GENOCEA BIOSCIENCES, INC.
Form 10-K
February 28, 2019

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

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FORM 10-K

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x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
OR
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number 001-36289

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GENOCEA BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

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

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

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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 Capital Market

Securities registered pursuant to Section12(g) of the Act: None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. o Yes x No
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. o Yes x No
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes o No
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). x Yes o 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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	x
		Emerging growth company	x

If an emerging growth company, indicate by a check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

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

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, 2018, the last business day of the registrant’s most recently completed second quarter, was: $52,786,883.

The number of shares outstanding of the registrant’s common stock as of February 26, 2019 was 112,371,154.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s definitive proxy statement related to its 2019 annual meeting of stockholders to be filed subsequently are incorporated by reference into Part III of this report.

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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”, 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:

- our estimates regarding the timing and amount of funds we require to file our investigational new drug ("IND") application and initiate clinical trials for GEN-009 and to continue our investments in immuno-oncology;
- our estimate for when we will require additional funding;
- our plans to commercialize GEN-009 and our other product candidates, including GEN-010 and GEN-011;
- 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 seeks to discover and develop novel cancer immunotherapies. We use our proprietary discovery platform, ATLAS, to profile CD4+ and CD8+ T cell (or cellular) immune responses to tumor antigens. We use insights arising from ATLAS to design novel cancer immunotherapies. We believe that ATLAS, which recreates each individual's T cell immune responses to their tumor in the laboratory, affords Genocea advantages in the design of novel cancer immunotherapies relative to our peers, who we believe rely primarily on software and processes such as "machine learning" to predict immunotherapy targets.

Our most advanced program is GEN-009, a neoantigen (or personalized) cancer vaccine, for which we are conducting a Phase 1/2a clinical trial. The GEN-009 program uses ATLAS to identify neoantigens, or tumor mutations unique to each patient, for inclusion in each patient's GEN-009 vaccine. We are also advancing GEN-011, a neoantigen adoptive T cell therapy program as well as GEN-010, a next-generation neoantigen vaccine program.

ATLAS Platform

Harnessing and directing the T cell arm of the immune system to kill tumor cells is increasingly viewed as having potential in the treatment of many cancers, and this approach has clearly shown efficacy in hematologic malignancies. Treatments arising from this approach must target specific differences present in a tumor, such as genetic mutations. However, the discovery of such T cell targets, or antigens, has been particularly challenging for two reasons. First, the diversity of human T cell responses means that an effective T cell target for one person may be different from an effective T cell target for another person. Second, the number of candidate targets for T cell responses can be very large with up to thousands of candidate antigens per patient in some cancers. These complexities represent fundamental barriers that traditional cancer immunotherapy target discovery tools, which rely largely on computer modeling - so-called predictive algorithms - have, as yet, only poorly addressed.

We have designed the ATLAS platform to overcome these T cell target discovery challenges. We believe that ATLAS represents the most comprehensive and accurate high-throughput system for T cell immune response profiling in the biopharmaceutical industry. ATLAS is designed to mimic the T cell arm of the human immune system of each patient that it profiles in a laboratory setting. Using ATLAS, we are able to measure T cell responses to the entire set of potential T cell targets for an individual’s cancer. Using ATLAS, we can determine if these T cell responses are statistically above or below a baseline measurement and can develop immunotherapies using only those targets and T cells determined to be most likely to kill an individual’s cancer.

We believe that we are a leader in the field of T cell-related immunotherapy discovery and development. Our management and scientific teams possess considerable experience in oncology, immunology, and vaccinology spanning research, manufacturing, clinical development and regulatory affairs.

Our Programs

Our cancer immunotherapies are designed to educate T cells to recognize and attack specific targets - or to introduce T cells already educated to attack these targets - and thereby kill cancer cells. We are first developing personalized

cancer vaccines by applying ATLAS to identify patient neoantigens that are associated with that individual's pre-existing immune responses to a tumor.

Neoantigens are personalized tumor mutations that are seen as “foreign” by an individual’s immune system. Data published in recent years have indicated that an individual’s response to neoantigens drives immune checkpoint inhibitor ("ICI") efficacy and that it is possible to vaccinate an individual against their own neoantigens. If approved, neoantigen vaccines could be used in combination with existing treatment approaches for cancer, including ICIs, to potentially direct and enhance an individual’s T cell response to the individual’s cancer, thereby potentially effecting better clinical outcomes. Data also support the potential of isolating and expanding T cell populations targeting specific neoantigens for therapeutic benefit.

Our lead immuno-oncology program, GEN-009, is an adjuvanted neoantigen peptide vaccine candidate designed to direct a patient's immune system to attack their tumor. GEN-009's neoantigens are identified by our proprietary ATLAS platform, which is designed to profile CD4+ and CD8+ cell immune responses to tumor antigens. Following ATLAS neoantigen identification, we manufacture a personalized vaccine for each patient using only those neoantigens determined to be stimulatory to the immune system by ATLAS.

In June 2018, we initiated a Phase 1/2a clinical trial for GEN-009 in a range of tumor types in subjects with no evidence of disease but at high risk of relapse. In January 2019, we announced that we had commenced dosing patients and completed enrollment in this first part of the trial. We expect to report immunogenicity results from the initial patient cohort late in the second quarter or early in the third quarter of 2019.

We have also initiated pre-clinical work on GEN-011, an adoptive T cell therapy to neoantigens identified by ATLAS. We currently expect to file an Investigational New Drug Application ("IND") with the U.S. Food and Drug Administration ("FDA") for GEN-011 in the first half of 2020.

Behind GEN-009, we also continue to explore GEN-010, our vaccine candidate employing next-generation antigen delivery technology, which could provide an opportunity for even better immunogenicity and/or efficiency of production.

We are also using ATLAS to amass libraries of novel candidate antigens for non-personalized cancer immunotherapies. Such programs would target non-mutated, shared tumor-associated antigens and cancers of viral origin.

For shared antigens, we have had and continue to conduct a number of research collaborations that provide blood and tumor samples to antigen discovery and immune-response profiling as follows:

- Dana Farber Cancer Institute (ongoing), Mayo Clinic (completed), and Checkmate Pharmaceuticals (completed)

The Company is not dependent on these research collaborations to develop its product candidates and no material financial obligations exist as part of these collaborations.

For cancers of viral origin, we have profiled the immune responses that several cohorts of patients made to 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 that ATLAS 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 herpes virus family in which we have deep experience through our previous development of GEN-003.

Our Immuno-oncology Product Candidate Pipeline

The following table describes our active programs in development:

Vaccine Candidate	Program	Stage of Development	Next Milestone	Anticipated Timeline
GEN-009	First generation neoantigen cancer vaccine	Phase 1/2a	Immunogenicity data from the first patient cohort	Late Q2/early Q3 2019
GEN-010	Second generation neoantigen cancer	Pre-clinical	Select delivery technology platform	Ongoing

	vaccine			
GEN-011	Adoptive T cell therapy	Pre-clinical	IND filing	First half of 2020

In addition to our immuno-oncology programs, we also have an investigational immunotherapy for the treatment of genital herpes, GEN-003. To date, GEN-003 has completed three positive clinical trials. However, we have ceased substantially all activities under the GEN-003 program and are exploring alternatives to maximize shareholder value from GEN-003.

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 product candidates, including GEN-009, if approved.

There are several companies attempting to develop new neoantigen cancer vaccines, including Advaxis Inc., Agenus Inc., BioNTech AG., CureVac AG., Gritstone Oncology Inc., Moderna Inc., and Neon Therapeutics Inc. We believe that GEN-009 has advantages against each of these product candidates based on the potential power of the ATLAS platform to comprehensively identify for each cancer patient the neoantigens to which such patient has a pre-existing immune response. We believe that selecting neoantigens for personal cancer vaccines using ATLAS will lead to more effective vaccines. However, there can be no assurance that one or more of these companies or other companies will not achieve similar or superior clinical results in the future as compared to GEN-009 or that our future clinical trials will be successful.

Similarly, there are other companies attempting to develop cellular therapies targeted towards neoantigens, either through transferring T cells that have been transduced with T-cell Receptors ("TCR") that recognize tumor antigens, or T cells that have been enriched from tumors in a non-specific way (tumor infiltrating lymphocytes), or T cells from the peripheral blood that have been expanded on multiple tumor-specific antigens. These include Achilles Therapeutics Ltd., Adaptive Biotechnologies Corp., BioNTech AG., Bluebird Bio Inc., Cellular Biomedicine Group Inc., Eutilex Co., Ltd., Iovance Biotherapeutics Inc., Kite Pharma, Inc., Neon Therapeutics Inc., Oncotherapy Science Inc., PACT Pharma Inc., and Ziopharm Oncology Inc. We believe that Genocea’s ATLAS true neoantigen selection will lead to better targeted and more effective cell therapy; 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-011, 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 based on, 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 and cell therapy fields. 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 and cell therapy 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 five issued U.S. patents. We hold an exclusive license from President and Fellows of Harvard College ("Harvard") to the first patent family, which covers methods related to the ATLAS discovery platform, including discovery of antigens expressed in neoplastic cells. This first patent family includes U.S. Patents 9,051,564 and 9,920,314, a pending U.S. application, issued patents in Europe, Canada, and Australia, and pending applications in Europe and Canada. Patents issuing from these applications are expected to expire in 2027, with the exception of U.S. Patents 9,051,564 and 9,920,314, which include Patent Term Adjustments and extend until December 2031 and June 2028, respectively. We wholly own a second patent family, which is specifically directed to the ATLAS platform as utilized by us, including for discovery of cancer- or tumor-related antigens. This second patent family includes U.S. Patents 8,313,894, 9,045,791, and 9,873,870, a pending U.S. patent application, issued patents in Europe, Canada, and Australia, and pending applications in Europe and Canada. 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. U.S. Patent 9,873,870 has a term that extends until July 2029. We wholly own the third patent family, which is directed to methods for cancer diagnosis, prognosis, and patient selection, as well as related compositions. This third family currently comprises a pending PCT application and a pending U.S. application. We wholly own three further potential patent families, currently comprising six provisional applications filed in late 2018 and early 2019. The provisional applications are directed to ATLAS-based methods for further selection of cancer- or tumor-related antigens, and for redirecting immune responses.

GEN-003 (Genital Herpes)

We wholly own a portfolio of patent applications directed to herpes simplex virus-2, or 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, and combination treatment with antiviral medications. The first patent family includes U.S. Patents

8,617,564 and 9,895,436, a pending U.S. application, and patents granted in Australia, China, Indonesia, Israel, Japan, Korea, Mexico, Malaysia, New Zealand, Russia, Singapore, and South Africa. Applications in Europe, Canada, Brazil, India, China and Hong Kong are pending in the first patent family. Patents that issue from applications in the first family are expected to expire in 2030. The term for U.S. Patent 8,617,564 includes Patent Term Adjustment and extends until at least November 2030. U.S. Patent 9,895,436 has a term that extends until May 2030. The second family includes a pending PCT application and a pending U.S. application. Patents that issue from applications in this family are expected to expire in 2037.

We own two further patent families covering follow-on HSV-2 vaccine compositions. The first family includes U.S. Patent 9,782,474, with a term that extends until 2031. The second family includes U.S. Patent 9,624,273, patents granted in Australia and Japan, and pending applications in Europe and Canada. U.S. Patent 9,624,273 has a term that extends until 2032; further patents that issue from applications in 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. The first patent family includes a pending U.S. application and issued patents in Europe, Canada, Australia, Japan, Brazil, New Zealand and South Africa. The second patent family includes U.S. Patent 8,821,881 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 issued U.S. patent in the second patent family, U.S. Patent 8,821,881, has a term that extends until August 2026 inclusive of Patent Term Adjustment.

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

Harvard University

In November 2007, we entered into an exclusive license agreement with Harvard University, 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 University intellectual property covers methods related to the ATLAS discovery platform, including discovery of antigens expressed in neoplastic cells, 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 University 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 University 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, regarding 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 certain aspects of the ATLAS platform covered by this family.

We are obligated to pay Harvard University 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, 2018, we incurred $231 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 sales-based royalty due 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. Based 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 University 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 University 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.

Manufacture Contracts

Oncovir

In January 2018, we entered into a License and Supply Agreement with Oncovir, Inc. (“Oncovir”). The agreement provides the terms and conditions under which Oncovir will manufacture and supply an immunomodulator and vaccine adjuvant, Hiltonol® (poly-ICLC) (“Hiltonol”), to us for use in connection with the research, development, use, sale, manufacture, commercialization and marketing of products combining Hiltonol with our technology (the “Combination Product”). Hiltonol is the adjuvant component of GEN-009, which will consist of synthetic long peptides or neoantigens identified using our proprietary ATLAS platform, formulated with Hiltonol. When paired with synthetic long peptides, Hiltonol has shown the ability to induce T cell responses, which we believe will be important for driving the clinical efficacy of GEN-009. Hiltonol is manufactured under good manufacturing practice ("GMP") conditions, has an existing drug master file, and has an extensive tolerability record when used alone and in combination with vaccine antigens. We are not required to purchase any minimum quantity of Hiltonol from Oncovir.

Oncovir granted us a non-exclusive, assignable, royalty-bearing worldwide license, with the right to grant sublicenses through one tier, to certain of Oncovir’s intellectual property in connection with the research, development, or commercialization of Combination Products, including the use of Hiltonol, but not the use of Hiltonol for manufacturing or the use or sale of Hiltonol alone. The license shall become perpetual, fully paid-up, and royalty-free on the later of January 25, 2028 or the date on which the last valid claim of any patent licensed to us under the agreement expires.

Under this agreement, we are obligated to pay Oncovir (i) an up-front payment in the mid-six figures in consideration of the license granted to us and for the initial supply of Hiltonol for the GEN-009 Phase 1/2 trial, (ii) a supply price for Hiltonol in the low-three figures per vial of Hiltonol for use in clinical trials or commercial use, (iii) a milestone payment in the low-six figures upon the achievement of certain clinical trial milestones for each Combination Product, (iv) a milestone payment in the mid-six figures upon the first marketing approval for each Combination Product in certain territories, and (v) tiered royalties in the low-single digits on a product-by-product basis based on the net sales of Combination Products.

We may terminate the agreement upon a decision to discontinue the development of the Combination Product or upon a determination by us or an applicable regulatory authority that Hiltonol or a Combination Product is not clinically safe or effective. The agreement may also be terminated by either party due to a material uncured breach by the other party, or due to the other party's bankruptcy, insolvency, or dissolution.

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.

Government Regulation

Biological products such as vaccines and adaptive cell therapies 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 process:

- 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, including approval by an independent Institutional Review Board (“IRB”), representing each clinical site before each clinical trial may be initiated;
- 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 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 also may 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 adverse events ("AEs") should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

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

- Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. 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 safety, purity, and potential of biological product 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 approval and 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 or terminate 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. Sponsors of all controlled clinical trials, except for Phase 1 trials, are required to submit certain clinical trial information for inclusion in the public clinical trial registry and results data bank maintained by the National Institutes of Health, which are publicly available at http://clinicaltrials.gov.

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, and for what indications will be approved, if any.

Under the Prescription Drug User Fee Act ("PDUFA"), as re-authorized for an additional five years in 2017, each BLA must be accompanied by a significant user fee. PDUFA also imposes annual product fees based on each approved biologic. 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 regulations 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 REMS, 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.

United States Fraud and Abuse, Transparency and Privacy Laws

In the United States, our business activities are subject to numerous other federal, state and local laws designed to prevent fraud and abuse, promote transparency in interactions with others in the healthcare industry or protect the privacy of individual information. 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, the United States Department of Health and Human Services ("HHS"), HHS' various divisions, including but not limited to, the Centers for Medicare & Medicaid Services ("CMS"), the Office of Inspector General, the Office for Human Research Protections, and the Office of Research Integrity, and other state and local government agencies.

Although we currently have no products approved for commercial sale, we may be subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws, for activities related to future sales of any of our product candidates that may in the future receive regulatory and marketing approval. Anti-kickback laws generally prohibit a pharmaceutical manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase, prescription or use of a particular drug. False claims laws generally prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for reimbursed drugs or services to third party payors (including Medicare and Medicaid) that are false or fraudulent. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices. There is therefore a possibility that our practices might be challenged under such laws.

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers with marketed products. The laws and regulations generally limit financial interactions between manufacturers and health care providers and/or require disclosure to the government and public of such interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, any future activities (if we obtain approval and/or reimbursement from federal healthcare programs for our product candidates) could be subject to challenge.

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 for 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 approval 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 coverage for those products under Medicaid, Medicare, and the 340B drug pricing programs. These programs are administered by various federal and state agencies and provide prescription drug benefits to individuals who are age 65 and over, low income, or disabled or allow healthcare providers that serve vulnerable populations to purchase prescription drugs at discounted prices. In the future, we may also seek to sell any approved product candidates to government purchasers. In order to obtain coverage for our products under government benefit programs, or to sell products to government purchasers, we may be required to track and report prices for our products, offer discounts to certain purchasers, or pay rebates on certain utilization.

In the United States, federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (the "Healthcare Reform Act") which expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under government healthcare programs. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the Healthcare Reform Act. For example, tax reform legislation was enacted at the end of 2017 that eliminates the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called “individual mandate”). In a May 2018 report, the Congressional Budget Office estimated that, compared to 2018, the number of uninsured will increase by 3 million in 2019 and 6 million in 2028, in part due to the elimination of the individual mandate. The Healthcare Reform Act has also been subject to judicial challenge. In December 2018, a federal district court judge, in a challenge brought by a number of state attorneys general, found the Healthcare Reform Act unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. Pending appeals, which could take some time, the Healthcare Reform Act is still operational in all respects.

There have been other reform initiatives under the Trump Administration, including initiatives focused on drug pricing. For example, in May of 2018, President Trump and the Secretary of the Department of Health and Human Services released a “blueprint” to lower prescription drug prices and out-of-pocket costs. Certain proposals in the blueprint, and related drug pricing measures proposed since the blueprint, could cause significant operational and reimbursement changes for the pharmaceutical industry. As another example, in November of 2018, CMS issued an advance notice of proposed rulemaking that proposed revisions to Medicare Part D to support health plans’ negotiation of lower drug prices with manufacturers and reduce health plan member’s out-of-pocket costs. The HHS Office of Inspector General issued a proposed rule in February of 2018 that would revise the federal anti-kickback statute to limit protection for discounts offered by pharmaceutical manufacturers to pharmacy benefit managers (“PBMs”), Medicare Part D plans, and Medicaid managed care plans that are not reflected in the price charged to the patient at the pharmacy counter and to provide protection only for certain types of service fees paid by pharmaceutical manufacturers to PBMs.

There have also been other efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our product candidates if approved for sale. We cannot, however, predict the ultimate content, timing, or effect of any changes to the Healthcare Reform Act or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

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. In light of the United Kingdom's vote in 2016 to leave the European Union, the so-called Brexit vote, there may be changes forthcoming in the scope of the centralized approval procedure as the terms of that exit are negotiated between the United Kingdom and the European Union.

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.

Executive Officers of the Registrant

The following table sets forth the name, age and position of each of our executive officers as of February 28, 2019.

Name	Age	Position
William Clark	50	President and Chief Executive Officer
Girish Aakalu, Ph.D.	45	Chief Business Officer
Michael Alfieri	54	Vice President, Finance and Principal Financial Officer
Pamela Carroll, Ph.D.	55	Senior Vice President, Immuno-oncology
Thomas Davis, M.D.	55	Chief Medical Officer
Jessica Baker Flechtner, Ph.D.	47	Chief Scientific Officer
Derek Meisner	48	Senior Vice President, General Counsel
Narinder Singh	46	Senior Vice President, Pharmaceutical Sciences and Manufacturing

William "Chip" Clark. Chip has served as our President and Chief Executive Officer since February 2011 after serving as our Chief Business Officer from August 2010 to February 2011. Chip has also served on our board of directors since February 2011. Prior to joining Genocea, he served as Chief Business Officer at Vanda Pharmaceuticals, a biopharmaceutical company he co-founded in 2004. While at Vanda, he led the company’s strategic and business development activities and played a central role in raising more than $400 million through business development deals and equity financings. Prior to Vanda, Chip was a principal at Care Capital, a venture capital firm investing in biopharmaceutical companies, after serving in a variety of commercial and strategic roles at SmithKline Beecham (now GlaxoSmithKline). Chip holds a B.A. from Harvard University and an M.B.A. from The Wharton School at the University of Pennsylvania.

Girish Aakalu, Ph.D. Girish joined Genocea in December 2018 as Chief Business Officer. In this role, he leads Genocea’s business development efforts. His broad skill set spans business development, corporate and R&D strategy, product portfolio management, commercial planning, and alliance management. Prior to joining Genocea, Girish was employed by the Ipsen Group, from May 2015 until December 2018, where he was most recently Vice President: Global Head of External Innovation, and Pfizer, Inc., from October 2007 until May 2015, where he held the title of Executive Director: Head of Strategy, Innovation & Operations for Pfizer’s External R&D Innovation team prior to his departure. His previous roles also include business development and oncology pipeline market planning positions at Genentech, Inc. and life science consulting experience at L.E.K Consulting. He received a B.A. in Biophysics with General and Departmental Honors from Johns Hopkins University, a Ph.D. in Cellular and Molecular Neurobiology following an M.S. in Biology from the California Institute of Technology and has completed executive education in Corporate Governance at Northwestern University - Kellogg School of Management.

Michael Alfieri. Mike has served as our Vice President of Finance since joining Genocea in May 2018 and our Principal Financial Officer since June 2018. Prior to joining Genocea, Mike served as Vice President of Finance at Radius Health, Inc. from January 2017 through May 2018, Corporate Controller at Merrimack Pharmaceutical, Inc. from July 2014 through January 2017 and the Executive Director of Finance and Corporate Controller at Anika Therapeutics, Inc. from September 2010 through July 2014. Mike began his career as a staff accountant in the Boston office of Price Waterhouse and spent nearly eight years in a regional public accounting firm prior to moving into industry. Mike holds a M.S. in Taxation and a B.S. in Accountancy, both from Bentley University (College).

Pamela Carroll, Ph.D. Pam has served as Senior Vice President of Immuno-oncology at Genocea since 2016. Prior to joining Genocea, Pam served as Senior Vice President of Research at Compass Therapeutics LLC. (2015-2016), Vice President of Janssen Oncology, Johnson and Johnson Innovation (2013-2015), and Vice President Oncology Discovery at Roche Pharma Research and Development (2011-2013). Earlier roles include Head of Research at the Belfer Institute for Applied Cancer Science at Dana Farber Cancer Institute and Director of Cancer Pathways at Merck Research Labs. Pam received her Ph.D. from Stony Brook University in Cell and Development Biology and performed postgraduate research at Stanford University.

Thomas Davis, M.D. Tom joined Genocea in October 2018 as Chief Medical Officer with over 20 years of academic and industry experience in immuno-oncology and cancer drug development. Most recently, he served as Chief Medical Officer of Gadeta B.V., a Dutch cell therapy company pursuing novel cancer targets from October 2017 to April 2018, where he steered a novel cell therapy technology into first-in human clinical studies. Prior to Gadeta B.V., he served as Chief Medical Officer of Celldex from 2006 to 2017, where he led all aspects of clinical and regulatory development including strategy, tactics, and execution. While at Celldex, Tom actively built and oversaw Clinical Science, Medical Affairs, Safety, Clinical Operations, Statistics, Regulatory Affairs, and Project Management, managed collaborations with large global pharmaceutical partners, and participated in investor relations activities. He also served as Chief Medical Officer at GenVec and as Senior Director of Clinical Science at Medarex.Prior to joining the industry, Tom supervised clinical efforts at the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI), and worked on the development of rituximab and idiotype vaccines at Stanford University. Dr. Davis received his B.A. in Biophysics from Johns Hopkins, his M.S. in Physiology and his M.D. from Georgetown University, and completed a fellowship in medical oncology at Stanford University.

Jessica Baker Flechtner, Ph.D. Jess joined Genocea in 2007, soon after the company was founded, and has held multiple scientific roles since joining Genocea. She has served as our Chief Scientific Officer since February 2016, Senior Vice President of Research from February 2014 to January 2016, Vice President of Research from January 2010 to February 2014, and Senior Director, Research and Development from 2007 to 2010. Prior to joining Genocea, 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, American Association for Cancer Research, Society for the Immunotherapy of Cancer, the President's Council of Cornell Women, and Women in Bio.

Derek Meisner. Derek joined Genocea in September 2018 as Senior Vice President and General Counsel. In this role, Derek manages Genocea's legal affairs and advises the company on business strategy and implementation. He has extensive experience as a corporate attorney, serving as the General Counsel to Boston-based financial services Quantopian, Inc. from 2016-2018, a prominent biotechnology investment firm (2015-2016) and alternative investment firm (2007-2014). Derek also previously served as Partner at the international law firm of K&L Gates, where he counseled various corporate clients on corporate governance, regulatory, and compliance matters, and as a Branch Chief in the Division of Enforcement of the U.S. Securities and Exchange Commission. Derek earned a B.A. from the University of Michigan and a J.D. from the American University, Washington College of Law.

Narinder Singh. Narinder joined Genocea in March 2018 as Senior Vice President, Pharmaceutical Sciences and Manufacturing. In this role, Narinder manages the manufacturing process development and manufacturing of Genocea's products. Narinder has extensive experience in process development, scale-up, technical operations, and manufacturing supply chain of biopharmaceuticals. Prior to joining Genocea, Narinder served as Vice President of Drug Product Development and Manufacturing at Momenta Pharmaceuticals from July 2015 to March 2018, responsible for process development and manufacturing of drug products for Momenta's biosimilars and novel product portfolio. Prior to Momenta, Narinder served as Director, Drug Product Technology at Amgen from June 2007 to July 2015, responsible for process development, commercialization, manufacturing and new technology development for drug products development of Amgen's biologics-based portfolio. He began his career at Amgen functioning in various junior technical roles, beginning in 1997. Narinder received an Integrated B.Tech/M.Tech. in Biochemical Engineering and Biotechnology from the Indian Institute of Technology, Delhi in 1995, an M.S. in Chemical Engineering from the University of Houston, and an M.B.A. from UCLA Anderson School of Management.

Employees

As of December 31, 2018, we had 61 full-time employees, of which 44 were engaged in research and development and 17 were engaged in finance, legal, business development, human resources, facilities, information technology or other general and administrative functions. None of our employees is represented by a labor union or covered by a collective bargaining agreement and we have not experienced any work stoppages. We consider our relations with our employees to be good.

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"). The SEC also 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. 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.

Item 1A. Risk Factors

Risks Related to Our Financial Position and Need for Additional Capital

We require additional financing to execute our operating plan and continue to operate as a going concern.

Our audited financial statements for the year ended December 31, 2018 have been prepared assuming we will continue to operate as a going concern, but we believe that our continuing operating losses raise substantial doubt about our ability to continue as such. We plan to continue to fund our operations through public or private equity offerings, strategic transactions, proceeds from sales of our common stock under our at-the-market equity offering program, our loan and security agreement with Hercules Capital, Inc. ("Hercules"), or by other means. However, adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed, or on attractive terms, we may be forced to implement further cost reduction strategies, including ceasing development of GEN-009 and/or other product candidates and other corporate activities.

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 $27.8 million and $56.7 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018 and 2017, we had accumulated deficits of approximately $292.0 million and $264.2 million, respectively. To date, we have not commercialized any products or generated any revenues from the sale of products and do not know whether or when we will generate product revenues or become profitable. To date, we have financed our operations primarily through private placements of our common stock and preferred stock, debt financings, our initial public offering ("IPO") completed in February 2014 and multiple public equity offerings.

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, other than GEN-003, which we have ceased developing, 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 clinical trials for GEN-009, our most advanced product candidate focused on neoantigen cancer vaccines, and initiate non-clinical or clinical 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 that 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, 2018, our cash and cash equivalents were $26.4 million. In February 2019, we raised approximately $14.2 million, after deducting approximately $0.8 million in placement agent fees, excluding offering costs, through a private placement with certain existing and new investors. We believe that we will continue to expend substantial resources for the foreseeable future developing GEN-009 and any other neoantigen cancer vaccine 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. Furthermore, because of the significant expense associated with conducting clinical trials, we cannot be certain we will have sufficient capital to complete such trials for a given product candidate.

Our future capital requirements depend on many factors, including:

- the costs associated with conducting additional clinical trials for GEN-009;
- the number and development requirements of other product candidates that we pursue, including the costs of filing an IND for GEN-011;
- 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 and cash equivalents, inclusive of the approximately $14.2 million from the February 2019 private placement, are sufficient to support our operating expenses and capital expenditure requirements into the first quarter of 2020.

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.

We cannot be certain that we will be successful in advancing GEN-009, our lead product candidate, through clinical development, obtaining regulatory approval for it, or commercializing it or any of our future product candidates.

At this time, GEN-009 is our most advanced product candidate and our future revenues, if any, will depend highly on the successful clinical progress, approval, and commercialization of GEN-009. GEN-009 and any future product candidate will require substantial clinical development, testing and regulatory approval before we are permitted to commence commercialization. This process can take many years and will require the expenditure of substantial resources and we expect it will require that we obtain substantial additional funding.

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 net debt financing in December. In January 2018, we raised additional net proceeds of approximately $51.7 million through concurrent public offerings of our common stock and warrants exercisable for shares of our common stock and preferred stock and warrants exercisable for shares of our common stock (the "Concurrent Offerings"). In February 2019, we raised additional net proceeds of approximately $14.2 million, after deducting approximately $0.8 million in placement agent fees, excluding offering costs, through

private placement. We have also periodically sold shares under our at-the-market equity offering program with Cowen and Company, LLC (the "ATM"). 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-009, our immuno-oncology program, or our other product candidates. For example, in September 2017, we ceased substantially all spending and activities related to GEN-003 and are currently exploring strategic alternatives for

advancing that product candidate. If we are unable to raise additional capital when needed, we may also be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our stockholders will experience substantial additional dilution if shares of our preferred stock are converted into, or outstanding options or warrants are exercised for, common stock.

As of February 15, 2019 there were 1,635 shares of our Series A convertible preferred stock outstanding, which are convertible, without payment of additional consideration, into 1,635,000 shares of our common stock. As of February 15, 2019, there were 32,270,688 shares of common stock issuable upon the exercise of warrants, having a weighted average exercise price of $1.14 per share, and 10,448,413 shares of common stock issuable upon the exercise of stock options outstanding, having a weighted average exercise price of $1.77 per share. The conversion of the outstanding shares of our Series A convertible preferred stock into, or exercise of outstanding options or warrants for, common stock would be substantially dilutive to the outstanding shares of common stock. Any dilution or potential dilution may cause our stockholders to sell their shares, which may contribute to a downward movement in the stock price of our common stock.

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-009, our only product candidate currently in active clinical trials. Any failure to successfully develop or commercialize the GEN-009 vaccine, or any significant delays in doing so, will have a material adverse effect on our business, result of operations and financial condition.

In September 2017, we ceased substantially all spending and activities related to GEN-003, our Phase 3-ready product candidate, and are currently exploring strategic alternatives for advancing that product candidate. We are now currently investing a significant portion of our efforts and financial resources in the development of the GEN-009, a neoantigen cancer vaccine which is currently in a Phase 1/2a clinical trial. Our ability to generate product revenue depends heavily on the success of clinical trials for GEN-009 and the successful development and commercialization of GEN-009. The successful development and commercialization of GEN-009 will depend on several factors, including the following:

- successful completion of all required clinical trials of GEN-009;
- obtaining marketing approvals from regulatory authorities for GEN-009;
- establishing manufacturing and commercialization arrangements between ourselves and third parties;
- establishing an acceptable safety and efficacy profile of GEN-009; and
- the availability of reimbursement to patients from healthcare payors for GEN-009.

Any failure to successfully develop or commercialize GEN-009 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 clinical development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenue.

GEN-009 is currently in a Phase 1/2a clinical trial. The results from this trial may not be successful. Even if the results are successful, such results 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. Our product candidates may require complex manufacturing processes and scaling up these processes can cause changes in the product that may not be apparent until the product is further tested during Phase 3 trials.

If the results of our 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.

Furthermore, we need to develop the supply chain for any product candidates we identify.

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-009 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 AEs 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.

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;
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment; and
- the acceptability of data obtained from studies conducted outside the United States to the FDA in support of a BLA.

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

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 caused by us or third parties in conducting Part 1/2a or subsequent clinical trials for GEN-009;
- delays by us in reaching a consensus with regulatory agencies on trial design, including the IND for GEN-011;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required Institutional Review Board ("IRB") approval at each clinical trial site;
- imposition of a clinical hold by regulatory agencies or an IRB for any reason, including safety concerns raised by other clinical trials of similar vaccines that may reflect an unacceptable risk with GEN-009 or after an inspection of clinical operations or trial sites;
- failure to perform in accordance with the FDA’s good clinical practices ("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. We cannot give any assurance that we will be able to resolve any delay caused by the 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-009, and our current and future potential product candidates 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.

We have concentrated our research and development efforts on T cell vaccine and immunotherapy technology, which is a novel approach for vaccines, immuno-therapies and medical treatments, and our future success is highly dependent on the successful development of T cell immunotherapies in general, and our active development product and current and future product candidates in particular. 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. 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. 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 AEs 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.

Our active development product, GEN-009, 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 of the immune system and improve the 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-009, may include one or more novel adjuvants. Any neoantigen cancer 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.

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 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-009, and any other current or potential future 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 clinical development product, GEN-009, 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, and intend to continue to rely on, on third party CROs and other third parties to assist in managing, monitoring and otherwise carrying out our GEN-009 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 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 intend to rely on third parties with respect to manufacturing GEN-009. We have also relied on third party suppliers and manufacturers to manufacture and supply vaccines for other 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 unavailability of a manufacturer that is capable of, or that has the capacity to, manufacture our clinical supply that results in delays or additional manufacturing costs;
- 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. For example, in September 2017, we ceased substantially all spending and activities related to GEN-003 and are currently exploring strategic alternatives for advancing that product candidate.

In addition, we are currently seeking to establish strategic partnerships with companies with adjuvant and delivery technologies for our neoantigen cancer vaccine candidates. If we are unable to successfully enter into these partnerships, our ability to develop our neoantigen cancer vaccine candidates may be adversely affected.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, patent applications, know-how and confidentiality agreements to protect the intellectual property related to our platform technology and product candidates. The patent position of biotechnology companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the United States Patent and Trademark Office ("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 and could limit or destroy our ability to develop or commercialize one or more of our products, or even any product. 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 be issued, 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.

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. Furthermore, both the U.S. and foreign patent systems permit third parties or, in some cases, the patent authorities themselves, to initiate proceedings challenging the scope and / or validity of issued patents, including for example, opposition, derivation, reexamination, inter partes review or interference proceedings. An adverse determination against our or our licensor's patent rights 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.

Filing, prosecuting and enforcing patents on our platform or product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from infringing our patents in all countries outside the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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 defend 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, and competitors or other third parties may challenge the validity or enforceability of those rights. To counter infringement or unauthorized use, or to defend against other challenges, 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 contested proceedings, a court or agency 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 such relevant 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, or our licensors fail to obtain and maintain intellectual property rights, 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. For example, our discovery platform is built, in part, around patents exclusively in-licensed from academic or research institutions. See “Business - In-License Agreements” and “Business - Other Collaborations” for a description of our outstanding license and collaboration agreements with Oncovir and Harvard. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. In that event, we may be required to expend significant time and resources to redesign our product candidates or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly.

Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. For example, in our existing license agreements, and we expect in our future agreements, patent prosecution of our licensed technology may be controlled by the licensor, and we may be required to reimburse the licensor for their costs of patent prosecution. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products covered by the intellectual property. Further, in our license agreements we may be responsible for bringing any actions against any third party for infringing the patents we have licensed. 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. For example, disputes may arise regarding intellectual property subject to a licensing agreement, including the scope of rights granted under the license agreement and other interpretation-related issues; the extent to which our technology infringes the intellectual property of the licensor that is not subject to the licensing agreement; the sublicensing of patent and other rights under any collaborative development relationships; our diligence obligations under the license agreement and what activities satisfy those diligence obligations; the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and the priority of invention of patented technology. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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-009 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. 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 coverage 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 instead 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 for which drugs they will provide coverage 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 require us to lower the price of or provide discounts on, 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 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 Healthcare Reform Act, as well as ongoing efforts to eliminate or significantly modify the Healthcare Reform Act. For example, recent tax reform legislation eliminating the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 is expected to increase significantly the number of uninsured. See “Business- Government Regulation-Reimbursement”. It is likely that federal and state legislatures within the United States as well as foreign governments will continue to consider changes to existing health care legislation.

We cannot predict the ultimate content, timing or effect of any changes to the Healthcare Reform Act or other federal and state reform efforts within the United States or abroad. There is no assurance that health care reform will not adversely affect our business and financial results, and we cannot predict how future legislative, judicial or administrative changes relating to healthcare reform will affect our business.

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.

In addition, other broader legislative changes have been adopted that could have an adverse effect upon, and could prevent, our products' or product candidates' commercial success. The Budget Control Act of 2011, as amended, or the Budget Control Act, includes provisions intended to reduce the federal deficit, including reductions in Medicare payments to providers through 2027. Any significant spending reductions affecting Medicare, Medicaid, or other publicly funded or subsidized health programs, or any significant taxes or fees imposed as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, or otherwise, could have an adverse impact on our anticipated product revenues.

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.

Other companies that are seeking to identify antigens for the development of vaccines and T cell receptor therapies using predictive tools include Achilles Therapeutics Ltd., Adaptive Biotechnologies Corp., BioNTech AG., Bluebird Bio Inc., Cellular Biomedicine Group Inc., Eutilex Co., Ltd., Iovance Biotherapeutics Inc., Kite Pharma, Inc., Neon Therapeutics Inc., Oncotherapy Science Inc., PACT Pharma Inc. and Ziopharm Oncology Inc.

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. 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 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. 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. We do not yet have any information related to whether GEN-009 may cause AEs or serious AEs.

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 the First Amendment to the 2014 Term Loan with Hercules. The First Amendment required us to draw an additional $5.0 million and permitted us to draw two additional $5.0 million tranches, which expired unused at December 15, 2016. On April 24, 2018 we entered into an amended and restated loan and security agreement with Hercules, which provided up to $14.0 million in debt financing in the form of a term loan (the "2018 Term Loan"). The proceeds from the 2018 Term Loan was used to refinance the 2014 Term Loan. As a result, at December 31, 2018, no amounts were outstanding under the 2014 Term Loan and $14.8 million was outstanding under the 2018 Term Loan.

All obligations under our 2018 Term Loan are secured by substantially all of our existing property and assets, excluding our intellectual property and in-licensed 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 the fact that:

- 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 2018 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 that 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. If we do not make scheduled payments when due, or otherwise materially breach or experience an event of default under our 2018 Term Loan, Hercules could accelerate our total loan obligation or enforce its security interest against us.

Failure to satisfy our current and future debt obligations under our 2018 Term Loan could result in an event of default. In addition, other events, including certain events that are not entirely in our control, such as the occurrence of a material adverse event on our business, could cause an event of default to occur. As a result of the occurrence of an event of default, Hercules could accelerate all of the amounts due. In the event of an acceleration of amounts due under our 2018 Term Loan, 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. If we are unable to pay amounts due to Hercules upon acceleration of the 2018 Term Loan or if Hercules enforces its security interest against our assets securing our indebtedness to Hercules, our ability to continue to operate our business may be jeopardized.

We are subject to certain restrictive covenants which, if breached, could result in the acceleration of our debt under the 2018 Term Loan and have a material adverse effect on our business and prospects.

Our 2018 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.

These restrictive covenants may prevent us from undertaking an action that we feel is in the best interests of our business. In addition, if we were to breach any of these restrictive covenants, Hercules could accelerate our indebtedness under the 2018 Term Loan or enforce its security interest against our assets, either of which would materially adversely affect our ability to continue to operate our business.

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. 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 as a result of our recent workforce reduction, the status of our clinical development programs and 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, 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:

- 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 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, until December 31, 2019. 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 $250.0 million as of June 30 in any given year, or if we have less than $100.0 million in annual revenues and the market value of our common stock held by non-affiliates is below $700.0 million, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, 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 we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act for that year.

Our largest stockholder, New Enterprise Associates (“NEA”), could exert significant influence over us and could limit your ability to influence the outcome of key transactions, including any change of control.

Our largest stockholder, NEA, beneficially owns, in the aggregate, shares representing approximately 31% of our outstanding common stock as of February 15, 2019. In addition, one member of our board of directors is associated with NEA. As a result, we expect that NEA will be able to exert significant influence over our business. NEA may have interests that differ from your interests, and it may vote in a way with which you disagree and that may be adverse to your interests. The concentration of ownership of our capital stock may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and may adversely affect the market price of our common stock.

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 and we may become involved in securities-related litigation, including securities class action litigation, that could divert management’s attention and harm our business and subject us to significant liabilities.

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.

Beginning on October 31, 2017, three putative class action complaints were filed in the U.S. District Court for the District of Massachusetts (the "District of Massachusetts" or the "Court"), naming the Company, Chief Executive Officer William D. Clark, and former Chief Financial Officer Jonathan Poole as defendants. The Court consolidated the three actions into one case, captioned Emerson et al. v. Genocea Biosciences, Inc., et al., Civil Action No.

17-cv-12137-PBS (D. Mass.), and appointed the Genocea Investor Group (a group of five purported shareholders) as lead plaintiff. On March 29, 2018, counsel for the lead plaintiff filed an amended complaint in the District of Massachusetts that alleged violations of the Securities Exchange Act of 1934 and Rule 10b-5 in connection with the Company's disclosures from March 31, 2016 to September 25, 2017 concerning the development of GEN-003. The amended complaint added Seth V. Hetherington, former Chief Medical Officer, to the original named defendants, and sought unspecified damages and costs. On December 6, 2018, the District of Massachusetts granted defendants' motion to dismiss the amended complaint for failure to state a claim. On January 7, 2019, the lead plaintiff filed a notice of appeal in the District of Massachusetts regarding the Court order dismissing the amended complaint. The appeal has been docketed in the First Circuit under the caption Yuksel, et al. v. Genocea Biosciences, et al., Civil Action No. 19-1036 (1st Cir.). The Company is unable at this time to determine whether the outcome of the securities action litigation would have a material impact on its results of operations, financial condition or cash flow.

Beginning on January 31, 2018, two putative shareholder derivative actions were filed in the U.S. District Court for

the District of Delaware, naming certain of the Company's officers and directors (including certain former directors and officers) as defendants, and naming the Company as a nominal defendant. On August 24, 2018, the court consolidated the two actions into one case, captioned In re Genocea Biosciences, Inc. Derivative Litigation, Civil Action No. 18-cv-00186-MN (D. Del.). The operative complaint in the now-consolidated action alleges violations of the Securities Exchange Act of 1934 and Rule 14a-9 in connection with disclosures made in the Company's Schedule 14A Proxy Statement, filed with the SEC on April 21, 2017. The complaint also alleges claims for breach of fiduciary duty, unjust enrichment, and waste of corporate assets. On August 10, 2018, the parties filed a joint stipulation and proposed order agreeing to stay the consolidated action until, inter alia, the entry of an order granting or denying any motion to dismiss the action in the District of Massachusetts, and on August 24, 2018, the court entered the joint stipulation agreeing to stay the consolidated action. In light of the December 6, 2018 order granting defendants' motion to dismiss in the District of Massachusetts, the Company and the plaintiffs in the derivative action entered into joint stipulation on February 5, 2019 to stay the derivative action through the duration of the appeal in the securities action. The Company is unable at this time to determine whether the outcome of the derivative litigation would have a material impact on our results of operations, financial condition or cash flows.
These lawsuits and 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.

Failure to comply with The NASDAQ Capital Market continued listing requirements may result in our common stock being delisted from The NASDAQ Capital Market.

If our stock price falls below $1.00 per share, we may not continue to qualify for continued listing on The NASDAQ Capital Market or Nasdaq Global Market. To maintain listing, we are required, among other things, to maintain a minimum closing bid price of $1.00 per share. If the closing bid price of our common stock is below $1.00 per share for 30 consecutive business days, we will receive a deficiency notice from Nasdaq advising us that we have a certain period of time, typically 180 days, to regain compliance by maintaining a minimum closing bid price of at least $1.00 for at least ten consecutive business days, although Nasdaq could require a longer period.

On June 15, 2018, we received a written notification from Nasdaq's Listing Qualifications Department that we had failed to comply with Nasdaq Listing Rule 5450(a)(1) because the bid price for our common stock over a period of 30 consecutive business days prior to such date had closed below the minimum $1.00 per share requirement for continued listing. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were afforded an initial period of 180 calendar days, or until December 12, 2018, to regain compliance with Rule 5450(a)(1). We determined that we would not be in compliance with Rule 5450(a)(1) by December 12, 2018, and on November 19, 2018, submitted an application to transfer our common stock from listing on the Nasdaq Global Market to the Nasdaq Capital Market. Doing so allowed us to become eligible for an additional 180 day compliance period provided for companies listed on the Nasdaq Capital Market, provided that we met the continued listing requirements for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the minimum bid price requirement, and provided written notice of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. In accordance with the original notification, we indicated in our transfer application that we met all of the other continuing listing requirements for the Nasdaq Capital Market, with the exception of the bid price requirement, and provided written notice of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. On December 13, 2018, we received notice from Nasdaq that we were granted an additional 180 calendar days, or until June 11, 2019, to regain compliance with the minimum $1.00 bid price per share requirement of the Nasdaq listing rules. Accordingly, at the opening of business on December 17, 2018, the listing of the shares of our common stock was transferred from the Nasdaq Global Market to the Nasdaq Capital Market. Our common stock continues to trade under the symbol "GNCA."

If at any time before June 10, 2019 the bid price of our common stock closes at or above $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notice that we have achieved compliance with the Nasdaq listing rules. If the we do not regain compliance by June 10, 2019, we expect that Nasdaq will provide written notice that our common stock will be delisted. At that time, we may appeal Nasdaq's determination to a Nasdaq hearing panel. Even if we do regain compliance with minimum closing bid price of $1.00 per share by June 10, 2019, there is no guarantee that we will remain in compliance thereafter. The delisting of our common stock would significantly affect the ability of investors to trade our common stock and negatively impact the liquidity and price of our common stock. In addition, the delisting of our common stock could materially adversely impact our ability to raise capital on acceptable terms or at all. Delisting from Nasdaq could also have other negative results, including the potential loss of confidence by our current or prospective third-party providers and collaboration partners, the loss of institutional investor interest, and fewer licensing and partnering opportunities.

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.

We cannot assure you that any 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. 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 the future, it may 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.

The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. 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 Nasdaq.

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.

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 are subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection any follow-on offerings of our common or preferred stock, our ability to utilize NOLs could be further limited by 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.

The comprehensive tax reform bill passed in late 2017 could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after 2018 and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge you to consult with your legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are currently subject to taxation in the United States and Massachusetts. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income

tax law, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

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. We have two leases at this address, and in aggregate, we occupy approximately 34,200 square feet of laboratory and office space. Both leases expire in February 2020. We believe that our existing facilities are sufficient for our present operations, but that in the near future our existing facility space will need to be expanded to meet the demands of our future lab operations or we will have to move into a new facility.

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, except as discussed below, 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.

Beginning on October 31, 2017, three putative class action complaints were filed in the U.S. District Court for the District of Massachusetts (the "District of Massachusetts" or the "Court"), naming the Company, Chief Executive Officer William D. Clark, and former Chief Financial Officer Jonathan Poole as defendants. The Court consolidated the three actions into one case, captioned Emerson et al. v. Genocea Biosciences, Inc., et al., Civil Action No. 17-cv-12137-PBS (D. Mass.), and appointed the Genocea Investor Group (a group of five purported shareholders) as lead plaintiff. On March 29, 2018, counsel for the lead plaintiff filed an amended complaint in the District of Massachusetts that alleged violations of the Securities Exchange Act of 1934 and Rule 10b-5 in connection with the Company's disclosures from March 31, 2016 to September 25, 2017 concerning the development of GEN-003. The amended complaint added Seth V. Hetherington, former Chief Medical Officer, to the original named defendants, and sought unspecified damages and costs. On December 6, 2018, the District of Massachusetts granted defendants' motion to dismiss the amended complaint for failure to state a claim. On January 7, 2019, the lead plaintiff filed a notice of appeal in the District of Massachusetts regarding the Court order dismissing the amended complaint. The appeal has been docketed in the First Circuit under the caption Yuksel, et al. v. Genocea Biosciences, et al., Civil Action No. 19-1036 (1st Cir.). The Company is unable at this time to determine whether the outcome of the securities action litigation would have a material impact on its results of operations, financial condition or cash flow.

Beginning on January 31, 2018, two putative shareholder derivative actions were filed in the U.S. District Court for the District of Delaware, naming certain of the Company's officers and directors (including certain former directors and officers) as defendants, and naming the Company as a nominal defendant. On August 24, 2018, the court consolidated the two actions into one case, captioned In re Genocea Biosciences, Inc. Derivative Litigation, Civil Action No. 18-cv-00186-MN (D. Del.). The operative complaint in the now-consolidated action alleges violations of the Securities Exchange Act of 1934 and Rule 14a-9 in connection with disclosures made in the Company's Schedule 14A Proxy Statement, filed with the SEC on April 21, 2017. The complaint also alleges claims for breach of fiduciary duty, unjust enrichment, and waste of corporate assets. On August 10, 2018, the parties filed a joint stipulation and proposed order agreeing to stay the consolidated action until, inter alia, the entry of an order granting or denying any motion to dismiss the action in the District of Massachusetts, and on August 24, 2018, the court entered the joint stipulation agreeing to stay the consolidated action. In light of the December 6, 2018 order granting defendants' motion to dismiss in the District of Massachusetts, the Company and the plaintiffs in the derivative action entered into joint stipulation on February 5, 2019 to stay the derivative action through the duration of the appeal in the securities action. The Company is unable at this time to determine whether the outcome of the derivative litigation would have a material impact on our results of operations, financial condition or cash flows.
The Company does not have contingency reserves established for any litigation liabilities.

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 Capital Market under the symbol "GNCA" since February 5, 2014.

Holders

As of February 26, 2019, there were approximately 20 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.

Recent Sales of Unregistered Securities

In February 2019, we entered into a private placement with certain existing and new investors providing for the purchase of up to approximately $39.2 million of our common stock and warrants to purchase shares of Genocea common stock, in two closings. The first closing occurred on February 14, 2019 (the "Initial Closing"). We sold 25,599,979 shares of common stock and, to one purchaser and its affiliates in lieu of shares of common stock, a pre-funded warrant to purchase 4,250,000 shares of common stock (the "Pre-Funded Warrant"), and accompanying warrants (the "Warrants" and together with the common stock and Pre-Funded Warrants, the "Units") to purchase an aggregate of 7,462,494 shares of common stock (the "Warrant Shares") at a purchase price of $0.5026 per Unit. The Warrants expire five (5) years following the Initial Closing (subject to early termination as noted below), have an exercise price of $0.5656 per Warrant Share, and were immediately exercisable upon issuance. The Pre-Funded Warrants expire twenty (20) years following the Initial Closing, have an exercise price of $0.5026 per share ($0.5025 of which was prepaid at the Initial Closing, leaving a remaining exercise price $0.01 per share), and were immediately exercisable upon issuance. The exercise price and number of shares of common stock issuable upon the exercise of the Warrants and the Pre-Funded Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Warrants and the Pre-Funded Warrants.

Contingent upon satisfactory top-line results from Part A of our Phase 1/2a clinical trial for GEN-009 (the "Data"), we will have the option to conduct a second closing (the "Second Closing") and offer up to an additional $24.2 million in shares of common stock to the purchasers at a purchase price per share that is equal to the greater of $0.4713 per share and a per share price that is derived from the volume weighted average price of our common stock from the date we release the Data through the date we exercise our option to proceed with the Second Closing. If a purchaser does not purchase at least 50% of the shares of common stock that it specified to purchase in the Second Closing (each such purchaser, a "Non-Participating Purchaser"), it will forfeit any unexercised Warrants purchased in the Initial Closing as our sole remedy for such failure. The other purchasers that are not Non-Participating Purchasers will have the option, but not the obligation, to purchase the shares of common stock allocated to the Non-Participating Purchasers in the Second Closing.

The securities sold in the offering were not registered under the Securities Act of 1933, as amended (the “Securities Act”), and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. Genocea has agreed to file a resale registration statement with the SEC within 60 days of the Initial Closing to register the resale of the shares of common stock issued or issuable in connection with each closing.

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.

Securities Authorized for Issuance under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2018.

Plan category	Number of securities to be issued upon exercise of outstanding stock options and warrants	Weighted-average exercise price of outstanding options and warrants	Number of securities remaining available for future issuance under equity compensation plans	
Equity compensation plans approved by security holders [1]	7,139,044	$ 2.35	1,977,407	(2)

[1] Includes information regarding our Amended and Restated 2014 Equity Incentive Plan.
[2] Does not include 3,470,847 shares added to the Amended and Restated 2014 Equity Incentive Plan under the evergreen provision on January 1, 2019.

Item 6. Selected Financial Data

Not applicable.

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 seeks to discover and develop novel cancer immunotherapies. We use our proprietary discovery platform, ATLAS, to profile CD4+ and CD8+ T cell (or cellular) immune responses to tumor antigens. We use insights arising from ATLAS to design novel cancer immunotherapies. We believe that ATLAS, which recreates each individual's T cell immune responses to their tumor in the laboratory, affords Genocea advantages in the design of novel cancer immunotherapies relative to our peers, who we believe rely primarily on software and processes such as "machine learning" to predict immunotherapy targets.

Our most advanced program is GEN-009, a neoantigen (or personalized) cancer vaccine, for which we are conducting a Phase 1/2a clinical trial. The GEN-009 program uses ATLAS to identify neoantigens, or tumor mutations unique to each patient, for inclusion in each patient's GEN-009 vaccine. We are also advancing GEN-011, a neoantigen adoptive T cell therapy program as well as GEN-010, a next-generation neoantigen vaccine program.

ATLAS Platform

Harnessing and directing the T cell arm of the immune system to kill tumor cells is increasingly viewed as having potential in the treatment of many cancers, and this approach has clearly shown efficacy in hematologic malignancies. Treatments arising from this approach must target specific differences present in a tumor, such as genetic mutations. However, the discovery of such T cell targets, or antigens, has been particularly challenging for two reasons. First, the diversity of human T cell responses means that an effective T cell target for one person may be different from an effective T cell target for another person. Second, the number of candidate targets for T cell responses can be very large with up to thousands of candidate antigens per patient in some cancers. These complexities represent fundamental barriers that traditional cancer immunotherapy target discovery tools, which rely largely on computer modeling - so-called predictive algorithms - have, as yet, only poorly addressed.

We have designed the ATLAS platform to overcome these T cell target discovery challenges. We believe that ATLAS

represents the most comprehensive and accurate high-throughput system for T cell immune response profiling in the biopharmaceutical industry. ATLAS is designed to mimic the T cell arm of the human immune system of each patient that it profiles in a laboratory setting. Using ATLAS, we are able to measure T cell responses to the entire set of potential T cell targets for an individual's cancer. Using ATLAS, we can determine if these T cell responses are statistically above or below a baseline measurement and can develop immunotherapies using only those targets and T cells determined to be most likely to kill an individual's cancer.

We believe that we are a leader in the field of T cell-related immunotherapy discovery and development. Our management and scientific teams possess considerable experience in oncology, immunology, and vaccinology spanning research, manufacturing, clinical development and regulatory affairs.

Our Programs

Our cancer immunotherapies are designed to educate T cells to recognize and attack specific targets - or to introduce T cells already educated to attack these targets - and thereby kill cancer cells. We are first developing personalized cancer vaccines by applying ATLAS to identify patient neoantigens that are associated with that individual's pre-existing immune responses to a tumor.

Neoantigens are personalized tumor mutations that are seen as "foreign" by an individual's immune system. Data published in recent years have indicated that an individual's response to neoantigens drives immune checkpoint inhibitor ("ICI") efficacy and that it is possible to vaccinate an individual against their own neoantigens. If approved, neoantigen vaccines could be used in combination with existing treatment approaches for cancer, including ICIs, to potentially direct and enhance an individual's T cell response to the individual's cancer, thereby potentially effecting better clinical outcomes. Data also support the potential of isolating and expanding T cell populations targeting specific neoantigens for therapeutic benefit.

Our lead immuno-oncology program, GEN-009, is an adjuvanted neoantigen peptide vaccine candidate designed to direct a patient's immune system to attack their tumor. GEN-009's neoantigens are identified by our proprietary ATLAS platform, which is designed to profile CD4+ and CD8+ cell immune responses to tumor antigens. Following ATLAS neoantigen identification, we manufacture a personalized vaccine for each patient using only those neoantigens determined to be stimulatory to the immune system by ATLAS.

In June 2018, we initiated a Phase 1/2a clinical trial for GEN-009 in a range of tumor types in subjects with no evidence of disease but at high risk of relapse. In January 2019, we announced that we had commenced dosing patients and completed enrollment in this first part of the trial. We expect to report immunogenicity results from the initial patient cohort late in the second quarter or early in the third quarter of 2019.

We have also initiated pre-clinical work on GEN-011, an adoptive T cell therapy to neoantigens identified by ATLAS. We currently expect to file an IND with the FDA for GEN-011 in the first half of 2020.

Behind GEN-009, we also continue to explore GEN-010, our vaccine candidate employing next-generation antigen delivery technology, which could provide an opportunity for even better immunogenicity and/or efficiency of production.

We are also using ATLAS to amass libraries of novel candidate antigens for non-personalized cancer immunotherapies. Such programs would target non-mutated, shared tumor-associated antigens and cancers of viral origin.

For shared antigens, we have had and continue to conduct a number of research collaborations that provide blood and

tumor samples to antigen discovery and immune-response profiling as follows:

- Dana Farber Cancer Institute (ongoing), Mayo Clinic (completed), and Checkmate Pharmaceuticals (completed)

The Company is not dependent on these research collaborations to develop its product candidates and no material financial obligations exist as part of these collaborations.

For cancers of viral origin, we have profiled the immune responses that several cohorts of patients made to 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 that ATLAS 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 herpes virus family in which we have deep experience through our previous development of GEN-003.

The following table describes our active immuno-oncology programs in development:

Vaccine Candidate	Program	Stage of Development	Next Milestone	Anticipated Timeline
GEN-009	First generation neoantigen cancer vaccine	Phase 1/2a	Immunogenicity data from the first patient cohort	Late Q2/early Q3 2019
GEN-010	Second generation neoantigen cancer vaccine	Pre-clinical	Select delivery technology platform	Ongoing
GEN-011	Adoptive T cell therapy	Pre-clinical	IND filing	First half of 2020

In addition to our immuno-oncology programs, we also have an investigational immunotherapy for the treatment of genital herpes, GEN-003. To date, GEN-003 has completed three positive clinical trials. However, we have ceased substantially all activities under the GEN-003 program and are exploring alternatives to maximize shareholder value from GEN-003.

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 financed our operations primarily through the issuance of our equity securities, debt financings, and amounts received through grants. As of December 31, 2018, we had received an aggregate of $339.5 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, 2018, our cash and cash equivalents were $26.4 million.

Since inception, we have incurred significant operating losses. Our net losses were $27.8 million and $56.7 million for the years ended December 31, 2018 and 2017, respectively, and our accumulated deficit was $292.0 million as of December 31, 2018. 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.

In January 2018, we completed the Concurrent Offerings in which we sold (i) 53.4 million shares of our common stock and accompanying Class A warrants to purchase up to 26.7 million shares of our common stock, at a combined price of $1.00 per share, and accompanying Class A warrant to purchase 0.5 shares of common stock for aggregate gross proceeds of approximately $53.4 million, and (ii) 1,635 shares of our Series A convertible preferred stock, which are convertible into 1.6 million shares of our common stock, and accompanying Class A warrants to purchase up to 0.8 million shares of our common stock for aggregate gross proceeds of approximately $1.6 million. Each Class A warrant has an exercise price of $1.20 per share and will expire five years from the date of issuance. We received net proceeds from these offerings of approximately $51.7 million, after deducting approximately $3.3 million in underwriting discounts and commissions, excluding offering costs payable by us.

In February 2019, the Company entered into a private placement with certain existing and new investors providing for the purchase of up to approximately $39.2 million of the Company's common stock and warrants to purchase shares of the Company's common stock, in two closings. In the first closing, the Company sold 25.6 million shares of common stock and 4.25 million pre-funded warrants to purchase common stock, along with accompanying warrants to purchase 0.25 shares of common stock for each share of common stock or pre-funded warrant purchased, for net proceeds to the Company of approximately $14.2 million, after deducting approximately $0.8 million in placement agent fees, excluding offering costs. The first closing of the private placement occurred on February 14, 2019, while the second closing is contingent on satisfactory top-

line immunogenicity results from the ongoing Phase 1/2a clinical trial for GEN-009, expected in late second quarter or early third quarter of 2019. Contingent on satisfactory top-line immunogenicity results from the ongoing Phase 1/2a clinical trial for GEN-009, Genocea will have the option to conduct a second closing and sell up to an additional $24.2 million of shares of common stock to the investors who participated in the first closing.

We believe that our cash and cash equivalents at December 31, 2018, together with the proceeds from the 2019 private placement, are sufficient to support our operating expenses and capital expenditure requirements into the first quarter of 2020.

Costs related to clinical trials can be unpredictable and there can be no guarantee that our current balances of cash, cash equivalents, and investments, combined with 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-009 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

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 CROs, 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,		Increase
	2018	2017	(Decrease)
Genital herpes (GEN-003)(1)	$ 635	$ 22,493	$ (21,858)
Immuno-oncology program (2)	21,139	11,685	9,454
Other research and development (3)	3,435	5,026	(1,591)
Total research and development	$ 25,209	$ 39,204	$ (13,995)

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

(2)Includes direct and indirect internal costs and external costs for our immuno-oncology research and development activities.

(3) Includes costs that are not specifically allocated by project, including facilities costs, depreciation expense, and other costs. In addition, costs for programs that were paused in 2016 or earlier are included in this line item.

We expect our overall research and development expenses will increase due to our continued development of our clinical operations and our supply chain capabilities for our GEN-009 program, as well as our advancement of GEN-011 through preparation and submission of an IND and subsequent initiation of a clinical trial.

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.

Restructuring costs

On September 25, 2017, we announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. We also announced that it is exploring strategic alternatives for GEN-003, its Phase 3-ready investigational immunotherapy for the treatment of genital herpes. Consequently, substantially all GEN-003 spending and activities were ceased, and we reduced our workforce by approximately 40 percent as of the quarter ended September 30, 2017. Pursuant to ASC 420, Exit or Disposal Cost Obligations, charges for employee severance, employee benefits, and contract terminations were recorded in the year ended December 31, 2017. Asset impairment charges, pursuant to ASC 360, Property, Plant, and Equipment, were also recorded in the year ended December 31, 2017 and primarily related to fixed assets specific to GEN-003 research and development activities.

Other income (expense)

Other income and expense consists of the change in warranty liability, interest expense, net of interest income, and other income (expense) for miscellaneous items, such as the transaction expenses associated with the allocation of proceeds from the Concurrent Offerings.

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 consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of consolidated financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate estimates, which include prepaid and accrued research and development expenses, stock-based compensation expense, and warrants to purchase redeemable securities. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances. Warrants to purchase redeemable securities are valued utilizing an option-based methodology to value the Warrants combined with a multi-scenario model, specifically a Monte Carlo simulation, to model the future movement of the stock price throughout the term of the Warrants. In addition, the valuation model considers the probability of the Company being acquired during each annual period within the Warrant term, as an acquisition event can potentially impact the settlement of the Warrants. 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 consolidated 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 consolidated financial statements.

Prepaid and Accrued Research and Development Expenses

As part of the process of preparing our consolidated 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 consolidated 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 measurable 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 patient visits amounts which are 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 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 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 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 incorporate 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.

We recognize forfeitures as they occur. Stock-based compensation expense recognized in the consolidated financial statements is based on awards that ultimately vest.

Stock-based compensation expense has been reported in our statements of operations and comprehensive loss as follows (in thousands):

	Years ended December 31,	
	2018	2017
Research and development	$ 620	$ 1,310
General and administrative	1,533	2,924
Total	$ 2,153	$ 4,234

We estimated the fair value of stock options of each employee stock award at the grant date using the following assumptions:

	Years ended December 31,	
	2018	2017
Expected volatility	77.6% - 79.3%	74.6% - 90.1%
Risk-free interest rate	2.61% - 3.10%	1.85% - 2.18%
Expected term (in years)	5.5 - 6.08	5.5 - 9.88
Expected dividend yield	0%	0%

At December 31, 2018, we had approximately $3.5 million of total unrecognized compensation expense, 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.

Warrants to Purchase Redeemable Securities

We have warrants to purchase redeemable securities as a liability on our balance sheets, in accordance with ASC 480, Distinguishing Liabilities from Equity (“ASC 480”). As the Warrants are liability-classified, the Company remeasures the fair value of the Warrants at each reporting date. The Company utilized an option-based methodology to value the Warrants combined with a multi-scenario model, specifically a Monte Carlo simulation, to model the future movement of the stock price throughout the term of the Warrants. In addition, the valuation model considers the probability of the Company being acquired during each annual period within the Warrant term, as an acquisition event can potentially impact the settlement of the Warrants.The assumptions used in calculating the estimated fair value of the Warrants represent the Company’s best estimates and include probabilities of settlement scenarios, future changes in the Company’s stock price, risk-free interest rates and volatility.

The Warrants are exercisable at any time, or from time-to-time during the period beginning on the date of issuance and expiring on the five-year anniversary of such issuance. In the event of an “Acquisition,” defined generally to include a merger or consolidation resulting in the sale of 50% or more of the voting securities of the Company, the sale of all, or substantially all, of the assets or voting securities of the Company, or other change of control transaction, as defined in the Warrants, the Company will be obligated to use its best efforts to ensure that the holders of the Warrants receive new warrants from the surviving or acquiring entity (the “Acquirer”). The new warrants to purchase shares in the Acquirer shall have the same expiration date as the Warrants and a strike price that is based on the proportion of the value of the Acquirer’s stock to the Company’s common stock. If the Company is unable, despite its best efforts, to cause the Acquirer to issue new warrants in the Acquisition as described above, then, if the Company’s stockholders are to receive cash in the Acquisition, the Company will settle the Warrants in cash and if the Company’s stockholders are to receive stock in the Acquisition, the Company will issue shares of its common stock to each Warrant holder.

Results of Operations

Comparison of the Years Ended December 31, 2018 and December 31, 2017

	Years Ended December 31,		Increase
(in thousands)	2018	2017	(Decrease)
Operating expenses:			
Research and development	$25,209	$39,204	$(13,995)
General and administrative	14,309	13,433	876
Restructuring costs	—	2,618	(2,618)
Total operating expenses	39,518	55,255	(15,737)
Loss from operations	(39,518)	(55,255)	(15,737)
Other income (expense):			
Change in fair value of warrant	14,757	—	14,757
Interest expense, net	(1,021)	(1,441)	(420)
Other income (expense)	(2,029)	(14)	2,015
Total other income (expense)	11,707	(1,455)	13,162
Net loss	$(27,811)	$(56,710)	$(28,899)

Research and development expenses

Research and development ("R&D") expenses decreased approximately $14.0 million to $25.2 million for the year ended December 31, 2018 from $39.2 million for the same period ended December 31, 2017. The decrease was due largely to reduced headcount-related costs of approximately $4.8 million, decreased external manufacturing costs of approximately $5.3 million, decreased clinical costs of approximately $1.5 million, and decreased consulting and professional services costs of approximately $1.3 million. The remaining decrease in year-over-year expenses was comprised of decreased lab-related costs of approximately $0.3 million, office and facility related costs of approximately $0.3 million and other R&D costs of approximately $0.4 million.

On a program basis, GEN-003 costs decreased $21.9 million in the year ended December 31, 2018, driven by reduced headcount-related costs of approximately $8.7 million, decreased external manufacturing related expenses of approximately $6.7 million, decreased consulting and professional service related costs of approximately $2.0 million and decreased clinical and lab related costs of approximately $3.9 million, following the September 2017 strategic pivot. GEN-009 and other immuno-oncology programs costs increased $9.5 million in the year ended December 31, 2018, driven by increased headcount, clinical, and consulting costs of approximately $7.1 million and increased external manufacturing and lab related costs of approximately $2.2 million to support the Phase 1/2a clinical trial for GEN-009. Increased spending on these programs was offset by lower costs on deprioritized infectious disease programs.

General and administrative expenses

General and administrative expense increased approximately $0.9 million to $14.3 million for the year ended December 31, 2018 from $13.4 million for the year ended December 31, 2017. The increase was primarily due to increased consulting and professional services costs of approximately $2.3 million, offset by reduced compensation and benefits costs of approximately $1.2 million, and depreciation costs of approximately $0.3 million, as compared to the prior year.

Restructuring costs

On September 25, 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. As a result, the Company incurred charges of approximately $1.1 million for employee severance and related costs, approximately $0.5 million related to contract termination clauses, and approximately $1.0 million in non-cash asset impairment charges.

Change in fair value of warrants

Change in fair value of warrants reflects the non-cash change in fair value of Class A warrants issued in connection with the Concurrent Offerings. The warrants were recorded at their fair value on the date of issuance and are remeasured as of any warrant exercise date and at the end of each reporting period. The decrease in the fair value of the warrants is primarily due to the decrease in our stock price in 2018.

Interest expense, net

Interest expense, net decreased by $0.4 million for the year ended December 31, 2018, as compared to the year ended December 31, 2017. The decrease reflects the lower outstanding principal balance on our debt facility, combined with increased interest income earned on our cash and cash equivalents in the current year.

Other income (expense)

Other income (expense) decreased $2.0 million for the year ended December 31, 2018, as compared to the year ended December 31, 2017. The decrease in other income (expense) for the year ended December 31, 2018 was primarily due to a $2.0 million expense in the first quarter of 2018 related to the Concurrent Offerings for the portion of issuance costs that were allocated to the warrants and were required to be immediately expensed.

Liquidity and Capital Resources

Overview

As of December 31, 2018, we had an accumulated deficit of approximately $292.0 million. We had cash and cash equivalents of $26.4 million at December 31, 2018.

Since our inception through December 31, 2018, we have received an aggregate of $339.5 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.

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.

In January 2018, we completed the Concurrent Offerings in which we sold (i) 53.4 million shares of our common stock and accompanying warrants to purchase up to 26.7 million shares of our common stock for aggregate gross proceeds of approximately $53.4 million and (ii) 1,635 shares of our Series A convertible preferred stock, which are convertible into 1.6 million shares of our common stock and accompanying warrants to purchase up to 0.8 million shares of our common stock for aggregate gross proceeds of approximately $1.6 million.

In February 2019, we entered into a private placement with certain existing and new investors providing for the purchase of up to approximately $39.2 million of our common stock and warrants to purchase shares of our common

stock, in two closings. In the first closing, we sold 25.6 million shares of common stock and 4.25 million pre-funded warrants to purchase common stock, along with accompanying warrants to purchase 0.25 shares of common stock for each share of common stock or pre-funded warrant purchased, for net proceeds of approximately $14.2 million, after deducting approximately $0.8 million in placement agent fees, excluding offering costs. The first closing of the private placement occurred on February 14, 2019, while the second closing is contingent on satisfactory top-line immu