GENOCEA BIOSCIENCES, INC.

FORM 10-K
(Annual Report)

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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2015
or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-36289

Genocea Biosciences, Inc.

(Exact name of registrant as specified in its charter)

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

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

Indicate by check mark 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. ☐

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). ☒ Yes ☐ 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 ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐
(Do not check if a smaller reporting company)	

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

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.

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price for such stock as reported on the NASDAQ Global Market on June 30, 2015 , the last business day of the registrant's most recently completed second quarter, was: $224,213,867 .

The number of shares outstanding of the registrant's common stock as of February 12, 2016 was 28,152,589 .

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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", "predict", "project", "should", "target", "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;
- our planned clinical trials for GEN-003;
- our estimates regarding the amount of funds we require to complete our clinical trials for GEN-003 and to continue our investments in our immuno-oncology and infectious disease pipeline;
- 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 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 biopharmaceutical company that discovers and develops novel vaccines and immunotherapies to address diseases with significant unmet needs. We use our proprietary discovery platform, ATLAS ™, to rapidly design vaccines and immunotherapies that act, in part, through T cell (or cellular) immune responses, in contrast to approved vaccines and immunotherapies, 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 and immunotherapies to address diseases where T cells are central to the control of the disease.

We have one product candidate in active Phase 2 clinical development, GEN-003, an immunotherapy for the treatment of genital herpes. We have another product candidate, GEN-004, a universal vaccine for the prevention of pneumococcal infections, for which we have suspended development pending further data analysis and consultation with our advisers after we did not achieve statistically significant results in our Phase 2a human challenge study. We also have active research and pre-clinical development programs for diseases including genital herpes, chlamydia and malaria. We are also actively adapting ATLAS to the discovery and development of cancer vaccines.

ATLAS Platform

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 target 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 target discovery challenges. We believe ATLAS represents the most comprehensive high-throughput system for T cell vaccine and immunotherapy discovery in the biopharmaceutical industry. ATLAS is designed to mimic the T cell arm 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 or cancer in blood samples from large, genetically diverse populations, allowing us to identify vaccine and immunotherapy targets associated with protective T cell responses to disease. By comparing antigens identified in individuals who naturally control their disease 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 we are a leader in the field of T cell vaccine and immunotherapy discovery and development. Our management and scientific teams possess considerable experience in vaccine, immunotherapy and anti-infective research, manufacturing, clinical development and regulatory matters.

GEN-003 — Phase 2 immunotherapy for genital herpes

Our lead program is GEN-003, a Phase 2 candidate therapeutic vaccine, or immunotherapy, that we are developing to treat genital herpes infections. Data from our double-blind, placebo-controlled, dose-escalating Phase 1/2a trial for GEN-003 represented the first reported instance of a therapeutic vaccine working against an infectious disease, and we have identified a dose in our Phase 2 trial which has showed an even greater reduction in viral shedding than the best dose in the Phase 1/2a trial.

Final analysis of the data from the Phase 1/2a trial showed that, for the best performing 30µg dose group, there was a sustained reduction in the viral shedding rate. After completion of dosing for this group, the viral shedding rate fell by 52% versus baseline and, at six months after the final dose, the shedding rate remained at 40% below baseline. The reduction in the genital lesion rate after completion of the third dose was greatest for the 30µg dose group at 48%. After six months, the reduction from baseline in genital lesion rate for this dose group was 65% and, after 12 months, the genital lesion rate was 42% lower than baseline. GEN-003 was safe and well tolerated over the 12 months of this trial.

Having identified a dose that, according to company-sponsored market research, delivers clinically meaningful efficacy in magnitude and durability, we are now conducting a 310-subject Phase 2 dose optimization trial. The objective of this trial is to confirm the results of the best performing dose in the Phase 1/2a trial and to test six other combinations of proteins and adjuvant to determine the optimal dose for future trials and potentially improve on the current profile of GEN-003.

In May 2015, we announced positive top-line data from the Phase 2 trial. Subjects were randomized to one of six dosing groups of either 30µg or 60µg per protein paired with one of three Matrix-M2 ™ adjuvant doses (25µg, 50µg, or 75µg). A seventh group received placebo. Subjects received three doses of GEN-003 or placebo at 21-day intervals. Baseline viral shedding and genital lesion rates were established for each subject in a 28-day observation period prior to the commencement of dosing by collecting 56 genital swab samples (two per day), which were analyzed for the presence of HSV-2 DNA, and by recording the days on which genital lesions were present. During the 28-day observation period immediately after completion of dosing, the best dose of 60µg per protein/75µg of adjuvant demonstrated a highly statistically significant ($p<0.0001$) 55% reduction from baseline in the viral shedding rate, the primary endpoint of the trial and a measure of anti-viral activity. All dose combinations tested, including the successful 30µg per protein/50µg of adjuvant dose from the prior Phase 1/2a trial, demonstrated a statistically significant viral shedding rate reduction versus baseline and only the lowest dose combination did not demonstrate a statistically significant reduction versus placebo. In a planned secondary analysis to assess impact on patient reported genital lesion rates, all dose groups, including the placebo group, demonstrated a statistically significant reduction from baseline. Furthermore, there was no difference in discontinuations in patient dosing due to adverse events ("AEs") across the different treatment arms.

In October 2015, we announced positive results from a planned interim analysis of data collected six months after dosing. At its best performing dose of 60µg per protein / 75µg of Matrix-M2 adjuvant, GEN-003 demonstrated a statistically significant 58% reduction from baseline in the viral shedding rate ($p < 0.0001$). In a planned secondary analysis, the proportion of patients receiving GEN-003 who were lesion-free at six months after dosing ranged from approximately 30% to 50%, similar to results reported in clinical trials with oral antiviral therapies. In addition, the time to first recurrence after completion of dosing showed a range of 152 days to greater than 180 days among dose groups. In a further secondary analysis measuring the impact on genital lesion rates, GEN-003 demonstrated sustained and statistically significant reductions from baseline in five of six dose groups ranging from 43% to 69%. The Phase 2 trial continues to show that GEN-003 is safe and well tolerated by patients, with no serious AEs related to the vaccine. Data from the 12-month observation period in this trial is expected later in the first quarter of 2016.

Following improvements that we have made to the manufacturing process for GEN-003 to enable production at commercial scale, we initiated patient screening in the fourth quarter of 2015 and commenced the dosing phase in January 2016 for a 135-subject Phase 2b study to confirm the efficacy of this new material. Subjects will be randomized to one of two dose levels of GEN-003 or a placebo. We expect to announce top-line viral shedding rate data from the 28-day observation period immediately after dosing from this study in the middle of 2016. The study will also compare GEN-003 efficacy to placebo for the clinical endpoints of: the proportion of patients who are lesion free at six and 12 months after dosing; the time to first lesion recurrence after dosing; and, the impact on percentage of days with genital herpes lesions at six and 12 months after dosing. Data from these six and 12 month clinical endpoints is expected in the second half of 2016 and the first quarter of 2017, respectively. All subjects will be followed for 12 months after the last dose.

In the second half of 2016, we intend to commence a Phase 2b study to investigate the potential benefits of using GEN-003 in combination with oral antiviral medicines. We also intend to conduct an end-of-Phase 2 meeting with the FDA in late 2016. We retain all rights to GEN-003 and plan to advance this program through regulatory approval and, if approved, 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.

If GEN-003 successfully completes clinical development and is approved, we believe it would represent an important new treatment option for patients with genital herpes.

GEN-004 — Universal vaccine for the prevention of pneumococcal infections

We also have a second T cell-stimulating vaccine candidate, GEN-004, a potential universal *Streptococcus pneumoniae* , or pneumococcus, vaccine to protect against the leading cause of infectious disease mortality worldwide, for which we have currently suspended development activities. GEN-004 is designed to stimulate T helper 17 ("Th17") cells, a rare cell type that provides immunity at epithelial and mucosal surfaces, in the nasopharynx to prevent colonization by pneumococcus.

In June 2014, we announced top-line data from a Phase 1 clinical trial for GEN-004. This trial met its safety, tolerability and immunogenicity goals including measurable increases in the blood of Th17 cells. We initiated a 98-subject Phase 2a trial in September 2014 to demonstrate that GEN-004 can reduce the frequency, magnitude and duration of colonization of pneumococcus in the nasopharynx in healthy adults.

In October 2015, we announced that top-line results from the Phase 2a clinical trial for GEN-004 showed consistent reductions versus placebo in the pre-specified endpoints of the rate and density of colonization, but that neither of the endpoints achieved statistical significance. GEN-004 was safe and well tolerated by subjects. GEN-004 reduced the colonization rate, measured by microbiological culture, by between 22% and 25% versus placebo across those measurement time points. When measured by the presence of pneumococcal DNA, the reductions ranged between 18% and 36%. Additionally the median density of colonization measured by microbiological culture for GEN-004 treated subjects ranged from zero to two colony forming units ("CFUs") per mL of nasal wash compared to one to 11 CFUs per mL for the placebo group. When measured by the presence of pneumococcal DNA, the median densities ranged from zero to 10 copies per mL in treated subjects and 19 to 52 copies per mL in placebo subjects. None of the differences were statistically significant. There was no difference in the duration of colonization between GEN-004 and placebo.

Although we did not achieve statistical significance in this study, the consistent apparent effect supports the vaccine concept and in the potential for GEN-004. We believe it is possible that future trials would require a change in some combination of dose, adjuvant or trial population to confirm any effect. Pending ongoing data analysis and consultation with our advisors to determine next steps for this program, we have suspended the development of GEN-004 from our near-term plans and will focus our resources on the ongoing GEN-003 program, and on maximizing the potential of our preclinical pipeline and our ATLAS technology for T cell target discovery.

Research and non-clinical development in oncology

We initiated a research collaboration with the Dana-Farber Cancer Institute ("DFCI") in 2014 to apply the ATLAS platform in immuno-oncology. This collaboration centered on ATLAS's potential to identify patterns of T cell response in cancer patients receiving checkpoint inhibitor ("CPI") therapy. By analyzing the immune responses of both responders and non-responders to CPI therapy, ATLAS successfully identified the cancer antigens to which either (or both) CD4+ or CD8+ T cells became activated. Although this research was not powered to draw firm conclusions, the analysis of T cell responses in patients receiving CPI therapy revealed a pattern indicating a greater breadth of T cell activation for responders than non-responders. The study also revealed preliminary evidence that different characteristics of T cell responses emerge when comparing patients who respond and those who do not. Some T cell responses did not correspond with improved patient outcomes, and may be classified as “decoys,” further validating the potential ability of ATLAS to distinguish clinically relevant targets of T cell response. The collaboration with Dana-Farber is ongoing as we continue to analyze more tumor samples to characterize T cell response profiles that may be prognostic of CPI efficacy, and to identify T cell antigens that may be included in novel immunotherapies.

In November 2015, we also announced a collaboration with the Memorial Sloan Kettering Cancer Center to screen the T cell responses of melanoma and non-small cell lung cancer patients treated with CPIs against the complete repertoire of patient-specific putative cancer neoantigens. The goals of the collaboration are to identify signatures of T cell response in cancer patients associated with response or non-response to CPI therapy and to discover new T cell cancer vaccine antigens. ATLAS will be used in conjunction with Memorial Sloan Kettering’s patient-specific cancer neoantigen sequences and blood samples from the same cancer patients.

In November 2015, we commenced a new program focused on Epstein-Barr Virus (“EBV”). EBV infection has been linked to cancers with high unmet needs such as non-Hodgkin’s lymphoma, nasopharyngeal carcinoma and gastric carcinoma. We believe the ATLAS platform is highly suited to the creation of a new immunotherapy for EBV given that T cell responses are understood to be crucial for protection against EBV. Furthermore, EBV is part of the herpesvirus family, in which we have years of experience through our development of GEN-003.

Research and non-clinical development in infectious disease

We have ongoing non-clinical development programs in chlamydia and a next generation genital herpes product and a research program funded by the Bill & Melinda Gates Foundation ("Gates Foundation") in malaria.

Our Product Candidate Pipeline

The following table describes our current development programs:

Vaccine Candidate	Program	Stage of Development	Next Milestone	Anticipated Timeline
GEN-003	Genital herpes Therapeutic	Phase 2	12-month data from Phase 2 dose optimization trial	Later in first quarter of 2016
GEN-004	Pneumococcus Prophylaxis	Suspended development pending further data analysis and consultation advisors		
GEN-002	Genital Herpes Prophylaxis	Pre-clinical	File investigational new drug ("IND")	2017
GEN-001	Chlamydia Prophylaxis	Pre-clinical	File IND	2018
GEN-005	Malaria Prophylaxis	Research	Complete current Gates Foundation collaboration	First half of 2016
	Epstein-Barr Virus	Research	Initiate screening studies	2016
	Immuno-oncology	Research	Present data from ongoing academic collaborations	2016

GEN-003 Market Opportunity

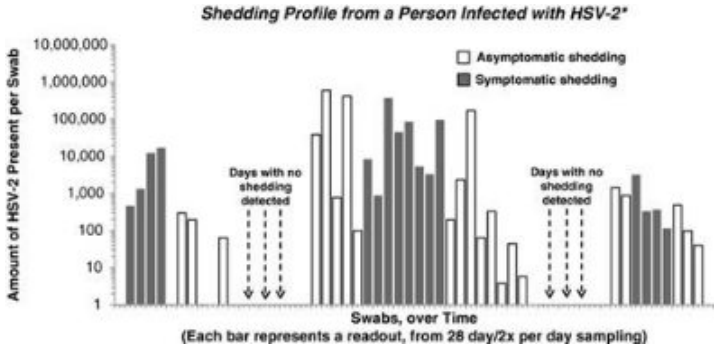
Genital Herpes

We are developing our lead product candidate, GEN-003, to treat patients with genital herpes 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 the herpes virus 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. ("Novavax"). See “—Other Collaborations—Novavax”.

Genital herpes is a sexually transmitted disease. Genital herpes infections have become an epidemic, spreading to approximately 16% of the United States population between the ages of 14 and 49, and more than 400 million people worldwide, according to the World Health Organization.

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 genital herpes 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 genital herpes experience significant distress because of the potential negative impact on their ability to form and maintain sexual relationships. Infection with genital herpes can involve substantial risks in addition to the infection itself. For example, persons with genital herpes infection have a threefold increased risk for human immunodeficiency virus, or HIV, acquisition. Additionally, pregnant women can transmit genital herpes 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 the herpes 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 Genital Herpes Treatment Options

There is no known cure for genital herpes. For patients infected with genital herpes, 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%.

A market research survey conducted on our behalf, which included primary research with more than 300 physicians in the United States, United Kingdom, Germany, France and Brazil, and a review of secondary sources, indicated that approximately 11 million people in the U.S. are diagnosed with genital herpes. Of those diagnosed, approximately 7 million are treated with oral anti-viral medicines. This research also indicated that approximately 2.5 million patients treat their disease chronically with daily anti-viral pills, and approximately 4.5 million patients treat episodically to reduce the severity of outbreaks when they occur. Of those patients treated chronically, approximately 30% continue to suffer three or more outbreaks of genital herpes per year and of those treated episodically, approximately 50% continue to suffer three or more outbreaks per year. This market research also indicated that the prevalence of genital herpes outside the United States is similar to the United States.

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

GEN-003: An Immunotherapy Candidate for Genital Herpes

In both our Phase 1/2a and Phase 2 studies we have shown that GEN-003 is the first immunotherapy known to have demonstrated a statistically significant reduction in viral shedding rate and the signs of clinical genital herpes disease as measured by genital lesion rates (see "Clinical Development" below). We believe that these clinical results continue to demonstrate that GEN-003 has the potential to be a first-in-class immunotherapy to treat genital herpes.

We believe that, if approved for the treatment of genital herpes 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 second 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, and more than 300 physicians who treat patients with HSV-2 infections, 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.

Taking together the results of the two market research surveys conducted on our behalf, we forecast a potential market share for GEN-003 in the US of approximately 3 million of the 11 million diagnosed patients. We believe that this translates into a revenue opportunity in the US of over $1 billion. These were limited surveys and may or may not be representative of how patients might ultimately use GEN-003, if at all, or how GEN-003 may be reimbursed if GEN-003 successfully completes clinical development and is approved by regulatory authorities.

Clinical Development

Our Phase 1/2a Clinical Trial

We completed 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 also measured, as an exploratory endpoint, the effect of

GEN-003 on the genital lesion rate. The trial was conducted at seven sites in the United States, including some of the leading institutions for scientific and clinical research of genital herpes. The trial was double-blind, placebo-controlled and dose-escalating. We enrolled subjects between 18 and 50 years of age. An independent Data Safety Monitoring Board monitored the safety of subjects enrolled in the clinical trial.

This trial enrolled 143 otherwise healthy subjects with a history of three to nine genital herpes 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 achieve the desired biological responses. There were three vaccine dose groups, based on the amount of protein. The lowest dose group subjects received 10µg of each protein; in the middle dose group, the protein doses increased to 30µg, and in the high dose group the protein dose was 100µg. For all subjects receiving GEN-003 (proteins plus adjuvant), the Matrix-M2 dose was 50µg. Subjects received three vaccinations, on days zero, 21 and 42.

The primary objective of this trial was to monitor the safety profile of the proposed vaccine. Overall, GEN-003 was well-tolerated. During the seven days following each injection, side-effects were generally those considered typically associated with vaccines, such as fatigue, site injection pain, tenderness and swelling. Among all vaccine dose groups, the frequency of AEs appeared greater among those subjects given the 10µg dose. In the 30µg and 100µg dose cohorts, the AE rate was lower than that of the 10µg cohort. In addition, the frequency of AEs appeared to diminish with subsequent doses. Beyond the week following vaccination with the GEN-003 immunotherapy, the AE types and frequencies appeared similar to those following vaccination with placebo. The AEs have been transient, resolved over a few days and 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.

Additionally, we measured the immunotherapy-induced T cell and B cell immune responses. We structured and statistically powered the trial to measure the proposed immunotherapy's impact on the viral shedding rate, an important marker of virus activity. We selected this endpoint because of the connection between shedding, symptomatic outbreaks, and risk of transmission of virus by sexual contact. 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.

We measured immunotherapy activity in two ways: the impact on viral shedding and the impact on signs of clinical genital herpes disease as measured by genital lesion rates, defined as the total days in which a patient reported the presence of a visible genital lesion during swabbing days, divided by the total number of swabbing days. The impact on viral shedding was determined by viral DNA present in swabs from subjects over the 28-day measurement period before receiving the assigned treatment and immediately after completing the three-dose regimen and again at six months and 12 months after the final dose. The genital lesion rate was measured at the same time points.

Final analysis of the data showed that for the best performing 30µg dose group, there was a sustained and statistically significant reduction in the viral shedding and genital lesion rates. After completion of dosing for this dose group, the viral shedding rate fell by 52% versus baseline ($p<0.001$) and, at six months after the final dose, the shedding rate remained at 40% below baseline ($p<0.001$). At 12 months, the viral shedding rate returned to baseline for this dose group. The reduction in the genital lesion rate after completion of the third dose was greatest for the 30µg dose group, at 48% ($p<0.001$). After six months, the reduction from baseline in genital lesion rate for this dose group was 65% ($p<0.001$) and after 12 months the genital lesion rate was 42% lower than baseline.

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* .

Ongoing Phase 2 Dose Optimization Trial

The objective of our Phase 2 dose optimization trial is to confirm the results of the best performing dose in the Phase 1/2a trial, and to test other combinations of protein and adjuvant to determine the optimal dose for future trials and potentially improve on the current profile of GEN-003. The Phase 2 study enrolled 310 subjects from 17 institutions in the United States. Subjects were randomized to one of six dosing groups of either 30 µg or 60 µg per protein paired with one of three Matrix-M2 adjuvant doses (25 µg, 50 µg, or 75 µg). A seventh group received placebo. Subjects received three doses of GEN-003 or

placebo at 21-day intervals. Baseline viral shedding and genital lesion rates were established for each subject in a 28-day observation period prior to the commencement of dosing by collecting 56 genital swab samples (two per day), which were analyzed for the presence of HSV-2 DNA, and by recording the days on which genital lesions were present. This 28-day observation period was repeated immediately after the completion of dosing, was repeated at six months following dosing and will be repeated at twelve months following dosing. No booster doses were given.

In May 2015, we announced that, at the 28-day observation period immediately after completion of dosing, the best dose of 60 µg per protein / 75 µg of adjuvant demonstrated a highly statistically significant ($p < 0.0001$) 55% reduction from baseline in the viral shedding rate, the primary endpoint of the trial and a measure of anti-viral activity. All dose combinations tested, including the successful 30 µg per protein / 50 µg of adjuvant dose from the prior Phase 1/2a trial, demonstrated a statistically significant viral shedding rate reduction versus baseline and only the lowest dose combination did not demonstrate a statistically significant reduction versus placebo. In a planned secondary analysis to assess impact on patient reported genital lesion rates, all dose groups, including the placebo group, demonstrated a statistically significant reduction from baseline. Furthermore, there was no difference in discontinuations in patient dosing due to AEs across the different treatment arms.

In October 2015, we announced positive results from the interim analysis of data collected six months after dosing. At its best performing dose of 60 µg per protein / 75 µg of adjuvant, GEN-003 demonstrated a statistically significant 58% reduction from baseline in the viral shedding rate ($p < 0.0001$), the primary endpoint of the study. In a planned secondary analysis, the proportion of patients receiving GEN-003 who were lesion-free at six months after dosing ranged from approximately 30% to 50%, similar to results reported in clinical trials with oral antiviral therapies. In addition, the time to first recurrence after completion of dosing showed a range of 152 days to greater than 180 days among dose groups. In a further secondary analysis measuring the impact on genital lesion rates, GEN-003 demonstrated sustained and statistically significant reductions from baseline in five of six dose groups ranging from 43% to 69%. The Phase 2 trial continued to show that GEN-003 was safe and well tolerated by patients, with no serious AEs related to the vaccine.

Next Steps: Phase 2b and Antiviral Combination GEN-003 Studies; End-of-Phase 2 Meeting

Following improvements that we have made to the manufacturing process for GEN-003 to enable production at commercial scale, we initiated patient screening in the fourth quarter of 2015 and commenced the dosing phase in January 2016 for a 135-subject Phase 2b study to confirm the efficacy of this new material. Subjects will be randomized to one of two dose levels of GEN-003 or a placebo. We expect to announce top-line viral shedding rate data from the 28-day observation period immediately after dosing from this study in the middle of 2016. The study will also compare GEN-003 efficacy to placebo for the clinical endpoints of: the proportion of patients who are lesion free at six and 12 months after dosing; the time to first lesion recurrence after dosing; and, the impact on percentage of days with genital herpes lesions at six and 12 months after dosing. Data from these six and 12 month clinical endpoints is expected in the second half of 2016 and the first quarter of 2017, respectively. All subjects will be followed for 12 months after the last dose.

In the second half of 2016, we intend to commence a Phase 2b study to investigate the potential benefits of using GEN-003 in combination with oral antiviral medicines. We also expect to conduct an end-of-Phase 2 meeting with the FDA in late 2016.

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 Center for Disease Control and Prevention ("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 may 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.

Our Pneumococcal Program (GEN-004)

Pneumococcal Disease

Our GEN-004 program, for which we have suspended development activities, is designed to prevent infections caused by all serotypes of 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 contained in several approved vaccines.

There are more than 90 serotypes, or strains, of pneumococcus known to exist. 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. Invasive pneumococcal disease ("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.

Limitations of Current Pneumococcal Vaccines

Global revenue of current pneumococcal vaccines exceeded $5.8 billion in 2014, more than 75% of which 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, along with Prevnar-7, the predecessor vaccine to Prevnar-13, have been 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.

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 is rapidly increasing. To our knowledge, all of these companies' product candidates are being developed to elicit a B cell response.

Clinical Development of GEN-004

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 antigen-presenting cells and T cells and screened the entire pneumococcus proteome, which consists of more than 2,200 proteins, to identify proteins associated with a strong T_H17 T cell response, as measured by their induction of the cytokine IL-17A, the predominant cytokine secreted by T_H17 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 IPD caused by any pneumococcal serotype, including those covered by the Prevnar franchise.

We demonstrated proof-of-concept of GEN-004 in a mouse model of nasal colonization. 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.

In June 2014, we announced positive top-line data from a Phase 1 clinical trial in the United States to evaluate the safety of, and immune response to, GEN-004. The Phase 1 clinical trial met its safety, tolerability and immunogenicity goals, including measurable increases in the blood of T_H17 cells. The Phase 1 clinical trial was a randomized, double-blind, dose-escalation, placebo-controlled clinical trial that enrolled 90 healthy adult volunteers. Serum IgG titers increased in a dose-dependent manner to each of the antigens included in GEN-004 and measurable increases in peripheral T_H17 responses were seen among subjects receiving the highest dose (100µg) with adjuvant. There were no serious AEs related to the vaccine.

Based on these data, a Phase 2a trial was initiated in the third quarter of 2014. Subjects in the clinical trial received either 100µg dose of GEN-004 with 350µg of adjuvant or placebo, and then was "challenged" intranasally with live

pneumococcus in the nasal cavity. We enrolled approximately 90 healthy adults in this trial and it was designed to monitor AEs, antibody and T-cell immune responses as determined by IgG and IL-17A, and incidence of post-challenge nasopharyngeal colonization.

In October 2015, we announced that top-line results from the Phase 2a clinical trial for GEN-004 showed consistent reductions versus placebo in the pre-specified endpoints of the rate and density of colonization, but that neither of the endpoints achieved statistical significance. GEN-004 was safe and well tolerated by subjects. GEN-004 reduced the colonization rate, measured by microbiological culture, by between 22% and 25% versus placebo across those measurement time points. When measured by the presence of pneumococcal DNA, the reductions ranged between 18% and 36%. Additionally the median density of colonization measured by microbiological culture for GEN-004 treated subjects ranged from zero to two CFUs per mL of nasal wash compared to one to 11 CFUs per mL for the placebo group. When measured by the presence of pneumococcal DNA, the median densities ranged from zero to 10 copies per mL in treated subjects and 19 to 52 copies per mL in placebo subjects. None of the differences were statistically significant. There was no difference in the duration of colonization between GEN-004 and placebo.

Although we did not achieve statistical significance in this study, the consistent apparent effect supports the vaccine concept and in the potential for GEN-004. We believe it is possible that future trials would require a change in some combination of dose, adjuvant or trial population to confirm any effect. Pending ongoing data analysis and consultation with our advisors to determine next steps for this program, we have suspended the development of GEN-004 from our near-term plans and will focus our resources on the ongoing GEN-003 program, and on maximizing the potential of our preclinical pipeline and our ATLAS technology for T cell target discovery.

Our Immuno-oncology Program

Cancer is among the leading causes of death worldwide, with the incidence estimated to grow to 22 million over the next two decades. In 2015 in the U.S., an estimated 1,658,370 new cases of cancer will be diagnosed, and 589,430 people will die from the disease.

Cancer starts in the human body when the otherwise orderly process of cell growth, division and death breaks down. As a result, abnormal or damaged cells that should die instead survive, grow and spread, forming solid tumors or cancers of the blood like leukemia. Although the body's immune system is designed to remove abnormal or damaged cells, cancerous cells are sometimes able to evade the immune system.

A recent breakthrough in treating cancer is the development of CPIs. Immune CPIs function by blocking the activity of checkpoint proteins, which inhibit normal immune responses to cancers. Several CPIs have recently been approved by the FDA, including Ipilimumab (Yervoy®), Nivolumab (Opdivo®) and Pembrolizumab (Keytruda®). Although these therapies unleash a robust T cell response, they don't work well for all patients - demonstrating limited efficacy and toxic effects in some populations.

We believe ATLAS may enable a better understanding of the T cell responses associated with CPI therapy, thereby potentially allowing physicians to better stratify patients according to their likely response to therapy. Additionally, we believe ATLAS may identify tumor-associated antigens or neoantigens which could form the core of general or personalized cancer vaccines.

We have two ongoing research collaborations to find cancer vaccine candidates and identify signatures of T cell response in CPI patients:

Dana Farber Cancer Institute

We conducted a pilot study with Darren Higgins, Ph.D., professor of microbiology and immunobiology at Harvard Medical School and F. Stephen Hodi, Jr., M.D., director of the Melanoma Center at Dana-Farber to retrospectively analyze CPI treated patients' T cell responses to 23 known tumor-associated antigens. ATLAS was used to examine the immune responses of both responders and non-responders to CPI therapy, revealing a pattern indicating a greater breadth of T cell activation for responders than non-responders. The study also found preliminary evidence that different characteristics of T cell responses emerge when comparing patients who respond and those who do not. The collaboration with Dana-Farber is ongoing as we continue to analyze more tumor and blood samples to characterize T cell response profiles

Memorial Sloan Kettering Cancer Center

We are collaborating with Timothy A. Chan, M.D., Ph.D., Vice Chair, Department of Radiation Oncology, and Jedd D. Wolchok, M.D., Ph.D., Chief of Melanoma and Immunotherapeutics Service at the Memorial Sloan Kettering Cancer Center to screen the T cell responses of melanoma and non-small cell lung cancer patients treated with CPIs against cancer neoantigens

Unique mutations identified by sequencing each cancer patient's tumor will be expressed in ATLAS and screened with T cells from the same patient, collected both before and after treatment with CPIs. In this way, each subject's own unique neoantigen T cell response profile will be identified, along with their signatures of T cell response to CPI therapy.

The ultimate goal of this project is to characterize the hallmarks of effective immunity in each patient so that they can be applied to the development of personalized immunotherapies in future prospective studies.

Our goal is to advance a personalized cancer vaccine into clinical development in 2017.

Our Epstein Barr Virus Program

EBV is associated with a number of cancers, such as post-transplant lymphoproliferative disease, non-Hodgkins lymphoma, nasopharyngeal carcinoma and gastric carcinoma. EBV is also the cause of infectious mononucleosis in adolescence and is associated with higher risk of a number of other serious diseases.

We believe that an effective immunotherapy against EBV needs to direct T cells and may have therapeutic potential against some or all of these diseases with large unmet needs. Furthermore, we believe that ATLAS is well-suited to identify the clinically important antigens which drive protective T cell responses to the virus.

Discovery research using ATLAS is ongoing to identify candidate T cell antigens to form the core of an immunotherapy that could potentially be advanced into clinical development.

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 non-clinical 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. We expect to complete antigen prioritization for candidate vaccines in 2016.

Our Malaria Program

Malaria is one of the deadliest infectious diseases in the world. Approximately 400 thousand to 800 thousand people died in 2013 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 "NMRC") and 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.

In September 2014, we announced the receipt of a $1.2 million grant from the Gates Foundation for the identification of protective T cell antigens for malaria vaccines, which extended our collaboration through 2016 and supports comprehensive screening of the malaria proteome to identify targets of protective T cell responses.

We remain 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. Although 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 product candidate, if approved.

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, which is currently on clinical hold. 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 genital herpes, including Agenus Inc., Admedus Ltd, Sanofi Pasteur and Vical Incorporated. GEN-003 is in more advanced clinical development than these product candidates being developed by these companies. Furthermore, we believe that GEN-003 has advantages against each of these product candidates based on the screens of human protection that we have conducted using ATLAS that include these competitors' antigens, published reports of non-clinical vaccine efficacy, announced clinical results in the case of Agenus, Inc. and Vical, 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.

Many of our competitors, 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. 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 ("U.S. PTO") 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 biologics license application ("BLA") we expect to apply for patent term extensions for patents covering our product candidates and their methods of use.

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 allowed U.S. applications. We hold an exclusive license from The Regents of the University of California ("UC") 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 ("Harvard") to the second patent family, which covers methods related to the ATLAS discovery platform. This second patent family includes U.S. Patent 9,051,564, a pending U.S. application and corresponding applications in Europe, Canada and Australia. Patents issuing from these applications are expected to expire in 2027 with the exception of U.S. Patent 9,051,564 which includes a Patent Term Adjustment and extends until December 2031. 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. Patents 8,313,894 and 9,045,791, 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. U.S. Patents 8,313,894 and 9,045,791 have terms that include Patent Term Adjustments and extend until August 2030 and August 2029, respectively.

GEN-003 (Genital Herpes)

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, and patents granted in Indonesia, Japan, Mexico, New Zealand, and Singapore. A U.S. application and applications in Europe, Canada, Australia, Japan, Brazil, Russia, India, China and five additional foreign jurisdictions are pending in the first patent family. A U.S. application and applications in Europe, Canada, 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. The term for the issued U.S. Patent 8,617,564 includes Patent Term Adjustment and extends until at least January 2031. We own a further patent family covering follow-on HSV-2 vaccine compositions, with applications pending in the U.S., Europe, Canada, Australia and Japan. Patents issuing from this family are expected to expire in 2032.

We hold a license from Isconova AB (now Novavax, Inc.) to two patent families covering Matrix-M2, the adjuvant used in GEN-003. Both patent families include a pending U.S. application and issued patents in Europe, Canada, Australia, Japan, Brazil, New Zealand and South Africa. These issued patents have patent terms until at least July 2023 and July 2024. The second patent family also includes issued U.S. Patent 8,821,881, which has a term that extends until August 2026 inclusive of a Patent Term Adjustment.

GEN-004 (Pneumococcus)

We co-own with Children’s Medical Center Corporation ("Children's"), a portfolio of patent applications directed to pneumococcus vaccines, including GEN-004. This 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, Japan, Brazil, Russia, India, China and eight additional foreign jurisdictions are pending in the first patent family. The first family also includes granted patents in Australia and New Zealand. A U.S. application and applications in Europe, Canada, Australia, Japan, Brazil, Russia, India, China and nine additional foreign jurisdictions are pending in the second patent family. The second family also includes a granted patent in New Zealand. 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 Children's interest in these patent rights. We co-own with Children's one further patent family covering follow-on pneumococcal vaccine compositions, with pending applications in the U.S., Europe, Canada, Australia, and Japan. Children's interest in these patent rights is also exclusively licensed to us.

GEN-001 (Chlamydia)

Our chlamydia patent portfolio previously included four patent families (one of which overlaps with the ATLAS portfolio). We held an exclusive license from Harvard to the first three patent families. We notified Harvard of our partial termination of the license agreement with regard to chlamydia antigens covered by these patent families on December 8th 2014. Effective March 8th 2015, the license agreement with Harvard with regard to chlamydia antigens covered by these patent families was terminated and we no longer hold an exclusive license to two of the three patent families, or to a chlamydia antigen covered by the remaining family. The remaining family covers certain aspects of the ATLAS platform, as well as one chlamydia antigen, and we maintain exclusive rights to aspects of the ATLAS platform covered by this family. We determined that the chlamydia antigens covered by these patent families were not relevant to the continued development of GEN-001. We wholly own the fourth patent family, which covers chlamydia vaccine and immunogenic compositions and methods for

inhibiting or treating chlamydia infections. A U.S. application and applications in Europe, Canada, Australia and Japan are pending in this patent family. Patents issuing therefrom are expected to expire in 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.

In-License Agreements

University of California

In August 2006, we entered into an exclusive license agreement with 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, 2015, 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 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 notified Harvard of our partial termination of the license agreement with regard to intellectual property covering chlamydia antigens on December 8, 2014. Effective March 8, 2015, the license agreement with Harvard with regard to intellectual property covering chlamydia antigens was terminated and we no longer hold a license to two of the three in-licensed Harvard patent families, or to a chlamydia antigen covered by the remaining family. The remaining family covers certain aspects of the ATLAS platform, as well as one chlamydia antigen, and we continue to maintain exclusive rights to aspects of the ATLAS platform covered by this family.

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, 2015, we paid $198 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.

Other Collaborations

Children's Medical Center Corporation

In September 2008, we entered into a collaborative research agreement with Children's, that was funded by PATH Vaccine Solutions ("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 Children's and covers pneumococcal vaccine compositions and methods for inhibiting or treating pneumococcus infections. In February 2010, we entered into an exclusive license agreement with Children's, which was amended and restated in March 2012. This agreement grants us an exclusive, worldwide, sublicensable license under Children's 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. Children's 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 Children's is subject to PATH's separate non-exclusive, royalty-free license from Children's 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 Children's milestone payments up to $390 thousand in the aggregate upon the achievement of certain development and commercial milestones. As of December 31, 2015, we paid $140 thousand in aggregate milestone payments. Upon commercialization of our products, we are obligated to pay Children's 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 Children's 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 Children's 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, Children's has the right to terminate in this agreement in whole or in part.

Unless earlier terminated, the agreement with Children's 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. Children's may terminate the agreement in the event of our bankruptcy, insolvency or similar circumstances; if we use confidential information to formally challenge Children's 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.

Novavax

In August 2009, we entered into an exclusive license and collaboration agreement with Isconova AB, a Swedish company which has subsequently been acquired by 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 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, 2015, we paid $275 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.

The agreement also contained a research funding clause for which we made monthly payments to Novavax between August 2009 and March 2012 of approximately $1.6 million. All amounts of research funding provided were to be refunded by Novavax. After December 31, 2015, any amounts remaining due from Novavax, including accrued interest, could be received

in cash upon 30-day written notice provided by us. We provided this notice in January 2016 and received the $1.6 million refund in February 2016.

Fujifilm

In February 2014, we entered into a supply agreement with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. ("Fujifilm"). The supply agreement provides the terms and conditions under which Fujifilm will manufacture and supply certain recombinant protein antigens to us for our Phase 2 clinical study for our lead product, GEN-003. Under this agreement, we are obligated to pay Fujifilm milestone payments up to the mid-seven figures upon the achievement of certain manufacturing milestones. As of December 31, 2015, we paid approximately $4.7 million in aggregate manufacturing milestone payments. Additionally, raw materials, resins and consumables purchased for the vaccine production are invoiced separately as such costs are incurred by Fujifilm. We pay Fujifilm's actual costs plus a percentage fee in the mid-single digits for these raw materials, resins and consumables. We also are required to pay reservation fees, which equal a percentage of production fees in the low-double digits, to reserve manufacturing slots in the production timeframe as agreed upon under the agreement. We are required to use commercially reasonable efforts to timely provide Fujifilm with the technology, materials and resources needed to produce and supply the recombinant protein antigen.

Our agreement with Fujifilm will expire on February 25, 2024. Subject to termination fees under applicable circumstances, we may terminate the agreement at any time by giving Fujifilm advance written notice. The agreement may also be terminated by either party due to a material uncured breach by the other party.

Baxter

In October 2014, we entered a product development and clinical supply agreement with Baxter Pharmaceutical Solutions LLC ("Baxter"). The product development and clinical supply agreement provides the terms and conditions under which Baxter will formulate, fill, inspect, package, label and test our lead product, GEN-003 for clinical supply. Under this agreement, we are obligated to pay Baxter amounts up to the low six digits for each batch of GEN-003 manufactured. Additionally, certain set-up fees and equipment purchased for the purposes of batch production will be invoiced separately by Baxter. We will pay set-up fees and equipment costs in the low six digits upon commencement of batch production. We also pay a monthly service fee in the low five digits for project management services for the duration of the arrangement. As of December 31, 2015, we paid approximately $367 thousand under this agreement.

Our agreement with Baxter expires on October 23, 2021. Subject to termination fees under applicable circumstances, we may terminate the agreement at any time by giving Baxter advance written notice. The agreement may also be terminated by either party due to a material uncured breach by the other party.

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 ("FD&C Act") and the Public Health Service Act ("PHS Act"), and other federal, state, local and foreign statutes and regulations. Both the FD&C and PHS Acts 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. Clinical testing of biological products is subject to FDA review before initiation. In addition, FDA approval must be obtained before marketing of biological products. The process of obtaining regulatory review and approval 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 ("GLP") 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 ("GCP") 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 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 good manufacturing practices ("GMPs") 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 ("GTP") 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 institutional review board ("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 AEs 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 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, 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 ("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 ("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 Department of Health and Human Services ("HHS"), and its various divisions, including but not limited to, the Centers for Medicare & Medicaid Services ("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, the Office for Human Research Protections, and the Office of Research Integrity, 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 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 PHS Act, pharmaceutical pricing program and also seek to sell the products to federal agencies. These programs are administered by various federal and state agencies to allow for individuals age 65 and over, low income, and disabled beneficiaries access to approved medicines and treatments. Under these programs, manufacturers are required to pay rebates, and the pricing of an approved treatment may be subject to various forms of price modifications.

Recent legislation, including the American Recovery and Reinvestment Act of 2009 (the "2009 Act") and the Affordable Care Act enacted in March 2010 (the "2010 Act") may impact health care financing by both governmental and private payors. The 2009 Act provides funding for the federal government to compare the effectiveness of different treatments for the same illness. 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. The 2010 Act was designed to reduce the cost of health care which could 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 ("CTA") much like an IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country. In all cases, the clinical trials must be conducted in accordance with GCPs and other applicable regulatory requirements.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. 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 non-clinical 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 from third-party manufacturers who are sole source suppliers to us. We intend to identify and qualify contract manufacturers to provide the protein process development, protein production, adjuvant production, and fill-and-finish services prior to submission of a BLA to the FDA.

Employees

As of December 31, 2015, we had 87 full-time employees. Of these 87 employees, 69 employees are engaged in research and development and 18 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 ("SEC"). 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 SEC at the SEC'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 SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. 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 $42.5 million, $35.3 million, and $20.8 million for the years ended December 31, 2015, 2014, and 2013, respectively. As of December 31, 2015 and 2014, we had accumulated deficits of approximately $157.9 million and $115.4 million, respectively. 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, debt financing, our initial public offering ("IPO") completed in February 2014, and follow-on public offerings in March 2015 and August 2015 and we do not expect to generate any product revenues in the foreseeable future. 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 non-clinical technology development and development activities. 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 2 program for GEN-003, our most advanced product candidate that we are developing for the treatment of genital herpes infections;
- initiate additional non-clinical, clinical or other studies for our other product candidates;
- manufacture material for clinical trials and for commercial sale;
- seek regulatory approvals for any 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 non-clinical 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, 2015, our cash, cash equivalents and investments were $106.4 million. We believe that we will continue to expend substantial resources for the foreseeable future developing GEN-003 and our non-clinical product candidates, including our potential immuno-oncology 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 our ongoing Phase 2 program for GEN-003;
- 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 cost of our general and administrative functions;
- 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 our existing cash, cash equivalents and investments will be sufficient to fund our projected operating expenses and capital expenditure requirements into the second half of 2017, by which time we anticipate that we will have conducted an end of Phase 2 meeting with the FDA for GEN-003 and the Phase 3 program for GEN-003 will have commenced. 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 non-clinical 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. In 2015, we raised additional net capital of approximately $95.2 million through follow-on public offerings in March and August along with $4.7 million of debt financing in December. 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 capital when needed, we would be required to delay, limit, reduce or terminate our product development or commercialization efforts for GEN-003 or our non-clinical product candidates, or our immuno-oncology program, 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

We are substantially dependent on the success of the clinical development of GEN-003, our only product candidate currently in an active clinical trial. Any failure to successfully develop or commercialize the GEN-003 vaccine, or any significant delays in doing so, will have a material adverse effect on our business, result of operations and financial condition.

We have invested a significant portion of our efforts and financial resources in the development of the GEN-003 vaccine for genital herpes, the only product candidate we have that is currently in an active clinical development following the suspended development for our product candidate GEN-004 in October 2015. Our ability to generate product revenue depends heavily on the successful development and commercialization of GEN-003. The successful development and commercialization of GEN-003 will depend on several factors, including the following:

- Successful completion of our ongoing and additional clinical studies of GEN-003;
- Obtaining marketing approvals from regulatory authorities for GEN-003;
- Establishing manufacturing and commercialization arrangements between ourselves and third parties;
- A continued acceptable safety and efficacy profile of GEN-003; and
- The availability of reimbursement to patients from healthcare payors for GEN-003.

Any failure to successfully develop or commercialize GEN-003 or any significant delays in doing so will have a material adverse effect on our business, results of operations and financial condition.

Because our active product candidate is 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 non-clinical and clinical results for GEN-003 are not necessarily predictive of the final results of our ongoing or future clinical trials. Success in non-clinical 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. Among other reasons for the potential failure of earlier, smaller clinical trials to be replicated in later, larger clinical trials is the fact that manufacturing scale up is necessary to prepare for Phase 3 development and commercialization. Because our products require complex manufacturing processes, scaling up these processes can cause changes in the product that may not be apparent until the product is tested in humans.

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 AEs 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.

In addition to product candidates being developed in our non-clinical and clinical programs, we have plans to expend resources in our immuno-oncology program. Our immuno-oncology program is at early stage, we currently have no product candidates under this program, and our efforts to identify and develop product candidates under this program may not be successful.

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 non-clinical 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 or our other current or potential future clinical and non-clinical 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 immunotherapy, or we may never obtain regulatory approval for these product candidates for any indication 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 ongoing 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 ("CROs") and physicians;
- different standards for the conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners;
- he 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 for the intended indications. 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 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 GCPs 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 AEs 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 active product candidate, GEN-003, and our current and future potential product candidates, including any arising out of our immuno-oncology program, are or will be based on T cell activation, which is a novel approach for vaccines, immunotherapies 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 and immunotherapies may prevent further development or approval of our current and future product candidates. Because of the novelty of this approach, there may be unknown safety risks associated with the vaccines and immunotherapies 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 and immunotherapies. 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 and immunotherapy technology, and our future success is highly dependent on the successful development of T cell vaccines and immunotherapies in general, and our active development product and current and future product candidates in particular. There can be no assurance that any development problems we or others researching T cell vaccines and immunotherapies 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, of physicians to prescribe and of patients to receive novel vaccines.

Our active development product, GEN-003 includes a novel vaccine adjuvant and our other current and potential future 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 such product candidates.

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. 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 and immunotherapies will be subject to ongoing regulatory review, which may result in significant additional expense. Additionally, our product candidates, including our active development product, GEN-003, and any other current or potential future vaccine or immunotherapy 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 indications 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 or immunotherapy potentially over many years. In addition, if the FDA approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, AE 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 ("cGMP"), and GCP, for any clinical trials that we conduct post-approval.

Later discovery of previously unknown problems with an approved product, including AEs 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 non-clinical studies and clinical trials for our product candidates, including our active development product, GEN-003, and any other current or future 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 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, non-clinical 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, including under our agreements with Fujifilm and Baxter. For example, we rely on third party suppliers and manufacturers to manufacture and supply vaccines for our GEN-003 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 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. 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 non-clinical 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 applications. 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 and collaboration agreements that are important to our business, and we may enter into additional license or collaboration 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 current or future product candidates. See "Business — In-License Agreements" and "Business — Other Collaborations" for a description of our outstanding license and collaboration agreements with UC, Harvard, Children's, Novavax, and the DFCI.

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 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 genital herpes. GEN-003, our active development product and lead product candidate, will compete with these products, if approved.

In addition, one or more products not currently approved for the treatment of genital herpes, including pritelivir (AiCuris) and HerpV (Agenus) and other vaccines in development by Admedus, Ltd and Vical Incorporated may in the future be granted marketing approval for the treatment of genital herpes or other conditions for which GEN-003 might be approved.

Other companies that are seeking to identify antigens for the development of vaccines and T cell receptor therapies using predictive tools include Foundation Medicine, Neon Therapeutics, Gritstone Oncology, Immatics Biotechnologies GmbH, Immunocore Limited, and Adaptive Biotechnologies.

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, including recruiting patients, 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 Phase 2 clinical trials for GEN-003. Serious AEs deemed to be caused by our product candidates could have a material AE on the development of our product candidates and our business as a whole. The most common AEs 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 AEs in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected AEs may be observed.

If we or others identify undesirable side effects caused by any of 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 December 2015, we entered into an amendment (the "First Amendment") to our Loan Agreement (the "2014 Term Loan") with Hercules Technology Growth Capital, Inc. (“Hercules”). The First Amendment required us to draw an additional $5.0 million and permits us to draw two additional $5.0 million tranches. One $5.0 million tranche is immediately available to draw through December 15, 2016 and a second $5.0 million tranche becomes available through December 15, 2016, subject to the Company demonstrating sufficient evidence of continued clinical progression of its GEN-003 product and making favorable progress in applying its proprietary technology platform toward the development of novel immunotherapies with application in oncology. At December 31, 2015, $17.0 million was outstanding under the amended 2014 Term Loan.

During the amendment negotiations, but after the third quarter Form 10-Q was filed, we identified three separate covenant violations that resulted in an event of default (as defined in the 2014 Term Loan) as of September 30, 2015. Pursuant to the 2014 Term Loan, upon an event of default, Hercules can accelerate the repayment of all amounts due under the 2014 Term Loan at its discretion. Hercules did not make a repayment demand and the First Amendment included a waiver of these covenant violations. The First Amendment also modified the loan agreement for the specific instances in which these violations arose.

All obligations under our 2014 Term Loan 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 2014 Term Loan could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and Hercules 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 2014 Term Loan could result in an event of default and, as a result, Hercules could accelerate all of the amounts due. In the event of an acceleration of amounts due under our 2014 Term Loan 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, Hercules 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 2014 Term Loan 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, Jonathan Poole, our Chief Financial Officer, Eric Hoffman, our Chief Business 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.

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.

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 ongoing 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

We are eligible to be treated as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company", as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board providing for supplemental auditor's reports for additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. For example, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" if the market value of our common stock held by non-affiliates is below $75.0 million as of June 30 in any given year, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We cannot predict what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

An inactive market may impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as

consideration. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors and, as a result of these and other factors, the price of our common stock may fall.

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;
- the timing of the release of results of our clinical trials;
- results of clinical trials of our competitors' products;
- regulatory actions or legal developments with respect to our products or our competitors' products;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks; and
- changes in general market and economic conditions.

In addition, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products, or to a lesser extent our markets. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert

our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

We have had a material weakness in internal control over financial reporting in the past and cannot assure you that additional material weaknesses will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in material misstatements in our financial statements which could require us to restate financial statements, cause investors to lose confidence in our reported financial information and have a negative effect on our stock price.

As reported in our Quarterly Report on Form 10-Q filed with the SEC on May 9, 2014, during the quarter ended March 31, 2014, management and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting (as defined in the Public Company Accounting Oversight Board's Auditing Standard No. 5) related to the accounting for a non-cash stock compensation expense for a milestone-based stock option award. We have remediated this material weakness, by implementing corrective measures as described in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.

We cannot assure you that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses or significant deficiencies, cause us to fail to meet our periodic reporting obligations or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting. The existence of a material weakness or significant deficiency could result in errors in our financial statements that could result in a restatement of financial statements, cause us to fail to meet our reporting obligations and cause investors to lose confidence in our reported financial information, leading to a decline in our stock price.

We incur significant costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we incur significant legal, insurance, accounting and other expenses that we did not incur as a private company. In addition, our administrative staff are required to perform additional tasks. For example, in anticipation of becoming a public company, we adopted additional internal controls and disclosure controls and procedures and bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws. We invest resources to comply with evolving laws, regulations and standards, and this investment could result in increased general and administrative expenses and may divert management's time and attention from product development activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In connection with our IPO, we increased our directors' and officers' insurance coverage, which increased our insurance cost. In the future, it will be more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

In addition, in order to comply with the requirements of being a public company, we have and may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934 as amended is accumulated and communicated to our principal executive and financial officers. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our ordinary shares could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the NASDAQ Global Market.

Since becoming a public company, we are required to comply with certain of the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly

and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment must include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statement.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company" as defined in the JOBS Act. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

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

Provisions in our amended and restated certificate of incorporation and amended and restated by-laws contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management. 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 by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our by-laws.

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 amended and restated certificate of incorporation, our amended and restated by-laws 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.

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 (the "Code"), a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses ("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. 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 amended and restated 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 amended and restated 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 amended and restated certificate of incorporation or our amended and restated by-laws 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 amended and restated 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 amended and restated 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 the source of gain for our stockholders.

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. In June 2015, we signed a second operating lease for additional office space in the same building (the "2015 Lease"). In the aggregate, we occupy approximately 34,200 square feet of laboratory and office space at this address. Both leases have initial terms that expire on February 28, 2017, and the 2015 Lease has a three-year renewal option. We believe that our existing facilities are sufficient for our present operations, but that over time, our existing facility space will need to be expanded to meet the demands of our future lab operations.

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. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported on the NASDAQ Global Market.

	Year ended December 31, 2015		Year ended December 31, 2014	
	High	Low	High	Low
First quarter (1)	$ 12.50	$ 6.15	$ 23.99	$ 10.90
Second quarter	$ 14.29	$ 9.00	$ 23.99	$ 16.76
Third quarter	$ 16.18	$ 6.63	$ 20.00	$ 8.90
Fourth quarter	$ 8.20	$ 4.27	$ 9.44	$ 7.00

(1) For the quarter ended March 31, 2014, the period is from February 5, 2014, the date on which our common stock first began to trade on the NASDAQ Global Market after the pricing of our initial public offering, through March 31, 2014, the end of our first fiscal quarter.

Holders

As of February 11, 2016, there were approximately 24 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

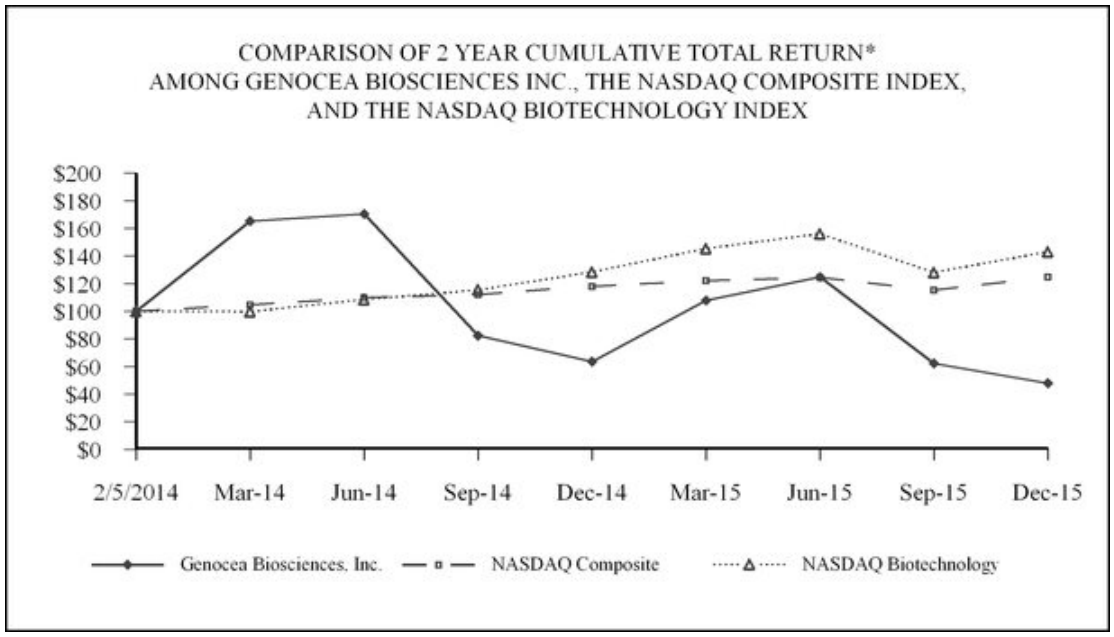
Dividends

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.

Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the performance of our common stock to the NASDAQ Composite Index and to the NASDAQ Biotechnology Index from February 5, 2014 (the first date that shares of our common stock were publicly traded) through December 31, 2015. The comparison assumes $100 was invested after the market closed on February 5, 2014 in our common stock and in each of the foregoing indices, and it assumes reinvestment of dividends, if any.



* $100 invested on 2/5/2014 in stock or index, including reinvestment of dividends. Fiscal year ending December 31, 2015.

Cumulative Total Return Comparison

	2/5/2014	Mar-14	Jun-14	Sep-14	Dec-14	Mar-15	Jun-15	Sep-15	Dec-15
Genocea Biosciences, Inc.	100.00	165.36	170.45	82.27	63.64	107.82	124.82	62.27	47.91
NASDAQ Composite	100.00	104.67	109.89	112.01	118.06	122.17	124.31	115.17	124.82
NASDAQ Biotechnology	100.00	99.66	108.44	115.41	128.26	145.21	156.00	127.93	142.91

Recent Sales of Unregistered Securities

None.

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

Initial Public Offering

In February 2014, we completed our initial public offering ("IPO") of 5.5 million 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 of 1933, as amended, (the "Securities Act") pursuant to a registration statement on Form S-1 (File No. 333-193043), which was declared effective by the SEC on February 4, 2014. Citigroup Global Markets, Inc. and Cowen and Company, LLC ("Cowen") acted as joint book-running managers of the offering and as representatives of the underwriters. Stifel, Nicolaus & Company, Incorporated ("Stifel") and Needham & Company, LLC ("Needham") 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 approximately $2.4 million of 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 December 31, 2015, all of the net proceeds from the IPO have been used and were utilized to fund the preclinical and clinical development of our product candidates and other general corporate purposes.

Item 6. Selected Financial Data

The selected statements of operations data for each of the three years in the period ended December 31, 2015 and the balance sheet data at December 31, 2015 and 2014 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statements of operations data for the periods ended December 31, 2012 and 2011 and the balance sheet data at December 31, 2013, 2012, and 2011 has 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.

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 consolidated 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 consolidated financial statements and are qualified in their entirety by the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

	Years Ended December 31				
	2015	2014	2013	2012	2011
Grant revenue	$ 670	$ 308	$ 731	$ 1,977	$ 1,820
Operating expenses:					
Research and development	28,049	23,727	15,695	11,240	13,543
General and administrative	13,987	9,747	4,961	3,690	3,004
Total operating expenses	42,036	33,474	20,656	14,930	16,547
Loss from operations	(41,366)	(33,166)	(19,925)	(12,953)	(14,727)
Other expense:					
Change in fair value of warrants	—	(725)	(222)	93	75
Loss on debt extinguishment	—	(435)	(200)	—	—
Interest expense, net	(1,117)	(970)	(459)	(507)	(33)
Other expense	(1,117)	(2,130)	(881)	(414)	42
Net loss	$ (42,483)	$ (35,296)	$ (20,806)	$ (13,367)	$ (14,685)
Comprehensive loss	$ (42,483)	$ (35,296)	$ (20,806)	$ (13,367)	$ (14,685)
Reconciliation of net loss to net loss applicable to common stockholders					
Net loss	$ (42,483)	$ (35,296)	$ (20,806)	$ (13,367)	$ (14,685)
Accretion of redeemable convertible preferred stock to redemption value	—	(180)	(1,605)	(1,781)	(1,605)
Net loss attributable to common stockholders	$ (42,483)	$ (35,476)	$ (22,411)	$ (15,148)	$ (16,290)
Net loss per share attributable to common stockholders - basic and diluted (1)	$ (1.74)	$ (2.27)	$ (75.46)	$ (51.35)	$ (55.41)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	24,460	15,618	297	295	294

(in thousands)	At December 31 2015	2014	2013	2012	2011
Balance Sheet Data:					
Cash, cash equivalents and investments	$ 106,432	$ 47,079	$ 12,208	$ 11,516	$ 5,742
Working Capital	89,226	42,173	8,382	7,932	3,852
Total assets	112,142	50,332	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	247,578	147,941	—	—	—
Total stockholders' equity (deficit)	89,661	32,507	(80,131)	(58,402)	(43,562)

(1) See Note 2 within the notes to our consolidated 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 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 biopharmaceutical company that discovers and develops novel vaccines and immunotherapies to address diseases with significant unmet needs. We use our proprietary discovery platform, ATLAS ™, to rapidly design vaccines and immunotherapies that act, in part, through T cell (or cellular) immune responses, in contrast to approved vaccines and immunotherapies, 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 and immunotherapies to address diseases where T cells are central to the control of the disease.

We have one product candidate in active Phase 2 clinical development, GEN-003, an immunotherapy for the treatment of genital herpes. We have another product candidate, GEN-004, a universal vaccine for the prevention of pneumococcal infections, for which we have suspended development pending further data analysis and consultation with our advisers after we did not achieve statistically significant results in our Phase 2a human challenge study. We also have active research and pre-clinical development programs for diseases including genital herpes, chlamydia and malaria. We are also investigating the application of ATLAS to immuno-oncology target discovery.

GEN-003 — Phase 2 immunotherapy for genital herpes

Our lead program is GEN-003, a Phase 2 candidate therapeutic vaccine, or immunotherapy, that we are developing to treat genital herpes infections. Data from our double-blind, placebo-controlled, dose-escalating Phase 1/2a trial for GEN-003 represented the first reported instance of a therapeutic vaccine working against an infectious disease, and we have identified a dose in our Phase 2 trial which has showed an even greater reduction in viral shedding than the best dose in the Phase 1/2a trial.

Final analysis of the data from the Phase 1/2a trial showed that, for the best performing 30µg dose group, there was a sustained reduction in the viral shedding rate. After completion of dosing for this group, the viral shedding rate fell by 52% versus baseline and, at six months after the final dose, the shedding rate remained at 40% below baseline. The reduction in the genital lesion rate after completion of the third dose was greatest for the 30µg dose group at 48%. After six months, the reduction from baseline in genital lesion rate for this dose group was 65% and, after 12 months, the genital lesion rate was 42% lower than baseline. GEN-003 was safe and well tolerated over the 12 months of this trial.

Having identified a dose that, according to company-sponsored market research, delivers clinically meaningful efficacy in magnitude and durability, we are now conducting a 310-subject Phase 2 dose optimization trial. The objective of this trial is to confirm the results of the best performing dose in the Phase 1/2a trial and to test six other combinations of proteins and adjuvant to determine the optimal dose for future trials and potentially improve on the current profile of GEN-003.

In May 2015, we announced positive top-line data from the Phase 2 trial. Subjects were randomized to one of six dosing groups of either 30µg or 60µg per protein paired with one of three Matrix-M2 ™ adjuvant doses (25µg, 50µg, or 75µg). A seventh group received placebo. Subjects received three doses of GEN-003 or placebo at 21-day intervals. Baseline viral shedding and genital lesion rates were established for each subject in a 28-day observation period prior to the commencement of dosing by collecting 56 genital swab samples (two per day), which were analyzed for the presence of HSV-2 DNA, and by recording the days on which genital lesions were present. During the 28-day observation period immediately after completion of dosing, the best dose of 60µg per protein/75µg of adjuvant demonstrated a highly statistically significant ($p<0.0001$) 55% reduction from baseline in the viral shedding rate, the primary endpoint of the trial and a measure of anti-viral activity. All dose combinations tested, including the successful 30µg per protein/50µg of adjuvant dose from the prior Phase 1/2a trial, demonstrated a statistically significant viral shedding rate reduction versus baseline and only the lowest dose combination did not demonstrate a statistically significant reduction versus placebo. In a planned secondary analysis to assess impact on patient reported genital lesion rates, all dose groups, including the placebo group, demonstrated a statistically significant reduction from baseline. Furthermore, there was no difference in discontinuations in patient dosing due to AEs across the different treatment arms.

In October 2015, we announced positive results from a planned interim analysis of data collected six months after dosing. At its best performing dose of 60µg per protein / 75µg of adjuvant, GEN-003 demonstrated a statistically significant 58% reduction from baseline in the viral shedding rate ($p < 0.0001$). In a planned secondary analysis, the proportion of patients receiving GEN-003 who were lesion-free at six months after dosing ranged from approximately 30% to 50%, similar to results reported in clinical trials with oral antiviral therapies. In addition, the time to first recurrence after completion of dosing showed a range of 152 days to greater than 180 days among dose groups. In a further secondary analysis measuring the impact on genital lesion rates, GEN-003 demonstrated sustained and statistically significant reductions from baseline in five of six dose groups ranging from 43% to 69%. The Phase 2 trial continues to show that GEN-003 is safe and well tolerated by patients, with no serious adverse events related to the vaccine. Data from the 12-month observation period in this trial is expected later in the first quarter of 2016.

Following improvements that we have made to the manufacturing process for GEN-003 to enable production at commercial scale, we initiated patient screening in the fourth quarter of 2015 and commenced the dosing phase in January 2016 for a 135-subject Phase 2b study to confirm the efficacy of this new material. Subjects will be randomized to one of two dose levels of GEN-003 or a placebo. We expect to announce top-line viral shedding rate data from the 28-day observation period immediately after dosing from this study in the middle of 2016. The study will also compare GEN-003 efficacy to placebo for the clinical endpoints of: the proportion of patients who are lesion free at six and 12 months after dosing; the time to first lesion recurrence after dosing; and, the impact on percentage of days with genital herpes lesions at six and 12 months after dosing. Data from these six and 12 month clinical endpoints is expected in the second half of 2016 and the first quarter of 2017, respectively. All subjects will be followed for 12 months after the last dose.

In the second half of 2016, we intend to commence a Phase 2b study to investigate the potential benefits of using GEN-003 in combination with oral antiviral medicines. We also intend to conduct an end-of-Phase 2 meeting with the FDA in late 2016. We retain all rights to GEN-003 and plan to advance this program through regulatory approval and, if approved, 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.

If GEN-003 successfully completes clinical development and is approved, we believe it would represent an important new treatment option for patients with genital herpes.

GEN-004 — Universal vaccine for the prevention of pneumococcal infections

We also have a second T cell-stimulating vaccine candidate, GEN-004, a potential universal *Streptococcus pneumoniae* , or pneumococcus, vaccine to protect against the leading cause of infectious disease mortality worldwide. GEN-004 is designed to stimulate T helper 17 ("Th17") cells, a rare cell type that provides immunity at epithelial and mucosal surfaces, in the nasopharynx to prevent colonization by pneumococcus.

In June 2014, we announced top-line data from a Phase 1 clinical trial for GEN-004. This trial met its safety, tolerability and immunogenicity goals including measurable increases in the blood of Th17 cells. We initiated a 98-subject

Phase 2a trial in September 2014 to demonstrate that GEN-004 can reduce the frequency, magnitude and duration of colonization of pneumococcus in the nasopharynx in healthy adults.

In October 2015, we announced that top-line results from the Phase 2a clinical trial for GEN-004 showed consistent reductions versus placebo in the pre-specified endpoints of the rate and density of colonization, but that neither of the endpoints achieved statistical significance. GEN-004 was safe and well tolerated by subjects. GEN-004 reduced the colonization rate, measured by microbiological culture, by between 22% and 25% versus placebo across those measurement time points. When measured by the presence of pneumococcal DNA, the reductions ranged between 18% and 36%. Additionally the median density of colonization measured by microbiological culture for GEN-004 treated subjects ranged from zero to two colony forming units ("CFUs") per mL of nasal wash compared to one to 11 CFUs per mL for the placebo group. When measured by the presence of pneumococcal DNA, the median densities ranged from zero to 10 copies per mL in treated subjects and 19 to 52 copies per mL in placebo subjects. None of the differences were statistically significant. There was no difference in the duration of colonization between GEN-004 and placebo.

Although we did not achieve statistical significance in this study, the consistent apparent effect supports the vaccine concept and in the potential for GEN-004. We believe it is possible that future trials would require a change in some combination of dose, adjuvant or trial population to confirm any effect. Pending ongoing data analysis and consultation with our advisors to determine next steps for this program, we have suspended the development of GEN-004 from our near-term plans and will focus our resources on the ongoing GEN-003 program, and on maximizing the potential of our preclinical pipeline and our ATLAS technology for T cell target discovery.

Research and non-clinical development in oncology

We initiated a research collaboration with the Dana-Farber Cancer Institute ("DFCI") in 2014 to apply the ATLAS platform in immuno-oncology. This collaboration centered on ATLAS's potential to identify patterns of T cell response in cancer patients receiving checkpoint inhibitor ("CPI") therapy. By analyzing the immune responses of both responders and non-responders to CPI therapy, ATLAS successfully identified the cancer antigens to which either (or both) CD4+ or CD8+ T cells became activated. While this research was not powered to draw firm conclusions, the analysis of T cell responses in patients receiving CPI therapy revealed a pattern indicating a greater breadth of T cell activation for responders than non-responders. The study also revealed preliminary evidence that different characteristics of T cell responses emerge when comparing patients who respond and those who do not. Some T cell responses did not correspond with improved patient outcomes, and may be classified as “decoys,” further validating the ability of ATLAS to distinguish clinically relevant targets of T cell response. The collaboration with DFCI is ongoing as we continue to analyze more tumor samples to characterize T cell response profiles that may be prognostic of CPI efficacy, and to identify T cell antigens that may be included in novel immunotherapies.

In November 2015, we also announced a collaboration with the Memorial Sloan Kettering Cancer Center to screen the T cell responses of melanoma and non-small cell lung cancer patients treated with CPIs against the complete repertoire of patient-specific putative cancer neoantigens. The goals of the collaboration are to identify signatures of T cell response in cancer patients associated with response or non-response to CPI therapy and to discover new T cell cancer vaccine antigens. ATLAS will be used in conjunction with Memorial Sloan Kettering’s patient-specific cancer neoantigen sequences and blood samples from the same cancer patients.

In November 2015, we commenced a new program focused on Epstein-Barr Virus (“EBV”). EBV infection has been linked to cancers with high unmet needs such as non-Hodgkin’s lymphoma, nasopharyngeal carcinoma and gastric carcinoma. We believe the ATLAS platform is highly suited to the creation of a new immunotherapy for EBV given that T cell responses are understood to be crucial for protection against EBV. Furthermore, EBV is part of the herpesvirus family, in which we have years of experience through our development of GEN-003.

Research and non-clinical development in infectious disease

We have ongoing non-clinical development programs in chlamydia and genital herpes prophylaxis and a research program funded by the Bill & Melinda Gates Foundation ("Gates Foundation") in malaria.

Financing and business operations

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 for 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. As of December 31, 2015, we had received an aggregate of $278.8 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At December 31, 2015, our cash and cash equivalents and investments were $106.4 million.

Since inception, we have incurred significant operating losses. Our net losses were $42.5 million and $35.3 million for the years ended December 31, 2015 and 2014, respectively, and our accumulated deficit was $157.9 million as of December 31, 2015. 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.

In March 2015, we completed an underwritten public offering of 6.3 million shares of our common stock at a public offering price of $8.25 per share for an aggregate offering price of $51.7 million. In August 2015, we completed another underwritten public offering of 3.9 million shares of our common stock at a public offering price of $13.00 per share for an aggregate offering price of $50.1 million. We received net proceeds from these offerings of approximately $95.7 million, after deducting approximately $6.1 million in underwriting discounts and commissions, excluding offering costs payable by us.

We believe that our cash, cash equivalents and investments at December 31, 2015 are sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2017. Through this timeframe, we expect to have results from multiple Phase 2 GEN-003 studies including the twelve-month data from our ongoing dose optimization clinical trial, a Phase 2b study to test the efficacy of GEN-003 following changes in the manufacturing process to allow for production at commercial scale and a study to investigate the potential benefits of using GEN-003 in combination with oral antiviral medicines. In late 2016, we also expect to have conducted our FDA end of Phase 2 meeting for GEN-003 and we expect to commence Phase 3 studies in the second half of 2017. However, costs related to clinical trials can be unpredictable and therefore there can be no guarantee that our current balances of cash, cash equivalents and investments, and any proceeds received from other sources, will be sufficient to fund our studies or 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 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

Grant revenue

Grant revenue consists of revenue earned to conduct vaccine development research. We have received grants from private not-for-profit organizations 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 ("CROs"), contract manufacturing organizations ("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 performance or 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 (in thousands):

	Years ended December 31,		
	2015	2014	2013
Genital herpes (GEN-003)(1)	$ 15,555	$ 15,147	$ 7,730
Pneumococcus (GEN-004)(1)	3,260	4,778	5,848
Other research and development (2)	9,234	3,802	2,117
Total research and development	$ 28,049	$ 23,727	$ 15,695

(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 certain technology platform development costs related to ATLAS.

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, GEN-003.

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 higher costs for insurance, hiring activities, and professional services, such as 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, cash equivalent and investment portfolio.

Other expense, net

Other expense consists of fair value adjustments on warrants to purchase preferred stock. Upon completion of our IPO on February 10, 2014, warrants to purchase preferred stock were converted to warrants to purchase common stock and as a

result, the Company no longer recorded fair value adjustments for its warrants. Other expense also consists of loss on debt extinguishment.

Accretion of redeemable convertible 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 completed our IPO and all shares of preferred stock were converted into 11,466,479 shares of our Common Stock. No accretion of preferred stock is recorded after this date as no shares of preferred stock are 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 ("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, prepaid and accrued research and development expenses, stock-based compensation expense, common stock warrants, warrants 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.

Prepaid and Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our prepaid and accrued research and development expenses. 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 prepaid and accrued research and development expenses 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 prepaid and accrued research and development expenses 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 recording service fees, we make estimates based upon the time period over which services will be performed or other observable and measureable progress points as defined in the contracts, such as number of subjects enrolled, number of sites, or quantity of services performed in each period. The calculated amount of service fee expense is compared to the actual payments made pursuant to the contract's billing schedule to determine the resulting prepaid or accrual position. Additionally, for each clinical site, we accrue 10% of the earned amounts 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

We have applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification ("FASB ASC"), Topic 718, *Compensation — Stock Compensation* (″ ASC 718"), to account for stock-based compensation for employees and ASC 718 and FASB ASC Topic 505, *Equity* (″ 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.

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 of our limited operating history as a publicly traded entity, 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 also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from its estimates. We use historical data to estimate forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our 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.

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):

	Years ended December 31,		
	2015	2014	2013
Research and development	$ 1,690	$ 1,511	$ 322
General and administrative	2,158	1,394	350
Total	$ 3,848	$ 2,905	$ 672

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,		
	2015	2014	2013
Expected Volatility	68.5%-85.3%	86.2%-103.6%	97.1%
Risk-free interest rate	1.56%-1.94%	1.75%-2.00%	0.59%-1.83%
Expected term (in years)	5.50 - 6.08	6.08	6.25
Expected dividend yield	0%	0%	0%

At December 31, 2015, we had approximately $8.3 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. Our stock-based compensation expense for stock options has increased primarily based upon headcount growth and the related number of stock option awards granted to new and existing employees.

Following the closing of our IPO, the fair value of our common stock is determined based on the quoted market price of our common stock on the NASDAQ Global Market. Prior to the closing of our IPO, we utilized significant estimates and assumptions in determining the fair value of our common stock for periods. 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 IPO or sale of our company.

For periods prior to the closing of our IPO, 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. 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, 2015 and December 31, 2014

	Years Ended December 31,		Increase
(in thousands)	**2015**	**2014**	**(Decrease)**
Grant revenue	$ 670	$ 308	$ 362
Operating expenses:			
Research and development	28,049	23,727	4,322
General and administrative	13,987	9,747	4,240
Total operating expenses	42,036	33,474	8,562
Loss from operations	(41,366)	(33,166)	(8,200)
Other expense:			
Other expense, net	—	(1,160)	1,160
Interest expense, net	(1,117)	(970)	(147)
Other expense	(1,117)	(2,130)	1,013
Net loss	$ (42,483)	$ (35,296)	$ (7,187)

Grant revenue

Grant revenue increased by $0.4 million for the year ended December 31, 2015 to $0.7 million from $0.3 million for the year ended December 31, 2014. The increase was due to a full year of activities performed related to a $1.2 million grant entered into with the Gates Foundation in September 2014.

Research and development expenses

Research and development ("R&D") expenses increased approximately $4.3 million to $28.0 million for the year ended December 31, 2015 from $23.7 million for the same period ended December 31, 2014. This net increase was attributable to increases of $2.1 million in R&D personnel costs, approximately $1.8 million in lab-related and facilities costs and other general increases to support research activities offset by a $1.0 million decrease in clinical costs and licensing payments. R&D headcount has increased by more than 55% to support the clinical and manufacturing activities related to our Phase 2 trials, along with hiring to support our oncology and other research programs. The decline in both clinical costs and licensing payments related to the relative timing of major clinical activities and milestones in 2015 versus 2014.

On a program basis, GEN-003 costs increased by $0.4 million largely due to (i) the ongoing Phase 2 dose optimization that began in the second half of 2014 (ii) costs incurred to drive improvements in the manufacturing process for GEN-003 to enable production at commercial scale, and (iii) costs related to the initiation of patient screening for a 135-subject Phase 2b study in the fourth quarter of 2015. Pre-clinical R&D increased by $5.4 million as we accelerated our investment in immuno-oncology research and collaborations and increased spending on our other product candidates and the development of the

ATLAS technology platform. These increases were offset by a $1.5 million cost decrease in GEN-004 due to our fourth quarter decision to suspend investment in this program.

General and administrative expenses

General and administrative expense increased $4.2 million to $14.0 million for the twelve months ended December 31, 2015 from $9.7 million for the twelve months ended December 31, 2014. The increase was due largely to additional personnel costs of $2.3 million attributable to higher headcount, increases in depreciation costs of approximately $0.4 million due to capital additions and expansion of our offices, and a $0.4 million increase in consulting and professional services mainly due to the recruitment and hiring activities that occurred during 2015. The remaining $1.1 million increase is generally attributable to higher public company overhead costs.

Other expense, net

Other expense decreased $1.2 million to zero for the year ended December 31, 2015. The decrease was due to a non-recurring adjustment recorded in the first quarter ended March 31, 2014 to the fair value of warrants to purchase preferred stock as a result of an increase in the fair value of the underlying stock both before and on the date of the completion of our IPO on February 10, 2014. Additionally, in the fourth quarter end December 31, 2014, we incurred a $0.4 million loss on our debt extinguishment of a term note.

Interest expense, net

Interest expense, net increased $0.1 million to $1.1 million for the year ended December 31, 2015 from $1.0 million for the same period ended December 31, 2014. The increase was due primarily to higher average principal balances on our outstanding debt for the year to date period in 2015 as compared to the same period in 2014 offset by higher levels of interest income on our investment portfolio.

Comparison of the Years Ended December 31, 2014 and December 31, 2013

	Years Ended December 31,		Increase
(in thousands)	**2014**	**2013**	**(Decrease)**
Grant revenue	$ 308	$ 731	$ (423)
Operating expenses:			
Research and development	23,727	15,695	8,032
General and administrative	9,747	4,961	4,786
Total operating expenses	33,474	20,656	12,818
Loss from operations	(33,166)	(19,925)	(13,241)
Other expense, net			
Other expense, net	(1,160)	(422)	(738)
Interest expense, net	(970)	(459)	(511)
Other expense	(2,130)	(881)	(1,249)
Net loss	$ (35,296)	$ (20,806)	$ (14,490)

Grant revenue

Grant revenue decreased $0.4 million to $0.3 million for the year ended December 31, 2014 from $0.7 million for the year ended December 31, 2013. The decrease was due to the completion of a grant to fund research for our pneumococcus program during 2013. In September 2014, we received $1.2 million from a grant entered into with the Gates Foundation. We recognized $0.3 million in revenue under the agreement in the fourth quarter of 2014.

Research and development expenses

R&D expense increased $8.0 million to $23.7 million for the year ended December 31, 2014 from $15.7 million for the year ended December 31, 2013. The increase was attributable to: an increase of $2.4 million in R&D personnel costs, including $1.2 million in stock-based compensation; an increase of $0.4 million in licensing milestones related to the start of

GEN-003 and GEN-004 Phase 2 clinical studies; an increase of $2.8 million in GEN-003 external costs, reflecting increased manufacturing costs and clinical trial costs; and an increase of $2.4 million in GEN-004 external costs, reflecting manufacturing costs and clinical trial costs.

General and administrative expenses

G&A expense increased $4.7 million to $9.7 million for the year ended December 31, 2014 from $5.0 million for the year ended December 31, 2013. The increase was primarily due to additional personnel costs in 2014 of $2.0 million, including $1.0 million in increased stock-based compensation due to the vesting of certain performance-based common stock options; $1.1 million in increased audit, legal and consulting expenses; and $0.7 million in public company overhead costs.

Other expense, net

Other expenses increased $0.8 million to $1.2 million for the year ended December 31, 2014 from $0.4 million for the year ended December 31, 2013. The increase was due to an increase in the fair value of warrants to purchase preferred stock as a result of an increase in the fair value of the underlying stock both before and on the date of the completion of our IPO on February 10, 2014. Additionally, an increase of $0.2 million related to the loss on debt extinguishment of a term note.

Interest expense, net

Interest expense, net increased $0.5 million to $1.0 million for the year ended December 31, 2014 from $0.5 million for the year ended December 31, 2013. The increase was due primarily to higher average principal balances related to our term loan in 2014 as compared to 2013.

Liquidity and Capital Resources

Overview

Since our inception through December 31, 2015, we have received an aggregate of $278.8 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At December 31, 2015, our cash, cash equivalents and investments were $106.4 million, comprised of $17.2 million in cash and cash equivalents and $89.2 million of investments.

In February 2014, we completed an IPO of 5.5 million 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.

In March 2015, we completed an underwritten public offering of 6.3 million shares of our common stock at a public offering price of $8.25 per share for an aggregate offering price of $51.7 million. In August 2015, we completed another underwritten public offering of 3.9 million shares of our common stock at a public offering price of $13.00 per share for an aggregate offering price of $50.1 million. We received net proceeds from these offerings of approximately $95.7 million, after deducting approximately $6.1 million in underwriting discounts and commissions, excluding offering costs payable by us.

Debt Financings

On November 20, 2014 (the "Closing Date"), we entered into a loan and security agreement (the “Loan Agreement”) with Hercules Technology Growth Capital, Inc. (“Hercules”) which provided up to $27.0 million in debt financing in three separate tranches (“2014 Term Loan”). The first tranche of $17.0 million was available through June 30, 2015, of which $12.0 million was drawn down at loan inception for which approximately $9.8 million of the proceeds were used to repay the previously existing $10.0 million loan agreement (the "2013 Term Loan"). We recorded a $435 thousand loss on extinguishment of debt in other expense on the Statements of Operations related to deferred debt charges, the unamortized portion of the original issue discount related to the 2013 Term Loan and other fees associated with extinguishing the debt. The option to draw down the remaining $5.0 million under the first tranche expired unused on June 30, 2015. The second tranche of $5.0 million was subject to certain eligibility requirements which were achieved as of June 30, 2015 and we had the option to draw down the second tranche on or prior to December 15, 2015. The second tranche expired unused on December 15, 2015 The third tranche of $5.0 million was not eligible to draw as we did not achieve positive results from its Phase 2a human challenge study of GEN-004.

In December 2015, we entered into an amendment to the Loan Agreement (the "First Amendment") with Hercules. The First Amendment required us to draw an additional $5.0 million and permits us to draw two additional $5.0 million tranches. One $5.0 million tranche is immediately available to draw through December 15, 2016 and a second $5.0 million tranche becomes available through December 15, 2016, subject to us demonstrating sufficient evidence of continued clinical progression of our GEN-003 product and making favorable progress in applying our proprietary technology platform toward the development of novel immunotherapies with application in oncology. At December 31, 2015, $17.0 million was outstanding under the amended 2014 Term Loan.

During the amendment negotiations, but after the third quarter Form 10-Q was filed, we identified three separate covenant violations that resulted in an event of default as of September 30, 2015. The violated covenants related to certain investments the Company held as well as certain financial reporting obligations. Pursuant to the 2014 Term Loan, upon an event of default, Hercules can accelerate the repayment of all amounts due under the 2014 Term Loan at their discretion. Hercules did not make a repayment demand and the First Amendment included a permanent waiver of these covenant violations subject only to certain requirements that are within our control. The First Amendment also modified the Loan Agreement for the specific instances in which these violations arose, including redefining permitted investments to be in line with our approved investment policies.

The 2014 Term Loan had an original maturity of July 1, 2018. The eligibility requirements for the second tranche also contained an election for us to extend the maturity date to January 1, 2019. During the second quarter of 2015, we elected to extend the maturity date of the 2014 Term Loan. The maturity date of January 1, 2019 remained unchanged by the First Amendment.

Each advance accrues interest at a floating rate per annum equal to the greater of (i) 7.25% or (ii) the sum of 7.25% plus the prime rate minus 5.0%. The 2014 Term Loan provided for interest-only payments until December 31, 2015, which was extended by us for a six-month period as the eligibility requirements for the second tranche were met during the second quarter of 2015. The First Amendment subsequently extended the interest only period through June 30, 2017. Thereafter, beginning July 1, 2017, principal and interest payments will be made monthly for 18 months with a payoff schedule based upon a 30-month amortization schedule, the original amortization term of the 2014 Term Loan. The remaining unpaid principal is due at January 1, 2019.

The 2014 Term Loan may be prepaid in whole or in part upon seven business days' prior written notice to Hercules. Prepayments will be subject to a charge of 3.0% if an advance is prepaid within 12 months following the Closing Date, 2.0%, if an advance is prepaid between 12 and 24 months following the Closing Date, and 1.0% thereafter. Amounts outstanding at the time of an event of default shall be payable on demand and shall accrue interest at an additional rate of 5.0% per annum on any outstanding amounts past due. We also are obligated to pay Hercules an end of term charge of 4.95% of the balance drawn when the advances are repaid.

In connection with the 2014 Term Loan, we issued a common stock warrant to Hercules on November 20, 2014. The warrant is exercisable for 73,725 shares of our common stock (equal to $607,500 divided by the exercise price of $8.24).

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 R&D services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

We believe that our cash, cash equivalents and investment securities at December 31, 2015 are sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2017. Through this timeframe, we expect to have results from multiple Phase 2 GEN-003 studies, including the twelve-month data from our ongoing dose optimization clinical trial, data from a Phase 2b study designed to confirm the efficacy of GEN-003 manufactured at commercial scale, and data from a study to investigate the potential benefits of using GEN-003 in combination with oral antiviral medicines. In the second half of 2016, we also expect to have conducted our FDA end of Phase 2 meeting for GEN-003 for genital herpes to enable the initiation of a Phase 3 program in the second half of 2017. We have suspended the development of GEN-004 from our near-term plans and will focus our resources on the ongoing Phase 2 program for GEN-003 and on maximizing the potential of our preclinical pipeline and our ATLAS technology for T cell target discovery. 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 and planned clinical trials for GEN-003;
- the progress, timing and costs of manufacturing GEN-003 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 and other product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- the receipt of marketing approval, revenue received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, grants, 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 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 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 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, 2015 and 2014 (in thousands):

	Years ended December 31,	
	2015	**2014**
Net cash used in operating activities	$ (38,356)	$ (27,604)
Net cash used in investing activities	(64,937)	(28,573)
Net cash provided by financing activities	100,494	64,027
Net increase in cash and cash equivalents	$ (2,799)	$ 7,850

Operating Activities

Net cash used in operations increased $10.8 million to $38.4 million for the year ended December 31, 2015 from $27.6 million for the year ended December 31, 2014. The increase was due primarily to increases in (i) the net loss of approximately $7.2 million, (ii) accounts payable and accrued expenses of $2.0 million, and (iii) stock based compensation of $0.9 million, offset by decreases in deferred revenue of $1.6 million and fair value of warrant liability of $0.7 million, along with other changes in our working capital accounts.

Investing Activities

Net cash used in investing activities increased $36.4 million to $64.9 million for the year ended December 31, 2015 from $28.6 million for the year ended December 31, 2014. The increase was due largely to a net $35.1 million increase in investments and an increase in cash used to purchase property and equipment of $1.3 million.

Financing Activities

Net cash provided by financing activities increased $36.5 million to $100.5 million for the year ended December 31, 2015 from $64.0 million for the year ended December 31, 2014. The increase was due largely to $35.2 million in higher net proceeds from two follow-on public offerings in 2015 compared to the proceeds from IPO in 2014, $3.4 million of additional borrowing proceeds primarily related to the First Amendment, both offset by a decrease of $2.2 million in proceeds from other common stock issuances that occurred in 2014.

The following table summarizes our sources and uses of cash for the years ended December 31, 2014 and 2013 (in thousands):

	Years Ended December 31,	
	2014	2013
Net cash used in operating activities	$ (27,604)	$ (19,873)
Net cash used in investing activities	(28,573)	(389)
Net cash provided by financing activities	64,027	20,954
Net increase in cash and cash equivalents	$ 7,850	$ 692

Operating Activities

Net cash used in operations increased $7.7 million to $27.6 million for the year ended December 31, 2014 from $19.9 million for the year ended December 31, 2013. The increase was due primarily to an increase in the net loss of approximately $14.5 million, partially offset by an increase of $0.2 million on loss on debt extinguishment, an increase in stock based compensation of $2.2 million, an increase in change in fair value of warrant liability of $0.5 million, an increase in non-cash interest expense of $0.2 million, an increase in depreciation expense of $0.2 million and an increase of $3.4 million in our working capital accounts.

Investing Activities

Net cash used in investing activities increased $28.2 million to $28.6 million for the year ended December 31, 2014 from $0.4 million for the year ended December 31, 2013. The increase was due largely to the purchase of marketable securities of $27.1 million and an increase in cash used to purchase property and equipment of $1.1 million.

Financing Activities

Net cash provided by financing activities increased $43.0 million to $64.0 million for the year ended December 31, 2014 from $21.0 million for the year ended December 31, 2013. The increase was due largely to the net proceeds from our IPO in 2014 of $60.0 million, net proceeds from the issuance of long-term debt of $11.8 million, net proceeds from the issuance of common stock of $2.0 million, an increase in proceeds from the exercise of stock options and warrants of $0.6 million, and an increase in proceeds from the issuance of common stock under the Employee Stock Purchase Plan ("ESPP") of $0.1 million, which was partially offset by the issuance of preferred stock of $15.3 million in 2013, the issuance of long-term debt of $10.0 million in 2013, and an increase in repayments of long-term debt of $6.2 million, which was due to the debt refinancing in November 2014.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Net Operating Loss Carryforwards

At December 31, 2015, we had United States federal and state net operating loss carryforwards of approximately $143.8 million and $128.5 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2035. At December 31, 2015, we had federal and state R&D tax credit carryforwards of approximately $3.7 million and $2.4 million available, respectively, to reduce future tax liabilities which expire at various dates through 2035. 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, 2015, we recorded a 100% valuation allowance against our net operating loss and R&D 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, 2015 (in thousands):

	Total	Less Than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Long-term debt(1)	$ 17,842	$ —	$ 9,808	$ 8,034	$ —
Operating leases	1,610	1,379	231	—	—
	$ 19,452	$ 1,379	$ 10,039	$ 8,034	$ —

(1) As of December 31, 2015, we had a total of $17.0 million in long-term debt due consisting of amounts due under the 2014 Term Loan. We are obligated to pay an end of term charge of 4.95% of the balance drawn when the principal balance is repaid. We have included $0.8 million in this table for the end of term charge based upon the debt outstanding at December 31, 2015.

In February 2014, we entered into a supply agreement with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. ("Fujifilm") for the manufacture and supply of certain antigens for its GEN-003 clinical program. Under the agreement, we are obligated to pay Fujifilm manufacturing milestones, in addition to reimbursement of certain production related costs, as production occurs. Additionally, the agreement required the payment of a reservation fee, which will equal a percentage of the expected production fees, to reserve manufacturing slots in the production timeframe. There are no minimum purchase obligations and we may cancel the agreement at any point subject to certain cancellation charges that may be applicable based upon the cancellation date and the start of production along with the payment for services rendered through the date of cancellation. The Company has incurred expenses of $4.1 million under this agreement for the year ended December 31, 2015.

In October 2014, we entered a product development and clinical supply agreement with Baxter Pharmaceutical Solutions LLC ("Baxter"). The product development and clinical supply agreement provides the terms and conditions under which Baxter will formulate, fill, inspect, package, label and test our lead product, GEN-003 for clinical supply. We are obligated to pay Baxter for each batch of GEN-003 manufactured. Additionally, certain set-up fees and equipment purchased for the purposes of batch production will be invoiced separately by Baxter. We are also responsible for the payment of a monthly service fee for project management services for the duration of the arrangement. There are no minimum purchase obligations and we may cancel the agreement at any point subject to payment for services rendered through the date of cancellation. The Company has incurred expenses of $702 thousand under this agreement for the year ended December 31, 2015.

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 ("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 ("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 do not expect to make milestone payments in 2016 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. We notified Harvard of our partial termination of the license agreement with regard to the chlamydia antigens on December 8, 2014. Effective March 8, 2015, the license agreement with Harvard with regard to the chlamydia antigens was terminated and we no longer hold a license to two of the three in-licensed Harvard patent families, or to a chlamydia antigen covered by the remaining family. The remaining family covers certain aspects of the ATLAS platform, as well as one chlamydia antigen, and we continue to maintain exclusive rights to aspects of the ATLAS platform covered by this family.

License Agreement 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 do not expect to make milestone payments in 2016 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 ("Children's"), in respect of Children's rights in jointly-owned patent rights covering certain Streptococcus antigens, we agreed to pay Children's 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 Children's specified milestone payments for development and commercialization of such vaccines. We do not expect to make milestone payments in 2016 under this agreement. If we sublicense the jointly-owned patent rights, we will owe Children's 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 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

We are exposed to market risk related to changes in interest rates. As of December 31, 2015 and 2014, we had cash, cash, cash equivalents and investments of $106.4 million and $47.1 million, respectively, consisting primarily of money market

funds, U.S Treasury securities, and FDIC insured certificates of deposits. 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 that 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. Although 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, 2015 and December 31, 2014, 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 beginning on page F-1 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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 (the "Exchange Act") is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015 (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our 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. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as the process designed by, or under the supervision of, our Chief Executive Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles ("GAAP"), and includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures are being made only in accordance with the authorizations of management and directors; and

(3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2015.

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2015, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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 February 17, 2016 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	47	President and Chief Executive Officer; Director (Class III)
Seth Hetherington, M.D.	63	Chief Medical Officer
Jonathan Poole	41	Chief Financial Officer
Eric Hoffman, Ph.D.	46	Chief Business Officer
Jessica Baker Flechtner, Ph.D.	44	Senior Vice President of Research
Paul Giannasca, Ph.D.	52	Vice President, Biopharmaceutical Development & Production
Kenneth Bate	65	Director (Class I)
Kevin Bitterman, Ph.D.	39	Director (Class I)
Katrine Bosley	47	Director (Class II)
Michael Higgins	53	Director (Class II)
Stephen Hoffman, M.D., Ph.D.	61	Director (Class II)
George Siber, M.D.	71	Director (Class III)

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. ("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 operational 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. ("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 and 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 has served as the industry representative to the Vaccines and Related Blood Products Advisory Committee of the FDA and the National Vaccine Advisory Committee of the U.S. Department of Health and Human Services.

Jonathan Poole has served as our Chief Financial Officer since joining our Company in April 2014. Prior to joining our Company, Mr. Poole served as Senior Vice President of Finance for Pipeline and Technical Operation at Shire plc ("Shire") from June 2013 through March 2014, leading finance support for Shire's global business development, research and development and technical operations activities. Mr. Poole previously served as divisional Chief Financial Officer of Shire HGT, Shire's rare disease division, from May 2010 through June 2013 and held various positions of increasing responsibility in finance at Shire from 2006 through May 2010. He began his career in the United Kingdom in investment banking at UBS Warburg and ING Barings and also worked as an investment manager for Avanti Capital plc, a United Kingdom private equity

investment firm. Mr. Poole holds an M.B.A. from London Business School and a BSc in biological sciences from Durham University in the United Kingdom.

Eric Hoffman, Ph.D. has served as our Chief Business Officer since joining our Company in December 2014. Prior to joining our Company, Dr. Hoffman served as Vice President of Corporate and Business Development, and also oversaw Program Management and Commercial Operations, at Idenix Pharmaceuticals, Inc. ("Idenix") from January 2012 until its acquisition by Merck & Co. in August 2014. Dr. Hoffman also held a role overseeing Investor Relations and Corporate Communications while at Idenix from January 2011 to December 2011. Prior to Idenix, Dr. Hoffman spent nearly five years, from 2006 to 2011, at Biogen Idec in investor relations and business development roles and spent more than five years from 2001 to 2006 on Wall Street as an equity research analyst at J.P. Morgan, Schwab Soundview Capital Markets and Bear Stearns. Before starting on Wall Street in 2001, he was a post-doctoral research scientist in the Department of Immunobiology at King's College London School of Medicine at Guy's Hospital, studying T-cell development from 1999 to 2000. He has authored several book chapters and peer-reviewed articles, including in Cell, Immunity, and Genes & Development. Dr. Hoffman holds a Ph.D. in Immunobiology from Yale University and a B.S. in Biology from Trinity University.

Jessica Baker Flechtner, 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, Vice President of Research from January 2010 to February 2014 and Senior Director of Research from March 2007 to January 2010. 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 various 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. He also served as Project Leader of the Clostridium difficile program and R&D Franchise Head for Nosocomials at Acambis/Sanofi Pasteur. Also at Acambis, he was Senior Director, Bacterial Research from 2002 to 2004 and Director of Bacterial Immunology from 2000 to 2001. 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.

Kenneth Bate has served as a member of our board of directors since September 2014. Mr. Bate is currently a director of AVEO Pharmaceuticals, Catabasis Pharmaceuticals, Epizyme Inc and Vanda Pharmaceuticals. Mr. Bate previously served as President and Chief Executive Officer of Archemix Corp. and NitroMed Inc., Chief Financial Officer of Millennium Pharmaceuticals Inc. and Biogen Inc., and co-founded JSB Partners LLC, a banking and advisory services firm for biopharmaceutical and life sciences companies. He holds a M.B.A. from the Wharton School of the University of Pennsylvania and a B.A. from Williams College. We believe that Mr. Bate's experience as a chief executive officer of multiple biotechnology companies, as well as his experience as a director of other companies, 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. Dr. Bitterman serves as a partner at Polaris Partners ("Polaris"), where he has been employed since 2004 and where he focuses on investments in life sciences companies. Prior to joining Polaris, Dr. Bitterman completed his Ph.D. in Genetics at Harvard Medical School. Dr. Bitterman was the founding CEO at Visterra Inc., Editas Medicine Inc. and Morphic Rock Therapeutic Inc. In additional to representing Polaris as a director of our Company, he currently represents Polaris as a director of Editas Medicine Inc., InSeal Medical, Kala Pharmaceuticals, Morphic Rock Therapeutic Inc. Neuronetics, Inc., Visterra, Inc., TARIS Biomedical, and Vets First Choice. He received a Ph.D. in Genetics from Harvard Medical School and a B.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 the Chief Executive Officer of Editas Medicine Inc. ("Editas"), a position to which she was appointed in June 2014. Prior to Editas, Ms. Bosley was the Entrepreneur-in-Residence at The Broad Institute from September 2013 to May 2014. She served as Chief Executive Officer of Avila Therapeutics Inc. ("Avila"), from May 2009 to March, 2012, when Avila was acquired by Celgene Corporation. Before Avila, she was Vice President, Strategic Operations at Adnexus Therapeutics Inc. ("Adnexus"), a Bristol-Myers Squibb Company and was Vice President, Business Development at 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 Scholar Rock LLC. She also is a member of the BIO Governing Board for Emerging Companies. Ms. Bosley graduated from Cornell University with a B.A. 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.

Michael Higgins has served as a member of our board of directors since February 2015. In January 2015, Mr. Higgins joined Polaris Venture Partners as an Entrepreneur-in-Residence. Prior to joining Polaris Venture Partners, Mr. Higgins served as Chief Operating Officer and Chief Financial Officer at Ironwood Pharmaceuticals ("Ironwood") from 2003 through 2014, playing a key role in Ironwood's evolution from a privately-funded discovery organization through its initial public offering and the launch of its first commercial product. Under his leadership, the company was able to raise more than one billion dollars to help support the development of the business during that period. Prior to his work at Ironwood, from 1997 through 2003, Mr. Higgins worked at Genzyme Corporation ("Genzyme") in a variety of leadership roles including Vice President, Corporate Finance and Vice President, Business Development. While at Genzyme, he was involved with multiple businesses including the Cell Therapy, Gene Therapy, and Orphan Disease business units. Previously, Mr. Higgins served as Chief Financial Officer of Procept, Inc., from 1992 to 1997 and led the company through its initial public offering. Mr. Higgins currently serves as a director of Pulmatrix, Inc. and Voyager Therapeutics. Mr. Higgins began his pharmaceutical career as a sales representative for Schering-Plough Corporation in 1986. Mr. Higgins earned his B.S. from Cornell University and holds a M.B.A. from the Amos Tuck School of Business at Dartmouth College. We believe that Mr. Higgin's financial and business expertise, including his diversified background as an executive officer in public pharmaceutical companies, qualifies him to serve as a member of our board of directors.

Stephen 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 served as a managing director at Skyline Ventures, a venture capital firm, from May 2007 to February 2014. 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. ("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.

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 ("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. Since 2007, Dr. Siber has served on the boards of directors of several vaccine

companies, including Crucell, Selecta Biosciences, Vedantra Pharmaceuticals and Affinivax Inc., and as a consultant or scientific advisory board member of ClearPath Vaccines Company, of which he is currently the Chief Scientific Officer, PaxVax, Vaxess Technologies, Inc., the Bill & Melinda Gates Foundation, PATH, the Wellcome Trust, the European Commission (on vaccinations), the National Institutes of Health, or NIH, and the Korean FDA. Dr. Siber serves as a member of the Board of Trustees of the International Vaccine Institute. Dr. Siber holds an M.D. 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.

Board Composition and Election of Directors

Board Composition

Our board of directors is currently comprised of seven members. Our board of directors has determined that each of Mr. Bate, Dr. Bitterman, Ms. Bosley, Mr. Higgins 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 amended and restated certificate of incorporation and amended and restated by-laws provide that the authorized number of directors may be changed only by resolution of our board of directors. Our amended and restated certificate of incorporation and amended and restated by-laws 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 by-laws that, our board of directors are 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 are divided as follows:

- the class I directors are Mr. Bate and Dr. Bitterman, whose terms expire in 2018;
- the class II directors are Ms. Bosley, Mr. Higgins, and Dr. Hoffman, whose terms expire in 2016; and
- the class III directors are Mr. Clark and Dr. Siber, whose terms expire in 2017.

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 Securities and Exchange Act of 1934 (the "Exchange Act"), to file reports of ownership and changes in ownership of our securities with the Securities and Exchange Commission ("SEC"). To our knowledge, based solely on review of these filings and written representations from the certain reporting persons, we believe that during the year ended December 31, 2015, our officers, directors and beneficial owners of more than 10% of our common stock have filed the appropriate forms under Section 16(a) of the Exchange Act at the time of filing our Annual Report on Form 10-K.

Board Committees

Our board of directors has three standing committees: the audit committee, the compensation committee and the nominating and corporate governance committee. Our board of directors may establish other committees from time to time.

Audit Committee

Our audit committee is composed of Mr. Bate, Ms. Bosley, and Mr. Higgins, with Mr. Higgins 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 each of Mr. Bate, Ms. Bosley and Mr. Higgins is an "audit committee financial expert" within the meaning of the SEC regulations and applicable listing standards of NASDAQ. The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the qualifications, performance and independence of our independent registered public accounting firm;
- pre-approving audit and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the internal audit plan with the independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon the audit committee's review and discussions with management and the Company's independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by the rules of the SEC to be included in our annual proxy statement;
- viewing all related party transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing and discussing with management and our independent registered public accounting firm our earnings releases and scripts.

Compensation Committee

Our compensation committee is composed of Mr. Bate, Dr. Hoffman and Dr. Bitterman, with Mr. Bate serving as chairman of the committee. Our board of directors has determined that Mr. Bate, Dr. Hoffman and Dr. Bitterman are "independent" as defined under the applicable listing standards of NASDAQ. The compensation committee's responsibilities include:

- annually reviewing and approving corporate goals and objectives relevant to the compensation of our chief executive officer;
- evaluating the performance of our chief executive officer in light of such corporate goals and objectives and determining and approving the compensation of our chief executive officer;
- reviewing and approving the compensation of our other executive officers;
- appointing, compensating and overseeing the work of any compensation consultant, legal counsel or other advisor retained by the compensation committee;
- conducting the independence assessment outlined in NASDAQ rules with respect to any compensation consultant, legal counsel or other advisor retained by the compensation committee;
- annually reviewing and reassessing the adequacy of the committee charter in its compliance with the listing requirements of NASDAQ;

- reviewing and establishing our overall management compensation philosophy and policy;
- overseeing and administering our equity compensation and other compensatory plans;
- reviewing and approving our equity and incentive policies and procedures for the grant of equity-based awards and approving the grant of such equity-based awards;
- reviewing and making recommendations to the board of directors with respect to director compensation; and
- reviewing and discussing with management the compensation discussion and analysis to be included in our annual proxy statement or Annual Report on Form 10-K.

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. The nominating and corporate governance committee's responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- developing and recommending to the board of directors a set of corporate governance principles;
- articulating to each director what is expected, including reference to the corporate governance principles and directors' duties and responsibilities;
- reviewing and recommending to the board of directors practices and policies with respect to directors;
- reviewing and recommending to the board of directors the functions, duties and compositions of the committees of the board of directors;
- reviewing and assessing the adequacy of the committee charter and submitting any changes to the board of directors for approval;
- consider and report to the board of directors any questions of possible conflicts of interest of board of directors members;
- provide for new director orientation and continuing education for existing directors on a periodic basis;
- performing an evaluation of the performance of the committee; and
- overseeing the evaluation of the board of directors and management.

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 ir.genocea.com. In addition, we have posted on our website all disclosures that are required by law, the rules of the SEC 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 Jonathan Poole, our Chief Financial Officer. 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 our 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 one 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 2015, on the recommendation of our compensation committee, our board of directors approved a base salary of $432,984 for Mr. Clark, $380,542 for Dr. Hetherington, and $329,600 for Mr. Poole, representing increases of 8.4%, 3.0% and 3.0%, respectively, from the base salary for each such executive in 2014.

Annual Cash Bonuses. Our annual cash bonus program promotes and rewards the achievement of key strategic business goals and individual performance goals. For fiscal 2015, the target annual bonus as a percentage of base salary was 50% for Mr. Clark and 35% for each of Dr. Hetherington and Mr. Poole. 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 Dr. Hetherington and Mr. Poole, 50% of their respective annual bonuses 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 2015, our compensation committee established the corporate performance goals for fiscal 2015, with each goal having a designated weighting. These corporate performance goals included key strategic and financial goals related to business development collaborations and financings, cash management, the development and commencement of certain clinical and commercial programs, and other strategic objectives related to our clinical pipeline. Also at the beginning of fiscal 2015, our chief executive officer, working with Dr. Hetherington and Mr. Poole, established their respective individual performance goals and their weightings. These goals included, to the extent applicable to the executive, 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 January 2016, our compensation committee met to review and consider the level of corporate and individual performance goals that were 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 fiscal 2015. The compensation committee reviewed and evaluated our performance against the pre-established corporate performance goals for fiscal 2015, taking into consideration Mr. Clark's evaluation of our performance in 2015. With respect to the individual performance goals applicable to Dr. Hetherington and Mr. Poole, our compensation committee also considered Mr. Clark's determination that Dr. Hetherington and Mr. Poole had achieved 85% and 120%, respectively, of such individual's performance goals. After reviewing the achievement of the fiscal year 2015 corporate performance goals, 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, an 80% level of achievement of corporate performance goals, the level of achievement of individual goals described above, and a fiscal year 2015 cash bonus of $173,200 for Mr. Clark, $109,881 for Dr. Hetherington, and $115,360 for Mr. Poole.

Equity Awards. Our named executive officers are eligible to participate in the Genocea Biosciences, Inc. 2014 Equity Incentive Plan ("2014 Equity Plan"). Our 2014 Equity Plan was adopted by our board of directors in connection with our initial public offering ("IPO"). Mr. Clark and Dr. Hetherington have also each been granted equity awards under the Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan ("2007 Equity Plan"). Following the adoption of the 2014 Equity Plan and our IPO, all equity-based awards have been and will be granted under our 2014 Equity Plan and no future awards will be made under the 2007 Equity Plan.

In February 2015, Mr. Clark, Dr. Hetherington, and Mr. Poole each received awards of time-vesting stock options to purchase 138,000, 51,000, and 95,000 shares, respectively, of our common stock under the 2014 Equity Plan. These stock options vest in equal monthly installments over the 48 months following the date of grant, generally subject to each executive's 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. We have in the past also granted stock options that are subject to performance-based vesting conditions, thereby incentivizing the achievement of key strategic goals. Pursuant to employment letter agreements with our named executive officers, their 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 all of our salaried employees.

Employment Letter Agreements. We have entered into an 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. See "—Employment Letter Agreements" below for additional details about these agreements.

Summary Compensation Table

The following table sets forth information about compensation awarded or paid to our named executive officers for fiscal years 2015 and 2014, in the case of all of our named executive officers, and 2013, in the case of Mr. Clark and Dr. Hetherington.

Name and principal position	Year	Salary ($)(2)	Bonus ($)(3)	Option awards ($)(4)	Nonequity incentive plan compensation ($)(5)	All other compensation ($)(6)		Total ($)
William Clark,	2015	427,392		1,253,040	173,200	4,162	1,901,094,000	1,857,794
President and Chief Executive Officer	2014	393,561	—	—	179,744	—	573,305,000	573,305
	2013	334,280	—	413,842	107,320	—	855,442,000	855,442
Seth Hetherington, M.D.,	2015	378,695	—	463,080	109,881	7,950	982,915,000	959,606
Chief Medical Officer	2014	366,074	—	—	119,612	—	485,686,000	485,686
	2013	331,459	—	176,616	88,989	—	597,064,000	597,064
Jonathan Poole,	2015	328,000		862,600	115,360	7,295	1,313,255,000	1,313,255
Chief Financial Officer (1)	2014	235,151	50,000	2,904,505	78,540	—	3,218,196,000	3,218,196

(1) Mr. Poole commenced employment with the Company in April 2014. As a result, no amounts with respect to fiscal year 2013 have been included for Mr. Poole in the table above. Amounts in the table for fiscal year 2014 represent Mr. Poole's compensation for the period he was employed by us.

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

(3) Amount reflects the signing bonus paid to Mr. Poole in connection with the commencement of his employment with us.

(4) Amounts shown reflect the aggregate grant date fair value of time-vesting stock options awarded in the respective fiscal year computed in accordance with Financial Accounting Standards Board Accounting Standards Codification ("FASB ASC"), Topic 718, *Compensation — Stock Compensation* (″ ASC 718"), and exclude the value of estimated forfeitures. Assumptions used in the calculation of these amounts are included in Note 10 to our consolidated 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 was based on the probable outcome of the performance conditions associated with the stock option as of the date of grant. No amount has been included in the table above for this stock option since the performance conditions were not considered probable to occur on the date of grant in 2013. The aggregate grant date fair value of this performance-vesting stock option if the highest levels of performance conditions were achieved is $252,981. This performance-vesting stock option awarded to Mr. Clark in 2013 vested in full upon the completion of our IPO on February 10, 2014.

(5) Amounts shown reflect the annual cash bonuses paid, or to be paid, in the case of fiscal year 2015, to the named executive officers that was earned based on the achievement of Company performance goals, in the case of Mr. Clark, and Company and individual performance goals, in the case of Dr. Hetherington and Mr. Poole.

(6) Amounts shown reflect employer matching contributions under our 401(k) plan during fiscal year 2015.

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, 2015. 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 ($)(5)	Option Expiration Date(6)
William Clark	24,716	(1)	—		—		$ 2.86	12/17/2020
	—		—		39,807	(2)	$ 2.86	12/17/2020
	340,568	(1)	—		—		$ 2.02	2/17/2021
	97,418	(3)	36,184	(3)	—		$ 3.45	7/25/2023
	81,670	(2)	—		—		$ 3.45	7/25/2023
	28,750	(1)	109,250	(1)	—		$ 9.08	2/26/2025
Seth Hetherington, M.D.	66,955	(4)	—		—		$ 2.02	2/17/2021
	11,562	(2)	—		—		$ 2.02	2/17/2021
	41,575	(3)	15,442	(3)	—		$ 3.45	7/25/2023
	10,625	(1)	40,375	(1)	—		$ 9.08	2/26/2025
Jonathan Poole	83,636	(4)	117,090	(4)	—		$ 17.89	4/7/2024
	19,791	(1)	75,209	(1)	—		$ 9.08	2/26/2025

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

(2) 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, and in the case of Dr. Hetherington, upon the company's achievement of a milestone related to the initiation of a clinical trial, 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 upon the completion of our IPO on February 10, 2014. The performance-based stock option awarded to Mr. Clark on December 17, 2010 remains

unvested as the performance condition has not yet been achieved. The performance-based stock option awarded to Dr. Hetherington vested in full in fiscal year 2012.

(3) 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.

(4) 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 (approximately 12 months from the grant date) and thereafter vest in equal monthly installments over the following 36 months, generally subject to the executive's continued employment.

(5) 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. For stock options granted following our IPO, the exercise price is the closing price of a share of our common stock on the date of grant of the stock option.

(6) All stock options have a 10-year term measured from the date of grant.

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. In fiscal year 2015, we commenced making an employer match of up to 50% for the first 6% of employee contributions. Employer matching contributions vest over a four-year period starting with the employee's date of hire. Mr. Clark and Dr. Hetherington have met the vesting requirements based upon the amount of time they have been employed by us, while Mr. Poole is partially vested in the matching contributions based upon his April 2014 date of hire.

Employment Letter Agreements

We have entered into employment letter agreements with each of our named executive officers. On January 16, 2014, we entered into an amended and restated employment letter agreement with each of Mr. Clark and Dr. Hetherington, each of which became effective prior to the completion of our IPO. We also entered into an employment letter agreement with Mr. Poole, who began serving as our Chief Financial Officer on April 7, 2014. Each employment letter agreement provides for an initial base salary, which has subsequently been increased, as well as a discretionary performance-based bonus, with a target, as a percentage of their base salary, of 50% for Mr. Clark and 35% for each of Dr. Hetherington and Mr. Poole. In addition, pursuant to Mr. Poole's employment letter agreement, he was entitled a cash signing bonus of $50,000, payable within 30 days of the commencement of his employment, and a stock option to purchase 200,726 shares of our common stock (which was equal to 1% of the total number of shares of our common stock outstanding on a fully diluted basis on the date of grant) under our 2014 Equity Plan. Each agreement also provides for severance payments and benefits upon certain terminations of the executive's employment 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 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, or 15 months, in the case of Dr. Hetherington and Mr. Poole, 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 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, or nine months, in the case of Dr. Hetherington and Mr. Poole, 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 (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 on an after-tax basis.

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 employment and not to solicit our employees or independent contractors for a period of 36 months following the termination of his employment. Each executive has also agreed to covenants relating to the use and disclosure of confidential information and the assignment of inventions.

2015 Director Compensation

The following table sets forth information concerning the compensation earned by our non-employee directors during 2015. All of our non-employee directors were compensated for service on our board of directors under our non-employee director compensation policy. 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 2015 is included in the "Summary Compensation Table" above.

D **irector Compensation**

Name	Fees earned or paid in cash ($)(1)	Option awards ($)(2)(3)	Total ($)
Kenneth Bate	53,334	45,781	99,115
Kevin Bitterman, Ph.D.	43,500	45,781	89,281
Katrine Bosley	74,500	45,781	120,281
Michael Higgins	42,014	91,563	133,577
Stephen Hoffman, M.D., Ph.D.	41,083	45,781	86,864
George Siber, M.D.	138,681	45,781	184,462

(1) Amounts represent annual director fees and, in the case of Dr. Siber, include consulting fees, for services rendered. Consulting fees paid to Dr. Siber were paid in equal bi-monthly installments and all other fees were paid quarterly in arrears.

(2) As of December 31, 2015, our directors held the following aggregate number of options to purchase shares of our common stock: Mr. Bate held options to purchase 15,126 shares of our common stock, Dr. Bitterman held options to purchase 5,042 shares of our common stock, Ms. Bosley held options to purchase 42,008 shares of our common stock, Mr. Higgins held options to purchase 10,084 shares of our common stock, Dr. Hoffman held options to purchase 5,042 shares of our common stock, and Dr. Siber held options to purchase 138,708 shares of our common stock. As of December 31, 2015, Ms. Bosley held 9,717 restricted shares, which she received upon the exercise of the option granted to her on February 4, 2013.

(3) Amount in the table represent the aggregate grant date fair value of the option to purchase 10,084 shares of our common stock granted to Mr. Higgins in February 2015, upon his election to our board of directors, pursuant to our non-employee director compensation policy. This stock option award will vest in equal installments on each of the first three anniversaries of the date of grant. All other directors received grants of time-based stock options to purchase 5,042 shares of our common stock that vest in full on the one-year anniversary of the respective dates of grant. These grant date fair value amounts were computed in accordance with ASC 718 and exclude the value of estimated forfeitures. Assumptions used in the calculation of these amounts are included in Note 10 to our financial statements included elsewhere in this Annual Report on Form 10-K.

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 were paid cash compensation from and after the completion of our IPO until December 31, 2015, as set forth in the following table:

	Annual Retainer
Board of Directors:	
All non-employee members	$ 35,000
Additional retainer for chair (1)	$ 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

(1) Effective January 1, 2016, the non-employee director compensation policy was amended to increase the annual additional retainer for the non-employee chair of the board of directors from $25,000 to $40,000. Our compensation committee recommended, and our board of directors approved, this increase after reviewing market data for board chairs of comparable companies.

Under our non-employee director compensation policy in effect from the completion of our IPO through December 31, 2015, each individual who was not an employee and who was initially appointed or elected to our board of directors was granted 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 vested annually in equal installments over a three-year period. In addition, each continuing non-employee director was eligible to receive, on the first business day following January 1st of each calendar year, an annual grant of stock options to purchase 5,042 shares of our common stock under our 2014 Equity Plan, which vests in full on the first anniversary of the grant date. The stock options were 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.

In December 2015, after reviewing market data for non-employee board compensation of comparable companies, our compensation committee recommended, and our board of directors approved, an amendment to the non-employee director compensation policy effective January 1, 2016. The amended policy provides that each non-employee director initially appointed or elected to our board of directors will be eligible to be granted stock options to purchase 25,000 shares of our common stock under our 2014 Equity Plan at the time of his or her initial appointment or election which vest annually in equal installments over the three-year period. The policy also provides that each non-employee director will be eligible to be granted stock options to purchase 15,000 shares of our common stock, which vest in full on the first anniversary of the grant date, with such grants to be made on the date of the Company's annual meeting of stockholders for the relevant year or as soon thereafter as is reasonably practicable, subject to the non-employee director remaining in service on such date. The annual awards of stock options for 2016 will be made at the 2016 annual meeting of stockholders and not on January 4, 2016.

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, June 5, 2013 and June 15, 2015, providing for a consulting fee of $5,000 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 of our Company, 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.

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, 2017.

Compensation Committee Report

The compensation committee has reviewed and discussed the Compensation Discussion and Analysis with management and recommends to the board of directors that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K for filing with the Securities and Exchange Commission.

In accordance with the rules of the Securities and Exchange Commission, this report is not to be deemed "soliciting material", or deemed to be "filed" with the Securities and Exchange Commission or subject to the Securities and Exchange Commission's Regulation 14A or Regulation 14C, other than as provided in Item 407 of Regulation S-K, or to the liabilities of Section 18 of the Exchange Act, except to the extent the Company specifically requests that the information be treated as soliciting material or specifically incorporates it by reference in documents otherwise filed.

February 17, 2016

Members of the Compensation Committee:

Kenneth Bate, Chair
Kevin Bitterman
Stephen Hoffman

The Compensation Committee Report shall not be deemed incorporated by reference by any general statement incorporating by reference this Annual Report on Form 10-K into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates this information by reference, and shall not otherwise be deemed filed under such Acts.

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 Mr. Bate, Dr. Hoffman and Dr. Bitterman, with Mr. Bate 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

The following table contains information about our equity compensation plans as of December 31, 2015.

Plan Category	Column A Number of securities to be issued upon exercise of outstanding stock options, warrants and rights	Column B Weighted-average exercise price of outstanding options, warrants and rights	Column C (2) 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)	2,723,311	$ 7.60	666,948
Equity compensation plans not approved by security holders	—	—	—
Total	2,723,311	$ 7.60	666,948

(1) Includes information regarding our 2007 Equity Plan, 2014 Equity Plan, and 2014 Employee Stock Purchase Plan.

(2) Includes 522,706 shares of our Common Stock available for issuance under our 2014 Equity Plan and 144,242 shares of our Common Stock available for issuance under our 2014 Employee Stock Purchase Plan.

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 February 1, 2016, 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 28,151,941 shares of our common stock outstanding as of February 1, 2016. The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, 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 February 1, 2016 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:		
FMR LLC, and related funds(1)		
245 Summer Street		
Boston, MA 02210	4,217,255	15.0%
Franklin Advisers, Inc.(2)		
One Franklin Parkway		
San Mateo, CA 94403	2,886,600	10.3%
S.R. One, Limited(3)		
c/o Corporation Service Company		
2595 Interstate Drive, Suite 103		
Harrisburg, PA 17110	2,121,668	7.5%
Skyline Venture Partners V, L.P.(4)		
525 University Avenue, Suite 610		
Palo Alto, CA 94301	1,992,415	7.1%
Polaris Venture Partners, and related funds(5)		
650 East Kendall Street, 4th Floor		
Cambridge, MA 02142	1,968,606	7.0%
Directors and Named Executive Officers:		
William Clark(6)	637,501	2.3%
Seth Hetherington, M.D.(7)	158,466	*
Jonathan Poole(8)	126,122	*
Kenneth Bate (9)	8,403	*
Katrine Bosley(10)	50,694	*
Kevin Bitterman, Ph.D.(11)	1,973,648	7.0%
Michael Higgins(12)	3,361	*
Stephen Hoffman, M.D., Ph.D.(13)	1,997,457	7.1%
George Siber, M.D.(14)	115,569	*
All executive officers and directors as a group (12 persons)(15)	5,274,995	18.7%

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

(1) Consists of 4,217,255 shares of common stock held by FMR LLC. Abigail Johnson, the Vice Chairman, the Chief Executive Officer, and the President of FMR LLC, has sole power to dispose of the 4,217,255 shares owned by FMR LLC. Members of the family of Johnson Family, including Abigail Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. For information regarding FMR LLC and its affiliates, we have relied on the Schedule 13G filed by FMR LLC with the SEC on February 12, 2016.

(2) Consists of 2,886,600 shares of common stock beneficially owned by one or more open- or closed-end investment companies or other managed accounts that are investment management clients of investment managers that are direct and indirect subsidiaries (each, an "Investment Management Subsidiary" and, collectively, the "Investment Management Subsidiaries") of Franklin Resources Inc. ("FRI"), including Franklin Advisers, Inc. Investment management contracts grant to the Investment Management Subsidiaries investment and/or voting power over the securities owned by such investment management clients. Franklin Advisers, Inc. has sole voting power over 2,886,600 shares of common stock. Franklin Biotechnology Discovery Fund, a sub-fund of Franklin Templeton Investment Funds, a Luxembourg registered SICAV has an interest in 1,796,800 shares of common stock. Charles B. Johnson and Rupert H. Johnson, Jr. (the "Principal Shareholders") each own in excess of 10% of the outstanding common stock of FRI and are the principal shareholders of FRI. FRI, the Principal Shareholders and each of the Investment Management Subsidiaries disclaim any pecuniary interest or beneficial ownership in any of these shares. For information regarding Franklin Advisers, Inc. and FRI, we have relied on the Schedule 13G/A filed by Franklin Advisers, Inc. with the SEC on February 10, 2016.

(3) Consists of 2,121,668 shares of common stock held by S.R. One, Limited, an indirect, wholly-owned subsidiary of GlaxoSmithKline plc.

(4) Consists of 1,992,415 shares of common stock held by Skyline Venture Partners V, L.P. ("Skyline"). The general partner of Skyline is Skyline Venture Management V, LLC. 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 except to the extent of his respective proportionate pecuniary interest therein. Stephen Hoffman has an assignee interest in Skyline. To the extent that he is deemed to share voting and investment powers with respect to the shares held by the Skyline Venture Funds, Dr. Hoffman disclaims beneficial ownership of all the shares held by the funds except to the extent of his proportionate pecuniary interest therein.

(5) Consists of (i) 1,899,578 shares of common stock held by Polaris Venture Partners V, L.P., (ii) 37,019 shares of common stock held by Polaris Venture Partners Entrepreneurs' Fund, L.P., (iii) 13,012 shares of common stock held by Polaris Venture Partners Founders' Fund V, L.P., and (iv) 18,997 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.

(6) Consists of 47,405 shares of common stock, 578,779 shares of common stock that can be acquired upon the exercise of outstanding options and 11,317 shares of common stock that can be acquired upon the exercise of options within 60 days of February 1, 2016.

(7) Consists of 21,000 shares of common stock, 132,967 shares of common stock that can be acquired upon the exercise of outstanding options and 4,499 shares of common stock that can be acquired upon the exercise of options within 60 days of February 1, 2016.

(8) Consists of 4,213 shares of common stock, 109,587 shares of common stock that can be acquired upon the exercise of outstanding options and 12,322 shares of common stock that can be acquired upon the exercise of options within 60 days of February 1, 2016.

(9) Consists of 3,361 shares of common stock that can be acquired upon the exercise of outstanding options and 5,042 shares of common stock that can be acquired upon the exercise of options within 60 days of February 1, 2016.

(10) Consists of 31,092 shares of common stock, 11,724 shares of common stock that can be acquired upon the exercise of outstanding options and 7,878 shares of common stock that can be acquired upon the exercise of options within 60 days of February 1, 2016.

(11) Consists of 1,968,606 shares of common stock held by Polaris Venture Partners or related funds. By virtue of the relationships described in footnote 5 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 5 above. Also consists of 5,042 shares of common stock that can be acquired upon the exercise of options within 60 days of February 1, 2016.

(12) Consists of 3,361 shares of common stock that can be acquired upon the exercise of options within 60 days of February 1, 2016.

(13) Consists of 1,992,415 shares of common stock held by Skyline or related funds. By virtue of the relationships described in footnote 4 above, Dr. Hoffman may be deemed to share beneficial ownership in the shares held by Skyline or related funds. Dr. Hoffman disclaims beneficial ownership of the shares referred to in footnote 4 above. Also consists of 5,042 shares of common stock that can be acquired upon the exercise of options within 60 days of February 1, 2016.

(14) Consists of 2,016 shares of common stock, 107,229 shares of common stock that can be acquired upon the exercise of outstanding options and 6,324 shares of common stock that can be acquired upon the exercise of options within 60 days of February 1, 2016.

(15) Consists of 4,080,324 shares of common stock, 1,116,602 shares of common stock that can be acquired upon the exercise of outstanding options, and 78,069 shares of common stock that can be acquired upon the exercise of options within 60 days of February 1, 2016.

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

The following is a description of transactions since January 2015, 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 Equity Offerings

In March 2015, we completed an underwritten public offering of 6.3 million shares of our common stock at a public offering price of $8.25 per share for an aggregate offering price of $51.7 million (the "March 2015 Offering"). In August 2015, we completed another underwritten public offering of 3.9 million shares of our common stock at a public offering price of $13.00 per share for an aggregate offering price of $50.1 million (the "August 2015 Offering"). The following table sets forth the number of shares of our common stock that were purchased by our 5% stockholders and their affiliates in these offerings:

	Number of Shares of Common Stock	
Investor	**March 2015 Offering**	**August 2015 Offering**
FMR LLC	730,000	550,000
S.R. One, Limited	300,000	150,000
Polaris Venture Partners	—	—
Franklin Advisers	850,000	175,000
Skyline Venture Partners	700,000	—

Indemnification Agreements

In connection with our IPO, 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, June 5, 2013 and June 15, 2015 and is in effect through June 17, 2017. 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 2012, Dr. Siber has been paid approximately $5 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

Pursuant to our related person transaction approval policy, if we want to enter into a transaction with a related person or an affiliate of a related person, our Chief Financial Officer will review the proposed transaction to determine, based on applicable NASDAQ and SEC 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 Chief Financial Officer 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 Mr. Bate, Dr. Bitterman, Ms. Bosley, Mr. Higgins 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	2015	2014
Audit Fees	$ 636,922	$ 559,117
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 636,922	$ 559,117

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 statements on Form S-1, Form S-3, and Form S-8.

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. 100% of audit fees were approved by the Audit Committee.

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

Consolidated Balance Sheets as of December 31, 2015 and 2014

Consolidated Statements of Operations for each of the three years in the period ended December 31, 2015

Consolidated Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2015

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for each of the three years in the period ended December 31, 2015

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2015

Notes to Consolidated 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 consolidated balance sheets of Genocea Biosciences, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2015. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Genocea Biosciences, Inc. at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 17, 2016

Genocea Biosciences, Inc.
Consolidated Balance Sheets
(In thousands, except per share data)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 17,259	$ 20,058
Investments, current portion	77,069	27,021
Prepaid expenses and other current assets	865	934
Total current assets	95,193	48,013
Property and equipment, net	4,083	1,956
Restricted cash	316	316
Investments, net of current portion	12,104	—
Other non-current assets	446	47
Total assets	$ 112,142	$ 50,332
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,757	$ 2,692
Accrued expenses and other current liabilities	3,975	2,593
Deferred revenue	235	555
Current portion of long-term debt	—	—
Other current liabilities	—	—
Total current liabilities	5,967	5,840
Non-current liabilities:		
Long-term debt	16,477	11,389
Deferred revenue, net of current portion	—	350
Other non-current liabilities	37	246
Total liabilities	22,481	17,825
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock	28	18
Authorized – 175,000 shares at December 31, 2015; Issued – 28,161 and 17,869 shares at December 31, 2015 and December 31, 2014, respectively; outstanding – 28,152 and 17,852 at December 31, 2015 and December 31, 2014, respectively		
Additional paid-in-capital	247,550	147,923
Accumulated other comprehensive loss	(7)	(7)
Accumulated deficit	(157,910)	(115,427)
Total stockholders' equity	89,661	32,507
Total liabilities and stockholders' equity	$ 112,142	$ 50,332

See accompanying notes to consolidated financial statements.

Genocea Biosciences, Inc.
Consolidated Statements of Operations
(In thousands, except per share data)

	Years Ended December 31,		
	2015	2014	2013
Grant revenue	$ 670	$ 308	$ 731
Operating expenses:			
Research and development	28,049	23,727	15,695
General and administrative	13,987	9,747	4,961
Total operating expenses	42,036	33,474	20,656
Loss from operations	(41,366)	(33,166)	(19,925)
Other expense:			
Change in fair value of warrants	—	(725)	(222)
Loss on debt extinguishment	—	(435)	(200)
Interest expense, net	(1,117)	(970)	(459)
Other expense	(1,117)	(2,130)	(881)
Net loss	$ (42,483)	$ (35,296)	$ (20,806)
Reconciliation of net loss to net loss applicable to common stockholders			
Net loss	$ (42,483)	$ (35,296)	$ (20,806)
Accretion of redeemable convertible preferred stock to redemption value	—	(180)	(1,605)
Net loss attributable to common stockholders	$ (42,483)	$ (35,476)	$ (22,411)
Net loss per share attributable to common stockholders-basic and diluted	$ (1.74)	$ (2.27)	$ (75.46)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	24,460	15,618	297

See accompanying notes to consolidated financial statements.

Genocea Biosciences, Inc.
Consolidated Statements of Comprehensive Loss
(In thousands, except per share data)

	Years Ended December 31,		
	2015	2014	2013
Net loss	$ (42,483)	$ (35,296)	$ (20,806)
Other comprehensive income (loss):			
Unrealized loss on available-for-sale securities	(7)	(7)	—
Comprehensive loss	$ (42,490)	$ (35,303)	$ (20,806)

See accompanying notes to consolidated financial statements.

Genocea Biosciences, Inc.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (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	Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
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	—	—	—	—	—	—
Accretion of dividends on redeemable convertible preferred stock	—	—	—	—	—	1,605	—	—	—	—	(682)	—	(923)	(1,605)
Exercise of stock options	—	—	—	—	—	—	—	—	7	—	9	—	—	9
Vesting of restricted stock	—	—	—	—	—	—	—	—	1	—	1	—	—	1
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	672	—	—	672
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)
Accretion of dividends on redeemable convertible preferred stock	—	—	—	—	—	180	—	—	—	—	(180)	—	—	(180)
Exercise of warrants for cash	—	—	51	33	—	—	—	—	—	—	—	—	—	—
Cashless exercise of warrants	—	—	317	98	—	—	—	—	54	—	—	—	—	—
Conversion of redeemable convertible preferred stock into common stock	(4,615)	(3,000)	(35,945)	(23,256)	(34,581)	(25,117)	(52,586)	(30,500)	11,466	11	81,763	—	—	81,774
Reclassification of warrants to additional paid-in capital	—	—	—	—	—	—	—	—	—	—	1,381	—	—	1,381
Issuance of common stock upon IPO, net of issuance costs of $2,403	—	—	—	—	—	—	—	—	5,500	6	58,971	—	—	58,977
Issuance of common Stock; ESPP purchase	—	—	—	—	—	—	—	—	16	—	93	—	—	93
Issuance of common Stock upon private placement offering, net of issuance costs of $36	—	—	—	—	—	—	—	—	223	—	1,964	—	—	1,964
Issuance of warrants, net of issuance costs of $6	—	—	—	—	—	—	—	—	—	—	334	—	—	334
Exercise of stock options	—	—	—	—	—	—	—	—	282	1	682	—	—	683
Vesting of restricted stock	—	—	—	—	—	—	—	—	8	—	10	—	—	10
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	2,905	—	—	2,905
Unrealized loss on investments	—	—	—	—	—	—	—	—	—	—	—	(7)	—	(7)

Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(35,296)	(35,296)
Balance at December 31, 2014	—	—	—	—	—	—	—	—	17,852	18	147,923	(7)	(115,427)	32,507
Issuance of common stock upon secondary public offering, net of issuance costs of $509	—	—	—	—	—	—	—	—	10,123	10	95,173	—	—	95,183
Issuance of common Stock; ESPP purchase	—	—	—	—	—	—	—	—	41	—	213	—	—	213
Exercise of stock options	—	—	—	—	—	—	—	—	128	—	383	—	—	383
Vesting of restricted stock	—	—	—	—	—	—	—	—	8	—	10	—	—	10
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	3,848	—	—	3,848
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(42,483)	(42,483)
Balance at December 31, 2015	—	—	—	—	—	—	—	—	28,152	28	247,550	(7)	(157,910)	89,661

See accompanying notes to consolidated financial statements.

Genocea Biosciences, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Years Ended December 31,		
	2015	**2014**	**2013**
Operating activities			
Net loss	$ (42,483)	$ (35,296)	$ (20,806)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	1,051	469	318
Stock-based compensation	3,848	2,905	672
Change in fair value of warrants liability	—	725	222
Non-cash interest expense	369	254	22
Loss on debt extinguishment	—	435	200
Changes in operating assets and liabilities:			
Restricted cash	—	—	97
Prepaid expenses and other current assets	266	(442)	27
Other long-term assets	(399)	782	(1,539)
Accounts payable	(1,431)	524	724
Deferred revenue	(670)	893	12
Accrued expenses and other liabilities	1,093	1,147	178
Net cash used in operating activities	(38,356)	(27,604)	(19,873)
Investing activities			
Purchases of property and equipment	(2,784)	(1,520)	(389)
Proceeds from maturities of investments	27,498	—	—
Purchase of investments	(89,651)	(27,053)	—
Net cash used in investing activities	(64,937)	(28,573)	(389)
Financing activities			
Proceeds from IPO, net of issuance costs	—	59,974	—
Proceeds from underwritten public offering, net of issuance costs	95,183	—	—
Proceeds from issuance of preferred stock, net	—	—	15,250
Proceeds from issuance of long-term debt, net of issuance costs	4,719	11,784	9,965
Repayment of long-term debt	—	(10,401)	(4,245)
Proceeds from sale of common stock, net of issuance costs	—	1,964	—
Proceeds from issuance of common stock under ESPP	213	93	—
Proceeds from exercise of stock options	383	683	42
Proceeds from the exercise of warrants	—	33	—
Payments made under capital lease	(4)	—	—
Payments for debt issuance costs	—	(103)	(58)
Net cash provided by financing activities	100,494	64,027	20,954
Net increase in cash and cash equivalents	$ (2,799)	$ 7,850	$ 692
Cash and cash equivalents at beginning of period	20,058	12,208	11,516
Cash and cash equivalents at end of period	$ 17,259	$ 20,058	$ 12,208
Supplemental cash flow information			
Cash paid for interest	$ 897	$ 815	$ 426
Supplemental disclosure of non-cash investing and financing activities			
Conversion of preferred stock to common stock upon closing of IPO	$ —	$ 81,774	$ —
Reclassification of prepaid IPO closing costs from non-current assets to additional paid-in capital	$ —	$ 997	$ —
Reclassification of warrants to additional paid-in capital	$ —	$ 1,381	$ —
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 180	$ 1,605
Vesting of restricted stock	$ 10	$ 10	$ 1
Cashless exercise of warrants	$ —	$ 98	$ —
Issuance of common stock warrant	$ —	$ 340	$ —
Equipment purchased under capital lease	$ —	$ 21	$ —
Property and equipment, net included in accounts payable and accrued expense	$ 394	$ —	$ —

See accompanying notes to consolidated financial statements.

1. Organization and operations

The Company

Genocea Biosciences, Inc. (the "Company") is a biopharmaceutical company that was incorporated in Delaware on August 16, 2006 and has a principal place of business in Cambridge, Massachusetts. The Company seeks to discover and develop novel vaccines and immunotherapies to address diseases with significant unmet needs through its AnTigen Lead Acquisition System ("ATLAS ™ ") proprietary discovery platform. ATLAS is used to rapidly design vaccines and immunotherapies that act, in part, through T cell (or cellular) immune responses, in contrast to approved vaccines and immunotherapies, which are designed to act primarily through B cell (or antibody) immune responses. The Company believes that by harnessing T cells, first-in-class vaccines and immunotherapies can be developed to address diseases where T cells are central to the control of the disease.

The Company has one product candidate in active Phase 2 clinical development, GEN-003, an immunotherapy for the treatment of genital herpes. The Company suspended development for another product candidate, GEN-004, a universal vaccine for the prevention of pneumococcal infections, pending further data analysis and consultation with the Company's advisers after statistically significant results were not achieved in a Phase 2a human challenge study. The Company also has active research and pre-clinical development programs for diseases including genital herpes, chlamydia and malaria and is investigating the application of ATLAS to immuno-oncology target discovery.

The Company 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 clinical stage companies, including dependence on key individuals, competition from other companies, the need and related uncertainty associated to the 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, 2015, the Company had an accumulated deficit of approximately $ 157.9 million . The Company had cash, cash equivalents and investments of $106.4 million at December 31, 2015. The Company believes that its existing cash, cash equivalents and investments and available borrowings under the Company's credit facility, will be sufficient to fund projected operating expenses and capital expenditure requirements into the second half of 2017.

Underwritten public offerings

On February 10, 2014, the Company completed its initial public offering ("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 of $2.4 million payable by the Company. In conjunction with this transaction, all shares of the Company's redeemable convertible preferred stock were converted into 11,466,479 shares of common stock, and 96,988 employee and nonemployee performance-based options vested.

On March 17, 2015, the Company completed an underwritten public offering of its common stock in which it sold 6,272,726 shares of common stock, including the exercise in full by the underwriters of their option to purchase an additional 818,181 shares of common stock, to the public at a price of $8.25 per share. The offering was completed under the shelf registration statement that was filed on Form S-3 and declared effective on March 10, 2015. Net proceeds of the underwritten public offering, after deducting the underwriting discounts and commissions, were $48.6 million , excluding offering expenses of $276 thousand incurred by the Company.

On August 4 2015, the Company completed an underwritten public offering of its common stock in which it sold an aggregate of 3,850,000 shares of common stock to the public at a price of $13.00 per share. The offering was completed under the shelf registration statement that was filed on Form S-3 and declared effective May 14, 2015. Net proceeds of the

underwritten public offering, after deducting the underwriting discounts and commissions, were $47 million , excluding offering expenses of $233 thousand incurred by the Company.

At-the-market equity offering program

On March 2, 2015, the Company entered into a Sales Agreement with Cowen and Company, LLC (the "Sales Agreement") to establish an at-the-market equity offering program (“ATM”) pursuant to which it was able to offer and sell up to $40 million of its Common Stock at prevailing market prices from time to time. On May 8, 2015, the Sales Agreement was amended to increase the offering amount under the ATM to $50 million of its Common Stock. As of December 31, 2015, the Company had not commenced sales under this program.

2. Summary of significant accounting policies

Principles of Consolidation

The consolidated financial statements include the accounts of Genocea Biosciences, Inc., and a wholly-owned subsidiary. All inter-company accounts and transactions have been eliminated

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 prepaid and accrued research and development expenses, stock-based compensation expense, the valuation of common stock warrants and 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.

For periods prior to the closing of the IPO, the Company utilized significant estimates and assumptions in determining the fair value of its 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 IPO 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.

Following the closing of the IPO, the fair value of common stock is determined based on the quoted market price of the common stock.

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, cash equivalents and investments

The Company determines the appropriate classification of its investments at the time of purchase. All liquid investments with original maturities of 90 days or less from the purchase date are considered to be cash equivalents. The Company’s current and non-current investments are comprised of certificates of deposit and government securities that are

classified as available-for-sale in accordance with FASB ASC Topic 320, Investments—Debt and Equity Securities. The Company classifies investments available to fund current operations as current assets on its balance sheets. Investments are classified as non-current assets on the balance sheets if (i) the Company has the intent and ability to hold the investments for a period of at least one year and (ii) the contractual maturity date of the investments is greater than one year.

Available-for-sale investments are recorded at fair value, with unrealized gains or losses included in Accumulated other comprehensive loss on the Company's balance sheets. Realized gains and losses are determined using the specific identification method and are included as a component of Interest expense, net. There were no realized gains or losses recognized for the twelve months ended December 31, 2015 and 2014.

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than-temporary, the Company considers its intent to sell, or whether it is more likely than not that the Company will be required to sell the investment before recovery of the investment's amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, the severity and the duration of the impairment and changes in value subsequent to period end. As of December 31, 2015, there were no investments with a fair value that was significantly lower than the amortized cost basis or any investments that had been in an unrealized loss position for a significant period.

Concentrations of credit risk and off-balance sheet risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and investments. The Company's cash, cash equivalents and investments are held in accounts with financial institutions that management believes are 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 financing costs

Offering costs related to debt and equity financing primarily consist of direct and incremental external expenses. In accordance with ASU No. 2015-03 *Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03") the Company presents debt issuance costs related to a recognized debt liability in the balance sheet as a direct deduction of the carrying value of the debt liability, consistent with the accounting treatment of debt discounts. The adoption of ASU 2015-03 in the quarter ended June 30, 2015 resulted in the reclassification of approximately $ 99 thousand , as of December 31, 2014, of unamortized capitalized debt issuance costs previously included in both other current and other non-current assets to a direct deduction of the carrying value of the debt liability. The adoption of this standard did not have material impact on the Company's financial conditions, results of operations, or cash flows. The amortization of deferred debt financing costs follows the effective interest rate method and was not impacted by the issuance or adoption of ASU 2015-03.

Offering costs related to registration statements and the initiation of the ATM are recorded as an asset and are reclassified to equity on a pro-rata basis based upon the successful selling of common shares compared to the available limits in either equity program. The costs are reviewed for impairment and will be recorded to expense if and when the Company determines that future equity offerings are not probable of occurring. At December 31, 2015, the Company had $304 thousand of deferred offering costs recorded as an Other non-current asset. There were no deferred offering costs at December 31, 2014.

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* , ("ASC 820") 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 and investments (Note 3) and warrants (Note 7).

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 6) 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 7), there have been no changes to the valuation methods utilized by the Company during the three years ended December 31, 2015. 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, 2015, 2014 and 2013.

Derivative Instruments

The Company occasionally issues financial instruments in which a derivative instrument is "embedded". Upon issuing the financial instrument, the Company assesses whether the economic characteristics of the embedded derivative are clearly and closely related to the economic characteristics of the remaining component of the financial instrument (i.e., the host contract) and whether a separate, non-embedded instrument with the same terms as the embedded instrument would meet the definition of a derivative instrument. When it is determined that (1) the embedded derivative possesses economic characteristics that are not clearly and closely related to the economic characteristics of the host contract and (2) a separate, stand-alone instrument with the same terms would qualify as a derivative instrument, the embedded derivative is separated from the host contract and carried at fair value with any changes in fair value recorded in current period earnings.

In connection with the issuance of the 2014 Term Loan and the First Amendment (Note 6), the Company evaluated all features of the agreement noting none that required bifurcation under FASB ASC Topic 815, *Derivatives and Hedging* ("ASC 815").

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

Development of Software for Internal Use

The Company accounts for the costs of software developed or obtained for internal use in accordance with ASC 350-40, *Internal-Use Software* . Costs of materials, consultants, payroll, and payroll-related costs for employees incurred in developing internal-use software are capitalized as incurred. These costs are included in Property and equipment, net. Costs incurred during the preliminary project and post-implementation stages are charged to expense.

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 in any reporting periods through December 31, 2015.

Revenue recognition

The Company has generated revenue solely through research and development grants with private not-for-profit organizations 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

Periodically, the Company receives grants from private not-for-profit organizations and federal agencies 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.

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.

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 FASB ASC Topic 505, *Equity,* ("ASC 505") 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 volatility of the Company's stock price, (b) the expected term of the award, (c) the risk-free interest rate, (d) expected dividends and (e) the estimated fair value of the Company's common stock on the measurement date. Due to the limited operating history of the Company as a public entity 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 prior to the IPO. Following the closing of the Company's IPO, the fair value of common stock is determined based on the quoted market price of the 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* ("ASC 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, 2015 and 2014, 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.

Earnings per share

Basic earnings 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.

Diluted earnings 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 loss and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. For all periods presented other comprehensive income (loss), if any, consists of unrealized gains and losses on the Company's investments.

Recent accounting pronouncements

Standard	Description	Effect on the financial statements
ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606)	The standard will replace existing revenue recognition standards and significantly expand the disclosure requirements for revenue arrangements. It may be adopted either retrospectively or on a modified retrospective basis to new contracts and existing contracts with remaining performance obligations as of the effective date. In July 2015, the FASB affirmed its proposal to defer the effective date of the new revenue standard for all entities by one year. As a result, public business entities will be required to apply the new revenue standard to annual reporting periods beginning after December 15, 2017. The standard will become effective for us on January 1, 2018 (the first quarter of the 2018 fiscal year). Early adoption is not permitted under GAAP.	At this time, the Company has not decided on which method it will use to adopt the new standard, nor has it determined the effects of the new guidelines on its results of operations and financial position. For the foreseeable future, the Company's revenues will be limited to grants received from government agencies or nonprofit organizations. The Company is currently evaluating the method of adoption and the impact of this standard on the financial statements.
ASU No. 2014-15, *Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15").	The standard requires a company to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued. This ASU is effective for annual and interim periods ending after December 15, 2016 and earlier application is permitted.	The Company is evaluating the effects of the new standard, but does not expect it will have a material impact on its financial conditions, results of operations, or cash flows.

3. Cash, cash equivalents and investments

As of December 31, 2015 and 2014, cash, cash equivalents and investments comprised funds in depository, money market accounts, U.S treasury securities, and FDIC-insured certificates of deposit.

The following table presents the cash equivalents and investments 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, 2015				
Money Market funds, included in cash equivalents	$ 14,207	$ 14,207	$ —	$ —
U.S treasuries, included in cash equivalents	$ 2,203	2,203	—	—
Investments - U.S. treasuries	$ 27,924	27,924	—	—
Investments - certificates of deposit	61,249	—	61,249	—
Total	$ 105,583	$ 44,334	$ 61,249	$ —
December 31, 2014				
Money Market funds, included in cash equivalents	$ 18,992	$ 18,992	$ —	$ —
Marketable securities - U.S. treasuries	27,021	27,021	—	—
Total	$ 46,013	$ 46,013	$ —	$ —

Cash equivalents and marketable securities 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 any fair value measurements provided by the pricing services as of December 31, 2015 and 2014.

Cash equivalents and investments at December 31, 2015 consist of the following (in thousands):

	Contracted Maturity	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents and investments					
U.S. Treasuries	60-184 days	$ 30,120	$ 7	$ —	$ 30,127
Certificates of deposit	91-365 days	49,145	—	—	49,145
Certificates of deposit	greater than 365 days	12,104	—	—	12,104
Total		$ 91,369	$ 7	$ —	$ 91,376

Interest income earned for the years ended December 31, 2015, 2014, and 2013, was $157 thousand , $32 thousand , and $6 thousand , respectively.

4. Property and equipment, net

Property and equipment, net consist of the following (in thousands):

	December 31,	
	2015	2014
Laboratory equipment	$ 3,943	$ 2,510
Furniture office equipment	610	186
Computer hardware	259	257
Leasehold improvements	1,433	799
Computer software	338	—
Total property and equipment	6,583	3,752
Accumulated depreciation	(2,500)	(1,796)
Property and equipment, net	$ 4,083	$ 1,956

Depreciation expense was $1.1 million , $0.5 million , and $0.3 million for the years ended December 31, 2015, 2014, 2013, respectively. The Company's internally developed computer software is not yet available to be placed into service and no amortization was recorded for the twelve months ended December 31, 2015.

5. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2015	2014
Payroll and employee-related costs	$ 1,736	$ 1,066
Research and development costs	1,359	1,117
Other current liabilities	880	410
Total	$ 3,975	$ 2,593

6. Long-term debt

2014 Term Loan, First Amendment

On November 20, 2014 (the "Closing Date"), the Company entered into a loan and security agreement (the “Loan Agreement”) with Hercules Technology Growth Capital, Inc. (“Hercules”) which provided up to $27.0 million in debt financing in three separate tranches (the “2014 Term Loan”). The first tranche of $17.0 million was available through June 30, 2015, of which $12.0 million was drawn down at loan inception for which approximately $9.8 million of the proceeds were used to repay all outstanding indebtedness under the previously existing $10.0 million loan agreement (the "2013 Term Loan"). The Company recorded a $435 thousand loss on extinguishment of debt in other expense on the Statements of Operations related to deferred debt charges, the unamortized portion of the original issue discount related to the 2013 Term Loan and other fees associated with extinguishing the debt. The option to draw down the remaining $5.0 million under the first tranche expired unused on June 30, 2015. The second tranche of $5.0 million was subject to certain eligibility requirements which were achieved as of June 30, 2015 and the Company had the option to draw down the second tranche on or prior to December 15, 2015. The second tranche expired unused on December 15, 2015 The third tranche of $5.0 million was not eligible to draw as the Company did not achieve positive results from its Phase 2a human challenge study of GEN-004.

In December 2015, the Company amended the Loan Agreement (the "First Amendment") with Hercules. The First Amendment required the Company to draw an additional $5.0 million and permits it to draw two additional $5.0 million tranches. One $5.0 million tranche is immediately available to draw through December 15, 2016 and a second $5.0 million tranche becomes available through December 15, 2016, subject to the Company demonstrating sufficient evidence of continued clinical progression of its GEN-003 product and making favorable progress in applying its proprietary technology platform toward the development of novel immunotherapies with application in oncology. At December 31, 2015, $17.0 million was outstanding under the amended 2014 Term Loan.

During the amendment negotiations, but after the third quarter Form 10-Q was filed, the Company identified three separate covenant violations that resulted in an event of default as of September 30, 2015. The violated covenants related to certain investments the Company held as well as certain financial reporting obligations. Pursuant to the 2014 Term Loan, upon an event of default, Hercules can accelerate the repayment of all amounts due under the 2014 Term Loan at their discretion. Hercules did not make a repayment demand and the First Amendment included a permanent waiver of these covenant violations subject only to certain requirements that are within our control. The First Amendment also modified the Loan Agreement for the specific instances in which these violations arose, including redefining permitted investments to be in line with the Company's approved investment policies.

2014 Term Loan

The 2014 Term Loan had an original maturity of July 1, 2018. The eligibility requirements for the second tranche also contained an election for the Company to extend the maturity date to January 1, 2019. During the second quarter of 2015, the Company elected to extend the maturity date of the 2014 Term Loan. The maturity date of January 1, 2019 remained unchanged by the First Amendment.

Each advance accrues interest at a floating rate per annum equal to the greater of (i) 7.25% or (ii) the sum of 7.25% plus the prime rate minus 5.0% . The 2014 Term Loan provided for interest-only payments until December 31, 2015, which was extended by the Company for a six -month period as the eligibility requirements for the second tranche were met during the second quarter of 2015. The First Amendment subsequently extended the interest only period through June 30, 2017. Thereafter, beginning July 1, 2017, principal and interest payments will be made monthly for 18 months with a payoff schedule based upon a 30 -month amortization schedule, the original amortization term of the 2014 Term Loan. The remaining unpaid principal is due at January 1, 2019.

The 2014 Term Loan may be prepaid in whole or in part upon seven business days’ prior written notice to Hercules. Prepayments will be subject to a charge of 3.0% if an advance is prepaid within 12 months following the Closing Date, 2.0% , if an advance is prepaid between 12 and 24 months following the Closing Date, and 1.0% thereafter. Amounts outstanding at the time of an event of default shall be payable on demand and shall accrue interest at an additional rate of 5.0% per annum on any outstanding amounts past due. The Company is also obligated to pay an end of term charge of 4.95% (the "End of Term Charge") of the balance drawn when the advances are repaid.

The 2014 Term Loan is secured by a lien on substantially all of the assets of the Company, other than intellectual property, provided that such lien on substantially all assets includes any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. The Loan Agreement contains non-financial covenants and representations, including a financial reporting covenant, and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries. There are no financial covenants.

Under the provisions of the 2014 Term Loan, the Company has also entered into account control agreements ("ACAs") with Hercules and certain of the Company's financial institutions in which cash, cash equivalents, and investments are held. These ACAs grant Hercules a perfected first priority security interest in the subject accounts. The ACAs do not restrict the Company's ability to utilize cash, cash equivalents, or investments to fund operations and capital expenditures unless there is an Event of Default and Hercules activates its rights under the ACAs.

The Loan Agreement contains a Material Adverse Effect provision that requires all material adverse effects to be reported under the financial reporting covenant. Loan advances are subject to a representation that no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing. Under the Loan Agreement, a Material Adverse Effect means a material adverse effect upon: (i) the business, operations, properties, assets or condition (financial or otherwise) of the Company; or (ii) the ability of the Company to perform the secured obligations in accordance with the terms of the Loan Agreements, or the ability of agent or lender to enforce any of its rights or remedies with respect to the secured obligations; or (iii) the collateral or agent's liens on the collateral or the priority of such liens. Any event that has a Material Adverse Effect is an event of default under the Loan Agreement and repayment of amounts due under the Loan Agreement may be accelerated by Hercules under the same terms as an event of default.

Events of default under the Loan Agreement include failure to make any payments of principal or interest as due on any outstanding indebtedness, breach of any covenant, any false or misleading representations or warranties, insolvency or bankruptcy, any attachment or judgment on the Company's assets of at least $100 thousand, or the occurrence of any material default of the Company involving indebtedness in excess of $100 thousand. If an event of default occurs, repayment of all amounts due under the Loan Agreement may be accelerated by Hercules, including the applicable Prepayment Charge.

The 2014 Term Loan is automatically redeemable upon a change in control whereas the Company must prepay the outstanding principal and any accrued and unpaid interest through the prepayment date including any unpaid agent's and lender's fees and expenses accrued to the date of the repayment including the End of Term Charge and the applicable Prepayment Charge. If a change in control occurs, repayment of amounts due under the Loan Agreement may be accelerated by Hercules.

In connection with the 2014 Term Loan, the Company issued a common stock warrant to Hercules on November 20, 2014. The warrant is exercisable for 73,725 shares of the Company's common stock (equal to $607,500 divided by the exercise price of $8.24). The exercise price and the number of shares are subject to adjustment upon a merger event, reclassification of the shares of common stock, subdivision or combination of the shares of common stock or certain dividends payments. The warrant is exercisable until November 20, 2019 and will be exercised automatically on a net issuance basis if not exercised prior to the expiration date and if the then-current fair market value of one share of common stock is greater than the exercise price then in effect. The warrant has been classified as equity for all periods it has been outstanding.

Contemporaneously with the 2014 Term Loan, the Company also entered into an equity rights letter agreement on November 20, 2014 (the "Equity Rights Letter Agreement"). Pursuant to the Equity Rights Letter Agreement, the Company issued to Hercules 223,463 shares of the Company's Common Stock for an aggregate purchase price of approximately $2.0 million at a price per share equal to the closing price of the Company's Common Stock as reported on The NASDAQ Global Market on November 19, 2014. The shares will be subject to resale limitations and may be resold only pursuant to an effective registration statement or an exemption from registration.

Additionally, under the Equity Rights Letter Agreement, Hercules has the right to participate in any one or more subsequent private placement equity financings of up to $2.0 million on the same terms and conditions as purchases by the other investors in each subsequent equity financing. The Equity Rights Letter Agreement, and all rights and obligations thereunder, will terminate upon the earlier of (1) such time when Hercules has purchased $2.0 million of subsequent equity financing securities in the aggregate and (2) the later of (a) the repayment of all indebtedness under the Loan Agreement and (b) the expiration or termination of the exercise period for the warrant issued in connection with the Loan Agreement. The Company allocated $36 thousand of financing costs to additional paid-in capital for issuance fees that were reimbursed to Hercules.

The Company incurred $280 thousand in debt financing costs related to the First Amendment which was recorded as a debt discount and will be amortized over the remaining loan term. In connection with the issuance of the 2014 Term Loan, the Company incurred $103 thousand of financing costs and also reimbursed Hercules $210 thousand for debt financing costs which has been recorded as a debt discount and will be amortized over the remaining loan term. The End of Term Charge is amortized ratably over the term loan period based upon the outstanding debt and the increase in the amount of End of Term Charge due to the additional borrowing from the First Amendment is being amortized from the First Amendment date through

maturity. The debt discount is being amortized to interest expense over the life of the 2014 Term Loan using the effective interest method. At December 31, 2015, the 2014 Term Loan bears an effective interest rate of 10.2% .

As of December 31, 2015 and 2014, the Company had outstanding borrowings under the 2014 Term Loan of $17.0 million and $12.0 million , respectively. Interest expense related to the 2014 Term Loan was $1.3 million and $0.1 million for the years ended December 31, 2015 and 2014, respectively. Interest expense related to the 2013 Term Loan was $0.8 million and $0.1 million for the years ended December 31, 2014 and 2013, respectively.

Future principal payments, including the End of Term Charge, on the 2014 Term Loan are as follows (in thousands):

	December 31, 2015
2016	$ —
2017	3,149
2018	6,659
2019	8,034
Total	$ 17,842

2013 Term Loan

On September 30, 2013, the Company entered into the 2013 Term Loan which provided up to $10.0 million . Upon the closing of the 2013 Term Loan, the Company drew down $3.5 million and paid off the remaining balance under the 2011 Term Loan (defined below). As part of the early repayment, the Company incurred a loss on debt extinguishment of $0.2 million . The 2013 Term Loan provided for a draw-down period on the remaining facility of $6.5 million , which the Company drew down on December 19, 2013. The Company was 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 2013 Term Loan bore interest at a rate of 8% per annum. The Company was also obligated to pay 2% of the advance on the final repayment date of each draw. The final payment was accrued over the term of the debt and recorded in accrued interest payable on the balance sheet as at December 31, 2013.

In connection with the 2013 Term Loan, the Company issued a warrant to purchase 689,655 shares of Series C Preferred Stock at $0.58 per share. Upon the completion of the Company's IPO, these Series C preferred stock warrants automatically converted into warrants exercisable for 57,954 shares of Common Stock at an exercise price of $6.90 per share (Note 7).

2011 Term Loan

In October 2011, the Company entered into a loan and security agreement which provided for up to $5.0 million in debt financing (“2011 Term Loan”). In March 2012, the Company drew down the full $5.0 million available under the terms of this arrangement. In May 2012, the Company began making 36 equal monthly payments of principal and accrued interest thereafter. During the 36 -month period, the 2011 Term Loan bore interest at the greater of the financial institution’s prime rate plus 4.75% or 8.00% . The Company was also obligated to pay 6.50% of the advance on the final repayment date of the draw, which was April 1, 2015. This final payment was accrued over the term of the debt and was recorded in accrued interest payable.

7. Warrants

As of December 31, 2015 and December 31, 2014, the Company had warrants outstanding that represent the right to acquire 77,603 shares of common stock, of which 73,725 represented warrants issued to Hercules in relation to the 2014 Term Loan and 3,878 represented warrants to purchase common stock issued in periods prior to the Company's IPO.

Hercules Warrants

In accordance with ASC Topic No. 815, “ *Derivatives and Hedging* ” (Topic No. 815), the Company determined the common stock warrant issued to Hercules to be equity classified. The Company estimated the fair value of this warrant as of the issuance date using a Black-Scholes option pricing model (with a 10% discount for lack of marketability) with the following assumptions:

	November 20, 2014
Fair value of underlying instrument	$ 9.05
Expected volatility	70.0 %
Expected term (in years)	5
Risk-free interest rate	1.64 %
Expected dividend yield	0.0 %

The Company utilized this fair value in its allocation of debt proceeds between debt and the warrants which was performed on a relative fair value basis. Ultimately, the Company allocated $334 thousand to the Hercules warrants and recognized this amount in additional paid-in capital.

As of December 31, 2015, the common stock warrants issued to Hercules had not been exercised and were still outstanding.

Warrants to purchase redeemable securities

As of December 31, 2013, the Company had outstanding warrants to purchase 2,291,512 shares of redeemable convertible preferred stock. On January 29, 2014, 21,695 warrants to purchase Series A preferred stock were exercised for cash. On February 4, 2014, an additional 28,926 warrants to purchase Series A preferred stock were exercised for cash. Prior to the completion of the Company's IPO on February 10, 2014, warrants to purchase 987,840 shares of Series A preferred stock were exercised in a cashless exercise for 316,932 shares of Series A preferred stock, which automatically converted into 26,633 shares of Common Stock upon the completion of the Company's IPO. Also upon the completion of the Company's IPO, warrants exercisable for 1,253,051 shares of redeemable convertible preferred stock were automatically converted into warrants exercisable for 105,297 shares of Common Stock. On February 12, 2014, 43,465 warrants were exercised in a cashless exercise for 16,593 shares of Common Stock. On April 23, 2014, 57,954 warrants were exercised in a cashless exercise for 37,250 shares of Common Stock. As of December 31, 2014, 3,878 of these warrants remained outstanding.

In connection with the completion of the Company's IPO, all the warrants exercisable for redeemable convertible preferred stock were automatically converted into warrants exercisable for Common Stock, resulting in the reclassification of the related warrant to purchase redeemable securities liability to additional paid-in capital as the warrants to purchase shares of Common Stock are accounted for as equity instruments. The warrant to purchase redeemable securities liability was re-measured to fair value prior to reclassification to additional paid-in capital. As of December 31, 2015 and 2014, the Company had no outstanding warrants to purchase redeemable securities liability.

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 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,		
	2015	2014	2013
Beginning balance	$ —	$ 656	$ 246
Warrants issued	—	—	188
Change in fair value	—	725	222
Warrants exercised	—	(323)	—
Reclassification to accumulated paid-in capital	—	(1,058)	—
Ending balance	$ —	$ —	$ 656

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. At December 31, 2013, 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. At December 31, 2013, the analytical valuation model used to calculate the fair value of warrants to purchase redeemable securities was a hybrid approach based on an Option-Pricing Model ("OPM") backsolve method and the Probability-Weighted Expected Return Model ("PWERM"). Thirty-five percent 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 fair value of warrants to purchase 21,695 shares of Series A preferred stock prior to exercise on January 29, 2014 was estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	January 29, 2014	
Fair value of underlying instrument	$ 0.65	
Expected Volatility	55.57	%
Expected term (in years)	0.04	
Risk-free interest rate	1.52	%
Expected dividend yield	0.0	%

These warrants were re-measured to a fair value of $8 thousand, which resulted in an increase in fair value of $2 thousand. The fair value of the warrants was reclassified to additional paid-in capital upon exercise on January 29, 2014.

The fair value of warrants to purchase 28,926 shares of Series A preferred stock prior to exercise on February 4, 2014 was estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	February 4, 2014	
Fair value of underlying instrument	$ 0.65	
Expected Volatility	55.03	%
Expected term (in years)	0.02	
Risk-free interest rate	1.46	%
Expected dividend yield	0.0	%

These warrants were re-measured to a fair value of $10 thousand, which resulted in an increase in fair value of $3 thousand. The fair value of the warrants was reclassified to additional paid-in capital upon exercise on February 4, 2014.

The fair value of warrants to purchase 987,840 shares of Series A preferred stock prior to a cashless exercise for 316,932 shares of Series A preferred stock on February 10, 2014, which automatically converted into 26,633 shares of Common Stock upon the completion of the Company's IPO, was estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	February 10, 2014	
Fair value of underlying instrument	$ 7.74	
Expected Volatility	50.81	%
Expected term (in years)	1	
Risk-free interest rate	1.48	%
Expected dividend yield	0.0	%

These warrants were re-measured to a fair value of $304 thousand, which resulted in an increase in fair value of $47 thousand. The fair value of the warrants was reclassified to additional paid-in capital upon exercise on February 10, 2014.

The fair value of warrants exercisable for 1,253,051 shares of redeemable convertible preferred stock, which were automatically converted into warrants exercisable for 105,297 shares of Common Stock, was estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	February 10, 2014
Fair value of underlying instrument	$ 6.96
Expected Volatility	92.9 %
Expected term (in years)	8.66
Risk-free interest rate	2.43 %
Expected dividend yield	0.0 %

The fair value of the remaining 105,297 warrants to purchase Common Stock were re-measured to a fair value of $1,058 thousand, which resulted in an increase in fair value of $673 thousand. The fair value of the warrants was reclassified to additional paid-in capital upon conversion on February 10, 2014.

8. Commitments and contingencies

Lease commitments

In February 2014, the Company signed an operating lease for office and laboratory space that commenced in March 2014 and expires in February 2017 (the "2014 Lease"). In June 2015, the Company signed a second operating lease for office space in the same building as the 2014 Lease, which also expires in February 2017 (the "2015 Lease"). The 2015 Lease has one three -year renewal period. Rent expense for the three years ended December 31, 2015, 2014, and 2013, was $1.2 million , $0.8 million , and $0.5 million , respectively.

The minimum future lease payments under both the 2014 Lease and the 2015 Lease are as follows (in thousands):

	December 31, 2015
2016	$ 1,379
2017	231
Total	$ 1,610

At December 31, 2015, the Company has an outstanding letter of credit of $316 thousand with a financial institution related to a security deposit for the 2014 Lease, which is secured by cash on deposit and expires on February 28, 2017. An additional unsecured deposit was required for the 2015 Lease.

Significant Contracts and Agreements

In addition to lease commitments, the Company enters into contractual arrangements that obligate it to make payments to the contractual counterparties upon the occurrence of future events. In the normal course of operations, the Company enters into license and other agreements and intends to continue to seek additional rights relating to compounds or technologies in connection with its discovery, manufacturing and development programs. These agreements may require payments to be made by the Company upon the occurrence of certain development milestones and certain commercialization milestones for each distinct product covered by the licensed patents (in addition to certain royalties to be paid on marketed products or sublicense income) contingent upon the occurrence of future events that cannot be reasonably estimated.

In March 2014, the Company announced a joint research collaboration with Dana-Farber Cancer Institute to characterize anti-tumor T cell responses in melanoma patients. This collaboration extends the use of the Company's proprietary ATLAS platform for the rapid discovery of T cell antigens to cancer immunotherapy approaches. Under this agreement, the Company recognized revenue of $30 thousand and none for the years ended December 31, 2015 and 2014, respectively.

In September 2014, the Company received $1.2 million in the form of a grant entered into with the Bill & Melinda Gates Foundation for the identification of protective T-cell antigens for malaria vaccines. The grant will allow for the continued expansion of the Company’s malaria antigen library and aid in the identification of novel protein antigens to facilitate the development of highly efficacious anti-infection malarial vaccines. The Company recognized revenue under the agreement of $640 thousand and $308 thousand for the years ended December 31, 2015 and 2014, respectively.

The Company relies on research institutions, contract research organizations, clinical investigators as well as clinical and commercial material manufacturers for its product candidates. Under the terms of these agreements, the Company is

obligated to make milestone payments upon the achievement of manufacturing or clinical milestones defined in the contracts. In some cases, monthly service fee for project management services are charged over the duration of the arrangement. In addition, clinical and manufacturing contracts generally require reimbursement to suppliers for certain set-up, production, travel, and other related costs as they are incurred. In some manufacturing contracts, the Company also may be responsible for the payment of a reservation fee, which will equal a percentage of the expected production fees, to reserve manufacturing slots in the production timeframe. Generally, the Company is liable for actual effort expended by these organizations at any point in time during the contract through the notice period. To the extent amounts paid to a supplier exceed the actual efforts expended, the Company records a prepaid asset, and to the extent actual efforts expended exceed amounts billed or billable under a contract, an accrual for the estimate of services rendered is recorded.

In February 2014, the Company entered into a supply agreement with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. ("Fujifilm") for the manufacture and supply of antigens for future GEN-003 clinical trials. Under the agreement, the Company is obligated to pay Fujifilm manufacturing milestones, in addition to reimbursement of certain material production related costs. Additionally, the Company is responsible for the payment of a reservation fee, which will equal a percentage of the expected production fees, to reserve manufacturing slots in the production timeframe. The Company incurred expenses under this agreement of $4.2 million , $3.5 million , and none for the years ended December 31, 2015, 2014 and 2013, respectively.

Litigation

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

9. Equity and net loss per share

At December 31, 2015, the Company authorized 175,000,000 shares of common stock at $0.001 par value per share, of which 28,161,313 shares of common stock were issued and 28,151,596 shares of common stock were outstanding.

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"). For the three years ended December 31, 2015, 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):

	Years ended December 31,		
	2015	2014	2013
Preferred stock	—	—	11,409
Warrants	78	78	193
Outstanding options	2,723	2,290	1,576
Total	2,801	2,368	13,178

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 received a cash payment in lieu of receiving fractional shares upon the completion of the Company's IPO on February 17, 2014. The Company's historical share and per share information were 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.

Restricted stock

During 2013, a Company director exercised stock options and received 31,092 shares of common stock that were subject to a Stock Restriction and Repurchase Agreement with the Company. Under the terms of the agreement, shares of common stock issued are subject to a vesting schedule and unvested shares are subject to repurchase by the Company. 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 grant.

At both December 31, 2015 and December 31, 2014, the Company had issued 35,964 shares of restricted common stock. At December 31, 2015, 9,717 shares of nonvested restricted stock were subject to repurchase by the Company. At December 31, 2014, 16,840 shares of nonvested restricted stock were subject to repurchase by the Company

10. Stock and employee benefit plans

The Company's board of directors adopted the 2014 Equity Incentive Plan (the "2014 Equity Plan"), which was approved by its stockholders and became effective prior to the commencement of the Company's IPO. The 2014 Equity Plan replaced the 2007 Equity Incentive Plan (the "2007 Equity Plan").

The 2014 Equity Plan provides for the grant of incentive stock options, non-qualified stock options, restricted stock and other awards to key employees and directors of, and consultants and advisors to, the Company. The maximum number of shares of common stock that may be delivered in satisfaction of awards under the 2014 Equity Plan is 903,494 shares, plus 219,765 shares that were available for grant under the 2007 Equity Plan on the date the 2014 Equity Plan was adopted. The 2014 Equity Plan provides that the number of shares available for issuance will automatically increase annually on each January 1, from January 1, 2015 through January 1, 2024, in amount equal to the lesser of 4.0% of the outstanding shares of the Company's outstanding common stock as of the close of business on the immediately preceding December 31 or the number of shares determined the Company's board of directors. On January 1, 2015 and 2016, the total number of shares available for issuance under the 2014 Equity Plan increased by 714,769 and 1,126,064 , respectively, for shares under this provision.

Outstanding options awards granted from the 2007 Equity Plan, at the time of the adoption of the 2014 Equity Plan, remain outstanding and effective. The shares of common stock underlying awards that are cancelled, forfeited, repurchased, expire or are otherwise terminated under the 2007 Equity Plan are added to the shares of common stock available for issuance under the 2014 Equity Plan. As of December 31, 2015, the number of shares of common stock that may be issued is 3,246,017 and 522,706 .

During the years ended 2015, 2014 and 2013, the Company granted a total of none , none , and 44,345 stock options, respectively, to consultants and members of its Scientific Advisory Board, which are included in the following stock option 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, 2015, 2014 and 2013 was $263 thousand , $324 thousand , and $143 thousand , respectively.

Stock Based Compensation Expense

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):

	Years ended December 31,		
	2015	2014	2013
Research and development	$ 1,690	$ 1,511	$ 322
General and administrative	2,158	1,394	350
Total	$ 3,848	$ 2,905	$ 672

Stock Options

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, 2014	2,290	$ 7.26	8.08	$ 5,332
Granted	715	$ 9.12		
Exercised	(128)	$ 3.00		
Canceled	(154)	$ 13.41		
Outstanding at December 31, 2015	2,723	$ 7.60	7.61	$ 2,840
Exercisable at December 31, 2015	1,410	$ 5.71	6.66	$ 2,507
Vested or expected to vest at December 31, 2015	2,605	$ 7.54	7.58	$ 2,793

During the years ended December 31, 2015, 2014 and 2013, the Company granted stock options to purchase an aggregate of 715,262 , 1,064,640 , and 559,742 of its common stock, respectively, with a weighted-average grant date fair values of $9.12 , $10.11 , and $3.41 , respectively.

The total intrinsic value of options exercised was $1.0 million , $3.1 million and was de minimis in the years ended December 31, 2015, 2014, and 2013, respectively. As of December 31, 2015, there was $8.0 million of total unrecognized compensation cost, net of related forfeiture estimates, related to employee nonvested stock options granted under the Company's equity plans.

The total unrecognized compensation costs, net of related forfeiture estimates, related to non-employees was $255 thousand , $55 thousand and was immaterial for the years ended December 31, 2015, 2014, and 2013, respectively.

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 2.73 years.

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,		
	2015	2014	2013
Expected Volatility	68.5% - 85.3%	86.2% - 103.6%	97.1%
Risk-free interest rate	1.56% - 1.94%	1.75% - 2.00%	0.59% - 1.83%
Expected term (in years)	5.50 - 6.08	6.25	6.25
Expected dividend yield	0%	0%	0%

Performance-Based Stock Options

The Company granted stock options to certain employees, executive officers and consultants, which contain performance-based vesting criteria. Milestone events are specific to the Company's corporate goals, which include, but are not limited to, certain clinical development milestones, business development agreements and capital fundraising events. Stock-based compensation expense associated with these performance-based stock options is recognized if the performance conditions are considered probable of being achieved, using management's best estimates. During the year ended December 31, 2014, the Company determined that 96,988 options related to performance-based milestones were probable of achievement and, accordingly, recorded $453 thousand in related stock-based compensation expense. As of December 31, 2014, there are 56,336 performance-based common stock options outstanding for which the probability of achievement was not deemed probable. During the year ended December 31, 2015, the Company recorded no stock based compensation expense related to the 56,336 performance-based common stock options that remain outstanding for which the probability of achievement was not deemed probable at December 31, 2015.

Employee Stock Purchase Plan

On February 10, 2014, the Company's board of directors adopted the 2014 Employee Stock Purchase Plan (the "2014 ESPP"). The 2014 ESPP authorizes the initial issuance of up to a total of 200,776 shares of common stock to participating eligible employees. The 2014 ESPP provides for six -month option periods commencing on January 1 and ending June 30 and commencing July 1 and ending December 31 of each calendar year. The first offering under the 2014 ESPP began on July 1, 2014. For the year ended December 31, 2014, the Company incurred $43 thousand in stock-based compensation expense and 15,622 shares were issued. For the year ended December 31, 2015, the Company incurred $113 thousand in stock-based compensation expense and 40,912 shares were issued. Shares remaining for future issuance under the plan were 144,242 as of December 31, 2015.

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. Beginning January 1, 2015, the Company began making matching contributions to participants in this plan which totaled $174 thousand for the year ended December 31, 2015.

11. Income taxes

For the years ended December 31, 2015 and 2014, 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. The significant components of the Company's deferred tax assets are comprised of the following:

	December 31,	
	2015	2014
Deferred tax assets:		
U.S and state net operating loss carryforwards	$ 54,570	$ 39,721
Research and development credits	5,226	3,655
Stock based compensation	1,410	770
Purchased intangibles	220	245
Capitalized organizational and start up expenditures	133	153
Accruals and other temporary differences	1,119	659
Total deferred tax assets	62,678	45,203
Less valuation allowance	(62,678)	(45,203)
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, 2015 and 2014. The valuation allowance increased approximately $17.5 million and $13.4 million during the years ended December 31, 2015 and 2014, respectively, due primarily to the generation of net operating losses during the period.

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:

	Years ended December 31,		
	2015	2014	2013
Federal income tax expense at statutory rate	34.0 %	34.0 %	34.0 %
State income tax, net of federal benefit	6.1 %	4.6 %	5.1 %
Permanent differences	(1.6)%	(2.1)%	(0.9)%
Research and development credit	2.6 %	1.8 %	3.6 %
Other	0.0 %	0.1 %	0.0 %
Change in valuation allowance	(41.1)%	(38.4)%	(41.8)%
Effective tax rate	0.0 %	0.0 %	0.0 %

As of December 31, 2015, 2014, and 2013, the Company had U.S. federal net operating loss carryforwards of approximately $143.8 million , $105.0 million , and $71.4 million , respectively, which may be available to offset future income tax liabilities and expire at various dates through 2035. As of December 31, 2015, 2014, and 2013, the Company also had U.S. state net operating loss carryforwards of approximately $128.5 million , $90.5 million , and $64.5 million , respectively, which may be available to offset future income tax liabilities and expire at various dates through 2035. Included in the federal and state net operating loss carryforwards are approximately $2.8 million , $1.9 million , and $130 thousand , respectively, of deductions related to the exercise of stock options. These amounts represent an excess tax benefit which will be realized when it results in the reduction of cash income tax in accordance with ASC 718.

As of December 31, 2015, 2014, and 2013, the Company had federal research and development tax credit carryforwards of approximately $3.7 million , $2.6 million , and $1.9 million , respectively, available to reduce future tax liabilities which expire at various dates through 2035. As of December 31, 2015, 2014, and 2013, the Company had state research and development tax credit carryforwards of approximately $2.4 million , $1.7 million , and $1.3 million , respectively, available to reduce future tax liabilities which expire at various dates through 2030.

Under the provisions of the Internal Revenue Code of 1986, as amended (the "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% , as defined under Sections 382 and 383 of the 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 Code, or could result in a change in control in the future.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2015 and 2014, 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, 2015, 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, 2012 through December 31, 2015. 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.

12. Quarterly financial information (unaudited, in thousands, except share and per share data)

	Three Months Ended,			
	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Revenue	$ 121	$ 115	$ 213	$ 221
Operating expenses	11,898	10,141	9,703	10,294
Net loss	(12,084)	(10,314)	(9,771)	(10,314)
Net loss per share - basic and diluted	$ (0.64)	$ (0.43)	$ (0.37)	$ (0.37)
Weighted-average number of common shares used in net loss per share - basic and diluted	18,834	24,154	26,610	28,118

	Three Months Ended,			
	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
Revenue	$ —	$ —	$ —	$ 308
Operating expenses	6,373	6,909	8,958	11,234
Net loss	(7,329)	(7,146)	(9,171)	(11,650)
Net loss per attributable to common stockholders	(7,509)	(7,146)	(9,171)	(11,650)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.76)	$ (0.41)	$ (0.53)	$ (0.66)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	9,859	17,346	17,465	17,696

13. Subsequent event

In August 2009, the Company entered into an exclusive license and collaboration agreement with Isconova AB, a Swedish company which subsequently was acquired by Novavax, Inc. ("Novavax"). Pursuant to the agreement, Novavax granted the Company 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. Matrix-M is the adjuvant used in GEN-003.

The agreement also contained a research funding clause for which the Company made monthly payments to Novavax between August 2009 and March 2012 of approximately $1.6 million . All amounts of research funding provided were to be refunded by Novavax. After December 31, 2015, any amounts remaining due from Novavax, including accrued interest, could be received in cash upon 30 -day written notice provided by the Company. The Company provided this notice in January 2016 and received the $1.6 million refund in February 2016.

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 February 17, 2016 .

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
/s/ William Clark William Clark	President and Chief Executive Officer and Director (Principal Executive Officer)	February 17, 2016
/s/ Jonathan Poole Jonathan Poole	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 17, 2016
/s/ Kenneth Bate Kenneth Bate	Director	February 17, 2016
/s/ Kevin Bitterman Kevin Bitterman, Ph.D.	Director	February 17, 2016
/s/ Katrine Bosley Katrine Bosley	Director	February 17, 2016
/s/ Michael Higgins Michael Higgins	Director	February 17, 2016
/s/ Stephen Hoffman Stephen Hoffman, M.D., Ph.D.	Director	February 17, 2016
/s/ George Siber George Siber, M.D.	Director	February 17, 2016

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	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)
4.4	Warrant Agreement between the Company and Hercules Technology Growth Capital, Inc., dated November 20, 2014 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on November 21, 2014)
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	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)
10.7	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)

Exhibit Number	Exhibit
10.8	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)
10.9†	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)
10.10†	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)
10.11†	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)
10.12†	Letter Agreement, dated April 7, 2014, between the Company and Jonathan Poole (incorporated by referenced to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on April 8, 2014)
10.13†	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)
10.14†	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)
10.15†	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)
10.16†	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)
10.17†	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)
10.18†	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)
10.19†	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)
10.20†	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)

Exhibit Number	Exhibit
10.21	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)
10.22†	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)
10.23+	Bioprocessing Services Agreement between the Company and FUJIFILM Diosynth Biotechnologies U.S.A., Inc. dated February 26, 2014 (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q, File No. 001-36289, filed on May 9, 2014)
10.24	Loan and Security Agreement between the Company and Hercules Technology Growth Capital, Inc., dated November 20, 2014 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on November 21, 2014)
10.25	Equity Rights Letter Agreement between the Company and Hercules Technology Growth Capital, Inc., dated November 20, 2014 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on November 21, 2014)
10.26+	Product Development and Clinical Supply Agreement between the Company and Baxter Pharmaceutical Solutions LLC, dated October 23, 2014 (incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K File No. 001-36289, filed on February 27, 2015)
10.27†	Fifth Amendment to the Consulting Agreement between Genocea Biosciences, Inc. and George Siber, dated June 15, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on June 19, 2015)
10.28	Amendment No. 1 to Loan and Security Agreement between the Company and Hercules Technology Growth Capital, Inc., dated December 17, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K File No. 001-36289, filed on December 18, 2015)
10.29	Sublease Agreement between the Company and the Smithsonian Institution, dated June 15, 2015 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on June 19, 2015)
21.1*	List of Subsidiaries of the Company
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 Chief Financial Officer
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 Chief Financial Officer

Exhibit Number	Exhibit
101. INS*	XBRL Instance Document
101. SCH*	XBRL Taxonomy Extension Schema
101. CAL*	XBRL Taxonomy Extension Calculation Linkbase
101. DEF*	XBRL Taxonomy Extension Definition Linkbase
101. LAB*	XBRL Taxonomy Extension Label Linkbase
101. PRE*	XBRL Taxonomy Extension Presentation Linkbase

* 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.

List of Registrant's Subsidiaries

Genocea Securities Corp., incorporated in Massachusetts, a wholly owned subsidiary.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-194021) pertaining to the Amended and Restated 2007 Equity Incentive Plan and 2014 Equity Incentive Plan of Genocea Biosciences, Inc.,
(2) Registration Statement (Form S-8 No. 333-197127) pertaining to the 2014 Employee Stock Purchase Plan of Genocea Biosciences, Inc.,
(3) Registration Statement (Form S-8 No. 333-202333) pertaining to the 2014 Equity Incentive Plan of Genocea Biosciences, Inc., and
(4) Registration Statement (Form S-3 No. 333-203981) of Genocea Biosciences, Inc.;

of our report dated February 17, 2016, with respect to the financial statements of Genocea Biosciences, Inc. included in this Annual Report (Form 10-K) of Genocea Biosciences, Inc. for the year ended December 31, 2015.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 17, 2016

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14 and 15d-14
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William D. Clark, Chief Executive Officer, certify that:

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

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

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

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

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

b) Designed such internal control over financial, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

/s/ WILLIAM D. CLARK

William D. Clark

President & Chief Executive Officer

Date: February 17, 2016

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14 and 15d-14
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jonathan Poole, Chief Financial Officer, certify that:

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

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

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

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

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

b) Designed such internal control over financial, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

/s/ JONATHAN POOLE

Jonathan Poole

Chief Financial Officer

Date: February 17, 2016

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Genocea Biosciences, Inc. (the "Company") for the period ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, William D. Clark, as the President & Chief Executive Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

/s/ WILLIAM D. CLARK

William D. Clark*

President &Chief Executive Officer

Date: February 17, 2016

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* A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-K or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Genocea Biosciences, Inc. (the "Company") for the period ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Jonathan Poole, as the Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

/s/ JONATHAN POOLE

Jonathan Poole*

Chief Financial Officer

Date: February 17, 2016

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*A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-K or as a separate disclosure document.