GENOCEA BIOSCIENCES, INC.
Form 10-K
March 21, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2013

or

o 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 001-36289

Genocea Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	**51-0596811** (I.R.S. Employer Identification No.)
100 Acorn Park Drive **Cambridge, Massachusetts** (Address of principal executive offices)	**02140** (Zip Code)

Registrant s telephone number, including area code: **(617) 876-8191**

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.001 par value	**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. o Yes x No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. o Yes x No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. o Yes x No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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 has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes o No

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 definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

EXPLANATORY NOTE: Under the Jumpstart Our Business Startups Act, the registrant qualifies as an emerging growth company. We therefore incorporate the scaled disclosures required of an emerging growth company in this Annual Report on Form 10-K.

Aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the last sale price for such stock on March 14, 2014: $243,967,654. The registrant has provided this information as of March 14, 2014 because its common stock was not publicly traded as of the last business day of its most recently completed fiscal quarter.

The number of shares outstanding of the registrant s common stock as March 14, 2014 was 17,310,770.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. The words anticipate , believe , contemplate , continue , could , estimate , expect , forecast , goal , intend , may , plan , potential , pred will , would , or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- the timing of results of our ongoing and planned clinical trials for GEN-003 and GEN-004;
- our estimates regarding the amount of funds we require to complete our two planned Phase 2 clinical trials for GEN-003 and our initiated Phase 1 trial and planned Phase 2a trial for GEN-004;
- our estimate for when we will require additional funding;
- our plans to commercialize GEN-003 and our other vaccine candidates;
- the timing of, and our ability to, obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- the potential benefits of strategic partnership agreements and our ability to enter into selective strategic partnership arrangements;
- our ability to quickly and efficiently identify and develop product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;

- our intellectual property position; and

- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the Risk Factors section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make or collaborations or strategic partnerships we may enter into.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to the Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I

Item 1. Business

Unless the context requires otherwise, references in this Annual Report on Form 10-K to Genocea , we , us and our refer to Genocea Biosciences, Inc.

Overview

We are a clinical stage biotechnology company that discovers and develops novel vaccines to address infectious diseases for which no vaccine or vaccines with limited effectiveness exist today. We use our proprietary discovery platform, ATLAS, to rapidly design vaccines that act through T cell (or cellular) immune responses, in contrast to approved vaccines, which are designed to act primarily through B cell (or antibody) immune responses. We believe that by harnessing T cells we can develop first-in-class vaccines to address infectious diseases where T cells are central to the control of the disease. In September 2013, we announced human proof-of-concept data for GEN-003, an immunotherapy, or therapeutic vaccine, candidate that we are developing to treat herpes simplex virus-2, or HSV-2, infections. These data from our ongoing Phase 1/2a trial represent the first reported instance of a vaccine significantly reducing viral shedding, an indicator of disease activity in HSV-2. If GEN-003 successfully completes clinical development and is approved, we believe it would represent a first-in-class vaccine for patients with HSV-2. We are also developing a second T cell vaccine, GEN-004 to protect against *Streptococcus pneumoniae*, or pneumococcus, a leading cause of infectious disease mortality worldwide. We have initiated a Phase 1 trial for GEN-004, which we anticipate completing by mid-2014. This Phase 1 trial is designated to demonstrate that T cell response associated with natural protection against pneumococcus. If this trial is successful, we plan to conduct a Phase 2 clinical trial to seek to demonstrate that GEN-004 can reduce pneumococcus in humans by mid-2015.

Vaccines represent a major healthcare success story, having eradicated or significantly reduced the global prevalence of many infectious diseases. To date, all approved vaccines have been developed primarily to elicit B cell responses. However, there remain many infections for which no effective vaccines or only partially effective vaccines exist. A major reason is that the organisms that cause these infections largely evade the antibody immune response generated by B cells, which can generally only address pathogens in the bloodstream. Such organisms may reside in host cells or mucosal surfaces of the nose and throat. To address these pathogens, vaccines targeting responses from the T cell arm of the immune system may present the solution.

We believe T cell vaccine discovery has been particularly challenging for two reasons. First, the diversity of human T cell responses contrasts with the generally uniform B cell responses in humans. Second, the number of candidate targets for T cell responses can be exponentially greater than for B cell responses. These complexities represent fundamental barriers that traditional vaccine discovery tools, which rely largely on empirically selecting the potential targets from the proteins of a pathogen and iteratively testing them in animal models, have not been able to address.

We have designed the ATLAS platform to overcome these T cell vaccine discovery challenges. We believe ATLAS represents the most comprehensive high throughput system for T cell vaccine discovery in the biopharmaceutical industry. ATLAS is designed to mimic one important part of the human immune system in a laboratory setting. Using ATLAS, we are able to measure T cell responses to the entire set of protein targets for a specific pathogen in blood samples from large, genetically diverse populations, allowing us to identify vaccine targets associated with protective T cell responses to disease. By comparing antigens identified in individuals who naturally control their infection with those who do not, we can select the antigens that may have the best likelihood of inducing protective T cell immune responses.

We have generated human proof-of-concept data for our lead product candidate, GEN-003, which we designed using ATLAS. GEN-003 is a therapeutic vaccine, or immunotherapy, candidate we are developing to treat people with HSV-2 infections. In data from our ongoing Phase 1/2a trial, we have shown that GEN-003 significantly reduces HSV-2 viral shedding in patients with moderate-to-severe infections. Shedding is an important marker of the disease, indicating that the virus has been released to skin cells, leading to symptomatic outbreaks and to transmission through sexual contact. We believe this represents the first time a vaccine has been shown to reduce HSV-2 viral shedding in humans. We also believe it represents the first time anti-viral efficacy has been observed for a vaccine designed primarily to elicit T cell responses to address an infectious pathogen for which T cell immunity is considered central to the control of the disease. Our ongoing clinical trial of GEN-003 is fully enrolled, and we expect to complete this trial and initiate a Phase 2 trial in mid-2014 to confirm these results and optimize a vaccine dose.

Our second program derived from ATLAS is GEN-004, a universal pneumococcal T cell vaccine that we are developing to protect against all strains of pneumococcus, the most common cause of bacterial pneumonia in the world. We have initiated a Phase 1 clinical trial of GEN-004 to evaluate its safety and immunogenicity in healthy subjects.

We believe we are a leader in the field of T cell vaccine discovery and development. Our management and scientific teams possess considerable experience in vaccine and anti-infective research, manufacturing, clinical development and regulatory matters. We have also assembled a team of leading advisors, led by George Siber, M.D., to guide the further development of our programs. Previously, Dr. Siber was the Chief Scientific Officer of Wyeth Vaccines, where he led the development of several first-in-class vaccines including the pneumococcal vaccine, Prevnar, the top selling vaccine in the world by value. He is also an inventor of Respigam and Cytogam, the first antibodies approved to protect against respiratory syncytial virus and cytomegalovirus, respectively. Dr. Siber is one of our directors and chairs our Scientific Advisory Board.

Since our inception and through December 31, 2013, we have received an aggregate of $92.0 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $6.7 million in grant revenue. We have spent approximately $40.5 million on research and development from 2011 through 2013.

Our Strategy

Our objective is to be the leading T cell vaccine company. Key components of our strategy are:

- **Continue to rapidly advance our lead vaccine candidate, GEN-003.** GEN-003 is a potential first-in-class therapeutic vaccine candidate we are developing to treat HSV-2 infections, for which we are currently conducting a Phase 1/2a trial. We intend to commence a Phase 2 trial in mid-2014 to optimize the vaccine dose, and a Phase 2b trial in mid-2015 to optimize the dosing regimen. We retain all rights to GEN-003 and plan to advance this program through regulatory approval and commercialize this vaccine through a focused commercial effort in the United States. Outside the United States, we intend to evaluate partnerships for GEN-003 opportunistically.

- **Advance GEN-004 into human proof-of-concept clinical trials.** Our second clinical-stage product candidate is GEN-004, a vaccine candidate designed to prevent infections caused by all strains of pneumococcus. We have demonstrated proof-of-concept of GEN-004 in mice. We have initiated a clinical trial GEN-004, and we believe we can demonstrate our novel T cell-based mechanism of action by mid-2014 and we can achieve human proof-of-concept in our Phase 2a clinical trial with GEN-004 by mid-2015. We believe such trials would provide the first evidence in humans that T cells could enable a universal vaccine against all strains of pneumococcus. We retain all rights to this program, other than certain rights we have granted in developing countries, and intend to opportunistically partner this program.

- **Advance our discovery stage and preclinical novel vaccine programs.** We expect similarly to advance our novel preclinical prophylactic vaccine programs against chlamydia, HSV-2 and malaria through human proof of concept. We will seek partnerships opportunistically for late-stage development and commercialization of such programs.

- **Utilize ATLAS, our vaccine discovery platform, to develop additional T cell vaccine candidates.** We intend to continue to use ATLAS to discover and advance novel T cell vaccines. Since we begin our vaccine candidate discovery process by profiling human populations

exposed to a pathogen, and use these subjects own cells to comprehensively screen the entire proteome of the pathogens, we believe we have a better chance of identifying vaccines likely to protect against pathogens of interest. We intend to opportunistically expand our pipeline using ATLAS to discover T cell vaccines against pathogens for which B cell vaccines are ineffective or non-existent.

Vaccine Overview

Vaccines represent a major healthcare success story. They have eradicated smallpox and dramatically reduced the mortality and morbidity associated with many other infectious diseases, such as diphtheria, measles, polio and tetanus. Today, there are vaccines approved to treat and protect against approximately 30 infectious diseases. Total global vaccine revenues in 2012 were $27 billion.

Vaccines trace their roots to the smallpox vaccine, first tested in 1796 by Edward Jenner. Dr. Jenner demonstrated that he could protect subjects against smallpox by inoculating them with cow pox, a similar virus. More than 200 years later, the concept of a vaccine remains the same: training the immune system to respond to an infectious pathogen by exposing it to that pathogen, or a component of that pathogen, in a controlled way. Most vaccines are prophylactic, preventing an invading organism from causing disease. A vaccine can also be therapeutic, fighting an existing infection.

How Vaccines Work

Vaccines rely on an ability of the human immune system called adaptive immunity to remember an invading organism and develop an immune response to it. When confronted with a new organism, the immune system first seeks to eliminate the pathogen through an initial response of the so-called innate immune system and then generates immunological memory, or adaptive immunity, in which the immune system recognizes and remembers the invasive pathogen in order to combat it in the future. A vaccine introduces a pathogen or a specific portion of a pathogen to the adaptive immune system in a controlled manner in order to invoke acquired immunity against the specific pathogen it is designed to address.

The adaptive immune system consists of two main components: the B cell arm, and the T cell arm. B cells and T cells are types of white blood cells, or lymphocytes. To date, vaccines have been thought to work primarily by harnessing the B cell arm of the adaptive immune system. The main function of B cells is to produce antibodies, a special type of protein that identifies and initiates processes to kill foreign organisms. Antibodies bind to one or more structures on the pathogen surface. These structures may be proteins or complex sugars, called polysaccharides, or other molecules, which are specific to the organism. Some B cells turn into so-called memory B cells following exposure to an organism, ensuring that the immune system will recognize the same pathogen in the future.

Current Vaccine Discovery

Vaccines available today have been developed to stimulate the production of antibodies and therefore protect against invading organisms that are primarily controlled by the B cell arm of the immune system. This type of immunity is effective against organisms that mediate disease in locations, primarily the bloodstream, that are accessible to antibodies and/or cells that kill organisms with the help of antibodies.

Scientists have employed two alternative approaches for designing vaccines to induce antibody responses. The first approach has been to present a modified version of the whole pathogen to the immune system. In this approach, the vaccine is either an inactivated, or killed, pathogen or an attenuated pathogen, where the pathogen is live but rendered far less infectious. The advantage of this approach is that it enables vaccine development without knowing the specific surface structure of the pathogen that antibodies target for response and immunological memory. There are also significant disadvantages to this approach. Inactivating or attenuating pathogens in a large-scale, reproducible way is challenging, and there is a concern that attenuated pathogens could reactivate and cause the diseases they were designed to prevent. Another limitation is the potential that side effects of the vaccine may be more severe than when only part of the organism is used as the vaccine. A recent example is the pertussis, or whooping cough, vaccine that was originally developed as a whole killed vaccine, but later changed to a subunit, or purified protein, vaccine because of the rare but severe side effects of the whole cell vaccine. Due to these challenges, and the resultant regulatory hurdles, vaccines are increasingly designed using a second, and more targeted, approach.

The second approach to design vaccines to induce an antibody response is to immunize with specific antigens, or immunogenic proteins, from the pathogen. Such antigens often are paired with either (1) an adjuvant that gives the immune system a danger signal to enhance the ability of the immune system to recognize the proteins as foreign substances or (2) a vector, such as a virus that is used to deliver the antigens to the immune system to enhance the response, or some combination of an adjuvant and vector are utilized. These so-called subunit, or purified

protein, vaccines, while generally easier to produce than whole pathogen vaccines, pose a different challenge: selecting the optimal antigen or antigens from the pathogen to elicit the desired immune response.

Modern vaccine antigen discovery largely consists of the search for the optimal antigens for immunological, and primarily B cell, responses. To date, this process has largely been empirical, meaning that it has required the testing of each potential antigen in animal models of disease to determine its ability to be recognized by the immune system. There is considerable time and cost associated with testing each antigen, singly and in various combinations, to determine which antigens can elicit the desired immune response. However, these hurdles have been somewhat mitigated by the fact that, for most pathogens currently addressed by vaccines, there is a small number of candidate antigens.

Limitations and Challenges of Current Vaccine Discovery

Despite more than 200 years of vaccine history, there remain many organisms for which effective or comprehensive vaccines do not exist. These include viruses such as HSV-2, cytomegalovirus, and Epstein-Barr virus, which causes mononucleosis, and bacteria that include pneumococcus, *Chlamydia trachomatis*, or chlamydia, and *Staphylococcus aureus*, or staphylococcus, which causes a wide range of soft tissue, organ and blood infections. Parasites such as *Plasmodium falciparum*, which causes much of the world s malaria, also have yet to be addressed with vaccines. Collectively, these organisms are responsible for millions of deaths and morbidity for millions more people annually.

Vaccines that elicit B cell responses generally do not work for these pathogens, in part because the organisms evade B cell-mediated immunity. Some pathogens, such as HSV-2 and chlamydia, spend most of their life cycles sequestered within host cells and are inaccessible to antibodies that primarily reside in the bloodstream. Mucosal surfaces of the nasopharynx (nose and throat), gastrointestinal tract and genitalia, are also less accessible to antibodies in the bloodstream and harbor pathogens such as pneumococcus and staphylococcus. To address these pathogens, vaccines that engage the T cell immune system may represent the optimal solution.

T cells, like B cells, are a type of white blood cell, of the immune system. They are generally classified as CD8+ cytotoxic T lymphocytes, or CTL, or killer T cells, and CD4+, or helper T cells. Killer T cells recognize and eliminate pathogen-infected host cells. On the other hand, helper T cells produce compounds called cytokines that stimulate other immune cells to help fight infection. To initiate T cell responses to an infection, another type of specialized white blood cell, called antigen-presenting cells, or APCs, engulf invading pathogens. APCs process pathogen-derived protein antigens into smaller pieces, or epitopes, and place them on their surface as epitopes for recognition by killer T cells or helper T cells. Upon recognition, T cells activate to help eliminate the infection. Activated T cells can also become long-lived memory T cells that respond to infection should the host contact the infectious agent again, thus providing long-term protective immunity.

As with B cell vaccine development, there are two potential approaches to developing vaccines that induce T cell immune responses. The first approach would be to develop an attenuated or inactivated pathogen vaccine. As discussed, such a vaccine may present significant manufacturing, safety and regulatory challenges. To date, no whole pathogen vaccine has been developed to induce T cell responses.

The second potential approach would be to develop a subunit vaccine. However, there have been relatively few advances toward identifying target antigens that will elicit T cell responses, and, without the right antigen or antigens, a vaccine will not elicit the optimal immune response.

Discovering T cell antigens is particularly challenging due to the human diversity of T cell response and to pathogen size. Humans can belong to one of nine different genetic supertypes that influence how epitopes are presented to T cells, and hence the set of proteins that make up a pathogen can range into the thousands. These challenges represent fundamental barriers to the development of vaccines against infectious organisms for which T cell immunity is critical for effective control.

Challenge #1: Diversity of human T cell responses. B cell responses to a particular antigen are generally more uniform across all humans than T cell responses. As a result, a vaccine designed to elicit a B cell response generally works across broad populations. However, the T cell arm of the immune system poses a complexity challenge. In contrast with a fairly uniform antibody response, each person has one of nine human leukocyte antigen, or HLA, supertypes that govern, among other things, the specific targets of T cell responses. A person belonging to one supertype may mount a T cell response to a different protein epitope or an entirely different protein than someone with a different supertype. Given these different HLA supertypes, modeling diseases in animals, which are typically bred from a single genetic lineage, cannot effectively account for or produce a vaccine candidate intended to address the human diversity in T cell responses.

Challenge #2: Complexity of target selection due to pathogen size. Antibodies produced by B cells typically target proteins on a pathogen s surface. For B cell vaccines targeting surface proteins, the number of potential targets has typically been limited. For example, the hepatitis B virus, addressable by two approved vaccines, consists of four proteins. Choosing the vaccine antigen from this small candidate list required testing only these four proteins, singly and in combination to find the most protective formulation. Here again, the T cell arm of the immune system works differently. It is not just surface proteins of a pathogen that can be targets for a vaccine, but rather every pathogen protein, collectively its full proteome , can be a target of T cell responses. The number of candidate antigens, therefore, increases substantially based on the genetic complexity of the pathogen. For example, for HSV-2 the proteome comprises nearly 80 proteins, substantially increasing the

complexity associated with target antigen selection, as the number of potential antigen combinations increases exponentially. The chlamydia proteome exceeds 900 proteins and the proteome for *Plasmodium falciparum*, a parasite that causes malaria, exceeds 5,000 proteins. In the case of such organisms, testing each protein in animals, singly and in various combinations to identify candidate antigens, could take many years. For many organisms, the complexities associated with the pathogen size have presented a fundamental barrier to discovering effective T cell vaccines.

The combination of these two challenges renders discovery of T cell antigens by traditional empirical methods exceedingly difficult. We believe these challenges explain why no approved vaccines have been developed on the basis of T cell responses.

The ATLAS Discovery Platform: A Novel Approach to Vaccine Discovery

We have developed a proprietary technology platform that is designed to overcome the challenges associated with developing vaccines that stimulate T cell immunity. We have engineered this technology into a high throughput discovery platform we call ATLAS, our AnTigen Lead Acquisition System. This system mimics part of the human T cell immune system *ex vivo*, or outside the body. By comparing antigens identified in individuals who naturally control their infection with those who do not, we can select the antigens that may have the best likelihood of inducing protective T cell immune responses. We believe that this enables ATLAS to rapidly identify targets of T cell responses that are applicable to broad populations, over the range of HLA supertypes and represents a comprehensive throughput system designed for T cell antigen discovery in the biopharmaceutical industry.

To use ATLAS, we collect T cells and APCs from hundreds of human donors who were naturally exposed to the disease-causing pathogen of interest. We segregate these donors into cohorts based on their clinical status. At one end of the spectrum are those exposed subjects who remained uninfected despite contact. At the other end of the spectrum, we include subjects who were unable to clear their infection or control their disease without significant intervention. If applicable, we also include subject cohorts between these ends of the spectrum, such as those with mild infections.

We also create a library of every protein in the proteome of the pathogen of interest. We express each individual protein in bacterial hosts, which are cultured with APCs from each human donor. As each donor s APCs ingest the complete proteomic library, they present peptide epitopes from each protein on their surface. These epitopes can be recognized by T cells derived from the same donor. If the T cell recognizes the epitope on the surface of the APC, which it will do if has seen the epitope before and is a memory T cell for that particular epitope, it will be activated. The level of activation can be quantified by the amount of interferon gamma, or IFN- , a cytokine produced by the T cell. We use the pattern of responses for each subject to infer which pathogen proteins are associated with productive, non-productive or even deleterious immune responses. The diagram below illustrates the process by which we use ATLAS to identify pathogens to elicit a T cell response.

We use ATLAS as a high throughput engine to comprehensively and rapidly screen human T cells to identify potentially relevant T cell vaccine antigens. Furthermore, ATLAS allows us to screen large proteomes in an efficient manner to identify antigens likely to best stimulate the T cell immune system, a process that is otherwise slow and labor intensive. By comparing antigens identified in individuals who control their infection with those who do not, we can select the antigens that may have the best likelihood of inducing protective immune responses. Since we discover the target antigens from human responses rather than animal responses, we believe we can use the targets to produce vaccine candidates that have a high probability of generating protective immunity in humans. To date, we have applied this platform to identify human T cell antigens from several viral and microbial proteomes, with sizes ranging from several dozen, as with HSV-2, to a few thousand expressed proteins, as with pneumococcus and chlamydia.

In summary, we believe that ATLAS offers all of the following important advantages over other approaches to vaccine design and discovery:

- **Enables vaccine discovery for pathogens that are generally inaccessible to antibodies.** For pathogens that reside in human cells or otherwise generally evade antibody responses, and which, as a result have not successfully been addressed by B cell vaccines, ATLAS represents a means to identify targets of effective T cell responses. This pathogen list includes dozens of bacteria, viruses and parasites that collectively account for millions of deaths and morbidity for millions more annually.

- **Decreases the risk of vaccine discovery failure by identifying targets of T cell responses in humans.** By comprehensively screening the T cell responses of persons who have mounted effective immune responses to infectious disease pathogens, and comparing these responses to those who have not, ATLAS identifies antigens that associate with protection in humans. By identifying the targets of human T cell responses *ex vivo* from human samples, rather than in animal models, we both account for diversity of human T cell responses and avoid being misled by discovery in animals.

- **Selects targets relevant to broad populations.** We believe ATLAS is highly efficient and can analyze T cells from a large number of individuals. Traditional analog vaccine antigen discovery necessarily focuses on the identification of epitopes that are able to be presented by APCs for only a minority of the target population. In contrast, we can process blood samples from hundreds of ethnically diverse subjects and therefore can ensure, from analyzing across the range of HLA supertypes, that our antigens are broadly relevant. As a result, we anticipate that both GEN-003 and GEN-004 will stimulate T cell responses across broad HLA types.

- **Reduces the time and cost of vaccine discovery.** As we have demonstrated in both our HSV-2 and pneumococcus programs, after we collect blood samples from human cohorts exposed to a pathogen, we believe we can identify vaccine candidates in less than one year and for a few million dollars, compared to the industry norms of up to 10 years and $100 million to discover B cell vaccines, according to GlaxoSmithKline.

We believe that our discovery platform can enable vaccine discovery for a wide range of infectious disease pathogens, in addition to our clinical stage vaccines. We have identified antigens that appear to associate with protective human responses in our prophylactic HSV-2 and chlamydia programs and demonstrated subsequently that these antigens can protect against disease in accepted animal models. We have also embarked upon a program to discover protective T cell antigens from *Plasmodium falciparum*, a causative agent of malaria under a program funded in part by an investment from the Bill & Melinda Gates Foundation, or the Gates Foundation. Many other pathogens evade antibody responses and therefore may be tractable to ATLAS, including those that cause tuberculosis, gonorrhea, and dengue fever.

We also believe ATLAS may offer utility in the discovery of new treatments for cancer. In recent years, new cancer immunotherapies such as Yervoy (ipilimumab; Bristol-Myers Squibb) have successfully delivered improved outcomes against cancers such as melanoma by reversing the inhibitive effect that cancer cells can have on T cell immune responses. Recruiting T cells to drive the containment of cancerous cells holds promise as a new approach to cancer treatment.

Knowing the target or targets of the T cell responses may enable the development of next-generation immunotherapies with greater specificity that, in theory, could offer further protection against cancer.

Antigen Discovery Using ATLAS A Vignette from the Discovery of GEN- 003 to Treat HSV-2

Strong evidence for the role of T cells in controlling an HSV-2 infection emerged when a researcher at the University of Washington, Christine Posavad, Ph.D., identified a previously unknown and relevant patient population. These people were each in a sexual relationship with someone that had an HSV-2 infection, but had no evidence of infection by culture of, or measurable antibody response to, HSV-2. However, these individuals had evidence of T cell memory against HSV-2, indicating previous contact with HSV-2. In these patients, Dr. Posavad concluded that T cells are the driver of the protective response, but she could not comprehensively screen for the specificity of T cells that drove this response.

Based in part on Dr. Posavad s observations and other emerging evidence of the role of T cells in controlling HSV-2 infection, we decided to use ATLAS to identify T cell stimulating antigens for HSV-2. We started by collecting blood from 195 people exposed to, or infected with, HSV-2. For each person, we documented the infection severity based on clinical records and assigned the subjects to a cohort according to this. Crucially, we included 43 subjects of the type identified by Dr. Posavad. We chose our sample size to enable statistical comparisons within and across cohorts. We also recruited genetically and ethnically diverse individuals to ensure broad HLA supertype coverage. The table below provides further details on the patients:

We also built two copies of a library consisting of each protein in the HSV-2 proteome. Since both killer and helper T cells are thought likely to play a role in controlling an HSV-2 infection, we believed that measuring both T cell responses would be necessary to optimize the design of a candidate vaccine. Research has shown that one cytokine T cells use to defend against HSV-2 is IFN- . Therefore, for each subject in the study, we separately measured the IFN- responses of helper T cell

and killer T cells to each HSV-2 protein. An example of the output from our assay measuring killer T cells for one subject is below. We generate similar assays for all subjects for both killer and helper T cells.

ATLAS enables the generation of the above outputs. In this particular subject, the responses to many proteins hovered at a low level, while several proteins elicited relatively strong T cell responses.

Analyzing the experimental results of the 195 ethnically diverse subjects has enabled us to associate T cell responses to individual proteins with better control or improved outcomes of HSV-2 infection. Using statistical analyses to identify commonalities and differences within the clinical cohorts and across them, we identified a small group of candidate antigens associated with protective T cell responses to HSV-2 in humans. We further produced and tested the selected antigens in animal models to arrive at the two proteins to be included in GEN-003. We believe that because we collected samples from ethnically diverse subjects, GEN-003 should work across patients regardless of HLA supertype. The entire process, including devising clinical cohorts, collecting the blood from 195 subjects, building two copies of the protein library, running proteins through ATLAS and determining priority candidate antigens took 15 months.

Our Product Candidate Pipeline

The following table describes our current development programs:

Vaccine Candidate	Program	Stage of Development	Next Milestone	Anticipated Timeline
GEN-003	HSV-2 Therapeutic	Phase 1/2a	Initiate Phase 2 trial	Mid-2014
GEN-004	Pneumococcus Prophylaxis	Phase 1	Complete Phase 1 trial	Mid-2014
GEN-001	Chlamydia Prophylaxis	Pre-clinical	File IND	2016
GEN-002	HSV-2 Prophylaxis	Pre-clinical	File IND	2016
GEN-005	Malaria Prophylaxis	Research	Initiate pre-clinical studies	Second half of 2014

GEN-003 Market Opportunity

Herpes Simplex Virus 2 (HSV-2)

We are developing our lead product candidate, GEN-003, to treat patients with HSV-2 infections. GEN-003 consists of two protein antigens. The first antigen is ICP4.2, a large fragment of the protein ICP4 that we discovered in ATLAS screens to be a T cell antigen associated with protection from infection or with less severe infection. The second antigen is glycoprotein D2, or gD2, a B cell antigen that is the target of antibodies that provide anti-viral activity during the time in the life cycle of HSV-2 where the pathogen is susceptible to inactivation by antibodies. gD2 was also a target of T cells in our ATLAS screens and was selected based on such ATLAS screens as ATLAS prioritized gD2 as the B cell antigen most associated with T cell responses. We pair the antigens with Matrix-M2, a novel adjuvant that we have licensed exclusively for this indication from Novavax, Inc., or Novavax. See Other Collaborations Isconova AB .

HSV-2 is a sexually transmitted disease. HSV-2 infections have become an epidemic, spreading to approximately 16% of the United States population between the ages of 14 and 49, and more than 500 million people worldwide, according to the Centers for Disease Control and Prevention, or CDC, and the World Health Organization, or WHO.

For infected individuals, the disease can manifest in a number of ways, with so-called viral shedding as the common element. For some of the virus life cycle, it lies dormant within nerve cells near the spine. Although there may be no visible sign of infection, the virus lives within these nerve cells. Periodically, the virus reactivates and virus travels to skin cells of the genitalia where they are released. The release of the virus is called viral shedding and can be detected by swabbing the genital area and testing the swab for the presence of viral DNA. For reasons not completely understood, reactivation of the virus within the nerve cells may occur, resulting in a large amount of virus shedding from skin and mucus membranes. If the replication is maintained for a long enough period of time and at a high enough level, the virus destroys the cells it inhabits and causes ulcers to form on the skin. Patients experiencing such visible ulcers are considered symptomatic patients. It is generally believed that the immune system responds to episodes of HSV-2 outbreaks by activating T cells that reduce viral replication and destroy infected cells, allowing healing and resolution of genital ulcers, usually after a few days, although for many patients ulcers return at variable intervals. Patients may also experience periodic, low-frequency viral shedding. Because the shedding at these times does not lead to the development of ulcers, these episodes are called asymptomatic

shedding. These asymptomatic patients continue to pose a disease transmission risk through sexual contact while shedding virus.

Some people, approximately 60% of those infected, are asymptomatic or fail to recognize or seek medical attention for an initial mild outbreak of ulcers. According to the New England Journal of Medicine, roughly 40% of persons infected with HSV-2 experience visible symptoms. It has been reported in the Annals of Internal Medicine that approximately 70% of the people with visible symptoms experience three or more outbreaks per year, which we consider to be moderate-to-severe disease. Patients with HSV-2 experience significant distress because of the potential negative impact on their ability to form and maintain sexual relationships. Infection with HSV-2 can involve substantial risks in addition to the infection itself. For example, persons with HSV-2 infection have a threefold increased risk for human immunodeficiency virus, or HIV, acquisition. Additionally, pregnant women can transmit HSV-2 to infants in childbirth, which can result in severe brain damage or death.

* Note: Each bar represents 1 swab; 2 swabs collected per day; the absence of a bar means no shedding was detected on the swab on a particular day.

The total number of days during a month that HSV-2 virus can be detected in the genital area with or without visible ulcers is called the shedding frequency. A pattern of shedding and outbreak for one person is illustrated in the graph above. Viral shedding is measured by collecting swabs of the genital area, following a protocol that has been used in decades of studies of HSV-2 viral shedding. In the example shown above, the subject collected swabs twice daily for 28 days. HSV-2 DNA was detectable in approximately 66% of the collected swabs, meaning the patient s shedding frequency is 66% for the period measured. Some swabs had no detectable viral DNA, meaning the subject did not shed virus at the time of sample collection (exemplified by the blank areas of the above graph). The magnitude of viral shedding varied widely from day to day and only sometimes resulted in clinical symptoms such as visible genital ulcers. Ulcers generally appear after several days of asymptomatic shedding and at times when the magnitude of shedding is highest. The extent, frequency, and duration of shedding vary from person to person, but the pattern is relatively consistent for each person.

Limitations of Current HSV-2 Treatment Options

There is no known cure for HSV-2. For patients infected with HSV-2, oral antiviral drugs are the only treatment option. The most commonly prescribed treatment is valacyclovir including Valtrex, marketed by GlaxoSmithKline. Other medications available are acyclovir (Zovirax, marketed by GlaxoSmithKline) and famciclovir (Famvir, marketed by Novartis). These drugs all work by limiting the ability of the virus to replicate when it emerges from latency. Sales for these oral antivirals totaled $1.6 billion globally in 2012, including nearly $700 million in the United States, according to IMS Health.

Some patients treat their disease episodically. At the onset of outbreaks, or in the case of some patients, at the onset of prodrome, a tingling sensation that may precede an outbreak, patients take antiviral medication to reduce the duration and severity of the outbreak. According to the approved Valtrex prescribing information, episodic treatment only reduces the duration of outbreaks by up to 50% when compared to placebo. Patients treating their symptoms episodically are not protected against asymptomatic viral shedding and, therefore, have no reduced risk of transmission of infection to an uninfected sexual partner while asymptomatic.

Some patients treat their infection with daily antiviral medication. This approach is called chronic suppressive therapy, and has been shown to reduce but not eliminate viral shedding, the frequency of symptomatic outbreaks of genital ulcers, and the risk of transmission of the infection to an uninfected sexual partner. Even on chronic suppressive therapy, based on the valacyclovir prescribing information, 35% of patients taking chronic suppressive therapy suffer outbreaks within six months after initiation of treatment and 46% of patients suffer outbreaks within 12 months. Patients taking chronic suppressive therapy reduce their disease transmission risk only by as much as 52%.

Due to the limited effectiveness of oral antiviral therapy, there remains a significant unmet medical need, against both the symptoms of HSV-2 and disease transmission risk from viral shedding.

GEN-003: A Therapeutic Vaccine Candidate for HSV- 2

GEN-003 is being studied in an ongoing Phase 1/2a trial. In a planned analysis of our data from this ongoing trial, we showed that GEN-003 is the first vaccine known to have demonstrated a statistically significant reduction in viral shedding. The data were presented in a late-breaker presentation at the Interscience Conference on Antimicrobial Agents and Chemotherapy in September 2013. The reduction in shedding appears to be durable, lasting for the six month period for which we have data. We believe that these initial clinical results demonstrate that GEN-003 has the potential to be a first-in-class vaccine to treat HSV-2.

We believe that, if approved for the treatment of HSV-2 infections, GEN-003 could address the unmet needs of patients in several ways. For patients taking episodic therapy, GEN-003 could offer reduced symptomatic and asymptomatic viral shedding, potentially reducing disease transmission risk. Since episodic therapy offers no protection against disease transmission during asymptomatic shedding, these patients and their sexual partners are unprotected when the infected partner is not taking anti-viral medication.

For patients on chronic suppressive therapy, we believe GEN-003 may provide both improved outcomes and increased convenience. For some patients, we anticipate that physicians will prescribe GEN-003 as baseline therapy. Such patients may still take oral antivirals in case of an outbreak to further control symptoms. Replacing daily therapy may offer convenience to these patients. For other patients, we anticipate that physicians may prescribe GEN-003 alongside chronic suppressive therapy. This combination therapy approach mirrors the treatment practice of other chronic viral infections such as HIV and hepatitis C virus. We anticipate that, since the mechanisms of action for GEN-003 and oral antiviral medication should complement each other, the control against symptoms and disease transmission risk offered by the combination would exceed that of either therapy alone. In a market research survey conducted on our behalf with more than 400 patients with HSV-2 infections in the United States, the United Kingdom, France and Germany, 56% of patients on chronic suppressive therapy indicated an intent to use GEN-003 in combination with other therapies and 37% of such patients indicated an intent to use GEN-003 on its own, if it were approved; 30% of patients on episodic therapy indicated an intent to use GEN-003 in combination with other therapies and 60% of such patients indicated an intent to use GEN-003 on its own, if it were approved; and 15% of patients not taking any HSV-2 therapy indicated an intent to use GEN-003 in combination with other therapies and 65% of such patients indicated an intent to use GEN-003 on its own, if it were approved. This was a limited survey and may or may not be representative of how patients might ultimately use GEN-003, if at all, if GEN-003 successfully completes clinical development and is approved by regulatory authorities.

Preclinical Evaluation of Our GEN-003 Product Candidate

We tested GEN-003 in the guinea pig therapy model, the standard animal model of recurrent disease. Guinea pigs are used because the course of infection in the animal closely mirrors that of humans, with an initial outbreak that resolves, followed by frequent and periodic recurrences that last a few days. GEN-003 decreased ulcers over time by up to 55% versus placebo, measured over 63 days after initial immunization. This is the standard interval across which to measure impact on ulcers in the guinea pig model. Additionally, the vaccine reduced viral shedding significantly. In the period after completing immunization, from days 37-63, GEN-003 almost completely eliminated viral shedding. We are unaware of any other vaccine demonstrating similar impact either on clinical symptoms or on viral shedding in this model.

Clinical Development

GEN-003-001 Our Phase 1/2a Clinical Trial

We are conducting a Phase 1/2a trial, testing the safety, T and B cell immunogenicity and impact on viral shedding of GEN-003 in subjects with documented recurrent HSV-2 infection. We are conducting the trial at seven sites in the United States, including some of the leading institutions for scientific and clinical research of HSV-2. The trial is double-blind, placebo-controlled and dose-escalating. We enrolled subjects between 18 and 50 years of age. An independent Data Safety Monitoring Board continues to monitor the safety of subjects enrolled in the clinical trial as well as the subject outcomes.

This trial is fully enrolled with 143 otherwise healthy subjects with moderate-to-severe HSV-2 infections, defined as experiencing between three and nine symptomatic outbreaks per year when not on suppressive therapy. Subjects were randomized into one of three dose cohorts. Within each cohort, subjects were randomized in a 3:1:1 ratio, whereby for every three subjects receiving GEN-003, one would receive placebo and one would receive the ICP4.2 and gD2 proteins without the Matrix-M2 adjuvant. We included this last cohort to demonstrate that Matrix-M2 was necessary to biological responses. There were three vaccine dose groups, based on the amount of protein. The lowest dose group subjects received 10 μg of

each protein combined with 50 µg of Matrix-M2. In the middle dose group, the protein doses increased to 30 µg. In the high dose group, subjects received 100 µg of each protein. Subjects received three vaccinations, on days zero, 21 and 42. The diagram below illustrates the dosing and swabbing regimen in the trial.

The primary objective of this trial is to monitor the safety profile of the proposed vaccine. Additionally, we are measuring the vaccine-induced T cell and B cell immune responses. We structured and statistically powered the trial to measure the proposed vaccine s impact on viral shedding, an important marker of virus activity. We selected this endpoint because of the direct connection between shedding, symptomatic outbreaks, and risk of transmission of virus by sexual contact. Without shedding, a patient will not experience symptomatic ulcers. Hence, a vaccine that reduces viral shedding would be expected to reduce symptoms as well. Every subject in the study swabbed their genitalia twice per day for 28 days before receiving the first assigned treatment injection, and after treatment, using the standard protocol that has been used for many clinical trials of HSV-2 shedding.

When we measured the viral DNA present in swabs from subjects over the 28-day measurement period after completing the three-dose regimen, subjects in the two highest GEN-003 dose cohorts showed a statistically significant reduction in viral shedding frequency from their own baseline shedding frequency, established over the 28-day measurement period preceding dosing, by an average of 50% ($p<0.001$) in the 30 µg dose cohort. GEN-003 reduced the magnitude of viral shedding by an average of 54% ($p=0.01$) in that same dose cohort. We are unaware of any other vaccine that has demonstrated such an impact on HSV-2 viral shedding in humans. The following chart summarizes the data demonstrating the statistically significant reduction in frequency of viral shedding following administration of GEN- 003 vaccine.

We believe the reduction in viral shedding afforded by GEN-003 will translate into a reduction in clinical symptoms because the link between viral shedding is well established. It has been shown that asymptomatic patients shed half as frequently as symptomatic patients. Oral anti-viral drugs, which reduce viral shedding frequency, also reduce the number of symptomatic outbreaks and the risk of transmission. And in populations where oral anti-viral drugs provide lower efficacy, the viral shedding rates are higher than in those populations where oral anti-viral drugs provide work well.

This Phase 1/2a clinical trial was not designed to measure the impact of GEN-003 on clinical symptoms. We believe that in a larger adequately powered, well controlled clinical trial GEN-003 may demonstrate clinical benefit, such as a reduction in frequency of HSV-2 outbreaks, could be shown to reach even more stringent statistical significance.

In this Phase 1/2a trial, we are also measuring and evaluating the durability of response to the vaccine. Durability of response is measured by having subjects conduct an additional 28-day, twice daily genital swab collection to measure viral shedding frequencies six months after vaccination. For the 30 μg dose cohort as shown in the graph below, reduction in viral shedding remains statistically significant relative to the subject s own baseline viral shedding rate. In comparison, there was no reduction in viral shedding for placebo patients either immediately after vaccination or six months later. While we have not yet tested any booster regimen, based on the durability of response to date, we anticipate booster doses, if necessary, would be administered at intervals greater than six months.

Our data have also demonstrated that GEN-003 induced a broad immune response in vaccinated subjects at all dose levels. T cell responses increased from baseline 21-fold to ICP4.2 and 10-fold to gD2. Subjects also experienced strong increases in antibody response to ICP4.2 and gD2, as measured by immunoglobulin G, or IgG, a standard measure of antibody response. The antibodies generated in response to the vaccine are able to prevent the virus from infecting new cells, as measured by a standard assay for evaluating the ability of the virus to infect cells *in vitro*. The chart below shows the T cell immune response aggregated across all dose levels.

Fold Increase in T Cell Response from Baseline by Treatment Group

Overall, GEN-003 has been well tolerated. During the seven days following each injection, side effects have generally been those considered typically associated with vaccines, such as fatigue, site injection pain, tenderness and

swelling. Among all vaccine dose groups, the frequency of adverse events, or AEs, appeared greater among those subjects given the 10 µg dose. In the 30 µg and 100 µg dose cohorts, the doses we intend to study in subsequent clinical trials, the AE rate was lower than that of the 10 µg cohort. In addition, the frequency of AEs appeared to diminish with subsequent doses. Beyond the week following vaccination with GEN-003 vaccine, the AE types and frequencies appeared similar to those following vaccination with placebo. The AEs have been transient, resolved over a few days and have resulted in only two subjects discontinuing further vaccinations: one for a combination of symptoms (myalgia and fatigue; and pain and tenderness at the injection site) and one for injection site pain.

In an interim analysis in our current Phase 1/2a trial of GEN-003 in an exploratory analysis of the impact on clinical symptoms of HSV-2 as measured by ulcer days, or the number of days of self-reported observation of ulcers over a four-week period by subjects, GEN-003 showed a statistically significant ($p < 0.001$) reduction at the 30 µg dose (n=29 subjects) immediately after three doses and at six months after the third dose of GEN-003. The reduction for the 30 µg dose at six months post treatment was 72%. The table below shows the number of ulcer days reported prior to treatment, immediately post treatment with three doses and at six months after the third dose for each of the doses measured in the trial, on a weighted-average basis for each dose cohort:

Self-Reported Days With Ulcers Over a Four-Week Period

	10 µg	30 µg	100 µg	placebo
Baseline (prior to treatment)	9.94	9.24	6.66	7.06
Immediately post-treatment	7.85	3.91	2.35	7.74
Six months post-treatment	8.47	2.59	4.89	7.72

While these are interim data from an early stage clinical trial in a limited number of subjects, we believe this endpoint or one that similarly measures impact on disease will be the endpoint for demonstrating efficacy in pivotal studies of GEN-003.

Next Steps: Phase 2 Dose Ranging and Dose Regimen Trials for GEN- 003

We plan to initiate a Phase 2 dose ranging trial of GEN-003 in mid-2014 and anticipate efficacy data by mid-2015. The primary trial objective is to optimize the vaccine dose. We expect to compare two protein levels, including the 30 µg dose, each combined with 25 µg, 50 µg or 75 µg of Matrix-M2, for a total of six dose cohorts. We anticipate the trial to enroll approximately 300 patients in total with similar or identical enrollment criteria and endpoints as the Phase 1/2a trial. Following completion of this Phase 2 dose ranging trial, we intend to complete a Phase 2b trial where we will seek to optimize our dosing regimen, or the number of doses and the interval between doses. We anticipate that clinical trial enrollment criteria and endpoints for both of these trials will be similar or identical to those of the preceding trials.

Potential for GEN-003 to Treat HSV-1 Infection

We anticipate that GEN-003 may also help a patient s immune system fight herpes simplex virus type-1, or HSV-1. HSV-1 is most commonly identified with cold sores and has infected approximately 60% of Americans, according to the CDC. Increasingly, HSV-1 has been associated with outbreaks of genital ulcers, though the frequency and severity of such outbreaks generally is less than those associated with HSV-2. HSV-1 and HSV-2 are related viruses and the proteins in GEN-003 are present in, and nearly identical to, those found in HSV-1. Consequently, we believe that GEN- 003 will be active against HSV-1 and thus intend to study the potential for GEN-003 to combat HSV-1.

The Opportunity to Prevent HSV-2 Infections

In addition to treating HSV-2 infection with GEN-003, we believe that ATLAS may help to develop a vaccine that can prevent HSV-2 from infecting healthy persons. We believe that a vaccine that has therapeutic effect may be the foundation for a preventative vaccine. Since there will not likely be pre-existing immune responses to build upon in uninfected subjects, the preventative vaccine may include additional or different antigens than those in GEN-003 to be fully protective. Using data from the same ATLAS screening effort with which we designed GEN-003, we identified eight additional candidate antigens that could be added to GEN-003 or included in another vaccine for prophylaxis of HSV-2 infections. We have already demonstrated that several of the eight candidate antigens can provide some protection against infection in initial studies in mice. A prophylactic vaccine may be an important step in halting the epidemic, and could be used to treat uninfected partners of HSV-2 infected subjects to prevent them from acquiring the disease. The vaccine could

also be used more broadly as a preventative measure. We intend to pursue development of a prophylactic HSV-2 vaccine and anticipate that we would partner this program at the appropriate point of clinical development.

GEN-004 Market Opportunity

Pneumococcal Disease

We are developing GEN-004 to prevent infections caused by pneumococcus. The Gates Foundation has noted that pneumococcus kills more children under age five globally than any other organism. GEN-004 consists of three whole Pneumococcal T cell protein antigens, SP0148, SP1912 and SP2108, combined with the adjuvant Alhydrogel, a form of alum that is available in several approved vaccines.

There are more than 90 serotypes, or strains, of pneumococcus known to exist. Each strain differs slightly in the composition of the polysaccharide capsule, a sugar-based component that covers the bacterial cell. These differences have likely arisen as the organism has evolved to evade human antibody responses. Pneumococcus is a bacterium that often resides harmlessly in the nose and throat but can cause otitis media, or middle ear infection, as well as pneumonia, an infection in the lungs. Such consequences of infection are considered non-invasive Pneumococcal disease, or NIPD.

Invasive Pneumococcal Disease, or IPD, arises when pneumococcus enters the bloodstream and potentially spreads to other organs. The consequences of IPD can be severe and, according to the CDC, 10% of patients with IPD die. IPD is classified into three categories. Bacteremic pneumonia is an infection in one or both lungs with pneumococcus also in the bloodstream. It is generally a more severe infection than pneumonia that is not invasive. Other examples of IPD include sepsis, the presence of bacterial infection in the blood along with symptoms such as fever, elevated heart rate and respiratory rate, and high or low white blood cell count, and meningitis, an inflammation of the brain and spinal column.

Limitations of Current Pneumococcal Vaccines

Global revenue exceeded $5 billion in 2012, of which more than 70% came from Prevnar-13, marketed by Pfizer, which is named for the 13 capsular polysaccharides types, derived from 13 strains of pneumococcus, included in the vaccine. Other Pneumococcal vaccines include Synflorix, marketed by GlaxoSmithKline, and Pneumovax-23, marketed by Merck. These vaccines have dramatically reduced IPD caused by the serotypes addressed by the vaccines.

The predecessor vaccine to Prevnar-13, Prevnar-7, led to the dramatic reduction of IPD caused by the seven vaccine serotypes of pneumococcus that are addressed by the vaccine. According to the CDC, the hospitalization rates due to IPD infection from these strains fell after the introduction of Prevnar-7, from 80 cases per 100,000 children in 2000 to less than 1 per 100,000 by 2007. In pre-approval randomized trials, Prevnar-7 was demonstrated to be safe and highly efficacious against IPD, moderately efficacious against pneumonia, and somewhat effective in reducing middle ear infection episodes and related office visits. The expectation is that Prevnar-13, introduced in 2010, will result in similar benefit against the seven serotypes covered by Prevnar-7 plus the additional six serotypes included in that vaccine.

Nevertheless, significant limitations exist with this and other pneumococcal vaccines. As noted previously, there are more than 90 known serotypes of pneumococcus. Prevnar-13 covers only 13 of these serotypes. Incidence of invasive disease caused by the 75+ serotypes not included in that vaccine are rapidly increasing. As a consequence, Pfizer is believed to be working on a third generation Prevnar vaccine. Already a complex vaccine, each of the polysaccharide shells included in Prevnar-13, representing 13 of the most common disease-causing serotypes of pneumococcus, is conjugated, or chemically linked, to a protein carrier. It is believed that there are limits to how many polysaccharides that physically can be included in the vaccine. Moreover, the protective capacity per serotype appears to diminish as new polysaccharides are added to the vaccine. Still, other large companies, including GlaxoSmithKline, Merck, and Sanofi Pasteur, are also believed to be working on new vaccines against pneumococcus. To our knowledge, all of these companies product candidates are being developed to elicit a B cell response.

GEN-004: A Prophylactic Vaccine Candidate for Pneumococcus

We have designed GEN-004 to fight more than 90 serotypes of pneumococcus, and to do so through a T cell-based mechanism of action that complements existing vaccines. Since 2009, we have collaborated with Rick Malley, M.D., of Boston Children s Hospital, a leading researcher on host immunity to pneumococcus. He was the first person to demonstrate that Pneumococci are rapidly cleared from the nose, before they can get into the lungs and bloodstream, by a type of helper T cell called TH17 cells. This is important because before pneumococci can cause IPD, they need to take up residence inside the

nose, known as colonization. If the immune system could be taught to make TH17 cells against pneumococci in sufficient quantities, then the bacteria will not have the ability to colonize, thus reducing or eliminating IPD occurrence. The majority of healthy adults are not colonized with pneumococcus, presumably due to TH17 responses that they have generated through natural exposure. We believe a vaccine that stimulates TH17 cells to reduce or prevent colonization of the nasopharynx by pneumococcus could be highly effective against all forms of pneumococcal disease including IPD and NIPD infections.

Guided by this insight, we used ATLAS to design a novel pneumococcal vaccine, GEN-004. Since adults are generally protected against colonization by pneumococcus, we screened the blood of 50 healthy, ethnically diverse adults using ATLAS. We collected their APCs and T cells and screened the entire pneumococcus proteome, which consists of more than 2,200 proteins, to identify proteins associated with a strong TH17 T cell response, as measured by their induction of the cytokine IL-17A, the predominant cytokine secreted by TH17 cells. Based on these studies, we identified three protein antigens that associate highly with a protective T cell response against pneumococcus in humans. Moreover, as these proteins are conserved in all sequenced strains of Pneumococci, we believe GEN-004 may be able to help protect against invasive Pneumococcal disease caused by any Pneumococcal serotype, including those covered by the Prevnar franchise.

We have demonstrated proof-of-concept of GEN-004 in a mouse model of nasal colonization, as demonstrated below. In this model, mice are immunized with the antigens adsorbed to ahydrogel and then challenged intranasally with live pneumococci. After 10 days, the nasal cavity is washed with saline, and the numbers of pneumococcal bacteria that colonized the nose are counted. We and others have shown that the prevention of colonization in this model is due to IL-17A secretion from helper T cells.

Clinical Development of GEN-004

We have filed an IND and initiated a Phase 1 clinical trial in the United States to evaluate the safety of, and immune response to, GEN-004. Immune responses will be measured by an increase in helper T cells that produce IL-17A in response to the antigens included in the vaccine. We expect to enroll as many as 90 healthy adults in this trial, and follow them for one year. This trial will help us to determine the ideal vaccine dose to test in subsequent Phase 2 trials. We expect the initial results will be available in the second quarter of 2014. If the vaccine induces a TH17 response, we believe this will be the first time a vaccine directed against pneumococcus in humans has done so.

In the third quarter of 2014, we intend to initiate a Phase 2a trial for GEN-004 in adults if the Phase 1 clinical trial is successful. We anticipate data from our Phase 2a trial in mid-2015. Subjects in the clinical trial will receive either GEN-004 or placebo, and then be challenged intranasally with live pneumococcus, much like in the mouse colonization model. This means that pneumococcus will be introduced to the nasal cavity. We expect to enroll as many as 75 healthy adults in this trial. We will monitor AEs, immune responses as determined by IL-17A, and incidence of post-challenge colonization. We will follow these patients for a year and expect the initial results will be available in the second quarter of 2015. If successful, we believe this has the potential to be the first time a protein subunit vaccine will have directly demonstrated a reduction in nasopharyngeal colonization in humans.

Our Chlamydia Program

Chlamydia is the most commonly reported bacterial sexually transmitted disease in the United States. According to the CDC, an estimated 2.9 million infections occur annually in the United States. Despite the widespread availability of antibiotics that are effective against *Chlamydia trachomatis*, the pathogen that causes chlamydia infections, incidence has increased at greater than 5% per year over the past decade, according to the CDC. A key reason for this is that chlamydia is often an asymptomatic infection, so infected individuals do not seek treatment, which can result in severe consequences, particularly in women, such as pelvic inflammatory disease, infertility and serious neonatal infections.

Despite the need, vaccine development to combat chlamydia has been virtually non-existent. There has not been a chlamydia vaccine clinical trial since the 1960s, in which an attenuated pathogen vaccine demonstrated no lasting protection and showed hints of disease exacerbation. Antibodies appear to be unlikely to protect against infection as the pathogen is intracellular for much of its life cycle. Additionally, as a large genome pathogen, *Chlamydia trachomatis* represents a large T cell antigen discovery challenge. For these reasons, we believe that chlamydia is a particularly attractive pathogen for use of ATLAS to identify a vaccine candidate.

We have achieved promising preclinical results from candidates generated using ATLAS. We collected blood from 144 subjects spanning multiple clinical cohorts, ranging from subjects whose infections spontaneously cleared, representing a putative natural protection cohort, to subjects with infertility caused by chlamydia infection. From the more than 900 proteins in the *Chlamydia trachomatis* proteome, we identified 22 novel proteins associated with a protective response. From these we have demonstrated that three proteins, when given in an animal model of infection and when paired with the Matrix-M2 adjuvant can significantly reduce infection risk.

If the program were to reach the clinic, we believe it would be the first vaccine against chlamydia to be in clinical trials in more than 50 years. If it can successfully prevent chlamydia infections, we believe it would address a major unmet clinical need. As resources permit, we intend to opportunistically pursue development of this program.

Our Malaria Program

Malaria is one of the deadliest infectious diseases in the world. Approximately 600 thousand to one million people died in 2010 due to malaria, primarily in the developing world. There is no vaccine to prevent malaria, an infection caused by the plasmodium parasites transmitted by mosquitoes. We previously collaborated with the Naval Medical Research Center, or NMRC, and recently initiated a second collaboration with the Gates Foundation for which malaria is a priority infectious disease. When the parasite is injected into the blood through the bite of an infected mosquito, it rapidly travels to the liver where it replicates exponentially, is released into the bloodstream, and causes sickness. T cells in the liver could potentially be used to kill the cells in which the parasite is hiding, before the parasite is able to replicate itself, and could therefore protect against blood infection. Both the Gates Foundation and NMRC have sponsored several studies investigating killed or attenuated whole organism vaccines, which induce immunity, but are impractical to manufacture due to the fact that the vaccines are based on irradiated parasites grown within the salivary glands of mosquitoes.

We are in the process of collecting blood samples from subjects immunized with the killed organism and who were either protected or not protected after live parasite challenge to use ATLAS to identify the protein antigens that are associated with protective T cell responses. The identification of the protein targets of the T cell responses can enable the generation of a protein plus adjuvant vaccine designed to induce liver T cell responses and prevent malaria disease in a safe, scalable and affordable way.

Competition

The biotechnology and pharmaceutical industries are characterized by intense and rapidly changing competition to develop new technologies and proprietary products. While we believe that our proprietary patent portfolio and T cell vaccine expertise provide us with competitive advantages, we face potential competition from many different sources, including larger and better-funded pharmaceutical companies. Not only must we compete with other vaccine companies but any products that we may commercialize will have to compete with existing therapies and new therapies that may become available in the future.

There are other organizations working to improve existing therapies or to develop new vaccines or therapies for our initially selected indications. Depending on how successful these efforts are, it is possible they may increase the barriers to adoption and success of our GEN-003 and GEN-004 product candidates, if approved. These efforts include the following:

- **HSV-2:** The current standard of care for the treatment of HSV-2 is valacyclovir, an oral antiviral medicine. Other currently approved oral antiviral medications include acyclovir and famciclovir. AiCuris, a private company based in Germany, is developing a new oral antiviral, pritelivir, and has advanced the compound into Phase 2 testing. We understand the company will pursue once-weekly dosing with this drug. We believe that GEN-003 may offer advantages in terms of improved symptom control, reduced disease transmission risk and improved compliance when compared to oral antivirals.

There are also several companies attempting to develop new therapeutic vaccines against HSV-2, including Agenus Inc., Coridon Pty Ltd, Sanofi Pasteur and Vical Incorporated. We believe GEN-003 has advantages against each of the vaccines being developed by these companies based on the screens of human protection that we have conducted using ATLAS that include these competitors antigens, published reports of preclinical vaccine efficacy, announced clinical results in the case of Agenus, Inc. and our own clinical results to date. However, there can be no assurance that one or more of these companies or other companies will not achieve similar or

superior clinical results in the future as compared to GEN-003 or that our future clinical trials will be successful.

- **Pneumococcus:** The current standard of care for the prevention of pneumococcus is Prevnar-7/Prevenar-13, marketed by Pfizer. In select countries, Synflorix, marketed by GlaxoSmithKline, is also widely accepted. Additionally, Pneumovax-23, marketed by Merck, is labeled by use for persons over 65. We believe that each of these companies is seeking to develop improvements to their product. We believe these represent incremental improvements, adding a few additional strains to their coverage. In addition, we are aware of a pneumococcus vaccine that Sanofi Pasteur has taken into Phase 1 trials. This is a protein subunit vaccine designed to cover all strains of pneumococcus, but was designed to induce B cell responses. For many pneumococcal strains with dense sugars on their surface, the protein targets of the antibodies induced by the vaccine will be blocked by sugars that cover them. We believe that by covering all known pneumococcus serotypes, with a T cell-based mechanism of action that complements existing vaccines, GEN-004 may offer broader protection than existing vaccines. However, there can be no assurance that one or more of these companies or other companies will not achieve similar or superior clinical results in the future as compared to GEN-004 or that our ongoing and future clinical trials of GEN-004 will be successful.

Many of our competitors, such as Merck, GlaxoSmithKline, and Sanofi Pasteur, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of vaccines and the commercialization of those vaccines. Accordingly, our competitors may be more successful than us in obtaining approval for vaccines and achieving widespread market acceptance. Our competitors vaccines may be more effective, or more effectively marketed and sold, than any vaccine we may commercialize and may render our vaccines obsolete or non-competitive.

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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. We expect any vaccines that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade

secrets relating to our proprietary technology platform and on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the vaccine field. We additionally rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available. Still further, we utilize trademark protection for our company name, and expect to do so for products and/or services as they are marketed.

Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover

these activities. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

We have developed or in-licensed numerous patents and patent applications and possess substantial know-how and trade secrets relating to the development and commercialization of vaccine products. As of the date of this Annual Report on Form 10-K, our patent portfolio includes the following:

ATLAS

Our discovery platform patent portfolio includes three patent families, currently comprising four issued U.S. patents and two pending U.S. applications. We hold an exclusive license from The Regents of the University of California to the first patent family, including U.S. Patent 6,004,815 and the related U.S. Patents 6,287,556 and 6,599,502. This first family includes claims to fundamental aspects of the ATLAS platform, developed by our scientific founder, Darren Higgins, Ph.D. while he was employed at the University of California, Berkeley. Patents in this family have a patent term until August 2018. We hold a further exclusive license from President and Fellows of Harvard College to the second patent family, which covers methods related to the ATLAS discovery platform. This second patent family includes a pending U.S. application and corresponding applications in Europe, Canada and Australia. Patents issuing from these applications are expected to expire in 2027. We wholly own the third patent family, which is specifically directed to the ATLAS platform as utilized by us. This third patent family includes U.S. Patent 8,313,894, a pending U.S. patent application, and corresponding pending applications in Europe, Canada and Australia. Patents issuing from applications in this family are expected to have a patent term until at least July 2029; issued U.S. Patent 8,313,894 has a term that includes Patent Term Adjustment and extends until at least June 2030.

GEN-003 (HSV-2)

We wholly own a portfolio of patent applications directed to HSV-2 vaccines, including GEN-003. This portfolio includes two patent families covering HSV-2 vaccine compositions and methods for inhibiting or treating HSV-2 infections. The first patent family includes U.S. Patent 8,617,564. A U.S. application and applications in Europe, Canada, Australia, Japan, Brazil, Russia, India, China and nine additional foreign jurisdictions are pending in the first patent family. A U.S. application and applications in Europe, Australia and Japan are pending in the second family. Patents that issue from applications in these families are expected to expire in 2030 and 2031; issued U.S. Patent 8,617,564 has a term that includes Patent Term Adjustment and extends until at least January 2031. We own a further patent family covering follow-on HSV-2 vaccine compositions.

We hold a license from the University of Washington to a patent family that includes U.S. Patent 8,197,824 and European Patent No. 2263686 covering compositions of certain HSV-2 proteins and methods for treating HSV infections. This family includes pending applications in the United States, Europe and Canada. This patent family has a patent term until at least July 2023.

We hold a license from Isconova AB (now Novavax) to two patent families covering Matrix-M2, the adjuvant used in GEN-003. Both patent families include issued patents in Europe; the first patent family also includes an issued patent in Japan. Applications in the United States, Canada, Australia, Japan (for the second family) and three additional foreign jurisdictions. These patent families have patent terms until at least July 2023 and July 2024.

GEN-004 (Pneumococcus)

We co-own with Children s Medical Center Corporation, or Childrens, a patent portfolio of patent applications directed to pneumococcus vaccines, including GEN-004. This patent portfolio includes two patent families covering pneumococcal vaccine compositions and methods for inhibiting or treating pneumococcal infections. A U.S. application and applications in Europe, Canada, Australia, Japan, Brazil, Russia, India, China and nine additional foreign jurisdictions are pending in the first patent family. A U.S. application and applications in Europe, Australia, Japan, Brazil, Russia, India, China and nine additional foreign jurisdictions are pending in the second patent family. Patents that issue from applications in these patent families are expected to have patent terms until at least 2030 and 2032, respectively. We hold an exclusive license to Childrens interest in these patent rights. We co-own with Childrens two further patent families covering follow-on pneumococcal vaccine compositions, and Childrens interest in these patents is also exclusively licensed to us.

GEN-001 (Chlamydia)

Our chlamydia patent portfolio includes four patent families (one of which overlaps with the ATLAS portfolio). We hold an exclusive license from President and Fellows of Harvard College to three of these four patent families. We wholly own the fourth patent family. The patent families cover chlamydia vaccine and immunogenic compositions and methods for inhibiting or treating chlamydia infections. A European Patent is issued in the first patent family; a U.S. application and applications in Canada and Australia are pending. A U.S. application and applications Europe, Canada, Australia and Japan are pending in the second and third patent families. A U.S. application and applications in Europe, Australia and Japan are pending in the fourth patent family. Patents issuing from applications in these four patent families are expected to expire between 2027 and 2031.

In addition to the above, we have established expertise and development capabilities focused in the areas of preclinical research and development, manufacturing and manufacturing process scale-up, quality control, quality assurance, regulatory affairs and clinical trial design and implementation. We believe that our focus and expertise will help us develop products based on our proprietary intellectual property.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional application. In the United States, a patent s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration of a United States patent as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a new drug application, or NDA, we expect to apply for patent term extensions for patents covering our product candidates and their methods of use.

In-License Agreements

University of California

In August 2006, we entered into an exclusive license agreement with The Regents of the University of California, or UC, granting us an exclusive, royalty-bearing sublicensable license to a patent family that includes claims to fundamental aspects of the ATLAS platform, to make, use, offer for sale, import and sell licensed products and services, and to practice licensed methods in all fields of use in the United States. This patent family consists entirely of issued United States patents with a patent term until August 2018. UC retains the right to practice and to allow other educational and non-profit institutions to practice, the licensed intellectual property licensed under the agreement for educational and research purposes.

Until first commercial sale of a licensed product or service, we are obligated to pay UC an annual license maintenance fee in the low five figures. Upon commercialization of our products and services covered by the licensed patents, we are obligated to pay UC royalties in the low single digits, subject to a minimum annual royalty in the low five figures, on the net sales of such products and services sold by us or our affiliates for the life of any licensed patents covering the products or services. The royalties payable to UC are subject to reduction for any third party payments required to be made, with a minimum floor in the low single digits. In addition, we agreed to pay UC a flat royalty in the low single digits on net sales of products sold by us or our affiliates which include a polypeptide, nucleotide sequence, biological organism or chemical entity identified in the practice of a licensed method or service, but not otherwise covered, by the licensed patent for the life of the licensed patents. If we receive any revenue (cash or non-cash) from any sublicensees, we must pay UC a percentage of such revenue, excluding certain categories of payments but including royalties on net sales by sublicensees, varying in the low-double digits for any sublicense depending on the scope of the license. Under the terms of the agreement, we are obligated to pay UC a specified development milestone payment and a specified commercial milestone payment up to $500 thousand in the aggregate for the first licensed product covered by the licensed patents, plus up to an additional $250

thousand if specified development and commercial milestones are met for each subsequent licensed product covered by the licensed patents. As of December 31, 2013, we have not made any milestone payments.

We are required to diligently develop and market licensed products, services and methods. If we are unable to meet our diligence obligations, even after any extension thereof, UC has the right, depending on the number of years the agreement has been effective, to either terminate the agreement or convert our exclusive license to a non-exclusive license.

Unless earlier terminated, the agreement with UC will remain in effect until the expiration of the last-to-expire patent under the licensed patent rights. We may terminate the agreement at any time by giving UC advance written notice. The agreement may also be terminated by UC in the event of a material breach by us that remains uncured after a specified period of time.

Harvard University

In November 2007, we entered into an exclusive license agreement with President and Fellows of Harvard College, or Harvard, granting us an exclusive, worldwide, royalty-bearing, sublicensable license to three patent families, to develop, make, have made, use, market, offer for sale, sell, have sold and import licensed products and to perform licensed services. This agreement was amended and restated in November 2012. The Harvard intellectual property covers methods related to the ATLAS discovery platform, as well as certain chlamydia immunogenic compositions and methods for inhibiting or treating chlamydia infections. Any patents within this portfolio that have issued or may be issued will expire normally in 2027 and 2028. Harvard retains the right to make and use, and to grant licenses to other not-for-profit research organizations to make and use, the licensed intellectual property for internal research, teaching and other educational purposes.

We are obligated to pay Harvard an annual license maintenance fee ranging from the low five figures to the mid five figures depending on the type of product and the number of years after the effective date of the agreement. For products covered by the licensed patent rights, we are obligated to pay Harvard milestone payments up to $1.8 million in the aggregate upon the achievement of certain development and regulatory milestones. For products discovered using the licensed methods, we are obligated to pay Harvard milestone payments up to $600 thousand in the aggregate for each of the first three products and up to $300 thousand in the aggregate for each additional product under the agreement upon the achievement of certain development and regulatory milestones. As of December 31, 2013, we have paid $66 thousand in aggregate milestone payments. Upon commercialization of our products covered by the licensed patent rights or discovered using the licensed methods, we are obligated to pay Harvard royalties on the net sales of such products and services sold by us, our affiliates and our sublicensees. This royalty varies depending on the type of product or service but is in the low single digits. The royalty based on sales by our sublicensees is the greater of the applicable royalty rate or a percentage in the high single digits or the low double digits of the royalties we receive from such sublicensee depending on the type of product. Depending on the type of commercialized product or service, royalties are payable until the expiration of the last-to-expire valid claim under the licensed patent rights or for a period of 10 years from first commercial sale of such product or service. The royalties payable to Harvard are subject to reduction, capped at a specified percentage, for any third party payments required to be made. In addition to the royalty payments, if we receive any additional revenue (cash or non-cash) under any sublicense, we must pay Harvard a percentage of such revenue, excluding certain categories of payments, varying from the low single digits to up to the low double digits depending on the scope of the license that includes the sublicense.

We are required to use commercially reasonable efforts to develop licensed products, introduce them into the commercial market and market them, in compliance with an agreed upon development plan. We are also obligated to achieve specified development milestones. If we are unable to meet our development milestones for any type of product or service, absent any reasonable proposed extension or amendment thereof, Harvard has the right, depending on the type of product or service, to terminate this agreement with respect to such products or to convert the license to a non-exclusive, non-sublicensable license with respect to such products and services.

Our agreement with Harvard will expire on a product-by-product or service-by-service and country-by-country basis until the expiration of the last-to-expire valid claim under the licensed patent rights. We may terminate the agreement at any time by giving Harvard advance written notice. Harvard may also terminate the agreement in the event of a material breach by us that remains uncured; in the event of our insolvency, bankruptcy, or similar circumstances; or if we challenge the validity of any patents licensed to us.

University of Washington

In January 2010, we entered into a patent license agreement with the University of Washington, or UW, which was subsequently amended and partially terminated with respect to specified patent rights in July 2012 and was further amended in September 2012 and November 2013. The agreement grants a worldwide, sublicensable, co-exclusive license to certain patent rights, and an exclusive license to certain other patent rights, to manufacture, have manufactured on our behalf, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of licensed products to prevent or treat HSV-2. Patents within the remaining licensed patent rights include claims to compositions of certain HSV-2 proteins and methods for treating HSV infections, with a patent term until at least July 2023. UW retains the right for itself and the Fred Hutchinson Cancer Research Center to make and use products and processes covered by the licensed patent rights for academic research, teaching and any other academic purpose.

Until the first commercial sale of a licensed product, we are obligated to pay UW an annual license maintenance fee in the low five figures. For each product covered by the licensed patent rights, we are obligated to pay UW milestone payments up to $750 thousand in the aggregate upon the achievement of certain development and commercial milestones. As of December 31, 2013, we have paid $25 thousand in milestone payments. Upon commercialization of our licensed products covered by the licensed patent rights, we are obligated to pay UW royalties in the low single digits on the net sales of such products sold by us, our affiliates and our sublicensees, subject to a minimum annual royalty payment in the low five figures following the first commercial sale of a licensed product. Royalties are payable on a country-by-country and licensed product-by-licensed product basis until the earlier of the termination of this agreement, or the date on which the manufacture, importation, use or sale of the licensed product is no longer covered by a valid claim of a licensed patent in such country. The royalties payable to UW are subject to reduction, capped at a specified percentage, for any third-party payments required to be made. In addition to the royalty payments, if we receive any additional revenue (cash or non-cash) under any sublicense, we must pay UW a percentage of such revenue, excluding certain categories of payments and payments made in consideration of additional intellectual property rights that are necessary or useful for commercialization of the licensed product, varying from the mid-single digits to the low double digit range depending on whether certain clinical study milestones have been achieved at the time the sublicense was granted.

We are required to use commercially reasonable efforts to commercialize the inventions covered by the licensed patents and to make and sell the licensed products within a reasonable period of time. We are also obligated to achieve specified development and regulatory performance milestones.

Our agreement with UW will expire on the date on which no valid claim in a licensed patent is pending or subsisting in any country worldwide. We may terminate the agreement on a licensed product-by-licensed product basis or in its entirety at any time by giving UW advance written notice. UW may also terminate the agreement in the event of a material breach by us that remains uncured within a specified timeframe; in the event of our insolvency, bankruptcy, or similar circumstances; or if we challenge the validity of the licensed patents.

Other Collaborations

Children s Medical Center Corporation

In September 2008, we entered into a collaborative research agreement with Childrens that was funded by PATH Vaccine Solutions, or PATH. The collaborative research project led to the identification of certain highly conserved pneumococcal antigens that are able to protect against colonization. The intellectual property covering these antigens is co-owned by us and Childrens and covers pneumococcal vaccine compositions and methods for inhibiting or treating pneumococcus infections. In February 2010, we entered into an exclusive license agreement with

Childrens, which was amended and restated in March 2012. This agreement grants us an exclusive, worldwide, sublicensable license under Childrens rights to the jointly-owned intellectual property to make, have made, use, sell, offer for sale, import and export licensed products and to practice licensed processes for the prevention and treatment of Streptococcus pneumoniae. Childrens retains the right to practice and use, and to allow academic non-profit research organizations to practice and use, the licensed intellectual property for research, educational, clinical and charitable purposes. Under the terms of the agreement, our license from Childrens is subject to PATH s separate non-exclusive, royalty-free license from Childrens to develop pneumococcal T cell-based protein vaccines worldwide and to market and sell such vaccines in developing countries.

For products covered by the licensed patent rights, we are obligated to pay Childrens milestone payments up to $390 thousand in the aggregate upon the achievement of certain development and commercial milestones. As of December 31, 2013, we have not made any milestone payments. Upon commercialization of our products, we are obligated

to pay Childrens royalties in the low single digits on the net sales of licensed products sold by us, our affiliates and our sublicensees. The royalties payable to Childrens are subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. Royalties are payable for the term of the license agreement, which is 15 years from the effective date of the amended and restated agreement or until expiration of the last-to-expire patent under the licensed patent rights, whichever period is longer. If we receive any additional revenue (cash or non-cash) under any sublicense, we must pay Childrens a percentage of such income varying from the mid-single digits to low double digits depending on the clinical stage of development of the product, provided that such percentage may increase to match our financial obligations to third parties.

We are required to use commercially reasonable efforts to bring at least one licensed product to market as soon as reasonably practical, consistent with sound and legal business practices and judgment and to accomplish the objectives set forth in an agreed upon development plan. If we are unable to meet our diligence obligations, even after any extensions thereof, Childrens has the right to terminate in this agreement in whole or in part.

Unless earlier terminated, the agreement with Childrens will remain in effect until the later of 15 years from the effective date of the amended and restated agreement or the expiration of the last to expire patent under the licensed patent rights. We may terminate the agreement in its entirety or on a country-by-country and licensed product-by-licensed product basis, at any time by giving Childrens advance written notice. Childrens may terminate the agreement in the event of our bankruptcy, insolvency or similar circumstances; if we use confidential information to formally challenge Childrens joint ownership of the licensed patent rights; or if we materially breach the agreement and do not cure such breach within a specified time period.

Isconova AB

In August 2009, we entered into an exclusive license and collaboration agreement with Isconova AB, now Novavax. The agreement grants us a worldwide, sublicensable, exclusive license to two patent families, to import, make, have made, use, sell, offer for sale and otherwise exploit licensed vaccine products containing an adjuvant which incorporates or is developed from Matrix-A, Matrix-C and/or Matrix-M technology, in the fields of HSV and chlamydia, and the time-limited exclusive fields of *Neisseria gonorrhoeae*, cytomegalovirus, or CMV, and *Mycobacterium tuberculosis*. After a specified period of time, the license grant to us in the time-limited exclusive fields will convert to a non-exclusive license with respect to all licensed intellectual property rights that were not jointly invented by us and Novavax under the collaboration. Under the terms of this agreement, Novavax also grants us a worldwide, sublicensable, non-exclusive license under such licensed intellectual property rights to import, make, have made, use, sell, offer for sale and otherwise exploit licensed products in the field of *Streptococcus pneumoniae*. Our rights in the field of *Streptococcus pneumoniae* are exclusive with respect to all intellectual property rights jointly invented by us and Novavax under the collaboration. The agreement further grants us certain limited rights to use Novavax trademarks.

For licensed products in each unique disease field under the agreement, we are obligated to pay Novavax milestone payments up to approximately $3 million in the aggregate upon the achievement of certain development and commercial milestones. As of December 31, 2013, we have paid $100 thousand in aggregate milestone payments. Upon commercialization of our products, we are obligated to pay Novavax royalties on the net sales of licensed products sold by us, our affiliates and our sublicensees. The royalties payable to Novavax are in the low single digits and vary on a country-by-country and licensed product-by-licensed product basis based on the amount of net sales and the nature and timing of the licensed product s development. The royalties payable to Novavax are subject to reduction if the licensed product is not covered by one or more valid claims of the licensed patent rights, or if we are required to make any third-party payments. Royalties are payable for 10 years from first commercial sale in any particular country or until the date on which offer for sale of a licensed product is no longer covered by a valid claim of the licensed patent rights in such country, whichever period is longer. In addition to the royalty payments, if we receive any additional revenue (cash or non-cash) under any sublicenses, we must pay Novavax a percentage of such revenue, up to the low double digits.

We are required to use commercially reasonable efforts to perform specified research activities in accordance with an agreed-upon research plan. We are also obligated to use commercially reasonable efforts consistent with prudent business judgment and business and market conditions to research, develop and carry out the commercialization of licensed products in HSV and chlamydia.

Our agreement with Novavax will expire on a country-by-country and licensed product-by-licensed product basis on the date of the expiration of the royalty term with respect to such licensed product in such country. We may terminate the agreement on a country-by-country and licensed product-by-licensed product basis or in its entirety at any time by giving

Novavax advance written notice. Both parties may also terminate the agreement in the event of a material breach by the other party that remains uncured or for bankruptcy, insolvency or similar circumstances. Novavax may terminate this agreement if we challenge the validity of any patents licensed to us.

Trade Secrets

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

United States Government Regulation

Biological products such as vaccines are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products. FDA approval must be obtained before clinical testing of biological products. FDA approval also must be obtained before marketing of biological products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals.

United States Biological Products Development Process

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an application for an IND, which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials according to the FDA s regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to

establish the safety and efficacy of the proposed biological product for its intended use;

- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with GMP, to assure that the facilities, methods and controls are adequate to preserve the biological product s identity, strength, quality and purity and, if applicable, the FDA s current good tissue practices, or GTPs, for the use of human cellular and tissue products;

- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate in humans, the product candidate enters the preclinical study stage. Preclinical studies, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and

formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical studies must comply with federal regulations and requirements including GLPs.

The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical studies may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such studies.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor s control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain AEs should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA s regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- *Phase 2.* The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- *Phase 3.* Clinical studies are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical studies, sometimes referred to as Phase 4 clinical studies, may be conducted after initial marketing approval. These clinical studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical studies must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the NIH and the investigators for serious and unexpected AEs, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor s initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB s requirements or if the biological product has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

United States Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee. PDFUA also imposes an annual product fee for biologics and an annual establishment fee on facilities used to manufacture prescription biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Within 60 days following submission of the application, the FDA reviews the BLA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP to assure and preserve the product s identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological 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 under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product 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 biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

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 GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure GMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions

that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product s safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

One of the performance goals agreed to by the FDA under the PDUFA is to review 90% of standard BLAs in 10 months from filing and 90% of priority BLAs in six months from filing, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Federal and State Fraud and Abuse, Transparency and Privacy Laws

In the United States, our business activities are subject to numerous other laws by federal and state authorities, in addition to the FDA, including but not limited to, the United States Federal Communications Commission, the United States Department of Health and Human Services, or HHS, and its various divisions, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS. These laws are enforced by various federal and state enforcement authorities, including but not limited to, the United States Department of Justice, and individual United States Attorney offices within the Department of Justice, HHS various enforcement divisions, including but not limited to, the Office of Inspector General, or OIG, the Office for Human Research Protections, or OHRP, and the Office of Research Integrity, or ORI, and other state and local government agencies.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, purchasing, leasing, ordering, or arranging for or recommending, the purchase lease, or order of any good, facility, service or item for which payment is made, in whole or in part, under a federal health care program, such as Medicare. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, or knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the federal government. Recently, the civil False Claims Act has been used to assert liability on the basis of kickbacks and improper referrals, improperly reported government pricing metrics such as Medicaid Best Price or Average Manufacturer Price, improper use of supplier or provider Medicare numbers when detailing a provider of services, improper promotion of drugs or off-label uses not expressly approved by the FDA in a drug s label, and misrepresentations with respect to the services rendered or items provided.

Additionally, the civil monetary penalties statute, among other things, imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal health care 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.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program and knowingly and willfully falsifying, concealing or covering up by trick,

scheme or device a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, health care benefits, items or services relating to health care matters.

Many states have similar fraud and abuse statutes and regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, private payors.

Additionally, the federal Physician Payments Sunshine Act within the Health Care and Education Reconciliation Act, or Health Care Reform Law, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program (with certain exceptions) to report to CMS, information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually to CMS certain ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business.

If our operations are found to be in violation of any of the health regulatory laws described above, or any other laws that apply to us, we may be subject to penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

Reimbursement

In both domestic and foreign markets, the commercial success of any approved products will depend, in part, on the availability of coverage and adequate reimbursement of such products from third-party payors, such as government health care programs, commercial insurance and managed care organizations. Patients who are provided vaccinations, and providers providing vaccinations, generally rely on third-party payors to reimburse all or part of the associated health care costs. Sales of any approved vaccines will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our approved vaccines will be paid by third-party payors. These third-party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. The containment of health care costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. In addition, there is significant uncertainty regarding the reimbursement status of newly approved health care products. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. If third-party payors do not consider our products to be cost-effective compared to other therapies, the payors may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

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

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

Medicare is a federal program administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that do not need to be administered by a physician). Medicare Part D is administered by private prescription

drug plans approved by CMS and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time.

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

Drug products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule, or FSS. FFS participation is required for a drug product to be covered and paid for by certain federal agencies and for coverage under Medicaid, Medicare Part B and the PHS pharmaceutical pricing program. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended to not exceed the price that a manufacturer charges its most-favored non-federal customer for its product. In addition, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TRICARE retail pharmacy program), Coast Guard, and PHS are subject to a cap on pricing (known as the federal ceiling price) and may be subject to an additional discount if pricing increases more than inflation.

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

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

The United States and state governments continue to propose and pass legislation designed to reduce the cost of health care. In March 2010, the United States Congress enacted the Health Care Reform Law which has the potential to change health care financing by both governmental and private payors. In the future, there may continue to be additional proposals relating to the reform of the United States health care system, some of which could further limit the prices we are able to charge, or the amounts of reimbursement available for our vaccine candidates once they are approved.

Outside the United States, ensuring adequate coverage and payment for our products will face challenges. In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. Recent budgetary pressures in many European Union countries are also causing governments to consider or implement various cost-containment measures, such as

price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost-containment measures. Cost-control initiatives could decrease the price we might establish for products that we may develop or sell, which would result in lower product revenues or royalties payable to us. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

Foreign Regulation

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

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

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. The decentralized procedure provides for approval by one or more concerned member states based on an assessment of an application performed by one member state, known as the reference member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state s assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Manufacturing

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical studies and clinical trials, as well as for commercial manufacture if our product candidates receive marketing approval. To date, we have obtained materials for GEN-003 and GEN-004 from third-party manufacturers who are sole source suppliers to us. For both product candidates, we intend to identify and qualify contract manufacturers to provide the protein process development, protein production and adjuvant production and fill-and-finish services prior to submission of an NDA to the FDA.

Employees

As of March 14, 2014, we had 44 full time employees. Of these 44 employees, 36 employees are engaged in research and development and 8 employees are engaged in finance, human resources, facilities and business and general management. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

Our Corporate Information

We were incorporated under the laws of the State of Delaware in August 2006. Our principal executive offices are located at 100 Acorn Park Drive, 5th Floor, Cambridge, Massachusetts 02140 and our telephone number is (617) 876-8191. Genocea® and the Genocea logo are registered trademarks.

Available Information

We maintain an Internet website at *http://www.genocea.com* where our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other documents and all amendments to those reports and documents are available without charge, as soon as reasonably practicable following the time they are filed with, or furnished to, the Securities and Exchange Commission. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document.

The public may read and copy any materials that we file with the Securities and Exchange Commission at the Securities and Exchange Commission s Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, the Securities and Exchange Commission maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the Securities and Exchange Commission. The public can obtain any documents that we file with the SEC at *http://www.sec.gov*.

Item 1A. Risk Factors

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our founding in 2006 and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biotechnology company, and we have not yet generated significant revenues. We have incurred net losses each year since our inception, including net losses of $20.8 million, $13.4 million and $14.7 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had accumulated a deficit of $80.1 million. To date, we have not commercialized any products or generated any revenues from the sale of products and have financed our operations primarily through private placements of our preferred stock and our initial public offering (IPO) completed in February 2014. We do not know whether or when we will generate product revenues or become profitable.

We have devoted most of our financial resources to research and development, including our clinical and preclinical technology development and development activities. To date, we have financed our operations primarily through the sale of equity securities and debt facilities and, to a lesser extent, through grants from governmental agencies and a private not-for-profit organization. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or additional grants. We have not completed pivotal clinical studies for any product candidate and it will be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payors and other factors.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue our Phase 1/2a clinical trial of GEN-003, our most advanced product candidate that we are developing for the treatment of HSV-2 infections, and commence a planned Phase 2 clinical trial in the second quarter of 2014 to optimize the vaccine dose, and a planned Phase 2b clinical trial in second quarter of 2015 to optimize the dosing regimen;

- continue our Phase 1 clinical trial of GEN-004, our second most advanced product candidate that we are developing to prevent infections caused by all strains of pneumococcus, and commence a planned Phase 2a clinical trial of GEN-004 by mid-2014;

- initiate additional preclinical, clinical or other studies for our other product candidates;

- manufacture material for clinical trials and for commercial sale;

- seek regulatory approvals for our product candidates that successfully complete clinical trials;

- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;

- seek to discover and develop additional product candidates;

- acquire or in-license other product candidates and technologies;

- make royalty milestone or other payments under any in-license agreements;

- maintain, protect and expand our intellectual property portfolio;

- attract and retain skilled personnel; and

- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any

particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

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

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

As of December 31, 2013, our cash and cash equivalents were $12.2 million and the net proceeds from our IPO that closed in February 2014 was $61.4 million, excluding offering expenses payable by us. We believe that we will continue to expend substantial resources for the foreseeable future developing GEN-003, GEN-004 and our pre-clinical product candidates. These expenditures will include costs associated with research and development, potentially acquiring new technologies, potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the progress, results and costs of the Phase 1/2a clinical trial and our two planned Phase 2 clinical trials of GEN-003;

- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates, including our Phase 1 clinical trial and our planned Phase 2a clinical trial of GEN-004;

- the number and development requirements of other product candidates that we pursue;

- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful and the outcome of regulatory review of our product candidates;

- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;

- the cost of manufacturing our product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization;

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;

- the costs involved in preparing, filing, prosecuting patent applications, maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation;

- the timing, receipt, and amount of sales of, or royalties or milestone payments on, our future products, if any; and

- the extent to which we acquire or in-license other products or technologies.

Based on our current operating plan, we believe that the net proceeds from our IPO in February 2014, together with our existing cash and cash equivalents and available future borrowings under our credit facility, will be sufficient to fund our projected operating expenses and capital expenditure requirements through at least the end of 2015. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us when needed, we would be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and development agreements with strategic partnerships with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidates, future revenue streams, research programs or product candidates or grant licenses on terms that are not favorable to us. If we are unable to raise additional when needed, we would be required to delay, limit, reduce or terminate our product development or commercialization efforts for GEN-003, GEN-004 or our preclinical product candidates, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to Clinical Development, Regulatory Review and Approval of Our Product Candidates

Because our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenue.

Our early encouraging preclinical and clinical results for GEN-003 and our preclinical results for GEN-004 are not necessarily predictive of the final results of our ongoing or future clinical trials. We have not yet completed our first human clinical trial, a Phase 1/2a trial of GEN-003.

Success in preclinical studies may not be predictive of similar results in humans during clinical trials, and successful results from early or small clinical trials of a vaccine candidate may not be replicated in later and larger clinical trials. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates or if we do not meet our clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates. Alternatively, even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy.

If we do not obtain regulatory approval for our current and future product candidates, our business will be adversely affected.

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, clinical trials, manufacturing, import, export and commercialization. In order to obtain regulatory approval for the commercial sale of any product candidate, we must demonstrate through extensive preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Clinical trials are expensive, time-consuming and uncertain as to outcome. We may gain regulatory approval for GEN-003, GEN-004 or our other preclinical product candidates in some but not all of the territories available or some but not all of the target indications, resulting in limited commercial opportunity for the approved vaccine, or we may never obtain regulatory approval for these product candidates in any jurisdiction.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. If patients are unwilling to participate in our studies because of negative publicity from adverse events in the biotechnology industries or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed or prevented. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

Additionally, in order to identify vaccine candidates using our ATLAS platform, we need to collect and process blood samples from human cohorts exposed to a pathogen. If we are unable to collect blood from a sufficient cohort for an indication we may be unable to identify additional product candidates.

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

- severity of the disease under investigation;
- design of the study protocol;
- size of the patient population;
- eligibility criteria for the trial in question;

- perceived risks and benefits of the product candidate under study;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate on-going or planned clinical trials, any of which would have an adverse effect on our business.

We may not be able to comply with requirements of foreign jurisdictions in conducting trials outside of the United States.

To date, we have not conducted any clinical trials outside of the United States. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country, should we attempt to do so, is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with contract research organizations, or CROs, and physicians;
- different standards for the conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners;
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment; and
- the acceptability of data obtained from studies conducted outside the United States to the FDA in support of a BLA.

If we fail to successfully meet requirements for the conduct of clinical trials outside of the United States, we may be delayed in obtaining, or be unable to obtain, regulatory approval for our product candidates in the United States or in countries outside of the United States.

We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays by us in reaching a consensus with regulatory agencies on trial design;

- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;

- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site;

- imposition of a clinical hold by regulatory agencies for any reason, including safety concerns raised by other clinical trials of similar vaccines that may reflect an unacceptable risk with GEN-003 or after an inspection of clinical operations or trial sites;

- failure to perform in accordance with the FDA s good clinical practices, or GCP, or applicable regulatory guidelines in other countries;

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

- delays caused by patients not completing participation in a trial or not returning for post-treatment follow-up;

- clinical trial sites or patients dropping out of a trial or failing to complete dosing;

- occurrence of serious adverse events in clinical trials that are associated with the product candidates that are viewed to outweigh its potential benefits; or

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial. Our IND for GEN-003 was subject to a clinical hold from January 2012 to July 2012. In our original

IND submission, we described a finding of osteonecrosis (microscopic evidence of bone and bone marrow death) in a toxicity study of GEN-003 conducted in mice. Because this finding was not present in toxicity studies conducted in other species, we reasoned that this was a mouse-specific finding and did not indicate a risk to humans in clinical trials. However, the FDA instituted a clinical hold and provided us with several options that would resolve this issue to their satisfaction. We selected the option to conduct an additional toxicity study in a highly relevant species (non-human primate) that would be more representative of a risk to humans. The study was conducted, no bone or bone marrow toxicity was observed, and the FDA subsequently lifted the clinical hold, allowing us to proceed with the first study in humans of GEN-003.

We cannot give any assurance that we will be able to resolve any future clinical holds imposed by the FDA or other regulatory authorities outside of the United States, or any delay caused by other factors described above or any other factors, on a timely basis or at all. If we are not able to successfully initiate and complete subsequent clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates.

Our product candidates, including GEN-003 and GEN-004, are based on T cell activation, which is a novel approach for vaccines and medical treatments. Consequently, it may be difficult for us to predict the time and cost of product development. Unforeseen problems with the T cell approach to vaccines may prevent further development or approval of our product candidates. Because of the novelty of this approach, there may be unknown safety risks associated with the vaccines that we develop. Regulatory agencies such as the FDA may require us to conduct extensive safety testing prior to approval to demonstrate a low risk of rare and severe adverse events caused by the vaccines. If approved, the novel mechanism of action of the vaccines may adversely affect physician and patient perception and uptake of our products.

We have concentrated our research and development efforts on T cell vaccine technology, and our future success is highly dependent on the successful development of T cell vaccines in general, and our product candidates in particular. There can be no assurance that any development problems we or others researching T cell vaccines may experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved.

Public perception of vaccine safety issues, including adoption of novel vaccine mechanisms of action, may adversely influence willingness of subjects to participate in clinical trials, or if approved, to prescribe and receive novel vaccines. For example, GEN-004 is being developed for prevention of Pneumococcal infections, and parental aversion to new vaccines or vaccines in general may adversely influence later stage clinical trials of this product candidate or, if approved, its commercial success.

GEN-003 includes a novel vaccine adjuvant and our other product candidates may include one or more novel adjuvants, which may make it difficult for us to predict the time and cost of product development as well as the requirements the FDA or other regulatory agencies may impose to demonstrate the safety of the product candidate.

Novel vaccine adjuvants, included in some of our product candidates, may pose an increased safety risk to patients. Adjuvants are compounds that are added to vaccine antigens to enhance the activation and improve immune response and efficacy of vaccines. Development of vaccines with novel adjuvants requires evaluation in larger numbers of patients prior to approval than would be typical for therapeutic drugs. Guidelines for evaluation of vaccines with novel adjuvants have been established by the FDA and other regulatory bodies and expert committees. Our product candidates, including GEN-003, may include one or more novel vaccine adjuvants. The safety of any vaccine, because of the presence of an adjuvant, may have side effects considered to pose too great a risk to patients to warrant approval of the vaccine. Traditionally, regulatory authorities have required extensive study of novel adjuvants because vaccines typically get administered to healthy populations, in particular infants, children and the elderly, rather than in people with disease. Such extensive study has often included long-term monitoring of safety in large general populations that has at times exceeded 10,000 subjects. This contrasts with the few thousand subjects typically necessary for approval of novel therapeutics. Although GEN-003 is being developed as a treatment, and therefore is not expected to be administered to

uninfected subjects, regulators nonetheless may require us to amass a prophylactic vaccine-like safety database. To date, the FDA and other major regulatory agencies have only approved vaccines containing five adjuvants, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States or elsewhere.

If we fail to obtain regulatory approval in jurisdictions outside the United States, we will not be able to market our products in those jurisdictions.

We intend to market our product candidates, if approved, in international markets. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to

obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, a vaccine must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our vaccine is also subject to approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our vaccines in any market.

Even if we receive regulatory approval for our product candidates, such vaccines will be subject to ongoing regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the vaccine potentially over many years. In addition, if the FDA approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMP, and GCP, for any clinical trials that we conduct post- approval.

Later discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- fines, warning letters, or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products; and

- injunctions or the imposition of civil, criminal and/or administrative penalties, damages, monetary fines, disgorgement, exclusion from participation in Medicare, Medicaid and other federal health care programs, and curtailment or restructuring of our operations.

The FDA s policies may change and additional government regulations may be enacted that could affect regulatory approval that we have received for our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct preclinical studies and clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We rely on third party CROs and other third parties to assist in managing, monitoring and otherwise carrying out our GEN-003 and GEN-004 clinical trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. We compete with many other companies for the resources of these third parties. The third parties on whom we rely generally may terminate

their engagements at any time, and having to enter into alternative arrangements would delay development and commercialization of our product candidates.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, the FDA and foreign regulatory authorities require compliance with regulations and standards, including GCP, for designing, conducting, monitoring, recording, analyzing, and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct our clinical trials, we are responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, the clinical trials of our product candidates may not meet regulatory requirements. If clinical trials do not meet regulatory requirements or if these third parties need to be replaced, preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates on a timely basis or at all.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We intend to rely on third parties to conduct some or all aspects of our product manufacturing, and these third parties may not perform satisfactorily.

We do not have any manufacturing facilities or personnel. We do not expect to independently conduct all aspects of our product manufacturing. We currently rely, and expect to rely, on third parties with respect to manufacturing. For example, we rely on third party suppliers and manufacturers to manufacture and supply vaccines for our initial GEN-003 and GEN-004 clinical trials. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Any of these third parties may terminate their engagement with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third parties for manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations regarding manufacturing.

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

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;

- reduced control as a result of using third party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance;

- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;

- the possible misappropriation of our proprietary information, including our trade secrets and know-how or infringement of third party intellectual property rights by our contract manufacturers; and

- disruptions to the operations of our third party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or affect our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

Third party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

If we are unable to manufacture our products in sufficient quantities, or at sufficient yields, or are unable to obtain regulatory approvals for a manufacturing facility for our products, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution.

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our product candidates at sufficient yields and at commercial-scale. We have no experience manufacturing, or managing third parties in manufacturing, any of our product candidates in the volumes that will be necessary to support large-scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality.

We expect to rely on third-parties for the manufacture of clinical and, if necessary, commercial quantities of our product candidates. These third-party manufacturers must also receive FDA approval before they can produce clinical material or commercial products. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third-parties give other products greater priority. We may not be able to enter into any necessary third-party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we may have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time-consuming and may result in delays.

Our reliance on contract manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our bulk vaccines on a commercial-scale, replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in the production of our vaccine. A third-party manufacturer may also encounter difficulties in production. These problems may include:

- difficulties with production costs, scale-up and yields;
- unavailability of raw materials and supplies;
- insufficient quality control and assurance;
- shortages of qualified personnel;
- failure to comply with strictly enforced federal, state and foreign regulations that vary in each country where product might be sold; and

- lack of capital funding.

As a result, any delay or interruption could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products.

A part of our strategy is to evaluate and, as deemed appropriate, enter into partnerships in the future when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

In addition, our strategic partners may breach their agreements with us, and we may not be able to adequately protect our rights under these agreements. Furthermore, our strategic partners will likely negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we would do so.

If we fail to establish and maintain strategic partnerships related to our product candidates, we will bear all of the risk and costs related to the development of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise which we do not have and for which we have not budgeted. This could negatively affect the development of any unpartnered product candidate.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, patent applications, know how and confidentiality agreements to protect the intellectual property related to our platform technology and product candidates. The patent position of biotechnology companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the United States Patent and Trademark Office, or U.S. PTO, 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. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our discovery platform or product candidates in the United States or in other countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or those of our licensors has been found, and prior

art that we have not disclosed could be used by a third party to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our discovery platform or product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications, or those of our licensors, may not adequately protect our platform technology, provide exclusivity for our product candidates, prevent others from designing around our patents with similar products, or prevent others from operating in jurisdictions in which we did not pursue patent protection. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If patent applications we hold or have in-licensed with respect to our platform or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates or ATLAS discovery platform, it could dissuade companies from collaborating with us. We or our licensors have filed several patent applications covering aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid and unenforceable or will be challenged by third parties. Any successful opposition to these patent applications, or patents that may issue from

them, or to any other patent applications or patents owned by or licensed to us, could deprive us of rights necessary for the successful commercialization of any product candidate that we may develop. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the U.S. PTO itself, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In the United States, for patent applications filed prior to March 16, 2013, assuming the other requirements for patentability are met, the first to invent is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. On March 16, 2013, the United States transitioned to a first to file system more like that in the rest of the world in that the first inventor to file a patent application is entitled to the patent. Under either the prior system or current one, third parties are allowed to submit prior art prior to the issuance of a patent by the U.S. PTO, and may become involved in opposition, derivation, reexamination, *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position with respect to third parties.

In addition, patents have a limited lifespan. In most countries, including the United States, the natural expiration of a patent is 20 years from the date it is filed. Various extensions of patent term may be available in particular countries, however in all circumstances the life of a patent, and the protection it affords, has a limited term. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. Such possible extensions include those permitted under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States, which permits a patent term extension of up to five years to cover an FDA-approved product. The actual length of the extension will depend on the amount of patent term lost while the product was in clinical trials. However, the applicable authorities, including the 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 be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data, and then may be able to launch their product earlier than might otherwise be the case.

Any loss of, or failure to obtain, patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products.

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

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary to enforce or defend our intellectual property rights, to protect our trade secrets and/or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Such litigation can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to litigate intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. 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 on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. 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.

Third-party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates, and to use our or our licensors proprietary technologies without infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other

intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination, and *inter partes* review proceedings before the U.S. PTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims for example to materials, formulations, methods of manufacture, methods of analysis, and/or methods for treatment related to the use or manufacture of our products or product candidates. In some cases, we may have failed to identify relevant such third-party patents or patent application. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our platform technology or our products or product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or product candidates and/or the use, analysis, and/or manufacture of our product candidates.

If any third-party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture, methods of analysis, and/or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we obtain a license. Such licenses may not be available on acceptable terms, if at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

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

We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party s trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages.

During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

We have in-licensed a portion of our intellectual property, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.

We are a party to a number of license agreements that are important to our business, and we may enter into additional license agreements in the future. Our discovery platform is built, in part, around patents exclusively in-licensed from academic or research institutions. Certain of our in-licensed intellectual property also covers, or may cover, GEN-003 and other product candidates. See Business In-License Agreements and Business Other Collaborations for a description of our license agreements with The Regents of the University of California, President and Fellows of Harvard College, University of Washington, Children s Medical Center Corporation, and Isconova AB.

Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in our drug discovery and development efforts, and our ability to enter into collaboration or marketing agreements for an affected product candidate, may be adversely affected.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of proprietary information.

In addition to the protection afforded by patents, we rely on confidentiality agreements to protect proprietary know-how that may not be patentable or that we may elect not to patent, processes for which patents are difficult to enforce and any other elements of our platform technology and discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. Although we use reasonable efforts to protect our know-how, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our know-how information to competitors. In addition, competitors may otherwise gain access to our know-how or independently develop substantially equivalent information and techniques.

Enforcing a claim that a third party illegally obtained and is using any of our know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect know-how. Misappropriation or unauthorized disclosure of our know-how could impair our competitive position and may have a material adverse effect on our business.

Risks Related to Commercialization of Our Product Candidates

Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payors and others in the medical community.

Even if we obtain marketing approval for GEN-003, GEN-004 or any other products that we may develop or acquire in the future, the product may not gain market acceptance among physicians, third-party payors, patients and others in the medical community. For example, we currently expect that GEN-003 will be required to be administered by injection initially and with boosters. Physicians or patients may not accept this product as a result of this anticipated dosing requirement. In addition, market acceptance of any approved products depends on a number of other factors, including:

- the efficacy and safety of the product, as demonstrated in clinical trials;

- the clinical indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any warnings that may be required on the label;

- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;

- the cost, safety and efficacy of treatment in relation to alternative treatments;

- the availability of adequate course and reimbursement by third-party payors and government authorities;

- relative convenience and ease of administration;

- the prevalence and severity of adverse side effects;

- the effectiveness of our sales and marketing efforts; and

- the restrictions on the use of our products together with other medications, if any.

Market acceptance is critical to our ability to generate significant revenue. Any product candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales and marketing organization.

In the future, we expect to build a focused sales and marketing infrastructure to market or co-promote some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to physicians;

- the lack of adequate numbers of physicians to prescribe any future products;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of any approved products will depend significantly on the availability of adequate coverage and reimbursement from third-party payors and may be affected by existing and future health care reform measures. Third-party payors, such as government health care programs, private health insurers and health maintenance organizations, decide which drugs they will provide coverage for and establish reimbursement levels. Coverage and reimbursement decisions by a third-party payor may depend upon a number of factors, including the third-party payor s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs. Coverage and reimbursement can vary significantly from payor to payor. As a result, obtaining coverage and reimbursement approval for a product from each government and other third-party payor will require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor separately, with no assurance that we will be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Also, we cannot be sure that coverage determinations or reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products. In addition, in the United States third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs.

Price controls may be imposed, which may adversely affect our future profitability.

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on

coverage, prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available vaccines in order to obtain or maintain coverage, reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. There can be no assurance that our vaccine candidates will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors reimbursement policies will not adversely affect our ability to sell our products profitably. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

The impact of recent health care reform legislation and other changes in the health care industry and in health care spending on us is currently unknown, and may adversely affect our business model.

In the United States, and in some foreign jurisdictions, the legislative landscape continues to evolve. Our revenue prospects could be affected by changes in health care spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws or judicial decisions, or new interpretations of existing laws or decisions, related to

health care availability, the method of delivery or payment for health care products and services could negatively impact our business, operations and financial condition. There is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act in 2010. It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing health care legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- the demand for any drug products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.

The development and commercialization of new drug products is highly competitive. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of our product candidates. Our objective is to design, develop and commercialize new products with superior efficacy, convenience, tolerability and safety. In many cases, the products that we commercialize will compete with existing, market-leading products.

Oral antivirals, such as valacyclovir and famciclovir, are products currently approved to treat patients with HSV-2. GEN-003, our lead product candidate, will compete with these products, if approved. In addition, one or more products not currently approved for the treatment of HSV-2, including pritelivir (AiCuris) and HerpV (Agenus) and other vaccines in development by Coridon Pty, Ltd and Vical Incorporated may in the future be granted marketing approval for the treatment of HSV-2 or other conditions for which GEN-003 might be approved.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. Large and established companies such as Merck & Co., Inc., GlaxoSmithKline plc, Novartis, Inc., Sanofi Pasteur, SA, Pfizer Inc. and MedImmune, LLC (a subsidiary of AstraZeneca PLC), among others, compete in the vaccine market. In particular, these companies have greater experience and expertise in securing government contracts and grants

to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products before we do. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

Our products may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.

Undesirable side effects caused by our products or even competing products in development that utilize a common mechanism of action could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. We are

currently conducting a Phase 1/2a clinical trial for GEN-003. Serious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole. The most common adverse events to date in the clinical trial evaluating the safety and tolerability of GEN-003 have been fatigue, myalgia (muscle pain), pain tenderness and induration (inflammatory hardening of the skin). Our understanding of the relationship between GEN-003 and these events, as well as our understanding of adverse events in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected adverse events may be observed.

If we or others identify undesirable side effects caused by our product candidates either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical trials may be put on hold;
- we may be unable to obtain regulatory approval for our vaccine candidates;
- regulatory authorities may withdraw approvals of our vaccines;
- regulatory authorities may require additional warnings on the label;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our products and could substantially increase commercialization costs.

Risks Related to Our Indebtedness

Our level of indebtedness and debt service obligations could adversely affect our financial condition, and may make it more difficult for us to fund our operations.

In September 2013 we entered into a secured credit facility pursuant to a working capital term loan facility with Ares Capital Corporation providing for term loans of up to an aggregate of $10.0 million. On September 30, 2013, we drew down an initial $3.5 million under our secured credit facility and paid off our then existing secured credit facility. We drew down the remaining $6.5 million in December 2013. All obligations under our secured credit facility are secured by substantially all of our existing property and assets, excluding our intellectual property and licensed-in technology. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

- we will need to repay our indebtedness by making payments of interest and principal, which will reduce the amount of money available to finance our operations, our research and development efforts and other general corporate activities; and

- our failure to comply with the restrictive covenants in our secured credit facility could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and the lender could seek to enforce its security interest in the assets securing such indebtedness.

To the extent additional debt is added to our current debt levels, the risks described above could increase.

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

Failure to satisfy our current and future debt obligations under our secured credit facility could result in an event of default and, as a result, our lender could accelerate all of the amounts due. In the event of an acceleration of amounts due under our secured credit facility as a result of an event of default, we may not have sufficient funds or may be unable to

arrange for additional financing to repay our indebtedness. In addition, our lender could seek to enforce its security interests in the assets securing such indebtedness.

We are subject to certain restrictive covenants which, if breached, could have a material adverse effect on our business and prospects.

Our secured credit facility imposes operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things:

- dispose of certain assets;
- change our lines of business;
- engage in mergers or consolidations;
- incur additional indebtedness;
- create liens on assets;
- pay dividends and make distributions or repurchase our capital stock; and
- engage in certain transactions with affiliates.

Risks Related to Our Business and Industry

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our products, conduct our clinical trials and commercialize our product candidates.

We are highly dependent on members of our senior management, including William Clark, our President and Chief Executive Officer, Seth Hetherington, M.D., our Chief Medical Officer, Jessica Flechtner, Ph.D., our Senior Vice President of Research, and Paul Giannasca, Ph.D., our Vice President, Biopharmaceutical Development and Production. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. We have employment agreements with each of these members of senior management and we maintain a keyman insurance policy on Mr. Clark for $2.0 million.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Our employees, independent contractors, principal investigators, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraudulent or other illegal activity by our employees, independent contractors, principal investigators, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails: to comply with the laws of the FDA and similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and similar foreign regulatory bodies; to comply with

manufacturing standards we have established; to comply with federal, state and foreign health care fraud and abuse laws and regulations; to report financial information or data accurately; or to disclose unauthorized activities to us. In particular, the promotion, sale and marketing of health care items and services, as well as certain business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and, structuring and commission(s), certain customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our relationships with health care professionals, institutional providers, principal investigators, consultants, customers (actual and potential) and third-party payors are, and will continue to be, subject, directly and indirectly, to federal and state health care fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

Our business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and state governments in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal health care program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly 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, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, health care

benefits, items or services relating to health care matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose requirements on certain covered health care providers, health plans, and health care clearinghouses as well as their respective business associates that perform services

for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;

- the federal Physician Payments Sunshine Act, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, ACA, and its implementing regulations requires manufacturers of drugs, devices, biologicals 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 United States 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, as well as ownership and investment interests held by physicians and their immediate family members, with data collection required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services required by March 31, 2014 and by the 90th day of each subsequent calendar year;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- federal government price reporting laws, changed by ACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts);

- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and

- state law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving health care items or services reimbursed by any third-party payor, including commercial insurers; state 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 that otherwise restricts payments that may be made to health care providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to health care professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects.

In addition, the regulatory approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws.

Efforts to ensure that our business arrangements will comply with applicable health care laws may involve substantial costs. It is possible that governmental and enforcement 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 health care laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigations;
- a diversion of management s time and our resources;
- substantial monetary awards to trial participants or patients;

- product recalls, withdrawals, or labeling, marketing or promotional restrictions;

- loss of revenue;

- the inability to commercialize any product candidates that we may develop; and

- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical trials in the amount of $5.0 million in the aggregate. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We must comply with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We use hazardous chemicals and radioactive and biological materials in certain aspects of our business and are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, distribution, storage, handling, treatment and disposal of these materials. We cannot eliminate the risk of accidental injury or contamination from the use, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials. In the event of contamination or injury, or failure to comply with environmental, occupational health and safety and export control laws and regulations, we could be held liable for any resulting damages and any such liability could exceed our assets and resources. We are uninsured for third- party contamination injury.

We may not be able to win government, academic institution or non-profit contracts or grants.

From time to time, we may apply for contracts or grants from government agencies, non-profit entities and academic institutions. Such grants have been our only source of revenue to date. Such contracts or grants can be highly attractive because they provide capital to fund the on- going development of our technologies and product candidates without diluting our stockholders. However, there is often significant competition for these contracts or grants. Entities offering contracts or grants may have requirements to apply for or to otherwise be eligible to receive certain contracts or grants that our competitors may be able to satisfy that we cannot. In addition, such entities may make arbitrary decisions as to whether to offer contracts or make grants, to whom the contracts or grants will be awarded and the size of the contracts or grants to each awardee. Even if we are able to satisfy the award requirements, there is no guarantee that we will be a successful awardee. Therefore, we may not be able to win any contracts or grants in a timely manner, if at all.

RISKS RELATED TO OUR COMMON STOCK

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

As of March 14, 2014, our executive officers, directors and principal stockholders who owned more than 5% of our outstanding common stock, in the aggregate, beneficially owned shares representing approximately 43.3% of our common stock. Therefore, these stockholders will have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, 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 believe are in your best interest as one of our stockholders.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, 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. Among other things, these provisions:

- authorize blank check preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;

- create a classified board of directors whose members serve staggered three-year terms;

- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, our chief executive officer or our president;

- prohibit stockholder action by written consent;

- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;

- provide that our directors may be removed only for cause;

- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum

- specify that no stockholder is permitted to cumulate votes at any election of directors;

- expressly authorize our board of directors to modify, alter or repeal our bylaws; and

- require supermajority votes of the holders of our common stock to amend specified provisions of our bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our certificate of incorporation, our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock

If our stock price is volatile, our stockholders could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders could incur substantial losses. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- 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 discover, develop, acquire or in-license 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;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and

- the other factors described in this Risk Factors section.

We incur significant costs as a result of operating as a newly-public company, and our management must devote substantial time to new compliance initiatives.

As a newly public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission and NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel must devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and make some activities more time-consuming and costly.

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur 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 14, 2014, we had outstanding 17,310,770 shares of common stock, of which 5,500,000 may be resold in the public market immediately without restriction, unless purchased by our affiliates or existing stockholders. The remaining 11,810,770 shares are restricted securities as such term is defined in Rule 144 of the Securities Act of 1933, as amended (the Securities Act). Moreover, holders of an aggregate of 11,464,036 shares of our common stock and holders of warrants to purchase 2,360 shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. Our existing NOLs may be subject to substantial limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize NOLs could be further limited by Section 382 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income. As described above under Risks Related to

Our Financial Position and Need for Additional Capital , we have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs.

Our certificate of incorporation designates the state or federal courts located in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that, subject to limited exceptions, the state and federal courts located in the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws or (4) any other action asserting a claim against us that is

governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

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

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. In addition, our ability to pay cash dividends is currently prohibited by the terms of our debt financing arrangement, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices are located at 100 Acorn Park Drive, 5TH floor, Cambridge, Massachusetts 02140, where we occupy approximately 23,666 square feet of laboratory and office space. Our lease term expires on February 28, 2017. We believe that our existing facilities are sufficient for our present and future operations, and we currently have no plans to lease additional space.

Item 3. Legal Proceedings

From time to time we are subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this Annual Report on Form 10-K, we do not believe we are party to any claim or litigation, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. **Mine Safety Disclosures**

Not applicable.

PART II

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

Market Information

Our common stock has been publicly traded on the NASDAQ Global Market under the symbol GNCA since February 5, 2014. Prior to that time, there was no public market for our common stock. As a result, we have not set forth quarterly information with respect to the high and low prices for our common stock for the two most recent fiscal years.

Holders

As of March 14, 2014, there were 55 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2013.

Plan category	Number of securities to be issued upon exercise of outstanding stock options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))

Equity compensation plans approved by security holders (1)	1,576,185	$	2.66	247,006
Equity compensation plans not approved by security holders				
Total	1,576,185	$	2.66	247,006

(1) Includes information regarding our 2007 Equity Incentive Plan.

Recent Sales of Unregistered Securities

Set forth below is information regarding securities sold by us during 2013 that were not registered under the Securities Act. Also included is the consideration, if any, received by us for the securities and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

Issuances of securities

On June 24, 2013, we issued 26,293,103 shares of Series C preferred stock at a price per share of $0.58 for total consideration of $15,250,000 to 21 investors.

Issuances of preferred stock were exempt pursuant to Rule 506 and Section 4(a)(2) of the Securities Act.

On September 30, 2013, in connection with the working capital term loan facility with Ares Capital Corporation, we issued a warrant to purchase 689,655 shares of our Series C preferred stock at an exercise price of $0.58 per share to Ares Capital Corporation.

Sale of the warrant was exempt pursuant to Rule 506 and Section 4(a)(2) of the Securities Act.

No underwriters were involved in the foregoing sales of securities. The securities were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act, including in some cases, Regulation D promulgated thereunder, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers of shares of preferred stock described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration. Effective upon the closing of our IPO on February 10, 2014, each share of our Series C preferred stock converted into our common stock on a 1-to-0.08 basis in connection with the 1-for-11.9 reverse stock split of our common stock effected on January 21, 2014.

Stock option and other equity awards

In 2013, we granted options to purchase a total of 559,742 shares of our common stock to employees and non-employees, at a weighted average price of $3.41 per share. During the same period, we issued 31,809 shares of common stock upon the exercise of options to purchase such shares of common stock at a weighted average price of $1.33 per share.

Option grants and the issuances of common stock upon exercise of such options were exempt pursuant to Rule 701 and Section 4(a)(2) of the Securities Act.

The issuance of stock options and the common stock issuable upon the exercise of such options, and the grant of restricted stock units and the issuance of common stock issuable upon vesting of such restricted stock units, were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Use of Proceeds from Equity Securities

In February 2014, we completed an initial public offering of 5,500,000 shares of our common stock at a price of $12.00 per share for an aggregate offering price of $66.0 million. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-193043), which was declared effective by the Securities and Exchange Commission on February 4, 2014 and, filed pursuant to Rule 462(b) of the Securities Act. Citigroup Global Markets, Inc. and Cowen and Company, LLC acted as joint book-running managers of the offering and as representatives of the underwriters. Stifel, Nicolaus & Company, Incorporated and Needham & Company, LLC acted as co-managers for the offering. The offering commenced on February 4, 2014 and did not terminate until the sale of all of the shares offered.

We received net proceeds from the offering of approximately $61.4 million, after deducting approximately $4.6 million in underwriting discounts and commissions, excluding offering costs payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours.

As of February 28, 2014 we have used approximately $1.8 million of the net proceeds primarily to fund working capital, capital expenditures and other general corporate purposes. We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10

percent or more of our common stock or to any affiliate of ours. We have invested the balance of the net proceeds from the offering in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities. There has been no material change in our planned use of the balance of the net proceeds from the offering as described in our final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act.

Item 6. Selected Financial Data

The selected statements of operations data for each of the three years in the period ended December 31, 2013 and the balance sheet data at December 31, 2013 and 2012 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected balance sheet data at December 31, 2011 have been derived from our audited financial statements not included in this Annual Report on Form 10-K. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our interim period results are not necessarily indicative of results to be expected in any future period.

The information set forth below should be read in conjunction with the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this Annual Report on Form 10-K and with our financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

(in thousands, except per share data)	Years Ended December 31, 2013	2012	2011	The Period from August 16, 2006 (Inception) to December 31, 2013
Statement of Operations Data:				
Grant revenue	$ 731	$ 1,977	$ 1,820	$ 6,694
Operating expenses:				
Research and development	15,695	11,240	13,543	60,122
General and administrative	4,961	3,690	3,004	20,952
Total operating expenses	20,656	14,930	16,547	81,074
Loss from operations	(19,925)	(12,953)	(14,727)	(74,380)
Other (expense) income:				
Other (expense) income	(422)	93	75	(32)
Interest expense, net	(459)	(507)	(33)	(1,691)
Other (expense) income	(881)	(414)	42	(1,723)
Net loss	$ (20,806)	$ (13,367)	$ (14,685)	$ (76,103)
Reconciliation of net loss to net loss attributable to common stockholders:				
Net loss	$ (20,806)	$ (13,367)	$ (14,685)	$ (76,103)
Accretion of redeemable convertible preferred stock to redemption value	(1,605)	(1,781)	(1,605)	(5,914)
Net loss attributable to common stockholders	$ (22,411)	$ (15,148)	$ (16,290)	$ (82,017)
Net loss per share attributable to common stockholders-basic and diluted (1)	$ (75.46)	$ (51.35)	$ (55.41)	$ (347.53)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	297	295	294	236

(in thousands)	As of December 31, 2013	2012	2011
Balance Sheet Data:			
Cash and cash equivalents	$ 12,208	$ 11,516	$ 5,742
Working Capital	8,382	7,932	3,852
Total assets	15,761	13,531	6,940
Preferred stock warrant liability	656	246	339
Preferred stock	81,562	64,707	47,848
Common stock and additional paid-in-capital			
Total stockholders (deficit) equity	(80,131)	(58,402)	(43,562)

(1) See Note 2 within the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K for a description of the method used to calculate basic and diluted net loss per common share.

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 the section entitled Selected Financial Data and our financial statements and related notes appearing in this

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Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the Risk Factors section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical stage biotechnology company that discovers and develops novel vaccines to address infectious diseases for which no vaccine or vaccines with limited effectiveness exist today. We use our proprietary discovery platform, ATLAS, to rapidly design vaccines that act through T cell (or cellular) immune responses, in contrast to approved vaccines, which are designed to act primarily through B cell (or antibody) immune responses. We believe that by harnessing T cells we can develop first-in-class vaccines to address infectious diseases where T cells are central to the control of the disease. In September 2013, we announced human proof-of-concept data for GEN-003, a therapeutic vaccine candidate that we are developing to treat herpes simplex virus-2, or HSV-2, infections. These data from our ongoing Phase 1/2a trial represent the first reported instance of a vaccine significantly reducing viral shedding, an indicator of disease activity in HSV-2. If GEN-003 successfully completes clinical development and is approved, we believe it would represent an important new treatment option for patients with HSV-2. We are also developing a second T cell vaccine candidate, GEN-004 for *Streptococcus pneumoniae* or pneumococcus, a leading cause of infectious disease mortality worldwide. We have initiated a Phase 1 trial for GEN-004, which we anticipate completing by mid-2014. This Phase 1 trial is designed to demonstrate the T cell response associated with natural protection against pneumococcus. If this trial is successful, we plan to conduct a Phase 2 clinical trial to seek to demonstrate that GEN-004 can reduce pneumococcus in humans by mid-2015.

We commenced business operations in August 2006. To date, our operations have been limited to organizing and staffing our company, acquiring and developing our proprietary ATLAS technology, identifying potential product candidates and undertaking preclinical studies and clinical trials of our product candidates. All of our revenue to date has been grant revenue. We have not generated any product revenue and do not expect to do so for the foreseeable future. We have primarily financed our operations through the issuance of our equity securities, debt financings and amounts received through grants. At December 31, 2013, we had received an aggregate of $92.0 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $6.7 million from grants. At December 31, 2013, our cash and cash equivalents were $12.2 million.

Since inception, we have incurred significant operating losses. Our net losses were $20.8 million, $13.4 million and $14.7 million for the years ended December 31, 2013, 2012 and 2011, respectively. At December 31, 2013, we had accumulated a deficit of $80.1 million. We expect to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We will need to generate significant revenue to achieve profitability, and we may never do so.

We believe that the net proceeds of our IPO completed in February 2014, together with our existing cash and cash equivalents at December 31, 2013, will enable us to fund our operating expenses and capital expenditure requirements through at least the end of 2015, by which time we expect to have completed our ongoing Phase 1/2a clinical trial and the first of our planned Phase 2 clinical trials for GEN-003 for HSV-2 and our Phase 1 clinical trial and our planned Phase 2a clinical trial for GEN-004 for pneumococcus. However, costs related to clinical trials can be unpredictable and therefore there can be no guarantee that the net proceeds from this offering and from these other sources will be sufficient to fund these studies or our operations through this period. These funds will not be sufficient to enable us to conduct pivotal clinical trials for, seek marketing approval for or commercially launch GEN-003, GEN-004 or any other product candidate. Accordingly, to obtain marketing approval for and to commercialize these or any other product candidates, we will be required to obtain further funding through public or private equity offerings, debt financings, collaboration and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital when needed would have a negative effect on our financial condition and our ability to pursue our business strategy.

Financial Overview

Revenue

Grant revenue consists of revenue earned to conduct vaccine development research. We have received grants from a private not-for-profit organization and federal agencies. These grants have related to the discovery and development of

several of our product candidates, including product candidates for the prevention of pneumococcus, chlamydia, and malaria. Revenue under these grants is recognized as research services are performed. Funds received in advance of research services being performed are recorded as deferred revenue. We plan to continue to pursue grant funding, but there can be no assurance we will be successful in obtaining such grants in the future.

We have no products approved for sale. We will not receive any revenue from any product candidates that we develop until we obtain regulatory approval and commercialize such products or until we potentially enter into agreements with third parties for the development and commercialization of product candidates. If our development efforts for any of our product candidates result in regulatory approval or we enter into collaboration agreements with third parties, we may generate revenue from product sales or from such third parties.

We expect that our revenue will be less than our expenses for the foreseeable future and that we will experience increasing losses as we continue our development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. Our ability to generate revenue for each product candidate for which we receive regulatory approval will depend on numerous factors, including competition, commercial manufacturing capability and market acceptance of our products.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred to advance our preclinical and clinical candidates, which include:

- personnel-related expenses, including salaries, benefits, stock-based compensation expense and travel;

- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, consultants and other vendors that conduct our clinical trials and preclinical activities;

- costs of acquiring, developing and manufacturing clinical trial materials and lab supplies; and

- facility costs, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

We expense internal research and development costs to operations as incurred. We expense third party costs for research and development activities, such as conducting clinical trials, based on an evaluation of the progress to completion of specific tasks such as patient enrollment, clinical site activations or information, which is provided to us by our vendors.

The following table identifies research and development expenses on a program-specific basis for our product candidates for the years ended December 31, 2013, 2012 and 2011(in thousands):

	Years Ended December 31,		
	2013	2012	2011
HSV-2 (GEN-003)(1)	$ 7,730	$ 5,605	$ 9,429
Pheumococcus (GEN-004)(1)	5,848	4,247	2,049
Other research and development(2)	2,117	1,388	2,065
Total research and development	$ 15,695	$ 11,240	$ 13,543

(1) Includes direct and indirect internal costs and external costs such as CMO and CRO costs.

(2) Includes costs related to other product candidates and technology platform development costs related to ATLAS.

At December 31, 2013, we had incurred an aggregate of $40.5 million in research and development expenses related to GEN-003 and GEN-004. We expect our research and development expenses will increase as we continue the manufacture of pre-clinical and clinical materials and manage the clinical trials of, and seek regulatory approval for, our product candidates. In the near term, we expect that our research and development expenses will increase as we conduct our ongoing phase 1/2a and planned Phase 2 clinical trials for GEN-003 and a Phase 1 and planned Phase 2a clinical trial for GEN-004.

We expect that the total costs to produce material for and to conduct our two planned Phase 2 clinical trials for GEN-003 will be approximately $25.0 million. With respect to GEN-004, we have started a Phase 1 clinical trial in the fourth quarter of 2013 and plan to start a Phase 2a clinical trial in the third quarter of 2014. We expect the total costs for these two trials, including the cost to manufacture the vaccine for these trials, will be approximately $8.0 million. Due to the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration, costs and timing of these clinical trials, and, as a result, the actual costs to complete these planned clinical trials may exceed the expected costs.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel, including stock-based compensation and travel expenses, in executive and other administrative functions. Other general and administrative expenses include facility-related costs, communication expenses and professional fees associated with corporate and intellectual property legal expenses, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in the future to support the continued research and development of our product candidates and to operate as a public company. These increases will likely include increased costs for insurance, costs related to the hiring of additional personnel and payments to outside consultants, lawyers and accountants, among other expenses. Additionally, if and when we believe a regulatory approval of our first product candidate appears likely, we anticipate that we will increase our salary and personnel costs and other expenses as a result of our preparation for commercial operations.

Interest Expense, Net

Interest expense, net consists primarily of interest expense on our long- term debt facilities and non-cash interest related to the amortization of debt discount and issuance costs, partially offset by interest earned on our cash and cash equivalents.

Other (Expense) Income

Other (expense) income consists of fair value adjustments on warrants to purchase preferred stock and loss on debt extinguishment.

Accretion of Preferred Stock

Certain classes of our preferred stock were redeemable beginning in 2017 at the original issuance price plus any declared or accrued but unpaid dividends upon written election of the preferred stockholders in accordance with the terms of our articles of incorporation. Accretion of preferred stock reflects the accretion of issuance costs and, for Series B preferred stock, cumulative dividends based on their respective redemption values. On February 10, 2014, we closed an initial public offering of our common stock and all shares of preferred stock were converted into 11,435,580 shares of our common stock. No accretion of preferred stock will be recorded after this date as no shares of preferred stock will be outstanding.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial position and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate estimates, which include, but are not limited to, estimates related to clinical trial accruals, stock-based compensation expense, warants to purchase redeemable securities, and reported amounts of revenues and expenses during the reported period. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances. Actual results may differ materially from those estimates or assumptions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses and other current liabilities. This process involves reviewing open contracts and purchase orders,

communicating with our personnel to identify services that have been performed for us and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued research and development expenses and other current liabilities as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses and other current liabilities include fees paid to CROs in connection with clinical trials, CMOs with respect to pre-clinical and clinical materials and intermediaries and vendors in connection with preclinical development activities.

We base our expenses related to clinical trials on our estimates of the services performed pursuant to contracts with clinical sites that conduct clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of required data submission. In accruing service fees, we estimate the time period over which services will be performed, enrollment of subjects, number of sites and services performed in each period. Additionally, we accrue 10% of the earned amounts at each clinical site, which is payable upon completion of the required data submission for the clinical trial. If our estimates of the status and timing of services performed differs 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, there has been no material differences from our estimates to the amount actually incurred.

Stock-Based Compensation

Since our inception in August 2006, we have applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, Topic 718, *Compensation Stock Compensation*, or ASC 718, to account for stock-based compensation for employees and ASC 718 and ASC 505, *Equity*, or ASC 505, for non-employees. We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant. Stock compensation related to non-employee awards is re-measured at each reporting period until the awards are vested. Described below is the methodology we have utilized in measuring stock-based compensation expense.

Determining the amount of stock-based compensation to be recorded requires us to develop estimates of the fair value of stock-based awards as of their measurement date. We recognize stock-based compensation expense over the requisite service period, which is the vesting period of the award. Calculating the fair value of stock-based awards requires that we make highly subjective assumptions. We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock, the fair value of our common stock on the measurement date, the expected term of our stock options, the risk free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Because we are a privately held company with a limited operating history, we utilize data from a representative group of publicly traded companies to estimate expected stock price volatility. We selected representative companies from the biopharmaceutical industry with characteristics similar to us. We use the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment* as we do not have sufficient historical stock option activity data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. For non-employee grants, we use an expected term equal to the remaining contractual term of the award. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention of paying cash dividends. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

Under ASC 718, we are required to estimate the level of forfeitures expected to occur and record stock-based compensation expense only for those awards that we ultimately expect will vest. For all periods presented, our estimated annual forfeiture rate was 10.52%.

Stock-based compensation expense includes options granted to employees and non-employees and has been reported in our statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Research and development	$ 322	$ 102	$ 117
General and administrative	350	205	197
Total	$ 672	$ 307	$ 314

We estimated the fair value of stock options of each employee stock award at the grant date using assumptions regarding the fair value of the underlying common stock on each grant date and the following additional assumptions:

	Years Ended December 31,		
	2013	2012	2011
Expected volatility	97.1%	99.2%	108.8%
Risk-free interest rate	0.59%-1.83%	0.99%	2.83%
Expected term (in years)	6.25	6.25	6.25
Expected dividend yield	0%	0%	0%

At December 31, 2013, we had approximately $1.0 million of total unrecognized compensation expense, net of related forfeiture estimates, which we expect to recognize over a weighted-average remaining vesting period of approximately three years. While our stock-based compensation expense for stock options has not been Significant to date, we expect the effect to grow in future periods due to the potential increases in the value of our common stock and increased number of stock options granted due to anticipated increases in our overall headcount.

We utilized significant estimates and assumptions in determining the fair value of our common stock. We granted stock options at exercise prices not less than the fair market value of our common stock as determined by the board of directors, with input from management. The board of directors determined the estimated fair value of our common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which we sold shares of redeemable convertible preferred stock, the superior rights and preferences of securities senior to our common stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company.

Our board of directors determined the fair value of our common stock considering, in part, the work of an independent third-party valuation specialist. The board determined the estimated per share fair value of our common stock at various dates considering 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. Following the closing of our IPO, the fair value of our common stock will be determined based on the quoted market price of our common stock. We engaged an independent third-party valuation specialist to perform contemporaneous valuations as of December 31, 2011, December 31, 2012, December 31, 2013, July 25, 2013, August 12, 2013 and October 21, 2013 and a retrospective valuation as of March 6, 2013. In conducting the valuations, the independent third-party valuation specialist considered all objective and subjective factors that it believed to be relevant for each valuation conducted in accordance with the Practice Aid, including our best estimate of our business condition, prospects and operating performance at each valuation date. Significant changes to the key assumptions used in the valuations could have resulted in different fair values of common stock at each valuation date.

Results of Operations

Comparison of the Years Ended December 31, 2013 and December 31, 2012

(in thousands)	Years Ended December 31, 2013	2012	Increase (Decrease)
Grant revenue	$ 731	$ 1,977	$ (1,246)
Operating expenses:			
Research and development	15,695	11,240	4,455
General and administrative	4,961	3,690	1,271
Total operating expenses	20,656	14,930	5,726
Loss from operations	(19,925)	(12,953)	(6,972)
Other (expense) income:			
Other (expense) income	(422)	93	(515)
Interest expense, net	(459)	(507)	48
Other expense	(881)	(414)	(467)
Net loss	$ (20,806)	$ (13,367)	$ (7,439)

Grant Revenue

Grant revenue decreased by $1.2 million for the year ended December 31, 2013 from the year ended December 31, 2012. This decrease was due to the completion of a grant to fund research for our pneumococcus program during 2012.

Research and Development Expenses

Research and development expenses increased by $4.5 million for the year ended December 31, 2013 from the year ended December 31, 2012. This increase was due primarily to higher costs of $2.9 million in 2013 attributable to external manufacturing costs for preclinical and clinical supply in preparation for the commencement of our toxicology and clinical trials for GEN-004, an increase of $0.3 million in 2013 attributable to the cost of our clinical trial for GEN-003 which began in the third quarter of 2012, an increase of $0.4 million attributable to the costs of the clinical trial for GEN-004 which began in the fourth quarter of 2013, an increase of $0.8 million due to higher salary and salary related costs and an increase of $0.1 million in consulting costs to support additional research and manufacturing efforts.

General and Administrative Expenses

General and administrative expenses increased by $1.3 million for the year ended December 31, 2013 from the year ended December 31, 2012. This increase was primarily due to additional overhead and personnel costs in 2013 of $0.3 million to support our on-going business development activities, $0.6 million in increased audit and tax expenses, $0.2 million related to higher legal patent expenses and $0.2 million in other general and administrative costs.

Other (Expense) Income

Other (expense) income consisted of the fair value adjustment of our warrants to purchase preferred stock and, for the year ended December 31, 2013, the loss on debt extinguishment. The decrease in other (expense) income for the year ended December 31, 2013 from the year ended December 31, 2012 of $0.5 million was due primarily to a $0.3 million increase in the fair value of our warrants to purchase preferred stock as a result of an increase in the fair value of the underlying preferred stock and $0.2 million loss on debt extinguishment recorded during the third quarter of 2013 with no comparable activity in the prior year.

Interest Expense, Net

Interest expense, net decreased $48 thousand for the year ended December 31, 2013 from the year ended December 31, 2012. The decrease was primarily attributable to lower average principal balances for the ended December 31, 2013 from the year ended December 31, 2012.

Comparison of the Years Ended December 31, 2012 and December 31, 2011

(in thousands)	Years Ended December 31, 2012	2011	Increase (Decrease)
Grant revenue	$ 1,977	$ 1,820	$ 157
Operating expenses:			
Research and development	11,240	13,543	(2,303)
General and administrative	3,690	3,004	686
Total operating expenses	14,930	16,547	(1,617)
Loss from operations	(12,953)	(14,727)	1,774
Other (expense) income:			
Other income	93	75	18
Interest expense, net	(507)	(33)	(474)
Other (expense) income	(414)	42	(456)
Net loss	$ (13,367)	$ (14,685)	$ 1,318

Grant Revenue

Grant revenue increased by $0.2 million from the year ended December 31, 2011 to the year ended December 31, 2012. This increase was due to the additional revenue in 2012 of $0.4 million related to a grant to fund research for our pneumococcus program and additional grant revenue of $0.1 million under our chlamydia grant offset by decreased revenue related to our government grant of $0.3 million due to lower costs incurred in our malaria program.

Research and Development Expenses

Research and development expenses decreased by $2.3 million from the year ended December 31, 2011 to the year ended December 31, 2012. This decrease was primarily due to higher costs in 2011 of $3.3 million attributable to material costs incurred in preparation for the commencement of our toxicology and Phase 1 clinical trial for GEN-003 which did not recur in 2012 and decreased purchases of lab supplies in 2012 of approximately $0.9 million. These decreases were partially offset by an increase in 2012 of $2.0 million attributable to the cost of our clinical trial for GEN-003 which began in the third quarter of 2012.

General and Administrative Expenses

General and administrative expenses increased by $0.7 million from the year ended December 31, 2011 to the year ended December 31, 2012. This increase was primarily due to additional overhead and personnel costs in 2012 of $0.2 million to support our on-going business development activities, $0.1 million in increased facility costs and $0.2 million related to higher legal patent expenses.

Other Income

Other income consisted of the fair value adjustment of our warrants to purchase preferred stock. The increase in other income from the year ended December 31, 2011 to the year ended December 31, 2012 of $18 thousand was due primarily to a decrease in the fair value of the underlying preferred stock.

Interest Expense, Net

Interest expense, net increased $0.5 million from the year ended December 31, 2011 to the year ended December 31, 2012. The increase in net interest expense was primarily attributable to an increase in amounts borrowed under our loan facility that we entered into in October 2011, resulting in additional borrowings of $5.0 million in March 2012.

Liquidity and Capital Resources

Overview

Since our inception and through December 31, 2013, we have received an aggregate of $92.0 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $6.7 million from grants. At December 31, 2013, our cash and cash equivalents were $12.2 million. In February 2014, we completed an IPO of 5,500,000 shares of our common stock at a price of $12.00 per share for an aggregate offering price of $66.0 million. We received net proceeds from the offering of approximately $61.4 million, after deducting approximately $4.6 million in underwriting discounts and commission, excluding offering costs payable by us.

Debt Financings

In October 2011 we entered into a Loan and Security Agreement, or the Term Loan, which provided for up to $5.0 million in debt financing. The Term Loan provided for a draw-down period on the loan through March 1, 2012. In March 2012, we drew down the full $5.0 million available through the facility.

From March 1, 2012 through May 1, 2012 we were obligated to make interest-only payments at the greater of (1) the lender s prime rate plus 5.0%, or (2) 8.0%. Thereafter, we were required to make 36 equal monthly payments of principal and accrued interest. During this 36-month period the Term Loan bore interest at the greater of (i) the lender s prime rate plus 4.75% or (ii) 8.0%. We were also obligated to pay 6.5% of the advance on the final repayment date, which was scheduled to be April 1, 2015. In connection with the Term Loan, we issued warrants to purchase 517,242 shares of Series B preferred stock at an exercise price of $0.58 per share. Upon execution of the Term Loan, the warrant to purchase 258,621 shares was immediately exercisable and the remaining warrant to purchase 258,621 shares became exercisable when we drew down the full amount of the loan on March 1, 2012. The $5.0 million term loan was collateralized by all of our corporate assets, excluding our intellectual property, and by a negative pledge on our intellectual property.

On September 30, 2013, we entered into a new loan agreement, or the New Term Loan, which provided up to $10.0 million in debt financing. Upon the closing, we drew down $3.5 million and paid off the outstanding principal and interest on the Term Loan. Under the terms of the New Term Loan, we can draw additional advances up to the remaining $6.5 million through December 31, 2013. On December 19, 2013, we drew down the remaining $6.5 million on the New Term Loan. Each advance shall be repaid in 42 monthly installments. For the first nine months following each advance, we are obligated to make interest only payments. Thereafter, we are required to make 33 equal monthly payments of principal together with interest. On the first business day of the 42nd month, we are also obligated to make a payment equal to 2.0% of the original principal amount of the advance. We may prepay the outstanding principal amount of the New Term Loan at any time. The New Term Loan was collateralized by a blanket lien on all our corporate assets, excluding our intellectual property, and by a negative pledge on our

intellectual property. In connection with the New Term Loan, we issued a warrant to purchase 689,655 shares of Series C preferred stock at an exercise price of $0.58 per share. Upon execution of the New Term Loan, the warrant was immediately exercisable to purchase 689,655 shares.

Operating Capital Requirements

Our primary uses of capital are, and we expect will continue to be for the near future, compensation and related expenses, manufacturing costs for pre-clinical and clinical materials, third party clinical trial research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

We believe that the net proceeds from our IPO completed in February 2014, together with our existing cash and cash equivalents and future amounts available under the New Term Loan, will be sufficient to fund our operations through at least the end of 2015. Based on our planned use of the net proceeds of this offering and our existing cash resources, we believe that our available funds following this offering will be sufficient to enable us to obtain clinical data from our ongoing Phase 1/2a clinical trial and planned GEN-003 Phase 2 clinical trials and our Phase 1 clinical trial and planned Phase 2a clinical trial for GEN-004. We expect that these funds will not be sufficient to enable us to seek marketing approval or commercialize any of our product candidates.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties

associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and costs of our ongoing Phase 1/2a clinical trial and the first of our planned Phase 2 clinical trials for GEN-003 and our Phase 1 clinical trial and planned Phase 2a clinical trial for GEN-004;

- the progress, timing and costs of manufacturing GEN-003 and GEN-004 for current and planned clinical trials;

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our other product candidates and potential product candidates;

- the outcome, timing and costs of seeking regulatory approvals;

- the costs of commercialization activities for GEN-003, GEN-004 and other product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;

- subject to receipt of marketing approval, revenue received from commercial sales of our product candidates;

- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;

- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements;

- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and

- the extent to which we in-license or acquire other products and technologies.

We expect that we will need to obtain substantial additional funding in order to commercialize GEN-003, GEN-004 and our other product candidates in order to receive regulatory approval. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interests of our existing stockholders may be materially diluted and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. In addition, debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely affect our ability to conduct our business. If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back or discontinue the development or commercialization of GEN-003, GEN-004 or our other product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to GEN-003, GEN-004 or our other product candidates that we otherwise would seek to develop or commercialize ourselves.

Cash Flows

The following table summarizes our sources and uses of cash for the years ended December 31, 2013 and 2012 (in thousands):

	Years Ended December 31,	
	2013	2012
Net cash used in operating activities	$ (19,873)	$ (12,681)
Net cash used in investing activities	(389)	(460)
Net cash provided by financing activities	20,954	18,915
Net increase in cash and cash equivalents	$ 692	$ 5,774

Operating Activities

The increase in net cash used in operations for the year ended December 31, 2013, as compared to the year ended December 31, 2012, was due primarily to an increase in the net loss of approximately $7.4 million along with changes in our working capital accounts.

Net cash used in operating activities was $19.9 million for the year ended December 31, 2013 and consisted primarily of net loss of $20.8 million adjusted for non-cash items including depreciation expense of $0.3 million, stock-based compensation expense of $0.7 million, an increase in the fair value of warrants of $0.2 million, loss on debt extinguishment of $0.2 million and a net decrease in operating assets and liabilities of $0.5 million.

Net cash used in operating activities was $12.7 million for the year ended December 31, 2012 and consisted primarily of a net loss of $13.4 million adjusted for non-cash items including depreciation expense of $0.3 million, stock-based compensation expense of $0.3 million, a decrease in the fair value of warrants of $0.1 million, and a net increase in operating assets and liabilities of $0.1 million.

Investing Activities

During the years ended December 31, 2013 and December 31, 2012, our investing activities used net cash of $0.4 million and $0.5 million, respectively. The use of net cash in all periods primarily resulted from purchases of property and equipment to facilitate our increased research and development activities and headcount.

Financing Activities

Net cash provided by financing activities was $21.0 million for the year ended December 31, 2013 compared to $18.9 million for the year ended December 31, 2012. Cash provided by financing activities for the year ended December 31, 2013 primarily consisted of $15.3 million in proceeds from the sale of preferred stock and $5.5 million from net proceeds from the issuance of long-term debt. Net cash provided by financing activities for the year ended December 31, 2012 consisted primarily of $15.1 million in net proceeds from the sale of preferred stock and $3.8 million from net proceeds from the issuance of long-term debt.

The following table summarizes our sources and uses of cash for the years ended December 31, 2012 and 2011 (in thousands):

	Years Ended December 31, 2012	2011
Net cash used in operating activities	$ (12,681)	$ (13,488)
Net cash used in investing activities	(460)	(318)
Net cash provided by (used in) financing activities	18,915	(189)
Net increase (decrease) in cash and cash equivalents	$ 5,774	$ (13,995)

Operating Activities

The decrease in net cash used in operations for the year ended December 31, 2012, as compared to the year ended December 31, 2011, was due primarily to a decrease in the net loss of approximately $1.3 million along with changes in our working capital accounts.

Net cash used in operating activities was $13.5 million for the year ended December 31, 2011 and consisted primarily of a net loss of $14.7 million adjusted for non-cash items including depreciation expense of $0.3 million, stock-based compensation expense of $0.3 million, a decrease in the fair value of warrants of $0.1 million and a net increase in operating assets and liabilities of approximately $0.6 million.

Net cash used in operating activities was $12.7 million for the year ended December 31, 2012 and consisted primarily of a net loss of $13.4 million adjusted for non-cash items including depreciation expense of $0.3 million, stock-based compensation expense of $0.3 million, a decrease in the fair value of warrants of $0.1 million, and a net increase in operating assets and liabilities of $0.1 million.

Investing Activities

During the years ended December 31, 2011 and December 31, 2012, our investing activities used net cash of $0.3 million and $0.5 million, respectively. The use of net cash in all periods primarily resulted from purchases of property and equipment to facilitate our increased research and development activities and headcount. The increase in net cash used in investing activities for the year ended December 31, 2011 as compared to the year ended December 31, 2012 was due primarily to an increase in laboratory equipment purchases in 2012.

Financing Activities

Net cash used in financing activities was $0.2 million for the year ended December 31, 2011 compared to net cash provided by financing activities of $18.9 million for the year ended December 31, 2012. Cash used in financing activities for the year ended December 31, 2011 consisted of $0.2 million in repayment of long-term debt related to an equipment loan for the acquisition of capital equipment. Net cash provided by financing activities for the year ended December 31, 2012 consisted primarily of $15.1 million in net proceeds from the issuance of Series C preferred stock and $5.0 million in borrowings under the Term Loan offset by repayments of long-term debt of $1.2 million.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Net Operating Loss Carryforwards

At December 31, 2013, we had United States federal and state net operating loss carryforwards of approximately $71.4 million and $64.5 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2033. At December 31, 2013, we had federal and state research and development tax credit carryforwards of approximately $1.9 million and $1.3 million available, respectively, to reduce future tax liabilities which expire at various dates through 2033. Net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of our company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. At December 31, 2013, we recorded a 100% valuation allowance against our net operating loss and research and development tax credit carryforwards, as we believe it is more likely than not that the tax benefits will not be fully realized. In the future, if

we determine that a portion or all of the tax benefits associated with our tax carryforwards will be realized, net income would increase in the period of determination.

Contractual Obligations

The following table summarizes our outstanding contractual obligations as of payment due date by period at December 31, 2013 (in thousands):

	Total	Less Than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
Long-term debt(1)	$ 10,000	$ 924	$ 7,273	$ 1,803	$
Operating Leases(2)	2,949	791	1,988	170	
Manufacturing Agreements(3)	1,524	1,524			
	$ 14,473	$ 3,239	$ 9,261	$ 1,973	$

(1) As of December 31, 2013, we had a total of $10.0 million in long-term debt due consisting of amounts due under the New Term Loan.

(2) In July 2012, we leased office and laboratory space at 100 Acorn Park Drive, Cambridge, MA that expires in February 2017.

(3) Consists of payments of approximately $1.5 million related to supply agreements to a contract manufacturer for the production of clinical materials.

We also have obligations to make future payments to third party licensors that become due and payable on the achievement of certain development, regulatory and commercial milestones. We have not included these commitments on our balance sheet or in the table above because the achievement and timing of these milestones is not fixed or determinable. These additional contractual commitments include the following:

License Agreement with The Regents of the University of California. Under our license agreement with The Regents of the University of California, or UC, in respect of UC patent rights covering aspects of our ATLAS discovery platform, we agreed to pay UC low single digit royalties on net sales by us of vaccine products comprising antigens identified through use of the ATLAS discovery platform covered by licensed UC patent rights. If we sublicense UC patent rights, we will owe UC a percentage of sublicensing revenue, including any royalty paid to us on net sales by sublicensees.

License Agreement with Harvard. Under our license agreement with President and Fellows of Harvard College, or Harvard, in respect of Harvard patent rights covering certain chlamydia antigens, we agreed to pay Harvard royalties in the high single-digits on worldwide net sales by us or our sublicensees of vaccine products comprising such chlamydia antigens. In addition, we are required to pay Harvard specified milestone payments for development of the first such chlamydia vaccine. Under the same license agreement, in respect of patent rights covering aspects of our antigen discovery platform, we agreed to pay Harvard royalties in the low single-digits on worldwide net sales by us or our sublicensees, for a period of 10 years from first commercial sale, of vaccine products comprising antigens (other than chlamydia antigens above) identified through use of the antigen discovery platform covered by licensed Harvard patent rights. In addition, we are required to pay Harvard specified milestone payments for development of such vaccines. We estimate that it is reasonably likely that we will make milestone payments in the low six figures through 2015 under this agreement. If we sublicense Harvard patent rights, we will owe Harvard a percentage of sublicensing revenue, excluding payments we receive based on the level of sales or profits.

License Ageement with Novavax. Under our license agreement with Isconova AB, now Novavax, Inc., in respect of Novavax patent rights and trademarks covering adjuvant Matrix-M, we agreed to pay Novavax tranched royalties in the low single-digits on worldwide net sales by us or our sublicensees of vaccine products comprising our antigens and Matrix-M. In addition, we are required to pay Novavax specified milestone payments for development and commercialization of the first vaccine in each unique disease field. We estimate that it is reasonably likely that we will make milestone payments in the low

six figures through 2015 under this agreement. If we sublicense Novavax patent rights, we will owe Novavax a percentage of the initial signing or upfront sublicensing fees we receive.

License Agreement with Children s Medical Center Corporation. Under our license agreement with Children s Medical Center Corporation, or Childrens, in respect of Childrens rights in jointly-owned patent rights covering certain Streptococcus antigens, we agreed to pay Childrens low single digit royalties on worldwide net sales by us or our sublicensees of vaccine products comprising such Streptococcus antigens. In addition, we are required to pay Childrens specified milestone payments for development and commercialization of such vaccines. We estimate that it is reasonably likely that we will pay milestone payments in the low six figures through 2015. If we sublicense the jointly-owned patent rights, we will owe Childrens a percentage of sublicensing revenue, excluding payments we receive based on the level of sales or profits.

We also enter into contracts in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for preclinical safety and research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice and do not include any minimum purchase commitments, and therefore are cancelable contracts and not included in the table above.

JOBS Act

In April 2012, the JOBS Act was enacted in the United States. 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, for complying with new or revised accounting standards. Thus, 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 non-emerging growth public companies.

Item 7A. Qualitative and Quantitative Disclosures About Market Risk

Our cash equivalents of $12.0 million and $11.0 million as of December 31, 2013 and 2012, respectively, consisted of money market funds. The investments in these financial instruments are made in accordance with an investment policy approved by our board of directors which specifies the categories, allocations and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments in which we invest could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing

interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio which may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations or our financial position would be materially affected by an immediate change of 10% in interest rates.

We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash equivalents and investment securities have significant risk of default or illiquidity. We made this determination based on discussions with our investment advisors and a review of our holdings. While we believe our cash equivalents and investment securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. All of our investments are recorded at fair value.

We are also exposed to market risk related to change in foreign currency exchange rates. We contract with certain vendors that are located in Europe which have contracts denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign exchange rate risk. As of December 31, 2013 and 2012, we had minimal liabilities denominated in foreign currencies.

Item 8. Financial Statements and Supplementary Data

Our financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-29 of this Annual Report on Form 10-K.

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Vice President of Finance and Administration, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2013. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information

required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2013, our Chief Executive Officer and Vice President of Finance and Administration concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management s Annual Report on Internal Controls Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting occurred during the fiscal year ended December 31, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Executive Officers, Significant Employees and Directors

Below is a list of the names, ages as of March 14, 2014 and positions, and a brief account of the business experience of the individuals who serve as our executive officers and directors as of the date of this Annual Report on Form 10-K.

Name	Age	Position
William Clark	45	President and Chief Executive Officer; Director (Class III)
Seth Hetherington, M.D.	61	Chief Medical Officer
Robert E. Farrell Jr., CPA	48	Vice President of Finance and Administration
Jessica Baker Flechtner, Ph.D.	42	Senior Vice President of Research
Paul Giannasca, Ph.D.	50	Vice President, Biopharmaceutical Development & Production
George Siber, M.D.	69	Director (Class III)
Kevin Bitterman, Ph.D.	37	Director (Class I)
Katrine Bosley	45	Director (Class II)
Simeon J. George, M.D.	34	Director (Class I)
Stephen J. Hoffman, M.D., Ph.D.	59	Director (Class II)

William Clark has served as our President and Chief Executive Officer since February 2011. Previously he served as our Chief Business Officer from August 2010 to February 2011. Mr. Clark has served on our board of directors since February 2011. Prior to joining our Company, he served as Chief Business Officer at Vanda Pharmaceuticals, Inc., or Vanda, a biopharmaceutical company he co-founded in 2004. While at Vanda, he lead the company s strategic and business development activities, and played a central role in raising more than $220 million in multiple public and private financings. Prior to Vanda, Mr. Clark was a principal at Care Capital, LLC, a venture capital firm investing in biopharmaceutical companies, after serving in a variety of commercial and strategic roles at SmithKline Beecham (now GlaxoSmithKline). Mr. Clark holds a B.A. from Harvard University and an M.B.A. from The Wharton School at the University of Pennsylvania. We believe that Mr. Clark s operation and historical experience with our Company gained from serving as our Chief Executive Officer, President and member of our board of directors, combined with his prior experience at Vanda and in the venture capital industry focusing on biopharmaceutical companies qualify him to serve as a member of our board of directors.

Seth Hetherington, M.D. has served as our Chief Medical Officer since joining our Company in January 2011. Prior to joining our Company, Dr. Hetherington served as Senior Vice President of Clinical and Regulatory Affairs at Icagen, Inc., or Icagen, from May 2006 through December 2010. Prior to Icagen, Dr. Hetherington served as Vice President, Clinical Development and Chief Medical Officer at Inhibitex Inc. from June 2002 through April 2005 and held various positions of increasing responsibility in clinical drug development at GlaxoSmithKline from 1995 through June 2002. Dr. Hetherington has also served as a faculty member at the University of North Carolina School of Medicine and held appointments at several leading academic medical centers, including the University of Tennessee, St. Jude Children s Research Hospital in Memphis and Albany Medical College. Dr. Hetherington earned his B.S. at Yale University and his M.D. at the University of North Carolina, Chapel Hill. He completed his postgraduate training in pediatrics and pediatric infectious diseases at the University of North Carolina and the University of Minnesota, respectively. Dr. Hetherington has published extensively in medical and scientific literature, and is board certified in both pediatrics and pediatric infectious diseases. He also served as the industry representative to the Vaccines and Related Blood Products Advisory Committee of the FDA. He currently serves as the industry representative on the National Vaccine Advisory Committee of the U.S. Department of Health and Human Services.

Robert E. Farrell Jr., CPA has served as our Vice President of Finance and Administration since joining our Company in May 2009. Prior to joining our Company, he served as Senior Director of Finance at Magen Biosciences, Inc., or Magen, from September 2008 to May 2009. In that position, he was responsible for all finance and administrative functions and he played a key role in the acquisition of Magen by PPD, Inc. Prior to Magen, Mr. Farrell held senior level financial positions at Oscient Pharmaceuticals Corp. and NeoGenesis Pharmaceuticals, Inc. where he built and directed all financial reporting efforts and helped guide the company through an initial public offering. Mr. Farrell is a licensed certified public accountant and holds a B.S. degree in Accounting from Bentley University.

Jessica Baker Fletchtner, Ph.D. has held multiple scientific roles since joining our Company in March 2007 and has served as our Senior Vice President of Research since February 2014 and our Vice President of Research from March 2007 through February 2014. Prior to joining our Company, Dr. Flechtner was an Immunology Consultant at BioVest International, Inc. from June 2006 to March 2007, where she guided the development of assays to evaluate the success of the company s autologous Follicular (Non-Hodgkin s) Lymphoma vaccine in patients. As a researcher at Mojave Therapeutics, Inc., or Mojave, and Antigenics Inc. (now Agenus), which acquired Mojave s intellectual property, from 2001 to 2005, Dr. Flechtner developed protein and peptide-based vaccines and immunotherapies for cancer, infectious disease, autoimmunity and allergy. She is an inventor on nine pending or issued patents and has multiple peer-reviewed scientific publications. Dr. Flechtner performed her post-doctoral work in the laboratory of Dr. Harvey Cantor at the Dana Farber Cancer Institute and Harvard Medical School and holds a Ph.D. in Cellular Immunology and B.S. in Animal Science from Cornell University. She is a member of the American Association of Immunologists and the American Society for Microbiology.

Paul Giannasca, Ph.D. has served as our Vice President, Biopharmaceutical Development & Production since joining our Company in January 2010. Prior to joining our Company, Dr. Giannasca served as Vice President, Development at Acambis (now Sanofi Pasteur) from 2004 to 2010. Prior to Acambis, he was a senior scientist at OraVax from 1995 to 1999, where he contributed to the company s research initiatives for several vaccines, focusing on evaluating vaccine adjuvants and elucidating mechanisms of vaccine-induced protection. Dr. Giannasca holds multiple patents covering active and passive immunization against *Clostridium difficile* disease and has published more than 25 papers in the areas of infectious diseases, vaccine-induced protection and vaccine development. Dr. Giannasca received his B.S. in Biology from Fairleigh Dickinson University and his Ph.D. in Molecular and Cellular Biology from the University of Massachusetts-Amherst. He completed his post-doctoral training at Harvard Medical School/Children s Hospital Boston.

George Siber, M.D. has served as a member of our board of directors since 2007. From 1996 to 2007, Dr. Siber served as Executive Vice President and Chief Scientific Officer of Wyeth Vaccines, or Wyeth. While at Wyeth, Dr. Siber oversaw the development and approval of multiple widely-used childhood vaccines, including Prevnar, a pneumococcal vaccine which has achieved multibillion dollar revenues; Acel-Imune, an acellular pertussis vaccine; and Meningitec, a meningococcal meningitis vaccine. Prior to Wyeth, Dr. Siber was Director of the Massachusetts Public Health Biologic Laboratories and a Harvard Medical School Associate Professor of Medicine at Dana Farber Cancer Institute. During this time, Dr. Siber led the research and manufacturing of multiple vaccines and immune globulins including Respigam, a human immune globulin against respiratory syncytial virus. Dr. Siber holds an MD degree from McGill University in Canada, received post-doctoral training in Internal Medicine at Rush-Presbyterian Hospital in Chicago and Beth Israel Hospital in Boston and Infectious Disease and vaccinology training at Children s Hospital and Beth Israel Hospital, Harvard Medical School Boston. We believe that Dr. Siber s experience in life sciences and vaccine industries and his experience overseeing the development of multiple vaccines qualifies him to serve as a member of our board of directors.

Kevin Bitterman, Ph.D. has served as a member of our board of directors since August 2006. Since 2004, Dr. Bitterman has served as principal at Polaris Partners, or Polaris, and focuses on investments in life sciences companies. Prior to joining Polaris, Dr. Bitterman completed his Ph.D. in genetics at Harvard Medical School. His doctoral research focused on the molecular regulation of caloric restriction and on modulation of a novel class of protein deacetylases. Dr. Bitterman is a cofounder of Sirtris Pharmaceuticals, Inc. acquired by GlaxoSmithKline and was the founding CEO at Visterra Inc. In additional to representing Polaris as a director of our Company, he currently represents Polaris as a director of InSeal Medical, Kala Pharmaceuticals, Neuronetics, Inc., Visterra, Inc., TARIS Biomedical, and Vets First Choice. Additionally, Dr. Bitterman is a board observer to Arsenal Medical and 480 Biomedical. He received a Ph.D. in Genetics from Harvard Medical School and a Bachelor s in Biology from Rutgers College. We believe that Dr. Bitterman s extensive experience investing in, guiding and leading start-up and early phase companies, as well as his experience as a director of other companies, qualifies him to serve as a member of our board of directors.

Katrine Bosley has served as a member of our board of directors since March 2013 and as our chairperson since August 2013. Ms. Bosley is currently the Entrepreneur-in-Residence at The Broad Institute. She served as Chief Executive Officer of Avila Therapeutics Inc., or Avila, from May 2009 to March, 2012, when Avila was acquired by Celgene Corporation. Before Avila, she was Vice President, Strategic Operations at Adnexus, a Bristol-Myers Squibb Company and was Vice President, Business Development at Adnexus Therapeutics Inc., or Adnexus, before that. She joined Adnexus from Biogen Idec where she held roles in business development, commercial operations, and portfolio strategy in the United States and Europe and led the in-licensing of Tysabri (natalizumab) among a number of other transactions. Earlier, she was part of the healthcare team at the venture firm Highland Capital Partners from 1993 to 1995. In addition to serving as a director of our Company,

Ms. Bosley currently serves as a director of Galapagos NV and Coco Therapeutics Ltd. Ms. Bosley graduated from Cornell University with a Bachelor of Arts degree in biology. We believe that Ms. Bosley s experience as a chief

executive officer of a biotechnology company and her breadth of experience in creating strategic and business development value qualifies her to serve as a member of our board of directors.

Simeon J. George, M.D. has served as a member of our board of directors since February 2009. Since 2007, Dr. George has served as partner of S.R. One, Limited, or S.R. One, and leads S.R. One s west coast investment activities. Prior to joining S.R. One, Dr. George was a consultant at Bain & Company from October 2006 to August 2007. In addition to serving as a director of our Company, Dr. George currently serves as a director of Anaphore, Auxogyn, Inc., HTG Molecular and Principia Biosciences. He received his BA in Neuroscience from the Johns Hopkins University, where he graduated Phi Beta Kappa, and received his MD from the University of Pennsylvania School of Medicine and his MBA (Mayer Scholar) from the Wharton School of the University of Pennsylvania. We believe that Dr. George s experience in the venture capital industry, particularly with biotechnology and pharmaceutical companies, as well as his experience as a director of other companies, qualifies him to serve as a member of our board of directors.

Stephen J. Hoffman, M.D., Ph.D. has served as a member of our board of directors since December 2010. Dr. Hoffman has been a Senior Advisor to PDL BioPharma, Inc. since February 2014. Prior to that, Dr. Hoffman has served as a managing director at Skyline Ventures, a venture capital firm, since May 2007. From January 2003 to March 2007, Dr. Hoffman was a general partner at TVM Capital, a venture capital firm. Prior to that, he served as President, Chief Executive Officer and a director of Allos Therapeutics, Inc., or Allos, a biopharmaceutical company, from 1994 to 2002, and as Chairman of the Board until 2012. From 1990 to 1994, Dr. Hoffman completed a fellowship in clinical oncology and a residency/fellowship in dermatology, both at the University of Colorado. Dr. Hoffman was the scientific founder of Somatogen Inc., a biotechnology company that was acquired by Baxter International, Inc., a global medical products and services company, in 1998, where he held the position of Vice President of Science and Technology from 1987 until 1990. In addition to serving as a director of our Company, he currently serves as a director of several biopharmaceutical companies, including AcelRx, Inc., Concert Pharmaceuticals, Inc., Collegium Pharmaceuticals, Inc., Dicerna Pharmaceuticals, Inc. and Proteon Therapeutics, Inc. Previously, Dr. Hoffman served on the board of directors of Sirtris Pharmaceuticals, Inc., a pharmaceutical company that was acquired by GlaxoSmithKline, in 2008. Dr. Hoffman holds a Ph.D. in bio-organic chemistry from Northwestern University and an M.D. from the University of Colorado School of Medicine. We believe that Dr. Hoffman s scientific, financial and business expertise, including his diversified background as an executive officer and investor in public pharmaceutical companies as well as a director of a public pharmaceutical company, qualifies him to serve as a member of our board of directors.

Board Composition and Election of Directors

Board Composition

Our board of directors is currently comprised of six members. Our board of directors has determined that each of Dr. Bitterman, Ms. Bosley, Dr. George and Dr. Hoffman is independent for NASDAQ purposes. Our directors hold office until their successors have been elected and qualified or until their earlier death, resignation or removal. There are no family relationships among any of our directors or executive officers.

Our certificate of incorporation and bylaws provide that the authorized number of directors may be changed only by resolution of our board of directors. Our certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

In accordance with the terms of our certificate of incorporation and bylaws, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. The members of the classes will are divided as follows:

- the class I directors are Dr. Bitterman and Dr. George;
- the class II directors are Ms. Bosley and Dr. Hoffman; and
- the class III directors are Mr. Clark and Dr. Siber.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

Section 16(a) Beneficial Ownership Reporting Compliance

Our directors, executive officers and beneficial owners of more than 10% of our common stock are required under Section 16(a) of the Exchange Act, to file reports of ownership and changes in ownership of our securities with the Securities and Exchange Commission. S.R. One Limited, a more than 10% stockholder of our common stock, was delinquent in filing a Form 3 with the pricing of our IPO on February 4, 2014. We completed our IPO of our common stock on February 10, 2014, and accordingly, we did not have a class of securities registered pursuant to Section 12 of the Exchange Act in 2013.

Board Committees

Our board of directors has three standing committees: the audit committee, the compensation committee and the nominating and corporate governance committee.

Audit Committee

Our audit committee is composed of Ms. Bosley, Dr. George and Dr. Hoffman, with Dr. Hoffman serving as chairman of the committee. Our board of directors has determined that each member of the audit committee meets the independence requirements of Rule 10A-3 under the Exchange Act and the applicable listing standards of NASDAQ. Our board of directors has determined that Ms. Bosley and Dr. Hoffman are audit committee financial expert within the meaning of the Securities and Exchange Commission regulations and applicable listing standards of NASDAQ.

Compensation Committee

Our compensation committee is composed of Dr. Bitterman and Dr. George, with Dr. Bitterman serving as chairman of the committee. Our board of directors has determined that each member of the compensation committee is independent as defined under the applicable listing standards of NASDAQ.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee is composed of Dr. Bitterman, Ms. Bosley and Dr. Hoffman, with Ms. Bosley serving as chairman of the committee. Our board of directors has determined that each member of the nominating and corporate governance committee is independent as defined under the applicable listing standards of NASDAQ.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. A current copy of the code is posted on the Investor Relations Corporate Governance section of our website, which is located at *www.genocea.com*. In addition we intend to post on our website all disclosures that are required by law, the rules of the Securities and Exchange Commission or NASDAQ stock market listing standards concerning any amendments to, or waivers from, any provision of the code.

Item 11. Executive and Director Compensation

Overview

The following discussion relates to the compensation of our President and Chief Executive Officer, William Clark, and our two most highly compensated executive officers (other than our Chief Executive Officer), Seth Hetherington, M.D., our Chief Medical Officer, and Jessica Flechtner, Ph.D., our Vice President of Research. These three executives are collectively referred to in this Annual Report on Form 10-K as our named executive officers. Each year, the compensation committee of our board of directors and our board of directors review and determine the compensation of our named executive officers.

Elements of Executive Compensation

The compensation of our named executive officers consists of base salary, annual cash bonuses and equity awards as well as employee benefits that are made available to substantially all salaried employees. Our named executive officers are also entitled to certain compensation and benefits upon certain terminations of employment and change of control transactions pursuant to employment letter agreements.

Base Salaries. Base salaries for our named executive officers are reviewed annually by our compensation committee and are set by our board of directors. When making its base salary recommendations to our board of directors, our compensation committee takes factors into account such as each executive s experience and individual performance, the company s performance as a whole, data from surveys of compensation paid by comparable companies, cost of living increases and general industry conditions, but does not assign any specific weighting to any factor. Our board of directors determines each named executive officer s base salary after reviewing the compensation committee s recommendation with respect to such salaries. In fiscal 2013, on the recommendation of our compensation committee, our board of directors approved a base salary of $335 thousand for Mr. Clark, $333 thousand for Dr. Hetherington and $242 thousand for Dr. Flechtner, representing an increase of 2.0%, 2.0% and 10.0%, respectively, from the base salary for each such executive in 2012.

Annual Cash Bonuses. Our annual cash bonus program promotes and rewards the achievement of key strategic business goals and individual performance goals. For fiscal 2013, the target annual bonus as a percentage of base salary for each of Mr. Clark, Dr. Hetherington and Dr. Flechtner was 40%, 30% and 25%, respectively. In the case of Mr. Clark, 100% of his annual bonus was based on the achievement of pre-established corporate performance goals and, in the case of Drs. Hetherington and Flechtner, 50% of the executive s respective annual bonus was based on the achievement of pre-established corporate performance goals and 50% was based on a quantitative and qualitative assessment of pre-established individual performance goals.

At the beginning of fiscal 2013, our compensation committee established the corporate performance goals for 2013, each having a designated weighting. These corporate performance goals included key strategic and financial goals related to business development and grant funding, maintenance of a certain level of cash reserves, the development and commencement of certain clinical and commercial programs, the completion of research reports, and other strategic objectives related to our clinical pipeline. Also at the beginning of fiscal 2013, our chief executive officer, working with each of Dr. Hetherington and Dr. Flechtner, established each executive s individual performance goals and their weightings. These goals included objectives related to oversight of clinical activities for compliance with laws, developing and conducting clinical programs and studies, research and development, managing studies according to schedule and within budgets, business and corporate development and demonstrating leadership with respect to direct reports.

In February 2014, our compensation committee met to determine the level of performance achieved for purposes of making its recommendation to our board of directors regarding the amount of the annual cash bonus to be paid to each of our named executive officers for performance in fiscal 2013. The compensation committee evaluated our performance against the pre-established corporate performance goals for 2013, taking into consideration Mr. Clark s evaluation of our performance in 2013. Mr. Clark also presented to the compensation committee his determination that Drs. Hetherington and Flechtner each had achieved 98% and 98%, respectively, of each such executive s individual performance goals. After determining that 80% of the corporate performance goals were achieved in fiscal 2013, and after considering Mr. Clark s determination regarding the level of achievement of individual performance goals, our compensation committee recommended, and our board of directors approved, a 2013 cash bonus of $107,320 for Mr. Clark, $88,989 for Dr. Hetherington and $54,087 for Dr. Flechtner

Equity Awards. Our named executive officers have been granted equity awards under the Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan, which we refer to as the 2007 Equity Plan . In connection with our IPO, our 2007 Equity Plan was frozen as to future grants and our board of directors

adopted the Genocea Biosciences, Inc. 2014 Equity Incentive Plan, or the 2014 Equity Plan. Following the completion of our IPO, all equity-based awards will be granted under the 2014 Equity Plan and our named executive officers are eligible to participate in this plan.

Each of our named executive officers received an award of time-vesting stock options under the 2007 Equity Plan in July 2013 to purchase 133,602, in the case of Mr. Clark, 57,017, in the case of Dr. Hetherington, and 56,378, in the case of Dr. Flechtner, shares of our common stock. These stock option awards vested as to 1/8th of the shares subject to the stock option on the date of grant and continue to vest in equal monthly installments over 42 months, generally subject to the executive s continued employment. In 2013, Mr. Clark also received a performance-vesting stock option to purchase 81,670 shares of our common stock, which vested in full upon the completion of our initial public offering. In connection with our IPO, our board of directors granted Dr. Flechtner a stock option to purchase 11,402 shares of our common stock under the 2014 Equity Plan, which vests in equal monthly installments over 48 months, generally subject to her continued employment.. Stock option awards serve to align the interests of our named executive officers with our shareholders because no value is created unless the value of our common stock appreciates after grant. Stock option awards also encourage retention through the use of time-based vesting conditions and the achievement of key strategic goals through the use of performance-based vesting conditions. Pursuant to agreements with our named executive officers, all of each executive s stock option awards will vest automatically upon certain terminations of employment following a change of control of our company. See Employment Letter Agreements below for additional details about these agreements.

Benefits. We provide modest benefits to our named executive officers, which are limited to participation in our 401(k) plan and basic health and welfare benefit coverage. These benefits are available to substantially all of our salaried employees.

Employment Letter Agreements. We have entered into an amended and restated employment letter agreement with each of our named executive officers that, in each case, includes severance and change of control protections. Our named executive officers are also subject to restrictive covenants, covering noncompetition, nonsolicitation and confidentiality.

Summary Compensation Table

The following table sets forth information about certain compensation awarded or paid to our named executive officers for fiscal years 2012, in the case of Mr. Clark and Dr. Hetherington, and 2013, in the case of all of our named executive officers.

Name and principal position	Year	Salary ($)(2)	Option awards ($)(3)	Nonequity incentive plan compensation ($)(4)	Total ($)
William Clark,	2013	334,280	413,842	107,320	855,442
President and Chief Executive Officer	2012	327,921		105,242	433,163
Jessica Flechtner, Ph.D.,	2013	238,333	174,637	54,087	467,057
Senior Vice President, Research(1)					

(1) Dr. Flechtner was not a named executive officer in fiscal year 2012 and, as a result, no amounts with respect to fiscal year 2012 have been included for Dr. Flechtner in the table above.

(2) Salaries include amounts contributed by the named executive officer to our 401(k) plan.

(3) Amounts shown reflect the aggregate grant date fair value of time-vesting stock options awarded in fiscal 2013, computed in accordance with FASB ASC Topic 718 and exclude the value of estimated forfeitures. Assumptions used in the calculation of these amounts are included in Note 12 to our financial statements included elsewhere in this Annual Report on Form 10-K. Mr. Clark was also granted a performance-vesting stock option in 2013. The grant date fair value of the performance-vesting stock option granted to Mr. Clark in fiscal year 2013 is based on the probable outcome of the performance conditions associated with the stock option as of the date of grant. No amount was included in the table above for this stock option since the performance conditions were not considered probable of occurring on the date of grant. The aggregate grant date fair value of the performance-vesting stock option assuming that the highest levels of performance conditions are achieved is $252,981. No stock options were awarded to our named executive officers in fiscal 2012.

(4) Amounts shown reflect the cash amount paid to the named executive officer that was earned based on the achievement of company and individual (in the case of Drs. Hetherington and Flechtner) performance goals.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information regarding equity awards held by our named executive officers as of December 31, 2013. Our named executive officers do not hold any equity awards other than stock options.

OPTION AWARDS

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: number of securities underlying unexercised unearned options (#)	Option Exercise Price ($)(7)	Option Expiration Date
William Clark,	33,172(1)	6,635(1)		2.86	8/19/2020
President and Chief Executive Officer	18,537(2)	6,180(2)		2.86	12/17/2020
			39,807(3)	2.86	12/17/2020
	241,232(2)	99,337(2)		2.02	2/17/2021
	30,616(4)	102,986(4)		3.45	7/25/2023
			81,670(3)	3.45	7/25/2023
[redacted]					
Jessica Flechtner, Ph.D.,	1,680(1)			1.67	5/15/2017
Senior Vice President, Research	420(1)			1.67	8/20/2017
	840(1)			1.67	1/23/2018
	8,403(5)			2.38	6/30/2019
	2,941(3)			2.38	6/30/2019
	4,376(2)	191(2)		2.86	3/28/2019
	10,333(2)	4,256(2)		2.02	2/17/2021
	5,462(6)			2.02	2/17/2021
	12,919(4)	43,459(4)		3.45	7/25/2023

(1) Reflects time-based stock options to purchase shares of our common stock that vest as to 25% of the shares subject to the stock option on the vesting commencement date and thereafter vest in equal monthly installments over the following 36 months, generally subject to the executive s continued employment.

(2) Reflects time-based stock options to purchase shares of our common stock that vest in equal monthly installments over 48 months following the vesting commencement date, generally subject to the executive s continued employment.

(3) Reflects performance-based stock options to purchase shares of our common stock that vest as to 100% of the shares subject to the stock option, in the case of Mr. Clark, upon the company s achievement of specified strategic financing or development milestones, in the case of Dr. Hetherington, upon the company s achievement of a milestone related to the initiation of a clinical trial, and in the case of Dr. Flechtner, upon the company s achievement of a specified financial goal, in each case, generally subject to the executive s continued employment. The performance-based stock option awarded to Mr. Clark on July 25, 2013 vested in full on February 5, 2014 upon the completion of our IPO.

(4) Reflects time-based stock options to purchase shares of our common stock that vested as to 1/8th of the shares subject to the stock option on the date of grant and that continue to vest in equal monthly installments over 42 months following the date of grant, generally subject to the executive s continued employment.

(5) Reflects a time-based stock option to purchase shares of our common stock that vested as to 6.25% of the shares subject to the stock option on the date of grant and that continues to vest in equal monthly installments on the last day of each calendar month thereafter, generally subject to the executive s continued employment.

(6) Reflects a time-based stock option to purchase shares of our common stock that vested as to 2,162 shares subject to the stock option on the date of grant and that continued to vest in equal monthly installments over the following 29 months, generally subject to the executive s continued employment.

(7) The exercise price of the stock options is not less than the fair market value of a share of our common stock, as determined by our board of directors based, in part, on an independent third party valuation.

Retirement Benefits

We do not maintain any qualified or non-qualified defined benefit plans or supplemental executive retirement plans that cover our named executive officers. We offer a tax-qualified retirement plan, which we refer to as our 401(k) plan, to eligible employees, including our named executive officers. Our 401(k) plan permits eligible employees to defer their annual eligible compensation subject to the limitations imposed by the Internal Revenue Service. We may, but are not required to, make discretionary profit-sharing contributions on behalf of eligible employees under this plan. We did not make any contributions on behalf of eligible employees in fiscal year 2013.

Employment Letter Agreements

On January 16, 2014, we entered into an amended and restated employment letter agreement with each of Mr. Clark, Dr. Hetherington and Dr. Flechtner, each of which was effective prior to the completion of our IPO. Each employment letter agreement provides for an initial base salary of $399,433, in the case of Mr. Clark, $369,458 in the case of Dr. Hetherington, and $287,012 in the case of Dr. Flechtner, as well as a discretionary performance-based bonus, with a target, as a percentage of base salary, of 50%, 35% and 30% for each of Mr. Clark, Dr. Hetherington and Dr. Flechtner, respectively. Each agreement also provides for certain payments and benefits upon a qualifying termination of the executive s employment following a change of control of our company as described below.

Termination of Employment without Cause or for Good Reason Following a Change of Control. If, within 12 months after a change of control (as defined in the executive s employment letter agreement), the executive s employment is terminated by us without cause or the executive terminates his or her employment for good reason (as such terms are defined in the executive s employment letter agreement), all stock options or other equity awards then held by the executive will fully vest. In addition, the executive will be entitled to receive base salary and payment of COBRA premiums for 18 months, in the case of Mr. Clark, 15 months, in the case of Dr. Hetherington, and 12 months, in the case of Dr. Flechtner, following such termination of employment.

Termination of Employment without Cause or for Good Reason. If the executive s employment is terminated by us without cause or the executive terminates his or her employment for good reason (as such terms are defined in the executive s employment letter agreement) other than following a change of control as described above, the executive will be entitled to receive base salary and payment of COBRA premiums

for 12 months, in the case of Mr. Clark, nine months, in the case of Dr. Hetherington, and six months, in the case of Dr. Flechtner, following such termination of employment.

Termination of Employment Due to Death or Disability. If the executive s employment is terminated by us due to the executive s disability or is terminated due to the executive s death, we will pay the executive a portion of the executive s target annual cash bonus for the year in which such termination of employment occurs, prorated based on the number of days the executive was employed during such year until the date of such termination.

Severance Subject to Release of Claims. Our obligation to provide the executive with any severance payments or other benefits under the executive s employment letter agreement is conditioned on the executive signing and not revoking an effective release of claims in our favor.

Other Termination of Employment. If the executive s employment is terminated for any reason other than by us without cause, by the executive for good reason, or due to the executive s death or disability, the executive will only be entitled to receive earned but unpaid base salary and any accrued but not used vacation as of the termination date.

280G Better-of Provision. In the event of a change in ownership or control of our company under Section 280G of the Internal Revenue Code of 1986, as amended, or the Code, and the regulations thereunder, if any portion of the payments made pursuant to the executive s employment letter agreement (or otherwise) constitutes an excess parachute payment within the meaning of Section 280G of the Code, the executive will be entitled to receive an amount of such payments reduced so that no portion of the payments would constitute an excess parachute payment, or the amount otherwise payable to the executive under the employment letter agreement (or otherwise) reduced by all applicable taxes, including the excise tax, whichever amount results in the greater amount payable to the executive.

Employment Conditioned on Restrictive Covenants. As a condition to the executive s employment with us, the executive was required to sign and must comply with the terms of an At-Will Employment, Confidential Information, Invention Assignment and Non-Competition Agreement, pursuant to which the executive has agreed not to compete with us for a period of 12 months following the termination of his or her employment and not to solicit our employees or independent contractors for a period of 36 months following the termination of his or her employment. Each executive has also agreed to covenants relating to the use and disclosure of confidential information and the assignment of inventions.

2013 Director Compensation

The following table sets forth information concerning the compensation earned by our directors during 2013. In 2013, Dr. Siber and Ms. Bosley were the only directors who were compensated for service on our board of directors. Mr. Clark receives no additional compensation for his service as a director, and, consequently, is not included in this table. The compensation received by Mr. Clark as our chief executive officer during 2013 is included in the Summary Compensation Table above.

Director Compensation

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)(2)	Total ($)
George Siber, M.D.	124,992	54,263	179,255
Katrine Bosley	32,500	192,355	224,855

(1) Amounts represent annual director and, in the case of Dr. Siber, consulting fees, for services rendered by Dr. Siber and Ms. Bosley. Amounts paid to Dr. Siber were paid in equal bi-monthly installments and amounts paid to Ms. Bosley were paid quarterly in arrears.

(2) Amounts represent the aggregate grant date fair value of awards of time-vesting stock options granted to Dr. Siber and Ms. Bosely in fiscal 2013. These amounts were computed in accordance with FASB ASC Topic 718 and exclude the value of estimated forfeitures. Assumptions used in the calculation of these amounts are included in Note 12 to our financial statements included elsewhere in this Annual Report on Form 10-K, except for the stock option award granted in October 2013 to Ms. Bosley, which amount was computed using

assumptions as of the date of grant of such award that are similar to those assumptions disclosed in Note 12 to our financial statements. Dr. Siber was also granted a performance-vesting stock option in fiscal 2013 that vested on February 5, 2014, upon completion of our IPO. The grant date fair value of the performance-vesting stock option granted to Dr. Siber in 2013 is based on the probable outcome of the performance conditions associated with this stock option as of the date of grant. No amount is included in the table above for this stock option since the performance conditions were not considered probable of occurring on the date of grant. The aggregate grant date fair value of this performance-vesting stock option assuming that the highest levels of performance conditions are achieved is $32,908.

As of December 31, 2013, our directors held the following aggregate number of options to purchase shares of our common stock: Dr. Siber held options to purchase 133,672 shares of our common stock, Ms. Bosley held options to purchase 36,966 shares of our common stock and Dr. Bitterman, Dr. George and Dr. Hoffman held no options to purchase shares of our common stock. As of December 31, 2013, Ms. Bosley held 24,615 restricted shares, which she received upon the exercise of the option granted to her on February 4, 2013.

Non-Employee Director Compensation Policy

In connection with our IPO, our board of directors adopted a non-employee director compensation policy that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, all non-employee directors will be paid cash compensation from and after the completion of our IPO, as set forth in the following table:

		Annual Retainer
Board of Directors:		
All non-employee members	$	35,000
Additional retainer for chair	$	25,000
Audit Committee:		
Members	$	7,500
Additional retainer for chair	$	7,500
Compensation Committee:		
Members	$	5,000
Additional retainer for chair	$	5,000
Nominating and Corporate Governance Committee:		
Members	$	3,500
Additional retainer for chair	$	3,500

Under our non-employee director compensation policy, each individual who is not an employee who is initially appointed or elected to our board of directors will be eligible to receive a grant of stock options to purchase 10,084 shares of our common stock under our 2014 Equity Plan at the time of his or her initial appointment or election to our board of directors, which will vest annually in equal installments over a three-year period. In addition, each continuing non-employee director will be eligible to receive, on the first business day following January 1st of each calendar year, an annual stock option grant to purchase 5,042 shares of our common stock, which will vest in full on the first anniversary of the grant date. The stock options will be granted with an exercise price equal to the fair market value of a share of our common stock on the date of grant and have a 10-year term.

Director Agreements

Dr. Siber

We entered into a consulting agreement with Dr. Siber dated May 16, 2007, as amended on June 30, 2009, December 16, 2010, June 15, 2011 and June 5, 2013, providing for a consulting fee of $10 thousand per month, for consulting services performed by Dr. Siber related to strategic scientific and business development as well as for his service as the chairman of our board of directors. Dr. Siber was also entitled to receive grants of restricted stock and stock options in connection with his service to us. All stock options granted to Dr. Siber pursuant to the consulting agreement will fully vest if, within 12 months following a change of control, either we (or our successor) terminate the consulting agreement without cause (as such term is described in the consulting agreement), or we (or our successor) do not offer to extend the term of the agreement. As of September 19, 2013, Dr. Siber ceased being the chairman of our board of directors and assumed the role of chairman of our scientific advisory board.

Dr. Siber has agreed not to solicit our employees, contractors, and customers for a period of 12 months following the termination of the consulting agreement and is subject to covenants relating to the use and disclosure of confidential information and the assignment of inventions. Unless extended or earlier terminated, the term of the consulting agreement will expire on June 17, 2015.

In 2013, performance-vesting and time-vesting stock options were granted to Dr. Siber. The performance-vesting stock option generally vests upon the company s achievement of certain financial goals, and vested in full upon our IPO based on the proceeds expected to be received. The time-vesting stock option generally vests in equal monthly installments over 48 months and vests in full upon a change of control, generally subject to Dr. Siber s continued service to our company.

Ms. Bosley

We entered into a letter agreement with Ms. Bosley, the chair of our board of directors, dated as of February 4, 2013, the date she was appointed to serve on our board of directors. Pursuant to the letter agreement, Ms. Bosley is entitled to an annual fee for board meeting attendance of $30,000 per year (which annual fee was subsequently increased to $50,000 per year) and, on February 4, 2013, we granted Ms. Bosley a stock option award that vests ratably over 48 months, subject to Ms. Bosley s continued service on our board of directors on the applicable vesting date, and vests as to all of the shares subject to the stock option immediately prior to the occurrence of a covered transaction (as defined in the 2007 Equity Plan). Ms. Bosley subsequently exercised this stock option and, with respect to the portion of the stock option that was not vested on the date it was exercised, received shares of restricted stock that vest on the same schedule as the stock option. Under the letter agreement, Ms. Bosley is also subject to covenants relating to the use and disclosure of confidential information. Unless earlier terminated, the letter agreement remains in effect so long as Ms. Bosley is a member of our board of directors and automatically terminates in the event of Ms. Bosley s removal or resignation from our board of directors or death. Effective as of the completion of our IPO, this letter agreement terminated and Ms. Bosley is eligible to participate in our non-employee director compensation policy described above on the same terms as other directors.

On September 19, 2013, Ms. Bosley assumed the role of chair of our board of directors. In connection with such appointment, on October 21, 2013 she was granted a stock option award that vests as to 25% of the shares subject to the stock option on the vesting commencement date and thereafter continues to vest in monthly installments over the following 36 months, subject to Ms. Bosley s continued service on our board of directors. All of the shares subject to the stock option will vest immediately prior to the occurrence of a covered transaction (as defined in the 2007 Equity Plan).

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or compensation committee. Our compensation committee is composed of Dr. Bitterman and Dr. George, with Dr. Bitterman serving as chairman of the committee. None of the members of our compensation committee has ever been employed by us. For a description of transactions between us and members of our compensation committee and affiliates of such members, please see the section of this Annual Report on Form 10-K titled Certain Relationships and Related Party Transactions .

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

Securities Authorized for Issuance Under Equity Compensation Plans

See Securities Authorized for Issuance Under Equity Compensation Plans in Item 5 of this Annual Report on Form 10-K.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information relating to the beneficial ownership of our common stock as of March 14, 2014, by: each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock; each of our directors; each of our named executive officers; and all directors and executive officers as a group.

The percentage of shares beneficially owned is computed on the basis of 17,310,793 shares of our common stock outstanding as of March 14, 2014. The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the Securities and Exchange Commission, and the information is not necessarily indicative of beneficial ownership for any other purpose. Shares of our common stock that a person has the right to acquire within 60 days of March 14, 2014 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Genocea Biosciences, Inc., Cambridge Discovery Park, 100 Acorn Park Drive, Cambridge, MA 02140

Name and Address of Beneficial Owned	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or greater stockholders:		
Polaris Venture Partners, and related funds(1) 650 East Kendall Street, 4th Floor Cambridge, MA 02142	1,895,862	11.0%
S.R. One, Limited(2) c/o Corporation Service Company 2595 Interstate Drive, Suite 103 Harrisburg, PA 17110	1,527,895	8.8
Johnson & Johnson Development Corporation(3) 410 George Street New Brunswick, NJ 08901	1,388,646	8.0
Lux Ventures, and related funds(4) 295 Madison Avenue, 24th Floor New York, NY 10017	1,098,328	6.3
CVF, LLC(5) 222 N. LaSalle Street, Suite 2000 Chicago, IL 60601	1,086,641	6.3
Skyline Venture Partners V, L.P.(6) 525 University Avenue, Suite 610 Palo Alto, CA 94301	1,041,484	6.0
Directors and Named Executive Officers:		
William Clark(7)	450,121	2.5
Seth Hetherington(8)	109,503	*
Jessica Baker Fletchtner(9)	54,791	*
George Siber, M.D.(10)	110,604	*
Kevin Bitterman, Ph.D.(11)	1,895,862	11.0
Katrine Bosley(12)	40,160	*
Simeon J. George, M.D.(13)	1,527,895	8.8
Stephen J. Hoffman		
All executive officers and directors as a group (10 persons)(14)	4,280,701	23.6%

* Represents beneficial ownership of less than one percent of our outstanding common stock.

(1) Consists of (i) 1,829,385 shares of common stock held by Polaris Venture Partners V, L.P., (ii) 35,653 shares of common stock held by Polaris Venture Partners Entrepreneurs Fund, L.P., (iii) 12,532 shares of common stock held by Polaris Venture Partners Founders Fund V, L.P., and (iv) 18,292 shares of common stock held by Polaris Venture Partners Special Founders Fund V, L.P. (together with Polaris Venture Partners V, L.P., Polaris Venture Partners Entrepreneurs Fund, L.P. and Polaris Venture Partners Founders Fund V, L.P., the Polaris Funds). North Star Venture Management 2000, LLC directly or indirectly provides investment advisory services to various venture capital funds, including the Polaris Funds. Jonathan Flint and Terrance McGuire, managing members of North Star Venture Management 2000, LLC, exercise voting and investment power with respect to North Star Venture Management, 2000. Each of the Polaris Funds has the sole voting and investment power with respect to the shares of the Company directly held by the applicable Polaris Fund. The respective general partners of the Polaris Funds may be deemed to have sole voting and investment power with respect to the shares held by such funds. The respective general partners disclaim beneficial ownership of all the shares held by the Polaris Funds except to the extent of their proportionate pecuniary interests therein. The members of North Star Venture Management 2000, LLC (the Polaris Management Members) are also members of Polaris Venture Management Co., V, L.L.C. (the general partner of each of the Polaris Funds). Jonathan Flint and Terrance McGuire, managing members of Polaris Venture Management Co. V, L.L.C., exercise voting and investment power with respect to Polaris Venture Management Co. V, L.L.C. As members of the general partner and North Star Venture Management 2000, LLC, the Polaris Management Members may be deemed to share voting and investment powers for the shares held by the Polaris Funds. The Polaris Management Members disclaim beneficial ownership of all such shares held by the funds except to the extent of their proportionate pecuniary interests therein. Kevin Bitterman, a director of the Company, has an assignee interest in Polaris Venture Management Co. V, L.L.C. To the extent that he is deemed to share voting and investment powers with respect to the shares held by the Polaris Funds, Dr. Bitterman disclaims beneficial ownership of all the shares held by the funds except to the extent of his proportionate pecuniary interest therein.

(2) Consists of 1,527,895 shares of common stock held by S.R. One, Limited. Simeon J. George is a partner at S.R. One, Limited. To the extent that he is deemed to share voting and investment powers with respect to the shares held by S.R. One, Limited, Dr. George disclaims beneficial ownership of all the shares held by S.R. One, Limited except to the extent of his proportionate pecuniary interest therein.

(3) Consists of 1,388,646 shares of common stock held by Johnson & Johnson Development Corporation.

(4) Consists of (i) 1,050,432 shares of common stock held by Lux Ventures II, L.P. (LV-II) and (ii) 47,896 shares of common stock held by Lux Ventures II Sidecar, L.P. (Sidecar), (together with LV-II, the Lux Funds). Lux Venture Partners II, L.P. (LVP-II) is the general partner of LV-II and Sidecar. Lux Venture Associates II, LLC (LVA-II) is the general partner of LVP-II and Lux Capital Management, LLC (LCM LLC) is the sole member of LVP-II. Robert Paull, Joshua Wolfe and Peter Hebert are the individual managers of LCM LLC (the Individual Managers). LVP II, LVA-II and LCM LLC disclaim beneficial ownership of such shares, except to the extent of their pecuniary interest therein. LCM LLC, as sole member, may be deemed to share voting and investment powers for the shares held by LV-II and Sidecar. As one of three individual managers, each of the Individual Managers disclaims beneficial ownership over the shares reported herein, and in all events disclaims beneficial ownership except to the extent of his pecuniary interest therein.

(5) Consists of 1,086,641 shares of common stock. Richard H. Robb, manager of CVF, LLC, exercises voting and investment power with respect to shares held by CVF, LLC. Mr. Robb disclaims beneficial ownership of all shares held by CVF, LLC except to the extent of his pecuniary interest therein.

(6) Consists of 1,041,484 shares of common stock held by Skyline Venture Partners V, L.P. The general partner of Skyline Venture Partners V, L.P. is Skyline Venture Management V, LLC. P. except to the extent of his proportionate pecuniary interest therein. John G. Freund and Yasunori Kaneko are Managers of Skyline Venture Management V, LLC and hereby disclaim beneficial ownership of all the shares held by Skyline Venture Partners V, L.P. except to the extent of their proportionate pecuniary interest therein.

(7) Consists of 427,676 shares of common stock that can be acquired upon the exercise of outstanding options and 22,445 shares of common stock that can be acquired upon the exercise of options within 60 days of March 14, 2014

(8) Consists of 99,549 shares of common stock that can be acquired upon the exercise of outstanding options and 9,954 shares of common stock that can be acquired upon the exercise of options within 60 days of March 14, 2014.

(9) Consists of 50,664 shares of common stock that can be acquired upon the exercise of outstanding options and 4,147 shares of common stock that can be acquired upon the exercise of options within 60 days of March 14, 2014

(10) Consists of 2,017 shares of common stock, 107,304 shares of common stock that can be acquired upon the exercise of outstanding options and 1,283 shares of common stock that can be acquired upon the exercise of options within 60 days of March 14, 2014.

(11) Consists of shares held by Polaris Venture Partners or related funds. By virtue of the relationships described in footnote 1 above, Dr. Bitterman may be deemed to share beneficial ownership in the shares held by Polaris Venture Partners or related funds. Dr. Bitterman disclaims beneficial ownership of the shares referred to in footnote 1 above.

(12) Consists of 31,092 shares of common stock, 7,773 shares of common stock that can be acquired upon the exercise of outstanding options and 1,295 shares of common stock that can be acquired upon the exercise of options within 60 days of March 14, 2014.

(13) Consists of shares held by S.R. One, Limited. By virtue of the relationships described in footnote 2 above, Dr. George may be deemed to share beneficial ownership in the shares held by S.R. One, Limited. Dr. George disclaims beneficial ownership of the shares referred to in footnote 3 above.

(14) Consists of (i) 3,456,866 shares of common stock and 823,835 shares of common stock that can be acquired upon the exercise of outstanding options and the exercise of options within 60 days of March 14, 2014.

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

The following is a description of transactions since January 2013, to which we have been a party, in which the amount involved exceeded or will exceed $120 thousand, and in which any related person had a direct or indirect material interest.

Participation in Initial Offering

In February 2014, we issued and sold an aggregate of 5,500,000 shares of our common stock in our IPO at a price of $12.00 for an aggregate purchase price of $66.0 million. Citigroup Global Markets, Inc. and Cowen and Company, LLC acted as joint book-running managers of the offering and as representatives of the underwriters. Stifel, Nicolaus & Company, Incorporated and Needham & Company, LLC acted as co-managers for the offering. The following table sets forth the number of shares of our common stock that were purchased by our 5% stockholders and their affiliates:

Investor	Number of Shares of Common Stock
Polaris Venture Partners	232,820
S.R. One, Limited	250,931
CVF, LLC	132,099
Johnson & Johnson Development Corporation	167,908
Skyline Venture Partners	250,931

Series C Preferred Stock Financing

In June 2013, we issued and sold an aggregate of 26,293,103 shares of our Series C preferred stock at a purchase price of $0.58 per share for an aggregate purchase price of $15.2 million. The following table sets forth the number of shares of our Series C preferred stock that we issued to our 5% stockholders and their affiliates in this transaction:

Investor	Shares of Series C Preferred Stock	Purchase Price ($)
CVF, LLC	6,465,517	3,750,000
Bill & Melinda Gates Foundation	4,310,345	2,500,000
Polaris Venture Partners and related funds	3,037,576	1,761,794
Lux Ventures, and related funds	2,647,659	1,535,642
S.R. One, Limited	2,425,979	1,407,068
Johnson & Johnson Development Corporation	2,093,607	1,214,292
Skyline Venture Partners V, L.P.	1,570,207	910,720
Cycad Group, LLC	1,257,048	729,088
Auriga Ventures, III FCPR	1,212,990	703,534

Indemnification Agreements

We entered into indemnification agreements with each of our directors and executive officers. These agreements will require us to indemnify these individuals and, in certain cases, affiliates of such individuals, to the fullest extent permissible under Delaware law against liabilities that may arise by reason of their service to us or at our direction, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

Registration Rights Agreement

We are a party to a registration rights agreement with certain holders of common stock, including some of our directors, executive officers and 5% stockholders and their affiliates and entities affiliated with our directors. The registration rights agreement provides these holders the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing.

Transactions with Our Executive Officers, Directors and 5% Stockholders

On May 16, 2007, we entered into a consulting agreement with Dr. George Siber, a member of our board of directors. The consulting agreement was amended on each of June 30, 2009, December 16, 2010, June 15, 2011 and June 5, 2013 and is in effect through June 17, 2015. Pursuant to the consulting agreement, Dr. Siber performs various consulting services for us, including determining our general scientific and business direction, recruitment of scientific advisory board members and consultants, recruitment of full-time management and scientific personnel and identifying and reviewing scientific developments and intellectual property. Since the beginning of our last fiscal year, Dr. Siber has been paid approximately $10 thousand per month under the consulting agreement. See Executive and Director Compensation Director Agreements Dr. Siber for further details on compensation paid to Dr. Siber under the consulting agreement.

Related Person Transactions Policy

We have adopted a related person transaction approval policy that will govern the review of related person transactions following the closing of this offering. Pursuant to this policy, if we want to enter into a transaction with a related person or an affiliate of a related person, our Vice President of Finance and Administration will review the proposed transaction to determine, based on applicable NASDAQ and Securities and Exchange Commission rules, if such transaction requires pre-approval by the audit committee and/or board of directors. If pre-approval is required, such matters will be reviewed at the next regular or special audit committee and/or board of directors meeting. We may not enter into a related person transaction unless our Vice President of Finance and Administration has either specifically confirmed in writing that no further reviews are necessary or that all requisite corporate reviews have been obtained.

Director Independence

Our board of directors has determined that Dr. Bitterman, Ms. Bosley, Dr. George and Dr. Hoffman are independent directors as defined under applicable NASDAQ rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Mr. Clark is not an independent director under these rules because he is our Chief Executive Officer and Dr. Siber is not an independent director under these rules because of his consulting relationship with us. See Transactions with Our Executive Officers, Directors and 5% Stockholders .

There are no family relationships among any of our directors or executive officers.

Item 14. Principal Accountant Fees and Services

Audit Fees

The following table summarizes the fees of Ernst & Young LLP, our independent registered public accounting firm, billed to us for each of the last two fiscal years.

Fee Category	2013	2012
Audit Fees	$ 1,197,124	$ 55,000
Audit-Related Fees		
Tax Fees		
All Other Fees		
Total Fees	$ 1,197,124	$ 55,000

Audit Fees. Consists of fees billed for professional services rendered for the audit of our annual financial statements, the review of interim financial statements and services provided in connection with our registration statement on Form S-1.

Audit-Related Fees. Consist of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported under Audit Fees.

Tax Fees. Consists of fees billed for tax compliance, tax advice and tax planning and includes fees for tax return preparation.

All Other Fees. Consists of all other fees billed other than those described above under Audit Fees, Audit-Related Fees and Tax Fees.

All such accountant services and fees were pre-approved by our audit committee in accordance with the Pre-Approval Policies and Procedures described below.

Pre-Approval Policies and Procedures

Our Audit Committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our registered public accounting firm. This policy generally provides that we will not engage our registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our Audit Committee or the engagement is entered into pursuant to one of the pre-approval procedures described below.

From time to time, our Audit Committee may pre-approve specified types of services that are expected to be provided to us by our registered public accounting firm during the next 12 months. Any such pre-approval is detailed as to the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statements

The following financial statements and supplementary data are filed as a part of this Annual Report on Form 10-K.

Report of Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2013 and 2012

Statements of Operations for each of the three years in the period ended December 31, 2013 and the period from August 16, 2006 (inception) to December 31, 2013

Statements of Redeemable Convertible Preferred Stock and Stockholders Deficit for each of the three years in the period ended December 31, 2013 and the period from August 16, 2006 (inception) to December 31, 2013

Statements of Cash Flows for each of the three years in the period ended December 31, 2013 and the period from August 16, 2006 (inception) to December 31, 2013

Notes to Financial Statements

Financial Statement Schedules

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

Exhibits

Those exhibits required to be filed by Item 601 of Regulation S-K are listed in the Exhibit Index immediately preceding the exhibits hereto and such listing is incorporated herein by reference.

Genocea Biosciences, Inc.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

Genocea Biosciences, Inc.

We have audited the accompanying balance sheets of Genocea Biosciences, Inc. (a development stage enterprise) (the Company) as of December 31, 2013 and 2012 and the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders deficit and cash flows for each of the three years in the period ended December 31, 2013 and for the period from August 16, 2006 (inception) to December 31, 2013. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, 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 Genocea Biosciences, Inc. (a development stage enterprise) as of December 31, 2013 and 2012 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013 and for the period from August 16, 2006 (inception) to December 31, 2013 in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 21, 2014

Genocea Biosciences, Inc.

(A Development Stage Company)

Balance Sheets

(In thousands, except per share data)

	December 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 12,208	$ 11,516
Restricted cash	157	97
Prepaid expenses and other current assets	510	520
Total current assets	12,875	12,133
Property and equipment, net	865	794
Restricted cash	158	315
Other assets	1,863	289
Total assets	$ 15,761	$ 13,531
Liabilities, redeemable convertible preferred stock and stockholders deficit		
Current liabilities:		
Accounts payable	$ 2,176	$ 1,452
Accrued expenses and other current liabilities	1,418	919
Deferred revenue	12	
Current portion of long-term debt	861	1,675
Current portion of deferred rent	26	155
Total current liabilities	4,493	4,201
Non-current liabilities:		
Long-term debt, net of current portion	8,933	2,370
Accrued interest payable	11	146
Deferred rent, net of current portion	237	263
Warrants to purchase redeemable securities	656	246
Total liabilities	14,330	7,226
Commitments and contingencies (Note 9)		
Redeemable convertible preferred stock:		
Seed convertible preferred stock, $0.001 par value; Authorized 4,615 shares; Issued and outstanding 4,615 shares at December 31, 2013 and 2012; aggregate liquidation preference of $3,000 at December 31, 2013 and 2012	3,000	3,000
Series A redeemable convertible preferred stock, $0.001 par value; Authorized 36,662 shares; Issued and outstanding 35,577 shares at December 31, 2013 and 2012; aggregate liquidation preference of $23,125 at December 31, 2013 and 2012	23,125	23,125
Series B redeemable convertible preferred stock, $0.001 par value; Authorized 35,099 shares; Issued and outstanding 34,581 shares at December 31, 2013 and 2012; aggregate liquidation preference of $24,937 and $23,332 December 31, 2013 and 2012, respectively	24,937	23,332
Series C redeemable convertible preferred stock, $0.001 par value; Authorized 53,276; Issued and outstanding 52,586 and 26,293 shares at December 31, 2013 and 2012, respectively; aggregate liquidation preference of $30,500 and $15,250 at December 31,	30,500	15,250

2013 and 2012, respectively				
Stockholders deficit				
Common stock, $0.001 par value; Authorized 191,690 shares; Issued 327 and 295 shares at December 31, 2013 and 2012, respectively; outstanding 303 and 295 at December 31, 2013 and 2012, respectively				
Additional paid-in-capital				
Deficit accumulated during the development stage		(80,131)		(58,402)
Total stockholders deficit		(80,131)		(58,402)
Total liabilities, redeemable convertible preferred stock and stockholders deficit	$	15,761	$	13,531

See accompanying notes to financial statements.

Genocea Biosciences, Inc.

(A Development Stage Company)

Statements of Operations and Comprehensive Loss

(In thousands, except per share data)

	Years Ended December 31,			The Period from August 16, 2006 (Inception) to December 31,
	2013	2012	2011	2013
Grant revenue	$ 731	$ 1,977	$ 1,820	$ 6,694
Operating expenses:				
Research and development	15,695	11,240	13,543	60,122
General and administrative	4,961	3,690	3,004	20,952
Total operating expenses	20,656	14,930	16,547	81,074
Loss from operations	(19,925)	(12,953)	(14,727)	(74,380)
Other (expense) income:				
Change in fair value of warrant	(222)	93	75	168
Loss on debt extinguishment	(200)			(200)
Interest expense, net	(459)	(507)	(33)	(1,691)
Other (expense) income	(881)	(414)	42	(1,723)
Net loss	$ (20,806)	$ (13,367)	$ (14,685)	$ (76,103)
Comprehensive loss	$ (20,806)	$ (13,367)	$ (14,685)	$ (76,103)
Reconciliation of net loss to net loss attributable to common stockholders				
Net loss	$ (20,806)	$ (13,367)	$ (14,685)	$ (76,103)
Accretion of redeemable convertible preferred stock to redemption value	(1,605)	(1,781)	(1,605)	(5,914)
Net loss attributable to common stockholders	$ (22,411)	$ (15,148)	$ (16,290)	$ (82,017)
Net loss per share attributable to common stockholders-basic and diluted	$ (75.46)	$ (51.35)	$ (55.41)	$ (347.53)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	297	295	294	236

See accompanying notes to financial statements.

Genocea Biosciences, Inc.

(A Development Stage Company)

Statements of Redeemable Convertible Preferred Stock and Stockholders Deficit

(In thousands)

	Seed Convertible Preferred Shares		Series A Redeemable Convertible Preferred Shares		Series B Redeemable Convertible Preferred Shares		Series C Redeemable Convertible Preferred Shares		Common Shares		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at August 16, 2006 (inception)		$		$		$		$		$	$	$	
Issuance of common stock (2006)									273		3		3
Issuance of restricted common stock (2006)									1				
Issuance of Seed Preferred stock, net of issuance costs of $72 (2006)	4,497	3,000									(3)	(69)	(72)
Conversion of notes payable and accrued interest into Seed Preferred stock (2006)	118												
Issuance of restricted common stock in exchange for services rendered (2007)									2		3		3
Issuance of common stock in exchange for license agreement (2007)									11		18		18
Issuance of restricted common stock (2008)									2		1		1
Exercise of stock options (2008)													
Issuance of Series A Preferred stock, net of issuance costs of $352 (2009)			29,083	18,904							(321)	(31)	(352)
Conversion of notes payable and accrued interest into Series A Preferred stock			6,494	4,221									

(2009)												
Exercise of stock options (2009)									1	1		1
Issuance of Series B Preferred stock, net of issuance costs of $437 (2010)					34,581	20,056				(252)	(185)	(437)
Issuance of common stock in exchange for license agreement (2010)									2	6		6
Exercise of stock options (2010)									1	2		2
Stock-based compensation expense										542		542
Accretion of dividends on redeemable convertible preferred stock						62					(62)	(62)
Net loss											(27,245)	(27,245)
Balance at December 31, 2010	4,615	3,000	35,577	23,125	34,581	20,118			293		(27,592)	(27,592)
Exercise of stock options									2	6		6
Stock-based compensation expense										314		314
Accretion of dividends on redeemable convertible preferred stock						1,605				(320)	(1,285)	(1,605)
Net loss											(14,685)	(14,685)
Balance at December 31, 2011	4,615	3,000	35,577	23,125	34,581	21,723			295		(43,562)	(43,562)
Issuance of Series C Preferred stock, net of issuance costs of $172							26,293	15,250		(172)		(172)
Exercise of stock options										1		1
Stock-based compensation expense										307		307
Accretion of dividends on redeemable convertible preferred stock						1,609				(136)	(1,473)	(1,609)
Net loss											(13,367)	(13,367)
Balance at December 31, 2012	4,615	3,000	35,577	23,125	34,581	23,332	26,293	15,250	295		(58,402)	(58,402)
Issuance of Series C Preferred stock							26,293	15,250				
Exercise of stock options									7	9		9

Stock-based compensation expense												672			672
Vesting of restricted stock										1		1			1
Accretion of dividends on redeemable convertible preferred stock							1,605					(682)	(923)		(1,605)
Net loss													(20,806)		(20,806)
Balance at December 31, 2013	4,615	$	3,000	35,577	$	23,125	34,581	$	24,937	52,586	$	30,500	303	$	$	$	(80,131)	$	(80,131)

See accompanying notes to financial statements

Genocea Biosciences, Inc.

(A Development Stage Company)

Statements of Cash Flows

(In thousands)

	Years Ended December 31,			The Period from August 16, 2006 (Inception) to December 31,
	2013	2012	2011	2013
Operating activities				
Net loss	$ (20,806)	$ (13,367)	$ (14,685)	$ (76,103)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	318	300	318	1,608
Stock-based compensation	672	307	314	1,836
Stock issued for services				21
Stock issued for interest				2
Stock issued for license agreement				6
Non-cash interest expense for warrant issuance				509
Change in fair value of warrants liability	222	(93)	(75)	(167)
Non-cash interest expense	22	46	12	310
Loss on debt extinguishment	200			200
Changes in operating assets and liabilities:				
Restricted cash	97	(315)		(315)
Prepaid expenses and other current assets	27	(145)	(82)	(451)
Other long-term assets	(1,539)	(237)		(1,776)
Accounts payable	724	515	283	2,144
Deferred revenue	12	(23)	(58)	12
Accrued expenses	468	(191)	551	1,387
Deferred rent	(155)	376	(66)	263
Accrued interest payable	(135)	146		10
Net cash used in operating activities	(19,873)	(12,681)	(13,488)	(70,504)
Investing activities				
Purchases of property and equipment	(389)	(460)	(318)	(2,474)
Net cash used in investing activities	(389)	(460)	(318)	(2,474)
Financing activities				
Proceeds from issuance of notes payable and warrants to purchase redeemable preferred stock				4,075
Proceeds from issuance of preferred stock, net	15,250	15,078		71,348
Proceeds from issuance of long-term debt	9,965	5,000		15,547
Repayments of long-term debt	(4,245)	(1,164)	(195)	(5,780)
Proceeds from sale of restricted and unrestricted common stock				3
Proceeds from exercise of stock options	42	1	6	52

Payments for debt issuance costs	(58)			(58)
Net cash provided by (used in) financing activities	20,954	18,915	(189)	85,187
Net increase (decrease) in cash and cash equivalents	$ 692	$ 5,774	$ (13,995)	$ 12,209
Cash and cash equivalents at beginning of period	11,516	5,742	19,737	
Cash and cash equivalents at end of period	$ 12,208	$ 11,516	$ 5,742	$ 12,209
Supplemental cash flow information				
Cash paid for interest	$ 426	$ 323	$ 25	$ 865
Supplemental disclosure of non-cash financing activities				
Accretion of redeemable convertible preferred stock to redemption value	$ 1,605	$ 1,781	$ 1,605	$ 5,914
Leasehold improvements financed by landlord	$	$ 237	$	$
Conversion of convertible debt and accrued interest to preferred stock	$	$	$	$ 4,298
Vesting of restricted stock	$ 1	$	$	$ 1

See accompanying notes to financial statements.

Genocea Biosciences, Inc.

(A Development Stage Company)

Notes to Financial Statements

1. Organization and operations

The Company

Genocea Biosciences, Inc. (the Company) is a clinical stage biopharmaceutical company that was incorporated in Delaware on August 16, 2006 and has a principal place of business in Cambridge, Massachusetts. The Company uses its proprietary platform technology called AnTigen Lead Acquisition System (ATLAS) to discover and develop novel vaccine candidates. The ATLAS proprietary technology platform mimics the human immune response in the laboratory, potentially improving the effectiveness of vaccine discovery and drastically reducing the time needed to create promising vaccines. Using the ATLAS platform, the Company is developing its most advanced product candidate, GEN-003, in a phase 1/2a clinical trial to treat patients with herpes simplex virus type-2 (HSV-2). The Company is also developing other product candidates, including GEN-004, which is being developed to prevent infections caused by pneumococcus.

The Company is in the development stage and is devoting substantially all of its efforts to product research and development, initial market development, and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other development stage companies, including dependence on key individuals, competition from other companies, the need for development of commercially viable products, and the need to obtain adequate additional financing to fund the development of its product candidates. The Company is also subject to a number of risks similar to other companies in the life sciences industry, including regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability, and dependence on key individuals.

As of December 31, 2013, the Company had a deficit accumulated during the development stage of approximately $80.1 million. The Company had cash and cash equivalents of $12.2 million as of December 31, 2013. The Company believes that the net proceeds from its initial public offering (IPO), completed in February 2014, together with its existing cash and cash equivalents will be sufficient to fund operations and capital expenditures for at least the next twelve months.

2. Summary of significant accounting policies

Basis of presentation and use of estimates

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company s management evaluates its estimates, which include, but are not limited to, estimates related to clinical trial accruals, stock- based compensation expense, warrants to purchase redeemable securities, and reported amounts of revenues and expenses during the reported period. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

The Company utilized significant estimates and assumptions in determining the fair value of its common stock (Common Stock). The Company utilized various valuation methodologies in accordance with the framework of the 2004 and 2013 American Institute of Certified Public Accountants Technical Practice Aids, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its Common Stock. Each valuation methodology includes estimates and assumptions that require the Company s judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company s Common Stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or a sale of the Company. Significant changes to the key assumptions used in

the valuations could result in different fair values of Common Stock at each valuation date and materially affect the financial statements.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company and the Company s chief operating decision maker view the Company s operations and manage its business in one operating segment, which is the business of developing and commercializing vaccines. The Company operates in only one geographic segment.

Cash and cash equivalents

The Company considers all highly liquid investments with maturities of 90 days or less from the purchase date to be cash equivalents. Cash and cash equivalents are held in depository and money market accounts and are reported at fair value.

Concentrations of credit risk and off-balance sheet risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company s cash and cash equivalents are held in accounts with a financial institution that management believes is creditworthy. The Company s investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no financial instruments with off-balance sheet risk of loss.

Deferred initial public offering costs

Deferred public offering costs, which primarily consist of direct, incremental legal and accounting fees relating to the IPO, are capitalized within other assets. The Company has incurred $1.6 million in IPO costs as of December 31, 2013. In February 2014, deferred issuance costs were offset against the proceeds upon completion of the IPO.

Fair value of financial instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurement and Disclosures*, established a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the

observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the financial instrument based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company s assumptions about the inputs that market participants would use in pricing the financial instrument and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported or disclosed fair value of the financial instruments and is not a measure of the investment credit quality. Fair value measurements are classified and disclosed in one of the following three categories:

- Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

- Level 2 Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

- Level 3 Valuations that require inputs that reflect the Company s own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in

determining fair value is greatest for instruments categorized in Level 3. A financial instrument s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Financial instruments measured at fair value on a recurring basis include cash equivalents (Note 3) and warrants to purchase redeemable securities (Note 8).

An entity may elect to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in net loss. The Company did not elect to measure any additional financial instruments or other items at fair value. The Company is also required to disclose the fair value of financial instruments not carried at fair value. The fair value of the Company s long-term debt (Note 7) is determined using current applicable rates for similar instruments as of the balance sheet dates and assessment of the credit rating of the Company. The carrying value of the Company s long-term debt approximates fair value because the Company s interest rate yield is near current market rates. The Company s long-term debt is considered a Level 3 liability within the fair value hierarchy.

Except for the valuation methodology utilized to value the warrants to purchase redeemable securities (Note 8), there have been no changes to the valuation methods utilized by the Company during the years ended December 31, 2013, 2012, and 2011 or the period from August 16, 2006 (inception) through December 31, 2013. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the years ended December 31, 2013, 2012 and 2011 or the period from August 16, 2006 (inception) through December 31, 2013.

Property and equipment

Property and equipment is stated at cost, less accumulated depreciation. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred, while costs of major additions and betterments are capitalized. Upon disposal, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets, which are as follows:

Asset	Estimated useful life
Laboratory equipment	5 years
Furniture and office equipment	5 years
Computer equipment and software	3-5 years
Leasehold improvements	Shorter of the useful life or remaining lease term

Impairment of long-lived assets

The Company evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value. The Company has not recognized any impairment losses through December 31, 2013.

Reverse stock split

On January 20, 2014, the Board of Directors and stockholders approved a 1-for-11.9 reverse stock split of the Company s Common Stock, which was effected on January 21, 2014. Stockholders entitled to fractional shares as a result of the reverse stock split will received a cash payment in lieu of receiving fractional shares. The Company s historical share and per share information has been retroactively adjusted to give effect to this reverse stock split. Shares of Common Stock underlying outstanding stock option were proportionately reduced and the respective exercise prices proportionately increased. Shares of Common Stock reserved for future issuance were presented on an as converted basis and the financial statements disclose the adjusted conversion ratios.

Revenue recognition

The Company has generated revenue solely through research and development grants with a private not-for-profit organization and federal agencies for the development and commercialization of product candidates.

The Company recognizes revenue in accordance with FASB ASC Topic 605, *Revenue Recognition* (ASC 605). Accordingly, revenue is recognized for each unit of accounting when all of the following criteria are met:

- persuasive evidence of an arrangement exist
- delivery has occurred or services have been rendered
- the fee is fixed or determinable
- collectability is reasonably assured

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company s balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as a current liability. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as a non-current liability.

Grant revenue

The Company has received grants from a private not-for-profit organization and federal agencies. Grant revenue consists of revenue earned from grants to conduct vaccine development research. Funds received in advance of services being performed are recorded as deferred revenue. Revenue under these grants is recognized as research services are performed. The Company recognized a total of $731 thousand, $2.0 million, and $1.8 million in 2013, 2012, and 2011, respectively, related to these grants. Since inception and through December 31, 2013, the Company has recognized a total of $6.7 million of revenue related to these grants, and has received a total of $6.7 million in cash receipts.

Multiple-element arrangements

The Company analyzes multiple-element arrangements based on the guidance in FASB ASC Topic 605-25, *Revenue Recognition Multiple-Element Arrangements* (ASC 605-25). The Company applies this guidance to new arrangements as well as existing arrangements that contain multiple deliverables. The Company determines the elements, or deliverables, included in the arrangement and allocates consideration under the arrangement to the various elements based on each element s relative selling price. The identification of individual elements in a multiple-element arrangement and the estimation of the selling price of each element involves significant judgment, including consideration as to whether each delivered element has stand-alone value to the collaborator.

The Company determines the estimated selling price for deliverables within the arrangement using vendor-specific objective evidence (VSOE) of selling price, if available, or third-party evidence of selling price if VSOE was not available or the Company s best estimate of selling price, if neither VSOE nor third-party evidence was available. The Company uses its best estimate of a selling price to estimate the selling price for licenses for its technology, know-how, and trademarks since it does not have VSOE or third-party evidence of selling price for these deliverables. In order to determine the best estimate of selling price, the Company considers market conditions, as well as entity- specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed estimates that include assumptions related to the market opportunity, estimated development costs, probability of success, and the time needed to commercialize assays. In validating its best estimate of selling price, the Company evaluates whether changes in the key assumptions used to determine best estimate of selling price would have a significant effect on the allocation of arrangement consideration between deliverables. The Company recognizes consideration allocated to an individual element when all other revenue recognition criteria are met for that element, which generally occurs upon delivery or over the period in which services are provided.

License agreement

In 2012, the Company entered into a license agreement with a not-for-profit entity whereby the not-for-profit entity could utilize certain programs discovered or developed by the Company in certain developing countries. The Company did not receive any up-front consideration related to this agreement; however, the Company is entitled to receive reimbursement

of a pro rata share of any payments, including milestone payments, that the Company is required to make under license agreements with third parties that comprise these programs. As of December 31, 2013, the licenses from third parties that comprise these programs have not been determined yet as these programs are either in the early stages of development or have not yet been identified. As a result, the Company is not currently eligible to receive any milestone payments under this arrangement.

Concurrent with the execution of the license agreement, the not-for-profit entity also purchased 4,310,345 shares of the Company s Series C Preferred Stock (Note 10).

At the inception of the agreement, the Company evaluated whether each potential milestone payment that could be received from the not-for-profit entity for reimbursement of a portion of milestones owed to third parties from existing license agreements that could comprise these programs is substantive and at risk to both parties on the basis of the contingent nature of the milestone. The evaluation included an assessment of whether (a) the consideration is commensurate with either (i) the entity s performance to achieve the milestone or (ii) the enhancement of the value of the delivered items as a result of a specific outcome resulting from the entity s performance to achieve the milestone; (b) the consideration related solely to past performance; and (c) the consideration was reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluated factors such as the scientific, regulatory, and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone, and whether the milestone considerations are reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Substantive, at-risk milestones are recognized as revenue when the milestone is achieved.

As there was no up-front consideration, there were no amounts to allocate to the various deliverables. The milestones under the arrangement related to reimbursement for milestone payments by the Company owed to third parties for existing license agreements that could comprise these programs are considered to be substantive and at risk and will be recognized when earned. Since the licenses from third parties that could comprise these programs have not been determined yet, the amount and timing of such milestones cannot be determined at this time.

Research and development expenses

Research and development costs are charged to expense as incurred in performing research and development activities. The costs include employee compensation costs, facilities and overhead, clinical study and related clinical manufacturing costs, regulatory and other related costs.

Nonrefundable advanced payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

Stock-based compensation expense

The Company accounts for its stock-based compensation awards to employees and directors in accordance with FASB ASC Topic 718, *Compensation-Stock Compensation* (ASC 718). ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock, to be recognized in the statements of operations and comprehensive loss based on their grant date fair values. Compensation expense related to awards to employees is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Share-based payments issued to non-employees are recorded at their fair values,

and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period in accordance with the provisions of ASC 718 and ASC Topic 505, *Equity,* and are expensed using an accelerated attribution model.

The Company estimates the fair value of its stock options using the Black- Scholes option pricing model, which requires the input of subjective assumptions, including (a) the expected stock price volatility, (b) the expected term of the award, (c) the risk-free interest rate, (d) expected dividends and e) the estimated fair value of its Common Stock on the measurement date. Due to the lack of a public market for the trading of its Common Stock and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. The Company computes historical volatility data using the daily closing prices for the

selected companies shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. Due to the lack of Company specific historical option activity, the Company has estimated the expected term of its employee stock options using the simplified method, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term for non-employee awards is the remaining contractual term of the option. The risk-free interest rates are based on the U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid, and does not expect to pay dividends in the foreseeable future. Refer to *Basis of presentation and use of estimates* in Note 2 for a discussion of the Company s estimated fair value of its Common Stock.

The Company is also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from its estimates. The Company uses historical data to estimate forfeitures and records stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from the Company s estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest.

Income taxes

Income taxes are recorded in accordance with FASB ASC Topic 740, *Income Taxes* (ACS 740), which provides for deferred taxes using an asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. The Company has evaluated available evidence and concluded that the Company may not realize the benefit of its deferred tax assets; therefore a valuation allowance has been established for the full amount of the deferred tax assets.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2013 and 2012, the Company does not have any significant uncertain tax positions. The Company s practice is to recognize interest and/or penalties related to income tax matters in income tax expense.

Net loss per share attributable to common stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Net loss attributable to common stockholders is calculated by adjusting the net loss of the Company for cumulative preferred stock dividends and accretion of preferred stock issuance costs. During periods of income, the Company allocates participating securities a proportional share of income determined by dividing total weighted average participating securities by the sum of the total weighted average common shares and participating securities (the two-class method). The Company s redeemable convertible preferred stock and restricted stock participate in any dividends declared by the Company and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, the Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. Diluted net loss per share attributable to common stockholders is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share attributable to common stockholders calculation,

preferred stock, stock options, unvested restricted stock, and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

Comprehensive loss

Comprehensive loss consists of net income or loss and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. The Company s net loss equals comprehensive loss for all periods presented.

Recent accounting pronouncements

The Company did not adopt any new accounting pronouncements during 2013 and there are no new accounting pronouncements that have been issued but not yet adopted, that will have a material effect on the Company s financial statements.

Subsequent events

The Company considers events or transactions that occur after the balance sheet date but prior to the date the financial statements are issued for potential recognition or disclosure in the financial statements.

3. Cash and cash equivalents

As of December 31, 2013 and 2012, cash and cash equivalents comprise funds in depository and money market accounts.

The following table presents the cash and cash equivalents carried at fair value in accordance with the hierarchy defined in Note 2 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2013				
Cash	$ 249	$ 249	$	$
Money Market funds, included in cash equivalents	11,959	11,959		
Total	$ 12,208	$ 12,208	$	$
December 31, 2012				
Cash	$ 512	$ 512	$	$
Money Market funds, included in cash equivalents	11,004	11,004		
Total	$ 11,516	$ 11,516	$	$

Cash equivalents have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. The Company validates the prices provided by its third party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by the pricing services as of December 31, 2013 or 2012.

4. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2013	**2012**
Prepaid tenant improvement costs	$ 237	$
Grant receivable		185
Prepaid rent		53
Other	273	282
Total	$ 510	$ 520

5. Property and equipment, net

Property and equipment, net consist of the following (in thousands):

	December 31,	
	2013	2012
Laboratory equipment	$ 1,694	$ 1,319
Furniture office equipment	14	14
Computer equipment and software	142	128
Leasehold improvements	344	344
Total property and equipment	2,194	1,805
Accumulated depreciation	(1,329)	(1,011)
Property and equipment, net	$ 865	$ 794

Depreciation expense was $318 thousand, $300 thousand, $318 thousand and $1.6 million for the years ended December 31, 2013, 2012, 2011 and the period from August 16, 2006 (inception) to December 31, 2013, respectively.

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2013	2012
Payroll and employee-related costs	$ 738	$ 628
Research and development costs	323	134
Accrued professional fees	303	157
Other	54	
Total	$ 1,418	$ 919

7. Long-term debt

During 2006, the Company issued $75 thousand of convertible debt to finance its operations. The notes incurred interest at 8% per year. On December 18, 2006, upon the issuance of the Seed Preferred Stock, $75 thousand of notes and $2 thousand of accrued interest converted into 118,277 shares of Seed Preferred Stock in a qualified financing, as defined (Note 10).

During 2008, the Company entered into note purchase agreements with various investors, which provided for up to $4.0 million in convertible debt to finance the operations of the Company. The notes incurred interest at 8% per year, and were convertible into shares of Series A Preferred Stock. In February 2009, the entire outstanding balance, plus $0.2 million of accrued interest, automatically converted into 6,494,438 shares of Series A Preferred Stock upon the issuance of the Series A Preferred Stock in a qualified financing, as defined (Note 10). In connection with this financing, the Company issued warrants to purchase 1,038,461 shares of Series A Preferred Stock (Note 8) at $0.65 per share.

In November 2008, the Company entered into a Loan and Security Agreement with a financial institution, which provided for up to $250 thousand in debt financing prior to a Series A Preferred Stock financing and up to $1.5 million after a Series A Preferred Stock financing (less the aggregate advances prior to a financing) to finance equipment purchases made by the Company (Equipment Term Loan). The Company

completed a Series A Preferred Stock financing in February 2009 (Note 10). The Equipment Term Loan provided for a draw-down period on the loan to October 30, 2009. In February 2010, the Company amended the Equipment Term Loan and extended the draw-down period until April 30, 2010. As of April 30, 2010, the Company had drawn $582 thousand under the agreement and no additional amounts are available under the agreement.

The terms of the Equipment Term Loan provided for repayment of each draw-down over a 42-month term, with interest-only payments for the first 6 months and 36 equal monthly payments of principal and accrued interest thereafter. The Equipment Term Loan bears interest at the greater of the lender s prime rate, plus 3.50% or 8.25%. Should an event of default occur, including the occurrence of a material adverse change, the Company would be liable for immediate repayment.

In connection with the Equipment Term Loan, the Company issued a warrant to purchase 46,154 shares of Series A Preferred Stock (Note 8) at $0.65 per share. The Equipment Term Loan holds all assets purchased under the program as collateral.

As of December 31, 2013, the remaining balance of the Equipment Term Loan was repaid.

In October 2011, the Company entered into a Loan and Security Agreement with a financial institution, which provided for up to $5.0 million in debt financing (Term Loan). The Term Loan provided for a draw-down period on the facility through March 1, 2012. On March 1, 2012, the Company drew down the full $5.0 million available under the terms of this arrangement.

From March 1, 2012 through May 1, 2012, the Company was obligated to make interest-only payments at the greater of the financial institution s prime rate plus 5.00% or 8.00%. The Company began making 36 equal monthly payments of principal and accrued interest thereafter. During the 36-month period, the Term Loan bears interest at the greater of the financial institution s prime rate plus 4.75% or 8.00%. The Company also is obligated to pay 6.50% of the advance on the final repayment date of the draw, which is April 1, 2015. This final payment was being accrued over the term of the debt and is recorded in accrued interest payable on the balance sheets.

In connection with the Term Loan, the Company issued a fully-exercisable warrant to purchase 517,242 shares of Series B Preferred Stock (Note 8). The Term Loan is collateralized by all the assets of the Company, except for those assets collateralized by the Equipment Term Loan.

On September 30, 2013, the Company entered into a new loan agreement which provided up to $10.0 million in debt financing (New Term Loan). Upon the closing of the New Term Loan, the Company drew down $3.5 million and paid off the remaining balance under the Term Loan. As part of the early repayment, the Company incurred a loss on debt extinguishment of $0.2 million. The New Term Loan provides for a draw-down period on the remaining facility of $6.5 million, which the Company drew down on December 19, 2013. The Company is obligated to make interest-only payments for the first 9 months and 33 equal payments of principal, together with accrued interest thereafter for each advance. The New Term Loan bears interest at a rate of 8% per annum. The Company is also obligated to pay 2% of the advance on the final repayment date of each draw. The final payment is being accrued over the term of the debt and recorded in accrued interest payable on the balance sheets. Should an event of default occur, including the occurrence of a material adverse change, the Company would be liable for immediate repayment of all amounts outstanding, including the 2% final payment associated with each draw.

In connection with the New Term Loan, the Company issued a warrant to purchase 689,655 shares of Series C Preferred Stock (Note 8) at $0.58 per share. The New Term Loan is collateralized by all the assets of the Company.

Future principal payments on the New Term Loan are as follows (in thousands):

	December 31, 2013
2014	$ 924
2015	3,636
2016	3,636
2017	1,804
Total	$ 10,000

8. Warrants to purchase redeemable securities

In 2009, the Company issued warrants to purchase 1,038,461 and 46,154 shares of Series A Preferred Stock associated with the issuance of convertible debt and the Equipment Term Loan, respectively (Note 7), at an exercise price of $0.65 per share. The warrants to purchase 1,038,461 shares of Series A Preferred Stock associated with the convertible debt expire on the later of February 11, 2014 or the date of an IPO. The warrant to purchase 46,154 shares of Series A Preferred Stock associated with the Equipment Term Loan expires on the earlier of November 18, 2018 or five years from the date of an IPO.

In 2011, the Company issued a warrant to purchase 517,242 shares of Series B Preferred Stock at an exercise price of $0.58 per share in connection with the Term Loan (Note 7). Upon signing the arrangement, the warrant was exercisable for 258,621 shares and, on March 1, 2012, the remaining shares under the warrant became exercisable when the Company drew down on the full amount allowable under the facility. The warrant to purchase 517,242 shares of Series B Preferred Stock associated with the Term Loan was determined to be debt issuance costs, and the fair value of $110 thousand on the date of issuance was recorded as a liability, and is being amortized through the statements of operations and comprehensive loss as additional interest expense over the life of the Term Loan. The warrant to purchase the Series B Preferred Stock expires on October 25, 2021.

On September 30, 2013, the Company issued a warrant to purchase 689,655 shares of Series C Preferred Stock at an exercise price of $0.58 per share in connection with a New Term Loan (Note 7). Upon signing of the arrangement, the full amount of shares subject to such amount were exercisable. The warrant to purchase the 689,655 shares of Series C Preferred Stock associated with the New Term Loan was determined to be debt issuance costs, and the fair value of $188 thousand on the date of issuance was recorded as a liability, and is being amortized on the statement of operations and comprehensive loss as additional interest expense over the life of the New Term Loan. The warrant to purchase the Series C Preferred Stock expires on September 30, 2023.

Since the underlying preferred stock is redeemable under certain circumstances, these warrants meet the criteria for liability accounting and, therefore, were reported at fair value on the issuance date and are remeasured at each balance sheet date with changes to fair value being recognized as a component of other (expense) income in the statement of operations.

Below is a summary of the warrants outstanding (in thousands):

	December 31,	
	2013	2012
Warrants to purchase Series A Preferred Stock	1,085	1,085
Warrants to purchase Series B Preferred Stock	517	517
Warrants to purchase Series C Preferred Stock	690	
Total	2,292	1,602

Each warrant is exercisable on either the physical settlement or net share settlement basis. Upon conversion of the Company s Preferred Stock into shares of Common Stock, the associated warrants to purchase shares of the Company s Preferred Stock will become exercisable into the same number of shares of Common Stock, adjusted for the impact of the 1-for-11.9 reverse stock split of the Company s Common Stock effected on January 21, 2014, and the exercise price will be adjusted proportionally.

There were no exercises, cancellations and expirations of warrants during the years ended December 31, 2013, 2012 and 2011 or for the period from August 16, 2006 (inception) to December 31, 2013.

Fair value

The following table presents the warrants to purchase redeemable securities recorded at fair value in accordance with the hierarchy defined in Note 2 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Signifinant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2013				
Warrants to purchase redeemable securities	$ 656	$	$	$ 656
Total	$ 656	$	$	$ 656
December 31, 2012				
Warrants to purchase redeemable securities	$ 246	$	$	$ 246
Total	$ 246	$	$	$ 246

These warrants are considered Level 3 liabilities because their fair value measurements are based, in part, on significant inputs not observed in the market and reflect the Company s assumptions as to the expected volatility of the Company s Preferred Stock. The Company determined the fair value of the warrants to purchase redeemable securities based on input from management and the Board of Directors, which utilized an independent valuation of the Company s enterprise value, determined utilizing an analytical valuation model. Any reasonable changes in the assumptions used in the valuation could materially affect the financial results of the Company.

The analytical valuation model used for the periods ended December 31, 2013, 2012 and 2011 are as follows:

	Analytical Valuation Model Used
December 31, 2013	Hybrid approach based on an OPM backsolve method and the PWERM (1)
December 31, 2012	Option-Pricing Model (OPM) backsolve method
December 31, 2011	Probability-Weighted Expected Return Model (PWERM)

(1) 35% of the value was attributed to the OPM backsolve method and 65% was attributed to the PWERM. After the enterprise value was determined, the total enterprise value was then allocated to the various outstanding equity instruments, including the warrants to purchase redeemable securities, utilizing the OPM.

The following table sets forth a summary of changes in the fair value of the Company s warrants to purchase redeemable securities, which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs (in thousands):

	Years ended December 31,		
	2013	2012	2011
Beginning balance	$ 246	$ 339	$ 304
Warrants issued	188		110
Change in fair value	222	(93)	(75)
Ending balance	$ 656	$ 246	$ 339

9. Commitments and contingencies

Significant Contracts and Agreements

In August 2006, the Company entered into an agreement to license certain intellectual property from The Regents of the University of California. The agreement required the Company to pay a non-refundable license fee of $25 thousand, and to issue 12,605 shares of common stock to the university. Such consideration was recorded in research and development expenses in 2006. The agreement calls for payments to be made by the Company upon the occurrence of a certain development milestone and a certain commercialization milestone for each distinct product covered by the licensed patents, in addition to certain royalties to be paid on marketed products or sublicense income. There were no other research and development expenses associated with this agreement in any of the other financial periods presented.

In November 2007, the Company entered into an agreement to license certain intellectual property from Harvard University. The agreement required the Company to pay a non-refundable license fee of $75 thousand, and to issue 10,773 shares of common stock to the university. Such consideration, which totaled $93 thousand, was recorded in research and development expenses in 2007. The agreement also calls for payments to be made by the Company upon the occurrence of certain development and regulatory milestones, in addition to certain royalties on marketed products or sub-license income. In addition, the Company must make annual maintenance fee payments, which vary depending on the type of products under development. The Company paid $83 thousand, $83 thousand, $50 thousand and $266 thousand in annual maintenance fees and clinical milestones to Harvard University for the years ended December 31, 2013, 2012, 2011 and the period from August 16, 2006 (inception) to December 31, 2013, respectively.

In August 2009, the Company entered into an agreement to license certain intellectual property from Isconova AB, now Novavax. The agreement required the Company to pay a non-refundable license fee of $750 thousand. The Company was also required to pay $200 thousand on the one-year anniversary in 2010. The agreement calls for payments to be made by the Company upon the occurrence of certain development and commercial milestones, in addition to certain royalties to be paid on marketed products or sublicense income. In addition, the Company has entered into a committed funding agreement whereby the Company is obligated to purchase a total of $1.6 million of services on a full-time equivalent basis. These services are expensed as incurred. The Company has expensed none, $290 thousand, $583 thousand and $1.7 million related to these services for the years ended December 31, 2013, 2012, 2011 and the period from August 16, 2006 (inception) to December 31, 2013, respectively.

In January 2010, the Company entered into an agreement to license certain intellectual property from the University of Washington. The agreement required the Company to pay a non-refundable license fee of $20 thousand, and to issue 2,100 shares of common stock to the university. These amounts were recorded in research and development expenses in 2010. The agreement also calls for payments to be made by the Company upon the occurrence of certain development and commercial milestones, in addition to certain royalties on marketed products or sublicense income. In addition, the Company must make annual maintenance fee payments, which vary depending on the number of years from the effective date. The Company has expensed $45 thousand, $15 thousand, $10 thousand and $90 thousand related to this agreement for the years ended December 31, 2013, 2012, 2011 and the period from August 16, 2006 (inception) to December 31, 2013, respectively.

Supply agreement

In August 2009, the Company entered into a supply agreement with a third party for the manufacture of chemical compounds used in the Company s product candidates. The agreement calls for payments to be made by the Company upon the occurrence of certain clinical milestones, in addition to reimbursement of certain consumables. In June 2013, the

Company entered into another supply agreement with the same vendor for the manufacture of chemical compounds to be used in the Company s next clinical trials. The Company has expensed $1.5 million, $180 thousand, $3.4 million and $7.4 million related to these agreements for the years ended December 31, 2013, 2012, 2011 and the period from August 16, 2006 (inception) to December 31, 2013, respectively.

Lease commitments

In April 2007, the Company leased office and laboratory space, and obtained facilities management services under an operating lease (the 2007 Facilities Lease) that was scheduled to expire in March 2012. The Company had an option to extend the lease by two years at a rate of the greater of $53 thousand per month or 95% of the then-current market rate. In December 2009, the Company leased additional space and amended the existing lease agreement. As a result of this amendment, the monthly rent payments were increased for the remaining term of the lease agreement. The Company took possession of this additional space in January 2010. In June 2011, the lease term was extended for an additional nine months from March 2012 and expired on December 31, 2012.

In October 2008, the Company leased laboratory space that expired on September 30, 2009. In August 2009, the Company extended the lease for an additional six-month period that expired in March 2010. In February 2010, the Company exercised an option to extend the lease for an additional 12- month period, expiring on March 31, 2011 at the same terms as the original lease. Since April 1, 2011, the Company has leased the laboratory space on a month-to-month basis under the same terms as the original lease. As of December 31, 2012, the month-to-month lease was terminated.

In July 2012, the Company leased office and laboratory space under an operating sublease (2012 Facilities Sublease) that expires in February 2014. The Company concurrently signed an operating lease for the same space with the master landlord (2012 Master Facilities Lease) that commences in March 2014 and expires in February 2017.

As of December 31, 2013, the minimum future lease payments under these operating leases are as follows (in thousands):

		Operating lease
2014	$	791
2015		976
2016		1,012
2017		170
Total minimum lease payments	$	2,949

The Company recorded $476 thousand, $1.1 million, $990 thousand and $4.8 million in rent expense for the years ended December 31, 2013 and 2012, and 2011 and the period from August 16, 2006 (inception) to December 31, 2013, respectively.

Restricted cash related to facilities leases

Restricted cash related to facilities leases consisted of the following (in thousands):

	December 31,	
	2013	2012
2007 Facilities Lease	$	$ 97
2012 Facilities Sublease	157	157
2012 Master Facilities Lease	158	158
Total	$ 315	$ 412

The Company had a letter of credit with a financial institution related to a security deposit for the 2007 Facilities Lease for $97 thousand, which was secured by cash on deposit. The 2007 Facilities Lease expired on December 31, 2012, and the amounts under the letter of credit were refunded to the Company in January 2013.

Additionally, the Company has two outstanding letters of credit with a financial institution related to security deposits for the 2012 Facilities Sublease and the 2012 Master Facilities Lease, for a total of $315 thousand, which are secured by cash on deposit.

Litigation

The Company does not believe it is a party to any litigation and does not have contingency reserves established for any litigation liabilities.

10. Redeemable convertible preferred stock

As of December 31, 2013, the total authorized capital stock of the Company was 321,340,959 shares, which included 4,615,385 shares of Seed Preferred Stock, $0.001 par value per share; 36,661,538 shares of Series A Preferred Stock $0.001 par value per share; 35,098,520 shares of Series B Preferred Stock, $0.001 par value per share; and 53,275,861 shares of Series C Preferred Stock, $0.001 par value per share. Upon the issuance of the Series C Preferred Stock in 2012, the terms and conditions of the Series B Preferred Stock, Series A Preferred Stock and the Seed Preferred Stock were modified through an amendment to the Certificate of Incorporation. These adjustments included making the Seed Preferred Stock and Series A Preferred Stock junior to the new Series C Preferred Stock related to redemption and liquidation rights and other changes in voting and corporate governance procedures. These adjustments were not considered material. On February 10, 2014, the Company closed its IPO. In conjunction with this transaction, all shares of the Company s redeemable convertible preferred stock were converted into 11,435,580 shares of Common Stock.

In December 2006, the Company issued 4,615,385 shares of Seed Preferred Stock for $0.65 per share (including 118,277 shares issued through the conversion of promissory notes) (Note 7).

In February 2009, the Company issued 20,938,102 shares of Series A Preferred Stock in exchange for $4.2 million of convertible notes, including accrued interest, along with gross proceeds of $9.4 million. In addition, in accordance with existing loan agreements (Note 7), the Company issued 1,084,615 warrants to purchase 1,084,615 shares of Series A Preferred Stock (Note 8) at an exercise price of $0.65 per share.

In December 2009, in accordance with the terms of the Series A Preferred Stock purchase agreement and upon the achievement of defined clinical milestones, the Company issued an additional 14,638,821 shares of Series A Preferred Stock to the Series A Preferred Stock investors, for gross proceeds of $9.5 million at the closing price of the initial issuance of $0.65 per share.

In December 2010, the Company issued 34,581,278 shares of Series B Preferred Stock for $0.58 per share, resulting in gross proceeds of $20.1 million.

In September 2012, the Company issued 26,293,103 shares of Series C Preferred Stock for $0.58 per share, resulting in gross proceeds of $15.3 million. In accordance with the terms of the Series C Preferred Stock purchase agreement, the Company will issue an additional 26,293,103 shares of Series C Preferred Stock for $0.58 per share for total gross proceeds of $15.3 million in an additional closing, contingent upon the achievement of defined scientific and corporate milestones, or

at the election of the individual holders of the Series C Preferred Stock. These scientific and corporate milestones were achieved in June 2013 and the Company issued the additional shares of Series C Preferred Stock.

General

Conversion

Shares of Series C Preferred Stock, Series B Preferred Stock, Series A Preferred Stock and Seed Preferred Stock are convertible into Common stock initially on a one-for-one basis, adjustable for certain dilutive events, including the 1-for-11.9 reverse stock split of the Company s Common Stock effected on January 21, 2014. The conversion ratio for the Series B Preferred Stock is also adjustable for accrued or declared but unpaid dividends. Upon conversion and at the election of 60% of the Series B Preferred Stockholders, the accrued dividends may be paid in cash, in which case, the Series B Preferred Stock would be convertible on a one-for-one basis adjusted for certain dilutive events, including the reverse stock split of the Company s Common Stock effected on January 21, 2014. The holders of the Series B Preferred Stock have irrevocably elected not to receive cash dividends upon the conversion of such stock. Conversion of all Preferred Stock is automatic upon a qualified financing event that is considered satisfactory by the holders of 66% of the outstanding Series C Preferred Stock and Series B Preferred Stock or election by at least 66% of the outstanding shares of Preferred Stock or voluntary at the option of the Preferred Stockholder. The Preferred Stockholders have irrevocably consented to the automatic conversion of all outstanding shares of Preferred Stock upon the closing of an initial public offering. As of December 31, 2013, all series of Preferred Stock, except for the Series B Preferred Stock, have a 1-for-1 conversion ratio, which was adjusted to 1-to-0.08 in connection with the 1-for-11.9 reverse stock split of the Company s Common Stock effected on January 21, 2014. The Series B Preferred Stock has a 1-to-1.24 conversion ratio as of December 31, 2013, which was adjusted to 1-to-0.10 in connection with the 1-for-11.9 reverse stock split of the Company s Common Stock effected on January 21, 2014.

Dividends

Holders of the Series C Preferred Stock, Series B Preferred Stock and Series A Preferred Stock are entitled to receive, when and if declared by the Board of Directors, dividends at the annual rate of 8% of the issue price per share and the Seed Convertible Preferred Shares are entitled to receive, when and if declared by the Board of Directors, dividends at an annual rate of $0.052 per share, subject to adjustment for stock splits, combinations, recapitalizations, or the like, with respect to such shares. Series C Preferred Stock, Series A Preferred Stock and Seed Preferred Stock dividends are non-cumulative and non-compounding. The Series B Preferred Stock dividends are cumulative and non-compounding.

The order of preference in the distribution of dividends, when and if declared by the Board of Directors, is made first to the Series C Preferred Stock, then to the Series B Preferred Stock, next to the Series A Preferred Stock, and lastly to the Seed Preferred Stock.

Liquidation Preference

Holders of the Series C Preferred Stock and the Series B Preferred Stock have preference in the event of a liquidation or dissolution of the Company equal to $0.58 per share, plus any accrued and/or declared but unpaid dividends. Holders of the Series A Preferred Stock have preference in the event of a liquidation or dissolution of the Company, which preference is junior to the liquidation preference for the Series C Preferred Stock and the Series B Preferred Stock, equal to $0.65 per share, plus any accrued and/or declared but unpaid dividends. Holders of

the Seed Preferred Stock have preference in the event of a liquidation or dissolution of the Company, which preference is junior to the liquidation preference of the Series C Preferred Stock, the Series B Preferred Stock and the Series A Preferred Stock, equal to $0.65 per share, plus any declared but unpaid dividends.

After all preferred stockholders have received their respective initial preference amounts, any assets remaining for distribution shall be distributed to the holders of Series C Preferred Stock, Series B Preferred Stock, Series A Preferred Stock and Common Stock pro rata in proportion to the total number of shares of Series C Preferred Stock, Series B Preferred Stock, Series A Preferred Stock and Common Stock, assuming conversion to Common Stock. As of December 31, 2013, the aggregate liquidation value for the Series C Preferred Stock, the Series B Preferred Stock, the Series A Preferred Stock and the Seed Preferred Stock was $30.5 million, $24.9 million, $23.1 million, and $3.0 million, respectively.

Voting Rights

Except for matters with specific voting rights, the holders of shares of Preferred Stock vote together with the holders of the Common Stock as a single class on any matter presented to the stockholders of the Company for their action or consideration at any meeting of the stockholders of the Company or by written consent of stockholders in lieu of meetings. The holders of the Preferred Stock are entitled to the number of votes equal to the number of shares of Common Stock into which each share of the Preferred Stock is convertible at the time of such vote. A vote of 66% of the Preferred Stockholders, voting as a single class, is required for any change to the Company s by-laws or number of Directors. In addition, the Preferred Stockholders also have the right to elect five of the eight Directors.

Redemption Rights

Each class of Preferred Stock is stated at its then current redemption value as of each balance sheet date presented.

The Series C Preferred Stock and the Series B Preferred Stock may be redeemed upon written election of the holders of 66% of the Series C Preferred Stock and Series B Preferred Stock on or after September 28, 2017. The Series C Preferred Stockholders and the Series B Preferred Stockholders will receive, through a series of three installments, $0.58 per share (subject to certain adjustments), plus any accrued or declared but unpaid dividends.

The Series A Preferred Stock may be redeemed upon written election of 60% of the Series A holders at any date after the redemption in full of the Series C Preferred Stock and Series B Preferred Stock. The holders will receive, through a series of three installments, $0.65 per share (subject to certain adjustments), plus any accrued and/or declared but unpaid dividends.

In addition, if the Company fails to complete a contractually defined research program under a license agreement with a not-for-profit entity (Note 2 Revenue Recognition), the not-for-profit entity, which is also the holder of 4,310,345 shares of Series C Preferred Stock as of December 31, 2013, has the right to redeem the shares or require the Company to find a third party to purchase the shares at a price equal to, in either case, either the initial purchase price of $0.58 per share or, at the not-for-profit s election, the current fair value as determined by an independent appraisal. In either case, should the Company, over the 12 months following such redemption, subsequently sell substantially all of its stock or assets or complete an IPO at a value greater than 200% of the price paid upon redemption, then the Company must reimburse the not-for-profit entity for the difference. If the Company s stock becomes freely tradable, then this redemption provision is terminated.

11. Common stock

At December 31, 2013, the Company had authorized 191,689,655 shares of Common Stock, $0.001 par value per share, of which 327,377 shares were issued and 302,762 were outstanding.

General

The voting, dividend and liquidation rights of the holders of shares of Common Stock are subject to and qualified by the rights, powers and preferences of the holders of shares of preferred stock. The Common Stock has the following characteristics:

Voting

The holders of shares of Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders and written actions in lieu of meetings. The Common Stockholders have the right to elect one of the eight Directors.

Dividends

The holders of shares of Common Stock are entitled to receive dividends, if and when declared by the board of directors. Cash dividends may not be declared or paid to holders of shares of Common Stock until paid on each series of outstanding preferred stock in accordance with their respective terms. As of December 31, 2013, no dividends have been declared or paid since the Company s inception.

Liquidation

After payment to the holders of shares of preferred stock of their liquidation preferences, the holders of the Common Stock are entitled to share ratably in the Company s assets available for distribution to stockholders, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or upon the occurrence of a deemed liquidation event.

Founders stock

During 2006, the Company issued 176,470 shares of restricted Common Stock to certain founders (recipients), for $0.001 per share (par value), for total proceeds of $2 thousand. The restricted stock vested 25% upon issuance, and the remaining 75% vested ratably over four years, during which time the Company had the right to repurchase the unvested shares held by a recipient at the amount paid if the relationship between such recipient and the Company ceased. At December 31, 2013, all of the restricted founders shares are fully vested and are no longer subject to repurchase by the Company. Also during 2006, the Company issued an additional 84,033 shares of Common Stock to founders for $0.001 per share, for total proceeds of $1 thousand. These shares were not subject to repurchase provisions.

Restricted stock

During 2006 and 2007, the Company s founders and certain employees were issued shares and entered into Stock Restriction and Repurchase Agreements with the Company. During 2013, a director of the Company early exercised stock options and received 25,262 shares of common stock which were subject to a Stock Restriction and Repurchase Agreement with the Company. Under the terms of the agreements, shares of Common Stock issued are subject to a vesting schedule. Vesting occurs periodically at specified time intervals and specified percentages. All shares of Common Stock become fully vested within four years of the date of distribution. As of December 31, 2013, the Company has issued 31,135 shares of restricted common stock of which 5,520 shares have vested and 24,615 shares were subject to repurchase by the Company.

Reserve for future issuance

The Company has reserved for future issuances the following number of shares of Common Stock (in thousands):

	December 31,	
	2013	**2012**
Conversion of Seed Preferred Stock	388	388
Conversion of Series A Preferred Stock	2,990	2,990
Conversion of Series B Preferred Stock	3,613	3,381
Conversion of Series C Preferred Stock	4,419	2,210
Stock-based compensation awards	1,823	1,100
Warrants to purchase Series A Preferred Stock	91	91
Warrants to purchase Series B Preferred Stock	43	43
Warrants to purchase Series C Preferred Stock	58	
Total	13,425	10,203

12. Stock-based compensation

In December 2006, the Company adopted the Genocea Biosciences, Inc. 2007 Equity Incentive Plan (the Plan), under which it may grant incentive stock options (ISOs), non-qualified stock options, restricted stock, and stock grants to purchase up to 147,058 shares of common stock. In February 2009, the Company amended the Plan to issue up to 663,235 shares of Common Stock. In December 2010, the Company amended the Plan to issue up to 378,151 additional shares of Common Stock. In August 2011, September 2012, and June 2013 the number of shares available for issuance under the Plan increased by an additional 42,016, 21,008 and 755,013 shares, respectively. Under the Plan, ISOs may not be granted with an exercise price less than fair market value of the Company s Common Stock on the date of the grant, and all options generally vest over a four-year period. These options expire ten years after the grant date.

Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the Plan. Options granted by the Company typically vest over a four year period. Certain of the options are subject to acceleration of vesting in the event of certain terminations of employment in connection with certain change of control transactions. Additionally, certain options are also subject to vesting upon the completion of the IPO or other development milestones. The options are exercisable from the date of grant for a period of ten years. For options granted to date, the exercise price equaled the fair market value of the Common Stock as determined by the board of directors on the date of grant.

During the years ended 2013, 2012 and 2011, the Company granted a total of 44,345, 49,127 and 3,361 stock options, respectively, to consultants and members of its Scientific Advisory Board, which are included in the following table. The options generally vest over a four-year period, and have a life of ten years. Certain senior advisors of the Company received options that vest upon the occurrence of certain milestones. Stock options issued to non-employees are accounted for using the fair value method of accounting, and are periodically revalued as the options vest, and are recognized as expense over the related service period. The total expense related to all nonemployee options for the years ended December 31, 2013, 2012 and 2011 was $143 thousand, $18 thousand and $(1) thousand, respectively. The total expense related to all nonemployee options from August 16, 2006 (inception) to December 31, 2013 was $364 thousand.

Total stock-based compensation expense is recognized for stock options granted to employees and non-employees and has been reported in the Company s statements of operations as follows (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Research and development	$ 322	$ 102	$ 117
General and administrative	350	205	197
Total	$ 672	$ 307	$ 314

The following table summarizes stock option activity for employees and nonemployees (shares in thousands):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2012	1,054	$ 2.26	7.65	$
Granted	560	$ 3.41		
Exercised	(32)	$ 1.40		
Canceled or forfeited	(6)	$ 2.10		
Outstanding at December 31, 2013	1,576	$ 2.66	7.64	$ 6,682
Exercisable at December 31, 2013	880	$ 2.33	6.79	$ 4,022
Vested or expected to vest at December 31, 2013	1,409	$ 2.65	7.57	$ 5,998

During the years ended December 31, 2013, 2012 and 2011, the Company granted stock options to purchase an aggregate of 559,742, 54,883 and 617,516 of its Common Stock, respectively, with a weighted-average grant date fair values of $3.41, $1.31 and $1.67, respectively.

The total intrinsic value of options exercised in the years ended December 31, 2013, 2012, 2011 and for the period August 16, 2006 (inception) to December 31, 2013 was di minimis. The total fair value of employee stock options vested in the years ended December 31, 2013, 2012, 2011 and for the period from August 16, 2006 (inception) to December 31, 2013 was $517 thousand, $339 thousand, $265 thousand and $1.4 million, respectively. As of December 31, 2013, there was $991 thousand of total unrecognized compensation cost related to employee nonvested stock options granted under the Plan. Additionally, as of December 31, 2013, the Company had a total of 184,973 employee and nonemployee performance based options outstanding, of which 168,067 vest upon the occurrence of the IPO. The compensation cost associated with these options will be recognized in the first quarter of 2014 upon the occurrence of the IPO and those costs are excluded from the $991 thousand of total unrecognized compensation cost as of December 31, 2013.

The total fair value of shares vested and total unrecognized compensation costs related to non-employees in the years ended December 31, 2013, 2012, 2011 and for the period from August 16, 2006 (inception) to December 31, 2013 was immaterial.

Total unrecognized compensation cost for employee and non-employee will be adjusted for future forfeitures. The Company expects to recognize that cost over a remaining weighted-average period of 3.82.

The Company estimates the fair value of each employee stock award on the grant date using the Black-Scholes option-pricing model based on the following assumptions and the assumptions regarding the fair value of the underlying Common Stock on each measurement date:

	Years Ended December 31,		
	2013	2012	2011
Expected volatility	97.1%	99.2%	108.8%
Risk-free interest rate	0.59%-1.83%	0.99%	2.83%
Expected term (in years)	6.25	6.25	6.25
Expected dividend yield	0%	0%	0%

13. 401(k) Savings plan

In 2007, the Company established a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code (401(k) Plan). The 401(k) Plan covers all employees who meet defined minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pretax basis. The Company has not made any contributions to the 401(k) Plan to date.

14. Income taxes

For the years ended December 31, 2013, 2012, 2011 and the period from August 16, 2006 (inception) to December 31, 2013, the Company did not record a current or deferred income tax expense or benefit. The Company s losses before income taxes consist solely of domestic losses.

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company s deferred tax assets are comprised of the following (in thousands):

	Year ended December 31,	
	2013	2012
Deferred tax assets:		
U.S and state net operating loss carryforwards	$ 27,616	20,146
Research and development credits	2,749	1,788
Stock based compensation	369	229
Purchased intangibles	269	294
Capitalized organizational and start up expenditures	173	194
Accruals and other temporary differences	478	310
Total deferred tax assets	31,654	22,961
Less valuation allowance	(31,654)	(22,961)
Net deferred tax assets	$	$

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company s history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2013 and 2012. The valuation allowance increased approximately $8.7 million and $5.4 million during the year ended December 31, 2013 and 2012, respectively, due primarily to the generation of net operating losses.

A reconciliation of income tax expense computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	Year ended December 31,		
	2013	2012	2011
Federal income tax expense at statutory rate	34.0%	34.0%	34.0%
State income tax, net of federal benefit	5.1%	6.8%	4.8%
Permanent differences	(0.9)%	(0.2)%	(0.2)%
Research and development credit	3.6%	0.0%	3.1%
Other	0.0%	0.0%	0.0%
Change in valuation allowance	(41.8)%	(40.6)%	(41.7)%
Effective tax rate	0.0%	0.0%	0.0%

As of December 31, 2013, 2012, 2011, the Company had U.S. federal net operating loss carryforwards of approximately $71.4 million, $51.7 million and $38.9, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2033. As of December 31, 2013, 2012 and 2011, the Company also had U.S. state net operating loss carryforwards of approximately $64.5 million, $49.0 million and $36.4 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2033.

As of December 31, 2013, 2012 and 2011, the Company had federal research and development tax credit carryforwards of approximately $1.9 million, $1.2 million and $1.2 million, respectively, available to reduce future tax liabilities which expire at various dates through 2033. As of December 31, 2013, 2012 and 2011, the Company had state research and development tax credit carryforwards of approximately $1.3 million, $929 thousand and $598 thousand, respectively, available to reduce future tax liabilities which expire at various dates through 2028.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financings since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2013 and 2012, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company s statements of operations and comprehensive loss.

For all years through December 31, 2013, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company s research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position for these two years. A full valuation allowance has been provided against the Company s research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

The Company files income tax returns in the United States and various state jurisdictions. The federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2010 through December 31, 2013. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, state or foreign tax authorities to the extent utilized in a future period.

15. Net loss per share attributable to common stockholders

As described in Note 2, *Summary of Significant Accounting Policies,* the Company computes basic and diluted earnings (loss) per share using a methodology that gives effect to the impact of outstanding participating securities (the two-class method). As the years ended December 31, 2013, 2012 and 2011 and the period from August 16, 2006 (inception) to December 31, 2013 resulted in net losses, there is no income allocation required under the two-class method or dilution attributed to weighted average shares outstanding in the calculation of diluted loss per share.

The following common stock equivalents, presented on an as converted basis, were excluded from the calculation of net loss per share for the periods presented, due to their anti-dilutive effect (in thousands):

	December 31,			The period from August 16, 2006 (inception) to December 31,
	2013	2012	2011	2013
Preferred stock	11,409	8,493	6,283	11,409
Warrants	193	135	113	193
Outstanding options	1,576	1,054	1,031	1,576
Total	13,178	9,682	7,427	13,178

16. Quarterly financial information (unaudited, in thousands, except share and per share data)

	Three Months Ended			
	March 31, 2013	June 30, 2013	September 30, 2013	December 31, 2013
Revenue	$ 259	$ 228	$ 224	$ 20
Operating expenses	4,790	4,977	4,699	6,190
Net loss	(4,664)	(4,957)	(4,839)	(6,346)
Net loss attributable to common stockholders	(5,059)	(5,357)	(5,244)	(6,751)
Net loss per share attributable to common stockholders-basic and diluted	$ (17.09)	$ (18.10)	$ (17.72)	$ (22.50)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	296	296	296	300

	Three Months Ended			
	March 31, 2012	June 30, 2012	September 30, 2012	December 31, 2012
Revenue	$ 608	$ 433	$ 400	$ 536
Operating expenses	3,297	2,547	4,008	5,078
Net loss	(2,729)	(2,249)	(3,726)	(4,663)
Net loss attributable to common stockholders	(3,130)	(2,648)	(4,131)	(5,239)
Net loss per share attributable to common stockholders-basic and diluted	$ (10.61)	$ (8.98)	$ (14.00)	$ (17.70)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	295	295	295	296

17. Subsequent events

The Company has completed an evaluation of all subsequent events after the audited balance sheet date of December 31, 2013 through March 21, 2014, the date the financial statements were issued, to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of December 31, 2013 and events which occurred subsequently but were not recognized in the financial statements.

On January 21, 2014, the Board of Directors and stockholders approved a 1-for-11.9 reverse stock split of the Company s Common Stock, which was effected on January 21, 2014. Stockholders entitled to fractional shares as a result of the reverse stock split will receive a cash payment in lieu of receiving fractional shares. The Company s historical share and per share information has been retroactively adjusted to give effect to this reverse stock split. Shares of Common Stock underlying outstanding stock options were proportionately reduced and the respective exercise prices were proportionately increased. Shares of Common Stock reserved for future issuance were presented on an as converted basis and the financial statements disclose the adjusted conversion ratios.

On February 10, 2014, the Company closed the IPO of its common stock pursuant to a registration statement on Form S-1, as amended. An aggregate of 5,500,000 shares of common stock registered under the registration statement were sold at a price of $12.00 per share. Net proceeds of the IPO were $61.4 million, excluding offering expenses payable by us. In conjunction with this transaction, all shares of the Company s redeemable convertible preferred stock were converted into 11,435,580 shares of common stock, and 168,067 employee and nonemployee performance based options vested.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 21, 2014.

GENOCEA BIOSCIENCES, INC.

By: /s/ William Clark

William Clark
President and Chief Executive Officer

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

Signature	Title	Date
	President and Chief Executive Officer and Director	March 21, 2014
/s/ William Clark William Clark	(Principal Executive Officer)	
/s/ Robert E. Farrell Robert E. Farrell, Jr., CPA	Vice President of Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	March 21, 2014
/s/ Kevin Bitterman Kevin Bitterrnan, Ph.D.	Director	March 21, 2014
/s/ Katrine Bosley Kartine Bosley	Director	March 21, 2014
Simeon J. George Simeon J. George, M.D.	Director	March 21, 2014
/s/ Stephen J. Hoffman Stephen J. Hoffman	Director	March 21, 2014
/s/ George Siber George Siber, M.D.	Director	March 21, 2014

Exhibit Number	Exhibit
3.1	Fifth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K, File No. 001-36289, filed on February 12, 2014)
3.2	Amended and Restated By-laws (incorporated by reference to Exhibit 3.2 to the Company s Current Report on Form 8-K, File No. 001-36289, filed on February 12, 2014)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
4.2	Form of Warrant to Purchase Preferred Stock, dated January 7, 2008 (incorporated by reference to Exhibit 4.2 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
4.3	Preferred Stock Purchase Warrant, dated October 25, 2011, issued to Lighthouse Capital Partners VI, L.P. (incorporated by reference to Exhibit 4.3 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
4.4	Preferred Stock Purchase Warrant, dated September 30, 2013, issued to Ares Capital Corporation (incorporated by reference to Exhibit 4.4 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
4.5	Fourth Amended and Restated Registration Rights Agreement (incorporated by reference to Exhibit 4.5 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.1	Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.2+	Amended and Restated Exclusive License Agreement between Children s Medical Center Corporation and Genocea Biosciences, Inc., dated March 23, 2012 (incorporated by reference to Exhibit 10.2 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.3+	Amended and Restated License Agreement between Genocea Biosciences, Inc. and President and Fellows of Harvard College, dated November 19, 2012 (incorporated by reference to Exhibit 10.3 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.4+	License and Collaboration Agreement between Genocea Biosciences, Inc. and Isconova AB, dated August 5, 2009, as amended on March 19, 2010, June 18, 2010, August 17, 2010, October 19, 2011 and February 6, 2012 (incorporated by reference to Exhibit 10.4 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.5+	Exclusive License Agreement for Escherichia Coli K12 to Deliver Protein to the Macrophage Cytosol between Genocea Biosciences, Inc. and The Regents of the University of California, dated August 18, 2006 (incorporated by reference to Exhibit 10.5 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.6+	Patent License Agreement between Genocea Biosciences, Inc. and University of Washington dated January 27, 2010, as amended on July 19, 2012 (incorporated by reference to Exhibit 10.6 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)

Exhibit Number	Exhibit
10.7	Loan and Security Agreement, dated September 30, 2013, by and between Ares Capital Corporation and Genocea Biosciences, Inc. (incorporated by reference to Exhibit 10.7 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.8	Lease, dated as of July 3, 2012, between TBCI, LLC and Genocea Biosciences, Inc. (incorporated by reference to Exhibit 10.8 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.9	Agreement Regarding Sublease, dated as of July 9, 2012, by TBCI, LLC, FoldRx Pharmaceuticals, Inc., Pfizer Inc. and Genocea Biosciences, Inc. (incorporated by reference to Exhibit 10.9 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.10	Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan, as amended on June 24, 2013 (incorporated by reference to Exhibit 10.10 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.11	Consulting Agreement between Genocea Biosciences, Inc. and George Siber, dated May 16, 2007, as amended on June 30, 2009, December 16, 2010, June 15, 2011 and June 5, 2013 (incorporated by reference to Exhibit 10.11 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.12	Amended and Restated Employment Letter Agreement between William Clark and Genocea Biosciences, Inc., dated January 16, 2014 (incorporated by reference to Exhibit 10.12 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 23, 2014)
10.13	Amended and Restated Employment Letter Agreement between Seth Hetherington, M.D. and Genocea Biosciences, Inc., dated January 16, 2014 (incorporated by reference to Exhibit 10.13 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 23, 2014)
10.14	Amended and Restated Employment Letter Agreement between Jessica Flechtner, Ph.D. and Genocea Biosciences, Inc., dated January 16, 2014 (incorporated by reference to Exhibit 10.14 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 23, 2014)
10.15	Genocea Biosciences, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.15 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.16	Genocea Biosciences, Inc. Cash Incentive Plan (incorporated by reference to Exhibit 10.16 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.17	Genocea Biosciences, Inc. Cash Bonus Program for Fiscal Years 2012, 2013 and 2014 (incorporated by reference to Exhibit 10.17 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.18+	Amendment No. 2 to Patent License Agreement between Genocea Biosciences, Inc. and University of Washington dated September 12, 2012 (incorporated by reference to Exhibit 10.18 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.19+	Amendment No. 3 to Patent License Agreement between Genocea Biosciences, Inc. and University of Washington dated November 7, 2013 (incorporated by reference to Exhibit 10.19 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.20	Form of Nonstatutory Stock Option Granted under the Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.20 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.21	Form of Incentive Stock Option Granted under the Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.21 to the Company s Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)

10.22	Form of Incentive Stock Option under the Genocea Biosciences, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.22 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)

Exhibit Number	Exhibit
10.23	Form of Nonstatutory Stock Option under the Genocea Biosciences, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.23 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.24	Letter Agreement, dated January 9, 2014 terminating the Letter Agreement between Genocea Biosciences, Inc. and Katrine Bosley, dated February 4, 2013 (incorporated by reference to Exhibit 10.24 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.25	Restricted Stock Agreement between Genocea Biosciences, Inc. and Katrine Bosley, dated November 7, 2013 (incorporated by reference to Exhibit 10.25 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.26	Genocea Biosciences, Inc. 2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.26 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 23, 2014)
10.27	Nonstatutory Stock Option granted under the Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan to Katrine Bosley, dated May 13, 2013 (incorporated by reference to Exhibit 10.28 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.28	Nonstatutory Stock Option granted under the Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan to Katrine Bosley, dated November 5, 2013 (incorporated by reference to Exhibit 10.29 to the Company s Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
23.1*	Consent of Ernst & Young LLP
31.1*	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Chief Executive Officer
31.2*	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Vice President of Finance & Administration
32.1**	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Executive Officer
32.2**	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Vice President of Finance & Administration

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* Filed herewith.

** Furnished herewith.

Indicates a management contract or compensatory plan.

+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been submitted separately to the Securities and Exchange Commission.