
Deferred rent	(24)	89	(128)
Net cash used in operating activities	(20,669)	(14,298)	(9,578)
Investing activities			
Purchases of property and equipment	(344)	(175)	(294)
Proceeds from the sale of property and equipment	—	43	—
Net cash used in investing activities	(344)	(132)	(294)
Financing activities			
Net proceeds from issuance of common stock upon initial public offering	57,807	—	—
Proceeds from exercise of preferred stock warrants	8,150	—	—
Proceeds from exercise of stock options	23	6	11
Proceeds from sale of convertible preferred stock, net of cash paid for issuance costs	—	29,668	10,615
Proceeds from sale of convertible preferred stock warrants	—	2,381	—
Net cash provided by financing activities	65,980	32,055	10,626
Net increase in cash and cash equivalents	44,967	17,625	754
Cash and cash equivalents, beginning of period	30,387	12,762	12,008
Cash and cash equivalents, end of period	$75,354	$30,387	$12,762
Supplemental disclosures:			
Conversion of shares of preferred stock into shares of common stock	81,394	—	—
Conversion of preferred stock warrants into shares of common stock	7,613	—	—

The accompanying notes are an integral part of these financial statements.

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS

1. Description of the Business

Immune Design Corp. (we, us or our) is a clinical-stage immunotherapy company with next-generation in vivo approaches designed to enable the body's immune system to fight disease. We have engineered our technologies to activate the immune system's natural ability to create tumor-specific cytotoxic T cells (CTLs) to fight cancer. We are developing multiple product candidates from our two discovery platforms, IMDZVex™ ("ZVex™") and GLAAS™. Our product candidates, LV305, CMB305 and G100, utilize multiple immuno-oncology approaches and are in Phase 1 clinical trials and we expect to initiate a Phase 1 clinical trial for CMB305 in the first quarter of 2015. CMB305 combines our two platforms, LV305 and a second agent G305, in a prime-boost approach. G305 is based on our GLAAS platform and is in a Phase 1 clinical trial. Although we plan to focus our development efforts on CMB305 and G100, we plan to conduct a small exploratory trial to compare LV305 and CMB305 in the same tumor types. After reviewing those data, we may elect to separately develop LV305.

We were incorporated in February 2008 in the State of Delaware. Our operations are headquartered in Seattle, Washington with additional facilities in South San Francisco, California.

Initial Public Offering

In July 2014, we completed an initial public offering (the IPO) of 5,000,000 shares of common stock at a price of $12.00 per share. In August 2014, we sold an additional 410,564 shares of common stock directly to our underwriters when they exercised portions of their over-allotment on two separate occasions at $12.00 per share. We received net proceeds of $57.8 million (inclusive of the exercise of the over-allotment) after deducting underwriting discounts and commissions and offering expenses totaling $7.1 million. In connection with the closing of the IPO, all outstanding shares of convertible preferred stock automatically converted into 9,769,422 shares of common stock. In July 2014, prior to the completion of the IPO, warrants to purchase 996,940 shares of common stock were exercised for $8.1 million in cash. Immediately prior to the closing of the IPO, warrants to purchase 978,592 shares were automatically net exercised, resulting in an issuance of an additional 311,923 shares of common stock. The significant number of shares issued in the third quarter of 2014 is expected to impact the year-over-year comparability of our net loss per share calculations through the third quarter of 2015. Upon completion of the IPO, the total shares of common stock authorized was 100,000,000 and the total shares of preferred stock authorized was 10,000,000.

Reverse Stock Split

On July 14, 2014, we filed an amendment to our amended and restated certificate of incorporation, effecting a 1-for-8.175 reverse stock split. All issued and outstanding stock and per share amounts contained in our financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). To conform with GAAP, the preparation of our financial statements requires management to make judgments, assumptions, and estimates that affect the amounts reported in our financial statements and accompanying notes. Estimates are used for, but not limited to, accruals for clinical trial activity, other accrued liabilities, and assumptions used in determining stock-based compensation expenses and convertible preferred stock warrant liability. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable. Actual results could differ materially from those estimates.

Segments

We operate in one segment and use cash flow as the primary measure to manage our business and do not segment the business for internal reporting or decision-making purposes.

Cash and Cash Equivalents

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and consist of investments in money market funds. In addition, we maintain cash balances with financial institutions in excess of

insured limits and do not anticipate any losses on such cash balances.

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Concentration of Risk
We limit our credit risk associated with cash and cash equivalents by placing our deposits with banks we believe are highly creditworthy and our investments with highly rated money market funds.
Accounts Receivable
Accounts receivable are amounts due from other companies related primarily to licensing fees, product sales and research and development services. We considered the need for an allowance for doubtful accounts and have concluded that no allowance was needed as of December 31, 2014 or 2013, as the estimated risk of loss on our accounts receivable was determined to be minimal.
Inventory
Inventory is recorded at the lower of cost or market. Cost includes amounts related to materials and labor, and is determined on a specific identification basis in a manner which approximates the first-in, first-out method. We record adjustments to inventory for potentially excess, obsolete, expired, or impaired items. We recorded $0 and $126,000 in cost of product sales associated with the expiration and obsolescence of products in 2014 and 2013, respectively.
Property and Equipment
Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over an estimated useful life that is generally three years, while leasehold improvements are amortized over the shorter of their estimated useful lives or the related lease term. 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. Maintenance and repairs are expensed as incurred. Asset improvements are capitalized.
Impairment of Long-Lived Assets
Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or any other significant adverse change that would indicate that the carrying amount of an asset is not recoverable.
Accrued Liabilities
Accrued liabilities represent accrued compensation including vacation accruals, unearned revenue and accrued expenses. As part of the process of preparing our financial statements, we are required to estimate our accrued professional services and research and development expenses. This process involves reviewing contracts and vendor agreements, communicating with our applicable personnel to identify services that have been performed on our behalf. We estimate the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us.
We base our expenses related to contract manufacturing and clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple contract manufacturing organizations and clinical research organizations that conduct and manage supply and clinical trials on our behalf. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. To date, we have not experienced any significant adjustments to our estimates.
Leases and Deferred Rent
We have entered into lease agreements for laboratory and office facilities. These leases are classified as operating leases. Rent expense is recognized on a straight-line basis over the term of the lease. Incentives granted under our facilities leases, including allowances to fund leasehold improvements and rent escalations are accrued as deferred

rent. Leasehold improvements funded by the lessor are capitalized and are recognized as reductions to rental expense on a straight-line basis over the term of the lease.

Series C Convertible Preferred Stock Warrant Liability

We account for our warrants in accordance with Accounting Standards Codification (ASC) Topic 480-10, Distinguishing Liabilities from Equity, which requires that a financial instrument, other than an outstanding share, that, at inception, includes an obligation to repurchase the issuer's equity shares regardless of the timing or likelihood of the redemption, shall be classified as a liability. We measure the fair value of the warrant liability based on the fair value of the warrants which we determine based on an allocation of our enterprise value to all classes of equity and preferred stock, including the warrants. In valuing the warrants, we utilized the income method approach in combination with a Monte Carlo simulation, which is a method that evaluates many possible value outcomes to establish the expected value of an asset. This methodology allows the modeling of securities with complex terms, such as the warrants, where path dependency, floors, caps, triggers, changes of control and down round financing provisions can be taken into account. In each reporting period, we record any change in fair value of the warrants as a non-operating gain or loss in the statements of operations. See note 11 for additional information.

Revenue Recognition

We derive our revenue from collaboration and licensing agreements and the sale of products associated with material transfer, collaboration and supply agreements.

Licensing fees, are recognized when the amounts are earned and determinable during the applicable period. We recognize up-front nonrefundable license fees when due under contractual agreements and when we do not have a continuing obligation to provide services related to the agreement. Revenue associated with nonrefundable up-front license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected term of our continued involvement in the research and development process. Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved, and the milestone payments are due and collectible. If not deemed substantive, we recognize such milestones as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process.

Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable, (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value. Payments received in advance of work performed are recorded as unearned revenue.

Certain agreements from which we derive our revenue include multiple deliverables. We recognize the revenue for each deliverable at fair value determined to be estimated selling price in cases when neither vendor specific objective evidence nor third-party evidence is available.

Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price to the customer is fixed or determinable; and (4) collectability is reasonably assured. The evaluation of these revenue recognition criteria requires significant management judgment. For instance, we use judgment to assess collectability based on factors such as the customer's creditworthiness and past collection history, if applicable. If we determine that collection of a payment is not reasonably assured, revenue recognition is deferred until receipt of payment. We also use judgment to assess whether a price is fixed or determinable including but not limited to, reviewing contractual terms and conditions related to payment terms.

Revenue from product sales of GLA is recognized when the risk of loss has passed to the customer or deferred until such time that risk of loss has passed. All revenues associated from the sale of GLA products supplied by us are reported under product sales with the applicable costs reported under cost of product sales. Product sales consist of the direct costs associated with the manufacture and formulation of GLA, including costs to purchase raw materials,

third-party contract manufacturing costs, assay testing and ongoing product stability testing.

We consider significant revenue concentrations to be customers who account for 10% or more of total revenues generated by us during the periods presented. We had collaboration partners that accounted for 55%, 28% and 16% of revenue for the year ended December 31, 2014, 77% and 13% of revenue for the year ended December 31, 2013; 50%, 34% and 12% of revenue for the year ended December 31, 2012. The collaboration

partners owed a total of 100% of accounts receivable as of December 31, 2014 and 2013, respectively. We do not believe the loss of such customers would have a material adverse effect on us.

Stock-Based Compensation

We account for stock-based compensation under the fair value method. Stock-based compensation costs related to employees and directors is measured at the grant date, based on the fair-value-based measurement of the award estimated using the Black-Scholes option-pricing model, and is recognized as expense over the requisite service period on a straight-line basis.

Options granted to non-employee service providers are accounted for at estimated fair value using the Black-Scholes option-pricing model and are remeasured over the vesting term as earned.

We recognize compensation expense for only the portion of options expected to vest. Therefore, management applied an estimated forfeiture rate that was derived from historical employee termination behavior. If the actual number of forfeitures differs from these estimates, adjustments to compensation expense may be required in future periods.

Research and Development

Research and development costs are expensed as incurred. Research and development costs primarily include personnel costs, materials and manufacturing to support clinical trials, fees paid to consultants and outside service providers, costs to conduct clinical trials and allocated overhead. Amounts incurred in connection with collaboration agreements are also included in research and development expense. Payments made prior to the receipt of goods or services to be used in research and development are deferred until the goods or services are received.

Income Taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and the operating loss and tax credit carry forwards. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Deferred tax assets and liabilities are measured at the balance sheet date using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period such tax rate changes are enacted. Our net deferred tax asset has been fully offset by a valuation allowance because of our history of losses. Any potential accrued interest and penalties related to unrecognized tax benefits within operations would be recorded as income tax expense. To date, there have been no interest or penalties charged to us related to the underpayment of income taxes.

Comprehensive Loss

Comprehensive loss is comprised of net loss and certain changes in equity that are excluded from net loss. There was no difference between comprehensive loss and net loss for the years ended December 31, 2014, 2013 and 2012.

Subsequent Events

We consider events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-15, related to an entity’s ability to continue as a going concern. ASU 2014-15 requires an entity's management to evaluate whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Public entities are required to apply ASU 2014-15 for annual reporting periods ending after December 15, 2016, and interim periods thereafter. Early application is permitted. We are evaluating the guidance to determine the potential impact on our results of operations, financial condition, cash flows, and financial statement disclosures.

In May 2014, the FASB, issued ASU No. 2014-09, related to the recognition of revenue. ASU 2014-09 requires entities to recognize revenue through the application of a five step model, which includes identification of the

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. ASU 2014-09 is effective retrospectively for annual or interim reporting periods beginning after December 15, 2016, with early application not permitted. We are evaluating the guidance to determine the potential impact on our results of operations, financial condition, cash flows, and financial statement disclosures.

3. Net Loss Per Share

We compute net loss per share attributable to common stockholders using the two-class method required for participating securities. We consider all series of our convertible preferred stock to be participating securities. In accordance with the two-class method, earnings allocated to these participating securities, which include participation rights in undistributed earnings, are subtracted from net income to determine total undistributed earnings to be allocated to common stockholders.

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Because of net losses recognized in each period, potential common shares issuable upon the exercise of outstanding stock options and warrants and the conversion of preferred shares in the IPO into common shares have not been reflected in the calculation of diluted net loss per share due to the anti-dilutive effect. Diluted net loss per share, therefore, does not differ from basic net loss per share.

The common stock issuable upon the conversion or exercise of the following dilutive securities has been excluded from the diluted net loss per share attributable to common stockholders calculation because their effect would have been antidilutive for the periods presented:

	DECEMBER 31,		
	2014	2013	2012
Convertible preferred stock	—	9,769,422	5,818,356
Options to purchase common stock	1,907,091	1,463,747	634,455
Warrants to purchase convertible preferred stock	—	1,975,532	—
	1,907,091	13,208,701	6,452,811

4. Fair Value of Financial Instruments

We measure and record cash and cash equivalents and convertible preferred stock warrant liabilities at fair value in the accompanying financial statements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value, is as follows:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Level 1 securities consist of highly liquid money market funds. The fair value of Level 1 assets has been determined using quoted prices in active markets for identical assets.

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3 within the valuation hierarchy. The Level 3 preferred stock warrant liability is measured at its estimated fair value on a recurring basis using the income method approach in combination with a Monte Carlo simulation. Inputs used to determine estimated fair value include the estimated fair value of the underlying stock at the valuation measurement date, the multiple scenarios outlining probabilities and the remaining contractual term of

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

the warrants, risk-free interest rates, expected dividends, and the expected volatility of the price of the underlying stock.

The following table summarizes our financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	DECEMBER 31, 2014			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Money market funds	$73,098	$—	$—	$73,098

	DECEMBER 31, 2013			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Money market funds	$30,030	$—	$—	$30,030
Liabilities:				
Convertible preferred stock warrant liability	$—	$—	$3,336	$3,336

We classify the convertible preferred stock warrant liability within Level 3 because the warrant liability is valued using valuation models with significant unobservable inputs. The estimated fair value of warrants accounted for as liabilities was determined on the issuance date and are subsequently remeasured to fair value at each reporting date. The change in fair value of the warrants is recorded in the statements of operations as a non-operating gain or loss by using a Monte Carlo option pricing model with the following assumptions:

Upon the issuance in October 2013 of our Series C convertible preferred stock, we used the following assumptions to estimate fair value: equity value of the entity, different conversion prices for different scenarios, time to maturity of 1.7 to 2.0 years under the different exercise scenarios, volatility of 82% and risk free interest rate of 0.3%.

For December 31, 2013, we used the following assumptions to estimate fair value: equity value of the entity, different conversion prices for different scenarios, time to maturity of 1.2 to 1.7 years under the different exercise scenarios, volatility of 82% and risk free interest rate of 0.3%.

In July 2014, immediately prior to the closing of the IPO all of our convertible preferred stock warrants were exercised. As of the exercise date, we used our IPO price to estimate the fair value of the warrants. Upon exercise of the warrants, the convertible preferred stock warrant liability was reclassified to stockholders' equity (deficit). See note 8 for additional discussion of the warrant exercise.

The following table shows the reconciliation of the convertible preferred stock warrant liability measured and recorded at fair value on a recurring basis, using significant unobservable inputs (Level 3) (in thousands):

	ESTIMATED FAIR VALUE
Balance as of January 1, 2013	$—
Fair value at issuance of convertible preferred stock warrant liability (October 16, 2013)	2,381
Change in fair value of convertible preferred stock warrant liability	955
Balance as of December 31, 2013	3,336
Change in fair value of convertible preferred stock warrant liability	4,277
Conversion of preferred stock warrant liability into additional-paid-in-capital	(7,613)
Balance as of December 31, 2014	$—

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

5. Inventory

Inventory consists of the following (in thousands):

	DECEMBER 31,	
	2014	2013
Raw materials	$—	$13
Finished goods	25	4
Total inventory	$25	$17

6. Property and Equipment

Property and equipment consists of the following (in thousands):

	DECEMBER 31,	
	2014	2013
Laboratory equipment	$2,060	$1,934
Leasehold improvements	135	98
Computer equipment and software	285	188
Office equipment, furniture, and fixtures	124	47
Total	2,604	2,267
Less: accumulated depreciation and amortization	(2,203)	(1,972)
Total property and equipment, net	$401	$295

Depreciation and amortization expense was $238,000, $407,000 and $548,000 for the years ended December 31, 2014, 2013 and 2012, respectively.

7. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	DECEMBER 31,	
	2014	2013
Research and development services	$1,845	$214
Legal and professional services	1,253	191
Employee compensation	1,379	649
Unearned revenue	524	28
Total accrued liabilities	$5,001	$1,082

8. Series C Convertible Preferred Stock Warrant Liability

In October 2013, in connection with the issuance of our Series C convertible preferred stock, we issued fully exercisable warrants for the purchase of 1,975,532 shares of our Series C convertible preferred stock at an exercise price of $8.175 per share.

All warrants were unexercised as of December 31, 2013. The estimated fair value for the 2013 warrants as of December 31, 2013 was $3.3 million. The fair value of the 2013 warrants was determined using the income method valuation model in combination with a Monte Carlo simulation in consideration of multiple early exercise triggers associated with the 2013 warrants.

In April 2014, we amended the warrants to provide for their automatic net exercise if the IPO price exceeded the exercise price, immediately prior to the closing of the IPO. In July 2014, immediately prior to the closing of the IPO, warrants representing 996,940 shares of common stock were exercised for $8.1 million in cash and warrants representing 978,592 shares of common stock were automatically net exercised for a total of 311,923 shares of

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

common stock. Upon exercise of the warrants, the convertible preferred stock warrant liability was reclassified to stockholders' equity (deficit).

9. Commitments and Contingencies

Operating Leases

We entered into a non-cancelable operating sublease agreement in September 2008, for office and research facilities at another Seattle, Washington location, and amended the lease in July 2009, September 2009, March 2010, and April 2010. In August 2012, we entered into a lease directly with the landlord of the building under the same material terms as our sublease, which sublease was then terminated. The lease provided for a leasehold improvement allowance of $448,000, which was reflected on the balance sheet as of December 31, 2012 as a leasehold improvement in property and equipment and as deferred rent. The lease also required us to pay additional amounts for operating and maintenance expenses. In March 2013, the lease for this facility expired and the associated leasehold improvements and accumulated depreciation were disposed as of March 31, 2013.

In December 2012, we entered into an operating sublease agreement for lab and office space at our new location in Seattle, Washington. The lease commenced in February 2013 and continues through November 2016, with an option to extend the term for an additional month. The terms of the facility lease provide for rental payments on a monthly basis and on a graduated scale. We recognize rent expense on a straight-line basis over the lease period and accrue for rent expense incurred but not paid. The lease also requires us to pay additional amounts for operating and maintenance expenses. As of December 31, 2014 and 2013, we have incurred $37,000 and $98,000, respectively, in leasehold improvements related to the lease and have recorded accumulated amortization of $50,000 and $22,000, as of December 31, 2014 and 2013, respectively.

In December 2013, we entered into a new operating lease agreement for office space in South San Francisco, California, and amended the lease in October and November 2014. The amended lease commenced in January 2015 and continues through January 2020, with an option to extend for an additional five years. The terms of the office lease provide for rental payments on a monthly basis and on a graduated scale. We recognize rent expense on a straight-line basis over the lease period and accrue for rent expense incurred but not paid. The lease also requires us to pay additional amounts for operating and maintenance expenses beginning January 2016. With the execution of the amended lease, we were required to provide a $121,000 letter of credit as a security deposit. As of December 31, 2014, no funds had been drawn down on the letter of credit.

As of December 31, 2014, future minimum lease payments are as follows (in thousands):

2015	$718
2016	713
2017	361
2018	372
2019	383
Total future minimum lease payments	$2,547

Rent expense under operating leases was approximately $576,000, $561,000 and $325,000, for the years ended December 31, 2014, 2013 and 2012, respectively.

Contingencies

We are also contingently obligated to pay any potential future milestone payments to third parties as part of certain collaboration and licensing agreements, which could total up to $2.4 million in aggregate payments for the first licensed GLA product we develop, up to $1.3 million in aggregate payments for each subsequent licensed GLA product we develop and up to $1.9 million in aggregate payments for the ZVex products we develop. It also does not include any potential future royalty payments we may be required to make under our licensing agreements as described in Note 10.

Payments under these agreements are uncertain due to the occurrence of the events requiring payment under these agreements, including our share of potential future milestone and royalty payments. These payments

generally become due and payable only upon achievement of certain clinical development, regulatory or commercial milestones.

10. License and Collaboration Agreements

Licenses Granted

In August 2014, we entered into an agreement with Sanofi under which we granted Sanofi an exclusive license for use of our GLAAS platform to discover, develop and commercialize products to treat a selected food allergy. Upon execution of the agreement, we received a $3.5 million upfront payment, recognized as revenue during the year ended December 31, 2014. The agreement provides for additional payments of up to $168.0 million based upon the attainment of certain development and commercialization milestones, and tiered royalties on sales of approved products. Sanofi may terminate the agreement at any time upon six months' written notice.

In October 2010, we entered into three separate license agreements with MedImmune, LLC (MedImmune) pursuant to which we granted MedImmune a worldwide, sublicensable, exclusive license to use GLA to develop and sell vaccines in three different infectious disease indications. In 2010, MedImmune paid us upfront payments under the license agreements. Under each license agreement, MedImmune is obligated to make additional payments based on achievement of certain development, regulatory, and commercial milestones for the licensed indication. MedImmune is also obligated to pay us a low double-digit percentage share of non-royalty payments that it receives from sublicensees and a mid single-digit royalty payments on net sales of licensed products, which royalty is subject to reduction under certain circumstances. Through December 31, 2014, MedImmune has paid us an aggregate of $5.5 million in upfront payments under the license agreements. Under each license agreement, MedImmune is obligated to make additional aggregate payments of $62.9 million to $75.0 million, depending on the infectious disease indication and the achievement of certain development, regulatory and commercial milestones for the licensed indication. For the year ended December 31, 2014 we recognized $1.0 million in revenue for the achievement of development milestones under these license agreements.

In May 2013, we entered into a nonexclusive license agreement granting Medicago, Inc. (Medicago) a right to research, develop, and commercialize GLA in the field of pandemic influenza. Medicago paid an upfront payment of $500,000 under the license agreement, which was recognized as revenue during the year ended December 31, 2013, and is also obligated to make additional payments of up to $9.5 million based on achievement of certain development and government contract milestones for the licensed indication. Medicago is also obligated to pay us a mid single-digit royalty on net sales of licensed products, which royalty is subject to reduction under license expiration.

In October 2011, we entered into an amended material transfer agreement with Sanofi US Services, Inc. which included an exclusive option to license GLA in the field of allergy and contract research support in exchange for multiple scheduled payments. We allocated a portion of the total payments as license income and the remaining portion to contract research services. We recognized $805,000 in license revenue and $200,000 in other revenue associated with this agreement in 2012.

Licenses Acquired

In July 2008, we licensed certain rights to research, develop, and commercialize GLA from the Infectious Disease Research Institute (IDRI) and amended the agreement in 2010. We paid an upfront fee and issued shares of our common stock valued at $59,000 for the license. We recorded the upfront cash payment and the fair value of the common stock as research and development expense in 2008, as the licensed rights had no alternative future use.

In addition, we agreed to pay certain fees in the future if we should elect to continue development of the applicable technologies, including payments upon achievement of certain development and commercialization milestones and royalty payments of single-digit percentage of net sales, if and when commercialized; however, we may terminate our development program at any time without obligation to IDRI. Under our license agreement with IDRI, we are obligated to share with IDRI a percentage of payments received from third-party licensees.

Through December 31, 2014, we have paid IDRI an aggregate of $1.9 million in upfront fees, milestone payments and sublicense revenue related to our sublicensees. We expensed these amounts to research and development expense, as the rights had no alternative future use. In 2013 we paid $140,000 in license related milestone payments which were

expensed in research and development expenses. We are obligated to pay IDRI up to $2.4

million in additional payments based on the achievement of certain developmental and regulatory milestones for the first GLA product, and up to $1.3 million in additional payments based on the achievement of certain developmental and regulatory milestones for each subsequent GLA product.

In 2009, we licensed certain patent rights directed to the production of dendritic cell-targeted therapeutic and prophylactic immunization strategies from the California Institute of Technology (Caltech) in exchange for shares of our common stock valued at $25,000. We make annual minimum royalty payments under the license. In addition, we agreed to pay certain fees in the future, including milestone payments upon achievement of certain development and commercialization milestones and royalty payments on net sales in the low single-digit percentage, if and when commercialized, if we should elect to continue development of the related technology; however, we may terminate our development program at any time without further obligation to Caltech. In addition, we are required to pay Caltech up to an aggregate of $1.6 million in additional payments upon the achievement of certain regulatory and sales milestones.

Collaborations

In October 2014, we entered into a collaboration with Sanofi Pasteur for the development of a Herpes Simplex Virus immune therapy. Sanofi Pasteur and Immune Design will each contribute product candidates to the collaboration: Sanofi Pasteur will contribute HSV-529, a clinical-stage replication-defective HSV vaccine product candidate, and Immune Design will contribute G103, our preclinical trivalent vaccine product candidate. The collaboration will explore the potential of various combinations of agents, including leveraging Immune Design's GLAAS platform, with the goal to select the best potential immune therapy for patients. Each company will develop the products jointly through Phase 2 clinical trials, at which point Sanofi Pasteur intends to continue development of the most promising candidate and be responsible for commercialization. Sanofi Pasteur will bear the costs of all preclinical and clinical development, with Immune Design providing a specific formulation of GLA from the GLAAS platform at its cost through Phase 2 studies. Immune Design will be eligible to receive future milestone and royalty payments on any product developed from the collaboration. The Company recognizes funding from collaborative research and development efforts as revenue as the Company performs or delivers the related services in accordance with contract terms as long as the Company will receive payment for such services upon standard payment terms. The costs of the related services performed are recorded as research and development expenses on the statement of operations. For the year ended December 31, 2014, the Company recognized $1.1 million in revenue under this collaboration arrangement. As of December 31, 2014, the Company has an outstanding receivable of $1.5 million under this collaboration agreement of which $492,000 was unearned.

11. Convertible Preferred Stock

In October 2013, we issued and sold 3,951,066 shares of our Series C convertible preferred stock at a price of $8.18 per share resulting in gross proceeds of $32.3 million, pursuant to a Series C convertible preferred stock and warrant purchase agreement. In connection with the issuance and sale of Series C convertible preferred stock we issued to the purchasers warrants, or 2013 warrants, to purchase an aggregate of 1,975,532 shares of our Series C convertible preferred stock at an exercise price of $8.175 per share.

In November 2012, we received gross proceeds of $10.6 million in exchange for the issuance of 1,130,165 shares of Series B convertible preferred stock at a price per share of $9.41. In aggregate, we received gross proceeds of $34.0 million in exchange for the issuance of 3,616,529 shares of Series B convertible preferred stock at a price per share of $9.41 between October 2010 and November 2012.

In aggregate, we received gross proceeds of $18.0 million in exchange for the issuance of 2,201,827 shares of Series A convertible preferred stock at a price per preferred share of $8.18 between June 2008 and January 2010.

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

A summary of convertible preferred stock is as follows (amounts in thousands, except share and per share data):

	DECEMBER 31, 2013				
	ISSUED PRICE PER SHARE	SHARES AUTHORIZED	SHARES ISSUED AND OUTSTANDING	AGGREGATE LIQUIDATION PREFERENCE	CARRYING VALUE
Series A	$8.18	2,201,834	2,201,827	$ 18,000	$17,922
Series B	$9.41	3,616,539	3,616,529	34,000	33,804
Series C	$8.18	7,064,220	3,951,066	32,300	29,668
		12,882,593	9,769,422	$ 84,300	$81,394

Each holder of convertible preferred stock is entitled to the number of votes equal to the number of our shares of common stock into which such shares of convertible preferred stock are convertible. Each share of convertible preferred stock is convertible at the option of the holder into the number of fully paid and non-assessable shares of common stock that result from dividing the original issue price by the conversion price of the convertible preferred stock. Currently, the conversion ratio for each series of convertible preferred stock is 1:1.

Holders of convertible preferred stock are entitled to receive noncumulative dividends at the rate of 8.0% per annum for each share of convertible preferred stock outstanding, when, and if declared by the board of directors. These dividends are payable in preference to common stock dividends. To date, we have not declared or paid any dividends. Convertible preferred stockholders are also entitled to receive dividends in a per share amount equal, on an as-if-converted basis, to the amount paid or set aside for each share of common stock.

In the event of our liquidation, dissolution, or winding up, the holders of convertible preferred stock will be entitled to receive payment out of the assets legally available for distribution for each share of convertible preferred stock held by them, of an amount per share of convertible preferred stock equal to the original issue price plus all declared and unpaid dividends on the convertible preferred stock. In the event that the available funds and assets are insufficient for full payment to the holders of convertible preferred stock on a per-share basis as outlined above, the entire assets and funds legally available for distribution will be distributed ratably among convertible preferred stock in proportion to the full amount to which they would otherwise be respectively entitled. Before any distribution or payment will be made to the holders of any common stock, payment shall be made first to the holders of Series C preferred stock, second to holders of Series B preferred stock, and third to the holders of Series A preferred stock. Upon completion of the distribution of assets as set forth above, all of the remaining assets, if any, will be distributed ratably among the holders of convertible preferred stock, on an as-if converted basis, and common stock.

In connection with the completion of the Company's IPO in July 2014, all outstanding shares of convertible preferred stock converted into 9,769,422 shares of common stock and all related warrants were exercised. See Note 8 for additional discussion of the exercise of the warrants.

12. Stockholders’ Equity (Deficit)

Common Stock

We had 16,878,817 and 369,460 shares of common stock outstanding as of December 31, 2014 and 2013, respectively. Shares of common stock reserved for future issuance were as follows:

	AS OF DECEMBER 31,	
	2014	2013
Shares to be issued upon conversion of convertible preferred stock	—	9,769,422
Shares to be issued upon exercise of convertible preferred stock warrants and conversion of convertible preferred stock	—	1,975,532
Shares to be issued under the employee stock purchase plan	155,220	—
Shares to be issued upon exercise of outstanding stock options	1,907,091	1,463,747

Shares available for future stock option grants	1,274,067	122,829
Shares of common stock reserved for future issuance	3,336,378	13,331,530

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Equity Incentive Plans

In April 2014, our board of directors adopted, and in July 2014 our stockholders approved the 2014 Employee Stock Purchase Plan (2014 ESPP). Upon the approval of the 2014 ESPP, 155,220 shares of our common stock were reserved for issuance under. The initial offering period has been set and will begin on April 1, 2015 and end on June 30, 2015. As of December 31, 2014, no shares have been purchased under the plan.

The total number of shares of common stock available for issuance under the 2014 ESPP will automatically increase annually on January 1 by (i) the lesser of 1% of the total number of shares issued and outstanding as of December 31 of the immediately preceding year or (ii) 200,000 shares. On January 1, 2015, in accordance with the 2014 ESPP annual increase provisions, the authorized shares increased by 168,788 shares.

In 2008, we adopted the 2008 Equity Incentive Plan (2008 Plan) for eligible employees, officers, directors, and consultants, which provides for the grant of incentive and non-statutory stock options, restricted stock awards, restructured stock unit awards grant, and stock appreciation rights. The terms of the stock awards, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2008 Plan.

In April 2014, our board of directors adopted, and in July 2014 our stockholders approved, the 2014 Omnibus Incentive Plan (2014 Plan) which provides for the granting of certain awards to eligible employees, officers, directors, and consultants. Upon approval of the 2014 Plan by the stockholders in July 2014, 1,400,000 shares of our common stock were reserved for issuance under the 2014 Plan and we ceased granting stock awards under the 2008 Plan. All shares of common stock subject to awards under the 2008 Plan that expire, terminate, or are otherwise surrendered, canceled, forfeited or repurchased without having been fully exercised or resulting in the issuance of common stock become available for issuance under the 2014 Plan.

Stock options granted under the 2008 Plan and 2014 Plan generally vest within four years and vested options are exercisable until ten years after the date of grant. Vesting of certain employee options may be accelerated in the event of a change in control of our company. We grant stock options to employees with exercise prices equal to the fair value of our common stock on the date of grant. There were a total of 1,406,767 shares of common stock authorized under the 2014 Plan as of December 31, 2014.

The total number of shares of common stock available for issuance under the 2014 Plan will automatically increase annually on January 1 by 4% of the total number of shares issued and outstanding as of December 31 of the immediately preceding year. On January 1, 2015, in accordance with the 2014 Plan and annual increase provisions, the authorized shares increased by 675,152 shares.

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Stock Option Activity
Summary stock option information is as follows:

	OPTIONS OUTSTANDING	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACT TERM (IN YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding at January 1, 2013	634,455	$1.12	8.67	
Granted	872,293	$1.27		
Exercised	(8,499)	$0.69		
Canceled	(25,141)	$1.41		
Expired	(9,361)	$1.26		
Outstanding at December 31, 2013	1,463,747	$1.20	8.67	$ 2,552
Granted	512,643	$12.27		
Exercised	(20,508)	$1.14		
Canceled	(47,261)	$3.21		
Expired	(1,530)	$1.48		
Outstanding at December 31, 2014	1,907,091	$4.16	8.16	$ 50,847
Vested and expected to vest after December 31, 2014	1,781,826	$3.94	8.08	$ 47,885
Exercisable at December 31, 2014	790,576	$1.24	6.87	$ 23,352

As of December 31, 2014, there was $6.1 million of total unrecognized stock-based compensation expense related to nonvested stock options that is expected to be recognized over a weighted-average period of 3.3 years. The total intrinsic value of options exercised during the years ended December 31, 2014, 2013 and 2012 was $243,000, $7,000 and $4,000, respectively.

Stock-Based Compensation Expense
Employee stock-based compensation expense recognized was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, as necessary, in subsequent periods if actual forfeitures differ from those estimates. Total stock-based compensation expense recognized in our statements of operations is as follows (in thousands):

	YEARS ENDED DECEMBER 31,		
	2014	2013	2012
Employee:			
Research and development	$421	$40	$30
General and administrative	703	111	75
Non-Employee:			
Research and development	216	39	43
General and administrative	4	65	96
Total stock-based compensation expense	$1,344	$255	$244

We use the Black-Scholes option pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes option pricing model requires us to make certain estimates and assumptions, including assumptions related to the expected price volatility of our stock, the period during which the options will be outstanding, the rate of return on risk-free investments, and the expected dividend yield of our stock.

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

To estimate the fair value of our common stock prior to our IPO, our board of directors periodically determined the per share fair value of our common stock at various dates using valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation. We performed these valuations contemporaneously as of December 31, 2012, October 16, 2013 and March 31, 2014. For financial reporting purposes, we also performed a retrospective valuation on December 31, 2013. Upon the completion of our IPO, the fair value of our common stock has been determined by the trading value of our common stock on NASDAQ.

The fair values of stock options granted to employees were calculated using the following assumptions:

	YEARS ENDED DECEMBER 31,		
	2014	2013	2012
Weighted-average estimated fair value	$9.32	$2.31	$0.97
Risk-free interest rate (1)	1.54% - 2.16%	0.97% - 1.99%	0.93% - 1.19%
Expected term of options (in years) (2)	5.50 - 6.75	5.45 - 6.08	5.85 - 6.07
Expected stock price volatility (3)	90% - 93%	90%	90%
Expected dividend yield (4)	—%	—%	—%

(1) The risk-free interest rate assumption was based on zero-coupon U.S. Treasury instruments that had terms consistent with the expected term of our stock option grants.

(2) We used the “simplified method” for options to determine the expected term of our stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

(3) Volatility is a measure of the amount by which a financial variable, such as share price, has fluctuated or is expected to fluctuate during a period. We analyzed the stock price volatility of companies at a similar stage of development to estimate expected volatility of our stock price.

(4) We have never declared or paid cash dividends and do not presently plan to pay cash dividends in the foreseeable future.

13. Income Taxes

No provision for income taxes has been recorded for the years ended December 31, 2014, 2013 and 2012 due to the operating losses incurred since inception for which no benefit has been recorded.

The reconciliation of the U.S. income tax rate to the effective income tax rate for continuing operations is as follows:

	AS OF DECEMBER 31,			
	2014		2013	
Statutory tax rate	35.00	%	35.00	%
Effect of:				
State income taxes net of federal tax benefit	—		—	
Permanent differences	(5.09	)	(2.41	)
Corrections to deferred assets	—		—	
Other	—		0.35	
General business credits	2.02		5.41	
Change in valuation allowance	(31.93	)	(38.35	)
Effective tax rate	—	%	—	%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Significant components of our deferred taxes are as follows (in thousands):

	AS OF DECEMBER 31,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	$29,052	$18,898
Research and development credit	2,658	1,969
Depreciation and amortization	174	174
Other temporary differences	292	232
Gross deferred tax assets	32,176	21,273
Deferred tax asset valuation allowance	(32,176)	(21,273)
Net deferred tax assets	$—	$—

Realization of deferred tax assets is dependent on future earnings, if any, the timing and amount of which are uncertain. Accordingly, the deferred tax assets have been offset by a valuation allowance. The valuation allowance relates primarily to net deferred tax assets from operating losses and research and development credits. The net deferred tax asset has been fully offset by a valuation allowance. The valuation allowance increased by $10.9 million and $6.1 million during 2014 and 2013, respectively.

As of December 31, 2014 and December 31, 2013, we had approximately $83.0 million and $54.0 million in federal net operating loss carryforwards and approximately $2.7 million and $2.0 million in federal research and development tax credit carryforwards, respectively. The net operating losses and federal research credits will begin to expire in varying amounts between 2028 and 2034 if not utilized.

The Tax Reform Act of 1986 (the Act) provides for a limitation on the annual use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could limit our ability to utilize these carryforwards. We may have experienced an ownership change, as defined by the Act, as a result of past financings. Accordingly, our ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore, we may not be able to take full advantage of these carryforwards for federal income tax purposes.

Certain net operating losses arise from the deductibility for tax purposes of compensation under nonqualified stock options equal to the difference between the fair value of the stock on the date of exercise and the exercise price of the options. For financial reporting purposes, the tax effect of this deduction when recognized is accounted for as a credit to stockholders' equity. We do not have any excess tax deductions on option exercises.

We file income tax returns in the U.S. federal jurisdiction as well and plan to file in the state of California. We are not currently under audit in any tax jurisdiction. Tax years from 2008 through 2014 are currently open for audit by federal and state taxing authorities.

We recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. During the years ended December 31, 2014 and 2013, we did not have any accrued interest or penalties associated with unrecognized benefits. Additionally, we did not have any unrecognized tax benefits at December 31, 2014 or 2013.

14. Legal Proceedings

TheraVectys SA v. Immune Design Corp.

In October 2013, TheraVectys SA, or TVS, a French biotechnology company, filed a complaint against us in the United States District Court for the District of Delaware. TVS alleged that it had entered into a contractual relationship with Henogen SA, or Henogen, in 2010 with respect to the production of lentiviral vector vaccines for TVS. Henogen is a contract manufacturing organization with which we contracted for the manufacture of our LV305 product candidate. TVS alleged that its contractual relationship with Henogen contained an exclusivity provision limiting Henogen's ability to participate in the manufacturing process of a vaccine based on lentiviral DNA Flap vectors for third parties, as well as a provision preventing Henogen from sharing or using certain TVS confidential

technology for manufacturing processes developed by TVS with or for the benefit of others. TVS alleged that we

entered into a contractual relationship with Henogen in 2012 to manufacture lentiviral vectors for vaccines, which TVS contends interfered with its contract with Henogen and resulted in the use of certain TVS confidential information and trade secrets. The complaint asserted three counts for relief: tortious interference with contractual relationship, unfair competition and misappropriation of trade secrets. TVS did not specify its claimed damages, other than to assert that they exceed $75,000. TVS also requested in its complaint injunctive relief enjoining us from importing, receiving possessing or using lentiviral vector vaccines developed or produced by Henogen, but never filed a motion seeking injunctive relief. The parties entered into several stipulations extending the deadline for us to respond to the complaint. On or about April 7, 2014, TVS filed a Notice of Voluntary Dismissal without prejudice of this lawsuit.

On or about July 24, 2014, shortly after our Registration Statement on Form S-1 was declared effective by the SEC for our initial public offering, TVS filed a new complaint against us in the Chancery Court of the State of Delaware, alleging facts substantially similar to the prior complaint. In addition, the complaint further alleges that we obtained shipments of lentiviral vectors for vaccines from Henogen and are conducting clinical trials with these lentiviral vectors. The complaint asserts four counts for relief: tortious interference with contractual relationship, unfair competition, misappropriation of trade secrets, and unjust enrichment; claimed damages were not specified. The complaint also requested injunctive relief enjoining us from using lentiviral vectors developed or produced by Henogen, using any other materials or information obtained by Henogen, and citing to the FDA or otherwise relying on any clinical trials using lentiviral vector vaccines developed or produced by Henogen.

On or about July 24, 2014, TVS also filed a motion for expedited proceedings in support of an anticipated motion for preliminary injunction. On August 8, 2014 the court granted TVS' motion for expedited proceedings and set a hearing date in mid-November 2014 for TVS' anticipated motion for preliminary injunction. In September 2014, TVS filed a motion to postpone the hearing date and delay the proceedings it previously sought to expedite. The court granted the motion and set a new date for the hearing. On or about December 15, 2014, TVS filed a motion for a preliminary injunction seeking, among other things, to enjoin us from making any use of lentiviral vectors pending final resolution of the litigation. A hearing was held on TVS's motion in January 2015.

By order dated March 9, 2015, the Chancery Court denied TVS' motion for a preliminary injunction. The court has not yet made any final determination on the merits of the lawsuit, which will be determined at a full trial which we expect will occur prior to the end of the third quarter of 2015. We intend to continue to vigorously defend this lawsuit.

European Patent Oppositions

In February 2013, a third party filed an opposition at the European Patent Office, or EPO, requesting revocation of European Patent No. 2068918 directed to GLA formulations and uses. This patent is owned by Infectious Disease Research Institute and under license to us. We are vigorously defending the grant of this patent, with a reply to the opposition brief having been filed on September 27, 2013. No date for an oral hearing has yet been set. This patent is an important part of our proprietary position for GLA in Europe. The final outcome of the proceedings is uncertain and will likely not be known for several years.

In October 2014, TVS filed an opposition at the EPO requesting revocation of European Patent No. 2456786 directed at improvements to our lentiviral vector. This opposition is not substantively related to the ongoing Delaware lawsuit previously disclosed, and to our knowledge, TVS is not using the technology claimed in this patent. We intend to vigorously defend the grant of this patent, and in light of other European patents and patent applications directed to our lentiviral platform technology, we do not believe the validity of this patent will have a material effect on the scope of our patent protection in Europe.

15. Employee Benefit Plan

We sponsor a 401(k) defined contribution plan for our employees. Employee contributions are voluntary. We may match employee contributions in amounts to be determined at our sole discretion. Currently, we have elected to satisfy the safe-harbor rules by matching contributions equal to 100% of employee salary deferrals that do not exceed 3% of the employee's compensation, plus 50% matching employee salary deferrals between 3% and 5% of the employee's compensation. Employer contributions have totaled approximately $153,000, $110,000, and $101,000 for the years ended December 31, 2014, 2013, and 2012 respectively.

Table of Contents
IMMUNE DESIGN CORP
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

16. Selected Quarterly Financial Information (Unaudited)
The following amounts are in thousands, except per share amounts:

	Quarter Ended March 31, 2014 (unaudited)	June 30, 2014	September 30, 2014	December 31, 2014
Total revenues	$25	$1,064	$3,544	$1,800
Net loss attributable to common stockholders	$(8,223)	$(6,126)	$(6,682)	$(13,120)
Basic and diluted net loss per share attributable to common stockholders	$(22.25)	$(16.57)	$(0.55)	$(0.78)

	Quarter Ended March 31, 2013 (unaudited)	June 30, 2013	September 30, 2013	December 31, 2013
Total revenues	$564	$882	$129	$24
Net loss attributable to common stockholders	$(2,941)	$(3,634)	$(3,994)	$(5,406)
Basic and diluted net loss per share attributable to common stockholders	$(8.14)	$(9.84)	$(10.81)	$(14.71)

17. Subsequent Events
By order dated March 9, 2015, the Chancery Court denied TVS' motion for a preliminary injunction. The court has not yet made any final determination on the merits of the lawsuit, which will be determined at a full trial which we expect will occur prior to the end of the third quarter of 2015. We intend to continue to vigorously defend this lawsuit.

Table of Contents

INDEX TO EXHIBITS

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
3.1	Amended and Restated Certificate of Incorporation of Immune Design Corp. (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2014).
3.2	Bylaws of Immune Design Corp. (incorporated herein by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
4.1	Specimen Common Stock Certificate of Immune Design Corp. (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.1	Amended and Restated Investor Rights Agreement, dated October 16, 2013, by and among Immune Design Corp. and the investors named therein (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.2+	Immune Design Corp. 2008 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.3+	Form of Option Agreement under the Immune Design Corp. 2008 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.4+	Immune Design Corp. 2014 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-8 (File No. 333-197748), as filed with the SEC on July 31, 2014).
10.5+	Form of Incentive Stock Option Agreement under the Immune Design Corp. 2014 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A (File No. 333-196979), as filed with the SEC on July 14, 2014).
10.6+	Form of Non-Qualified Option Agreement under the Immune Design Corp. 2014 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1/A (File No. 333-196979), as filed with the SEC on July 14, 2014).
10.7+	Immune Design Corp. 2014 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-8 (File No. 333-197748), as filed with the SEC on July 31, 2014).
10.8+	Employment Agreement, dated June 20, 2014, by and between Immune Design Corp. and Carlos Paya, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).

10.9+	Employment Agreement, dated June 19, 2014, by and between Immune Design Corp. and Wayne Gombotz, Ph.D. (incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.10+	Employment Agreement, dated June 23, 2014, by and between Immune Design Corp. and Stephen Brady (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.11+	Employment Agreement, dated June 19, 2014, by and between Immune Design Corp. and Jan Henrik ter Meulen, M.D. (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.12+	Employment Agreement, dated June 19, 2014, by and between Immune Design Corp. and Richard Kenney (incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.13+	Employment Agreement, dated June 18, 2014, by and between Immune Design Corp. and Paul Rickey (incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).

Table of Contents

10.14+	Form of Indemnification Agreement, by and between Immune Design Corp. and each of its directors and officers (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.15†	Amended and Restated License Agreement, dated November 5, 2010, by and between Immune Design Corp. and the Infectious Disease Research Institute (incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.16†	License Agreement, dated January 16, 2013, by and between Immune Design Corp. and The University of North Carolina at Chapel Hill (incorporated herein by reference to Exhibit 10.20 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on July 17, 2014).
10.17†	License Agreement, dated January 1, 2009, by and between Immune Design Corp. and the California Institute of Technology (incorporated herein by reference to Exhibit 10.21 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.18	Office Lease, dated November 21, 2013, by and between Immune Design Corp. and BXP 601& 651 Gateway Center LP, formerly known as Gateway Center LLC (incorporated herein by reference to Exhibit 10.22 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.19	First Amendment to Office Lease, dated October 27, 2014, by and between Immune Design Corp. and BXP 601 & 651 Gateway Center LP, formerly known as Gateway Center LLC.
10.20	Second Amendment to Office Lease, dated November 20, 2014, by and between Immune Design Corp. and BXP 601 & 651 Gateway Center LP, formerly known as Gateway Center LLC.
10.21	Sublease Agreement, dated December 20, 2012, by and between Immune Design Corp. and The Board of Regents of the University of Washington (incorporated herein by reference to Exhibit 10.23 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
23.1	Consent of Ernst & Young LLP.
24.1	Power of Attorney (included on the signature page to this registration statement).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certifications of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the Annual Report on Form 10-K of Immune Design Corp. for the year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) the Balance

Sheets, (ii) the Statements of Operations, (iii) the Statements of Convertible Preferred Stock and Stockholders' Deficit, (iv) the Statements of Cash Flow and (v) Notes to Financial Statements.

+ Indicates a management contract or compensatory plan.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

† Registrant has been granted confidential treatment for certain portions of this exhibit. This exhibit omits the information subject to this confidentiality treatment. Omitted portions have been filed separately with the SEC.