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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2019
OR
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission file number 001-36289

GENOCEA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

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

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

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

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	GNCA	Nasdaq Capital Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

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

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

Indicate by check mark 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). ☒ Yes ☐ No

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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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. ☐

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

The aggregate market value of the 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 Capital Market on June 30, 2019, the last business day of the registrant's most recently completed second quarter, was: $73,983,101.

The number of shares outstanding of the registrant's common stock as of February 11, 2020 was 27,643,773.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement related to its 2020 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", "will", "would", or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

- our estimates regarding the timing and amount of funds we require to conduct clinical trials for GEN-009, to continue preclinical studies and file an investigational new drug ("IND") for GEN-011, to continue preclinical studies for our other product candidates and to continue our investments in immuno-oncology;
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing;
- the timing of, and our ability to, obtain and maintain regulatory approvals for our product candidates;
- the potential benefits of strategic partnership agreements and our ability to enter into strategic partnership arrangements;
- our intellectual property position;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- our ability to quickly and efficiently identify and develop product candidates; and
- our commercialization, marketing and manufacturing capabilities and strategy.

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 using our ATLAS™ proprietary discovery platform. The ATLAS platform profiles each patient's $CD4^+$ and $CD8^+$ T cell immune responses to every potential target or "antigen" in that patient's tumor. We believe that this approach optimizes antigen selection for immunotherapies such as cancer vaccines and cellular therapies by identifying the antigens to which the patient can respond. Consequently, we believe that ATLAS could lead to more immunogenic and efficacious cancer immunotherapies.

Our most advanced program is GEN-009, a personalized neoantigen cancer vaccine, for which we are conducting a Phase 1/2a clinical trial. The GEN-009 program uses ATLAS to identify neoantigens, or immunogenic tumor mutations unique to each patient, for inclusion in each patient's GEN-009 vaccine. We are also advancing GEN-011, a neoantigen-specific adoptive T cell therapy program that also relies on ATLAS. We expect to file an IND application for GEN-011 in the second quarter of 2020.

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. This approach has been effective against hematologic malignancies and, more recently, certain solid tumors. Vaccines or cellular therapies employing this approach must target specific differences from normal tissue present in a tumor, such as antigens arising from genetic mutations. However, the discovery of optimal antigens for such immunotherapies has been particularly challenging for two reasons. First, the genetic diversity of human T cell responses means that effective antigens vary from person to person. Second, the number of candidate antigens can be very large, with up to thousands of candidates per patient in some cancers. An effective antigen selection system must therefore account both for each patient's tumor and for their T cell repertoire.

ATLAS achieves effective antigen selection by employing components of the T cell arm of the human immune system from each patient. Using ATLAS, we measure each patient's T cell responses to a comprehensive set of candidate neoantigens, tumor-associated antigens and tumor-associated viral antigens for their own cancer, allowing us to select those targets associated with the anti-tumor T cell responses that may kill that individual's cancer. We believe that ATLAS represents the most comprehensive and accurate system for antigen discovery. Further, we believe ATLAS identifies a novel candidate antigen profile, that of inhibitory T cell responses. Previously, all candidate antigens were thought either to be targets of effective anti-tumor responses (stimulatory), or irrelevant. However, using ATLAS, we have identified inhibitory antigens we call Inhibigens ™, which are shown to promote tumor progression in preclinical studies. We have also discovered that an antigen can be stimulatory in one patient and inhibitory in another, reinforcing the importance of selecting each patient's potentially immunogenic antigens.

The ATLAS portfolio comprises three patent families. The first two families comprise issued U.S. patents, with patent terms until at least 2031 and 2030, respectively, as well as granted foreign patents and pending U.S. and foreign applications. The third family is directed to ATLAS-based methods for cancer diagnosis, prognosis and patient selection, as well as related compositions. This patent family currently comprises pending applications in eleven foreign jurisdictions and a pending U.S. application. Patents issuing from these applications are expected to have a patent term until at least March 2038.

Our Immuno-Oncology Programs

Our cancer immunotherapies include a vaccine that is designed to educate T cells to recognize and attack specific cancer targets, and a cellular therapy intended to introduce T cells that have been educated to attack these targets. We believe that neoantigen vaccines could be used in combination with existing treatment approaches for cancer to potentially direct and enhance an individual's T cell response to his or her cancer, thereby potentially effecting better clinical outcomes. We also believe that isolating and expanding T cell populations targeting specific neoantigens through adoptive cell therapy could provide meaningful clinical benefit.

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

Our lead program, GEN-009, is an adjuvanted neoantigen peptide vaccine candidate. Using ATLAS to identify specific neoantigens, we then manufacture a personalized vaccine for each patient using only those neoantigens determined by ATLAS to be stimulatory to that patient's anti-tumor immune responses. We are currently conducting a Phase 1/2a clinical trial for GEN-009 across a range of solid tumor types:

- Part A of the trial is assessing the safety and immunogenicity of GEN-009 as monotherapy in certain cancer patients with no evidence of disease; and
- Part B of the trial, for which we have commenced dosing patients, is designed to assess the safety, immunogenicity, and preliminary antitumor activity of GEN-009 in combination with ICI therapy in patients with advanced or metastatic tumors.

Throughout 2019, we presented data from Part A of the clinical trial. In the data from the eight dosed patients that, we believe, confirms the potential antigen selection advantages of ATLAS:

- 100% of patients had measurable $CD4^+$ and $CD8^+$ T cell responses to their GEN-009 vaccine;
- Responses were detected against 99% of the administered vaccine neoantigens (N=88 administered antigens), a response rate in excess of that which has been reported previously in response to candidate neoantigen vaccines;
- GEN-009 elicited $CD8^+$ T cell responses *ex vivo*, which is a measure of T cell effector function, for 41% of vaccine neoantigens and $CD4^+$ T cell responses to 51% of neoantigens;
- GEN-009 elicited broad immune responses using an *in vitro* stimulation assay, which is a measure of central memory responses, with 87% of neoantigens eliciting a $CD4^+$ response and 57% of neoantigens eliciting a $CD8^+$ response;
- GEN-009 was well tolerated, with no dose-limiting toxicities observed; and
- Through January 31, 2020, we are not aware of any disease recurrence in any of the vaccinated patients.

As with any open label study, we may slow or pause enrollment to evaluate a smaller set of patients in an effort to assure that a preliminary clinical signal is seen. We anticipate reporting these preliminary clinical results for our GEN-009 Part B clinical trial in the second or third quarter of 2020. Based upon this evaluation, we will consider whether it is appropriate to continue the study.

We also are advancing GEN-011, an adoptive T cell therapy specific for neoantigens identified by ATLAS. Adoptive T cell therapies such as tumor infiltrating lymphocyte ("TIL") therapy offers an alternative treatment in solid tumors. TIL therapy, which relies on extracting TILs from each patient's solid tumor, non-specifically expanding them *ex vivo*, and reinfusing them into the cancer patient, has demonstrated measurable and sustainable tumor shrinkage in patients who failed immune checkpoint inhibitor ("ICI") therapy in mid-stage clinical studies. GEN-011 extracts and specifically expands ATLAS-identified neoantigen-specific T cells from each patient's peripheral blood rather than their tumor (as is done for TIL generation). We believe GEN-011 could provide potency, efficacy, and ease of manufacturing benefits over TIL therapy. We expect to file an IND application for GEN-011 with the U.S. Food and Drug Administration ("FDA") in the second quarter of 2020, with preliminary clinical results anticipated in the first half of 2021.

We also continue to explore additional program opportunities. We continue to evaluate GEN-010, our vaccine candidate employing next-generation antigen delivery technology, which we may advance to provide an opportunity for better immunogenicity and/or efficiency of vaccine production. In addition, we are using ATLAS to pursue discovery of novel candidate antigens for non-personalized cancer immunotherapies. Such programs could target shared neoantigens, non-mutated tumor-associated antigens, cancers of viral origin such as cancers driven by Epstein-Barr virus infection and Inhibigens[tm].

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 and cellular therapy 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 immuno-oncology 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 several companies attempting to develop new neoantigen cancer vaccines, including BioNTech SE, CureVac AG, Genentech, Inc., Gritstone Oncology Inc., Merck & Co., Inc., Moderna Inc., Nouscom, and Vaccibody AS. 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 SE, Cellular Biomedicine Group Inc., Eutilex Co., Ltd., Gilead Sciences, Inc., Iovance Biotherapeutics Inc., Marker 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 greater experience in the discovery and development of product candidates, obtaining FDA, and other regulatory approvals of vaccines and the commercialization of those vaccines or cell therapies. Accordingly, our competitors may be more successful than us in obtaining approval for vaccines and cell therapies and achieving widespread market acceptance. Our competitors' vaccines or cell therapies may be more effective, or more effectively marketed and sold, than any we may commercialize and may render our products 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 or cell therapies 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 ("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, an allowed U.S. application, and patents granted in Europe, Canada, and Australia. The granted foreign patents in this family are expected to expire in 2027. U.S. Patents 9,051,564 and 9,920,314 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, an allowed U.S. patent application, a pending U.S. patent application, issued patents in Europe, Canada, and Australia, and a pending application in Europe. The granted foreign patents in this family have a patent term until 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 pending applications in eleven foreign jurisdictions and a pending U.S. application. We wholly own three further patent families, each comprising a pending PCT application, claiming first priority to provisional applications filed in late 2018. These PCT applications are directed to ATLAS-based methods for further selection of cancer- or tumor-related antigens, and for redirecting immune responses and re-educating T cells.

License Agreements

Harvard University

We have an exclusive license agreement with Harvard University ("Harvard"), granting us an exclusive, worldwide, royalty-bearing, sublicensable license to three patent families, to develop, make, have made, use, market, offer for sale, sell, have sold and import licensed products and to perform licensed services related to the ATLAS discovery platform. We are also obligated to pay Harvard milestone payments up to $1.6 million in the aggregate upon the achievement of certain development and regulatory milestones. As of December 31, 2019, we have paid $0.3 million in aggregate milestone payments. We are obligated under this license agreement to use commercially reasonable efforts to develop, market and sell licensed products in compliance with an agreed upon development plan. In addition, we are obligated to achieve specified development milestones and in the event 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.

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 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.

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

Oncovir License and Supply Agreement

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.

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 will 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 low to mid six figure milestone payments upon the achievement of certain clinical trial milestones for each Combination Product and the first marketing approval for each Combination Product in certain territories as well as 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 adoptive 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 program 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.

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, for example, prevent fraud and abuse; promote transparency in interactions with others in the healthcare industry; protect the privacy of individual information; ensure integrity of research or protect human subjects involved in research. 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; require manufacturers to adopt certain compliance standards 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.

We may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. Numerous U.S. federal and state laws govern the collection, use, disclosure and storage of personal information. Various foreign countries also have, or are developing, laws governing the collection, use, disclosure and storage of personal information. Globally, there has been an increasing focus on privacy and data protection issues that may affect our business. *See "Risk Factors - Risks Related to Our Business and Industry".*

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, private health insurers, 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. In December 2019, a federal appeals court agreed that the individual mandate provision was unconstitutional, but remanded the case back to the district court to assess more carefully whether any provisions of the Healthcare Reform Act were severable and could survive. Pending action by the district court and resolution of any 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, legislation passed in 2019 revised how certain prices reported by manufacturers under the Medicaid Drug Rebate Program are calculated, a revision that the Congressional Budget Office has estimated will save the federal government approximately $3 billion in the next ten years.

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.

Information about our Executive Officers

The following table sets forth the name, age and position of each of our executive officers as of February 13, 2020.

Name	Age	Position
William Clark	51	President and Chief Executive Officer
Girish Aakalu, Ph.D.	45	Chief Business Officer
Thomas Davis, M.D.	56	Chief Medical Officer
Diantha Duvall	48	Chief Financial Officer
Jessica Baker Flechtner, Ph.D.	48	Chief Scientific Officer
Narinder Singh	48	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.

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.

Diantha Duvall. Diantha joined Genocea in March 2019 as the Chief Financial Officer. Prior to her appointment with Genocea, Ms. Duvall was Vice President, Controller and Chief Accounting Officer at Bioverativ, Inc. from February 2017 to January 2019. Prior to that, she worked at Biogen Inc., serving as Global Commercial Controller from February 2016 to January 2017, and U.S. Commercial Controller from February 2015 to January 2016. She also held a number of positions at Merck and Co. from May 2009 to January 2015. Her experiences at Merck spanned roles in venture investment, business development, joint ventures, and alliances, as well as operational controls and technical accounting. She also has extensive experience in SEC reporting, Sarbanes Oxley compliance, transaction support and risk management, having held multiple health industries positions within PricewaterhouseCoopers from 1996 to 2009. Ms. Duvall has a Master of Science in Accounting and Master of Business Administration from Northeastern University and a Bachelor of Arts from Colby College.

*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, and Vice President of Research from January 2010 to February 2014. From 2007 to February 2014, she held various roles of increasing seniority at Genocea. 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.

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, 2019, we had 59 full-time employees, of which 46 were engaged in research and development and 13 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, 2019 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 equity line of credit 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, GEN-011, 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 $39.0 million and $27.8 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of approximately $331.0 million. 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 multiple public equity offerings, private placements of our common and preferred stock and debt arrangements.

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 offerings or strategic transactions. We have not completed pivotal clinical studies for any product candidate, and it will be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payors and other factors.

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

- continue clinical trials for GEN-009, our most advanced product candidate;
- initiate non-clinical, clinical or other studies for GEN-011 and 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, 2019, our cash and cash equivalents were$40.1 million. We believe that we will continue to expend substantial resources for the foreseeable future developing GEN-009, GEN-011 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 timing and costs of our planned clinical trials for GEN-009 and GEN-011;
- the progress, timing, and costs of manufacturing GEN-009 and GEN-011 for planned clinical trials;
- the outcome, timing, and costs of seeking regulatory approvals, including an IND application for GEN-011;
- the initiation, progress, timing, costs, and results of preclinical studies and clinical trials for our other product candidates and potential product candidates;
- the terms and timing of any future collaborations, grants, licensing, consulting, or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone payments, royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and protecting our intellectual property rights, and defending against intellectual property related claims;
- the extent to which we in-license or acquire other products and technologies;
- the receipt of marketing approval;
- the costs of commercialization activities for GEN-009 and GEN-011 and other product candidates, if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution, and manufacturing capabilities; and
- revenue received from commercial sales of our product candidates.

Based on our current operating plan, we believe that our existing cash and cash equivalents are sufficient to support our operating expenses and capital expenditure requirements into the first quarter of 2021.

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 or GEN-011 through clinical development, obtaining regulatory approval for either product candidate, or commercializing either product candidate 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. In addition to GEN-009, we also are advancing preclinical work on GEN-011, for which we expect to file an IND with the FDA in the second quarter of 2020. GEN-009, GEN-011 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.

We are currently conducting our GEN-009 Part B clinical trial. As with any open label study, we may slow or pause enrollment to evaluate a smaller set of patients in an effort to assure that a preliminary clinical signal is seen. We anticipate reporting these preliminary clinical results for our GEN-009 Part B clinical trial in the second or third quarter of 2020. Based upon this evaluation, we will consider whether it is appropriate to continue the study. A decision to stop the study would result in a delay in the clinical progress, approval and commercialization of GEN-009.

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 and strategic transactions. 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 $13.8 million through private placement. In June 2019, we raised additional net proceeds of approximately $38.4 million through an underwritten public offering of our common stock and warrants exercisable for shares of our common stock. In October 2019, we entered into an agreement (the "Purchase Agreement") with Lincoln Park Capital ("LPC") from which we raised additional net proceeds of $2.5 million, and we have the right, at our sole discretion, to sell up to an additional $27.5 million of our common stock based on prevailing market prices of our common stock at the time of each sale. The Purchase Agreement limits our sales of shares of common stock to LPC to 5,227,323 shares of common stock, representing 19.99% of the shares of common stock outstanding on the date of the Purchase Agreement. The Purchase Agreement also prohibits us from directing LPC to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by LPC and its affiliates, would result in LPC and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of our common stock. 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, GEN-011, or our other product candidates.

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

As of February 11, 2020 there were 1,635 shares of our Series A convertible preferred stock outstanding, which are convertible, without payment of additional consideration, into 204,375 shares of our common stock. As of February 11, 2020, there were 5,122,183 shares of common stock issuable upon the exercise of warrants, having a weighted average exercise price of $7.66 per share, and 1,310,927 shares of common stock issuable upon the exercise of stock options outstanding, having a weighted average exercise price of $11.72 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 existing stockholders. 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.

SEC regulations limit the amount of funds we may raise during any 12-month period pursuant to our shelf registration statement on Form S-3.

Our public float was less than $75 million within 60 days of filing of this Annual Report on Form 10-K. As a result, under General Instruction I.B.6 to Form S-3, the amount of funds we can raise through primary public offerings of securities, including through our ATM, in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by our non-affiliates. We are subject to this limitation until such time as our public float exceeds $75 million. If we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays due to review by the SEC.

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.

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.

We are currently conducting our GEN-009 Phase 1/2a clinical trial. We anticipate reporting the preliminary clinical results for our GEN-009 Part B clinical trial in the second or third quarter of 2020. Based upon this evaluation, we will consider whether it is appropriate to continue the study. A decision to stop the study would result in a delay in the clinical progress, approval and commercialization of GEN-009. 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.

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, GEN-011 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 our product candidates, 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 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 GEN-011 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, GEN-011 and our 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, immunotherapies 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 product candidates are uniquely manufactured for each patient and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. If we or any of the third-party manufacturers with whom we contract encounter these types of difficulties, our ability to provide our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. Some of our third-party manufacturers are located outside the U.S., and we may encounter disruption in clinical material supplies due to logistics, as well as risk of adverse regulatory action due to local regulatory oversight.

We custom design and manufacture our product candidates. Manufacturing unique lots of these product candidates is susceptible to product loss or failure due to issues with:

- logistics associated with the collection of a patient's tumor or blood;
- batch-specific manufacturing failures or issues that arise due to the uniqueness of each patient-specific batch that may not have been foreseen;
- quality control testing failures;
- unexpected failures of batches placed on stability;
- novel assays, cell selection or other components within our manufacturing processes;
- significant costs associated with individualized manufacturing that may adversely affect our ability to continue development;
- successful and timely manufacture and release of the patient-specific batch;
- shipment issues encountered during transport of the batch to the site of patient care; and
- our reliance on single-source suppliers.

As certain of our product candidates are manufactured for each individual patient, we will be required to maintain a chain of identity with respect to each patient's sample, sequence data derived from such sample, analyze results of such patient's immunologic profile, and the custom manufactured product for each patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in product mix-up, adverse patient outcomes, loss of product, or regulatory action, including withdrawal of any approved products from the market. Further, as our product candidates are developed through early-stage clinical studies to later-stage clinical trials towards approval and commercialization, we expect that multiple aspects of the complicated collection, analysis, manufacture and delivery processes will be modified in an effort to optimize processes and results. These changes may not achieve the intended objectives, and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials.

Novel vaccine adjuvants, including those in our GEN-009 product candidate, 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, GEN-011 and any other 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 technical development, non-clinical studies and clinical trials for our product candidates, including our active clinical development product, GEN-009, GEN-011 and any other 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 and GEN-011 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 and GEN-011. 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 GEN-009 and GEN-011. 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.

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 - License Agreements" for a description of our in-license agreement with Harvard and Oncovir. 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, GEN-011 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 managed care 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 may 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 by the ongoing efforts to eliminate or significantly modify the Healthcare Reform Act. For example, recent tax reform legislation eliminated the tax penalty for individuals who do not maintain sufficient health insurance coverage. 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 2029. 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 SE, Cellular Biomedicine Group Inc., Eutilex Co., Ltd., Genentech, Inc., Gilead Sciences, Inc., Gritstone Oncology Inc., Iovance Biotherapeutics Inc., Marker Therapeutics, Inc., Merck & Co., Inc., Moderna Inc., Oncotherapy Science Inc., PACT Pharma Inc., Vaccibody AS 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 April 2018, we entered into an amended and restated loan and security agreement with Hercules Capital, Inc. (f/k/a Hercules Technology Growth Capital, Inc.) (“Hercules”), which was subsequently amended in November 2019 (as amended, the "2018 Term Loan"). The 2018 Term Loan provides up to $14.0 million of debt financing. The 2018 Term Loan has interest only payments through December 31, 2020. Thereafter, we are obligated to make payments that will include equal installments of principal and interest through the maturity date of May 2021. At December 31, 2019, $13.4 million was outstanding under the 2018 Term Loan, as amended.

All obligations under the 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 the 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 the 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 the 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 the 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.

The 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, Girish Aakalu, Ph.D., our Chief Business Officer, Tom Davis, M.D., our Chief Medical Officer, Diantha Duvall, our Chief Financial Officer, Jessica Flechtner, Ph.D., our Chief Scientific Officer, and Narinder Singh, our Senior Vice President of Pharmaceutical Sciences and Manufacturing. 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, based on 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; to 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.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We are subject to data protection laws and regulations that address privacy and data security. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions, which could include civil or criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "HIPAA"). While we are not a "covered entity" or "business associate" subject directly to regulation under HIPAA, HIPAA's criminal provisions can apply to entities other than "covered entities" or "business associates" in certain circumstances. Accordingly. we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted.

The collection and use of personal health data in the European Union is governed by the provisions of the General Data Protection Regulation ("GDPR") which came into effect in May 2018. This regulation imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States may result in significant fines and other administrative penalties. In the United States, several state legislatures are considering enacting new data privacy legislation. One example of such legislation that has already been passed is the California Consumer Privacy Act ("CCPA"), which takes effect on January 1, 2020. The CCPA gives California consumers (defined to include all California residents) certain rights, including the right to receive certain details regarding the processing of their data by covered companies, the right to request deletion of their data, and the right to opt out of sales of their data. The CCPA additionally imposes several obligations on covered companies to provide notice to California consumers regarding their data processing activities. The

CCPA provides for imposition of substantial fines on companies that violate the law and also confers a private right of action on data subjects to seek statutory or actual damages for breaches of their personal information.

Significant disruptions of information technology systems or security breaches could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, among other things, trade secrets or other intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, consultants, third-party vendors, and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks could also include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

Significant disruptions of our information technology systems, or those of our third-party vendors, or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information, including, among other things, trade secrets or other intellectual property, proprietary business information and personal information, and could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business.

Risks Related to Our Common Stock

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 30% of our outstanding common stock as of January 31, 2020. 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.

Further, any future lawsuits or 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 The 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."

On May 22, 2019, we effected a reverse stock split of our issued and outstanding common stock, par value $0.001, at a ratio of one-for-eight. As such, prior to June 10, 2019 the bid price of our common stock closed at or above $1.00 per share for a minimum of 10 consecutive business days, and Nasdaq provided written notice that we achieved compliance with the Nasdaq listing rules. Even though we did 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. 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. Due to the recent changes in the shareholder class action landscape, director and officer liability insurance has been more expensive. If this trend continues 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive office is 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. In March 2020, we will occupy an additional 22,440 square feet of laboratory and office space. The lease for just office space expires in February 2020, while the lease for laboratory and office space expires in February 2025. 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

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. We do not believe we are currently party to any pending legal action, arbitration proceeding or governmental proceeding, 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 or operating results. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

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 December 17, 2018. Prior to that, our common stock had been publicly traded on The Nasdaq Global Market since February 5, 2014.

Holders

As of February 11, 2020, there were approximately 14 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.

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, 2019.

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)	6,445,288	$ 8.48	245,430	(2)

(1) Includes information regarding our Amended and Restated 2014 Equity Incentive Plan.
(2) Does not include 1,098,116 shares added to the Amended and Restated 2014 Equity Incentive Plan under the evergreen provision on January 1, 2020.

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 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 using our ATLAS™ proprietary discovery platform. The ATLAS platform profiles each patient's $CD4^+$ and $CD8^+$ T cell immune responses to every potential target or "antigen" in that patient's tumor. We believe that this approach optimizes antigen selection for immunotherapies such as cancer vaccines and cellular therapies by identifying the antigens to which the patient can respond. Consequently, we believe that ATLAS could lead to more immunogenic and efficacious cancer immunotherapies.

Our most advanced program is GEN-009, a personalized neoantigen cancer vaccine, for which we are conducting a Phase 1/2a clinical trial. The GEN-009 program uses ATLAS to identify neoantigens, or immunogenic tumor mutations unique to each patient, for inclusion in each patient's GEN-009 vaccine. We are also advancing GEN-011, a neoantigen-specific adoptive T cell therapy program that also relies on ATLAS. We expect to file an IND application for GEN-011 in the second quarter of 2020.

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. 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, 2019, we had received an aggregate of $399.3 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, 2019, our cash and cash equivalents were $40.1 million.

Since inception, we have incurred significant operating losses. Our net losses were $39.0 million and $27.8 million for the years ended December 31, 2019 and 2018, respectively, and our accumulated deficit was $331.0 million as of December 31, 2019. 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 October 2019, we entered into a purchase agreement with LPC pursuant to which LPC purchased $2.5 million of our common stock at a purchase price of $2.587 per share. In addition, for a period of 30 months, we have the right, at our sole discretion, to sell up to an additional $27.5 million of our common stock (subject to certain ownership limitations) based on prevailing market prices of our common stock at the time of each sale. In consideration for entering into the purchase agreement, we issued 289,966 shares of our common stock to LPC as a commitment fee.

In June 2019, we completed an underwritten public offering in which we sold 10.5 million shares of our common stock at a price of $3.50 per share, for gross proceeds of approximately $36.8 million. This underwritten public offering also included an overallotment option for the underwriters for 1.6 million shares, which they exercised in full on June 26, 2019. This generated additional gross proceeds of $5.5 million. We incurred approximately $3.9 million of offering-related expenses, resulting in total net proceeds of $38.4 million.

In February 2019, we completed a private placement financing transaction in which we issued shares of our common stock, pre-funded warrant to purchase shares of our common stock, and warrants to purchase shares of our common stock for gross cash proceeds of approximately $15.0 million. We incurred $1.2 million of offering-related expenses, resulting in total net proceeds of $13.8 million.

In January 2018, we completed two underwritten public offerings in which we issued common stock, warrants, and preferred shares for net proceeds of approximately $51.7 million.

As reflected in our consolidated financial statements, we used cash to fund operating activities of $37.7 million for the year ended December 31, 2019 and had $40.1 million available in cash and cash equivalents at December 31, 2019. In addition, we had an accumulated deficit of $331.0 million and anticipate that we will continue to incur significant operating losses for the foreseeable future as we continue to develop our product candidates. Until such time, if ever, as we attempt to generate substantial product revenue and achieve profitability, we expect to finance our cash needs through a combination of equity offerings, strategic transactions, proceeds from sale of our common stock under our at-the-market equity offering program, and other sources of funding. If we are unable to raise additional funds when needed, we may be required to implement further cost reduction strategies, including ceasing development of GEN-009, GEN-011, and other corporate programs and activities. These factors, combined with our forecast of cash required to fund operations for a period of at least one year from the date of issuance of these consolidated financial statements, raise substantial doubt about our ability to continue as a going concern.

We believe that our cash and cash equivalents at December 31, 2019 are sufficient to support our operating expenses and capital expenditure requirements into the first quarter of 2021.

Costs related to clinical trials can be unpredictable and there can be no guarantee that our current balances of cash and cash equivalents combined with proceeds received from other sources, will be sufficient to fund our trials 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, GEN-011 or any other product candidate. Accordingly, we will be required to obtain further funding through public or private equity offerings, collaboration and licensing arrangements, or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all, which could result in a decision to pause or delay development or advancement of clinical trials for one or more of our product candidates. Similarly, we may decide to pause or delay development or advancement of clinical trials for one or more of our product candidates if we believe that such development or advancement is imprudent or impractical.

Financial Overview

Research and development expenses

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

- salaries and related expenses;
- expenses incurred under agreements with contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), consultants, and other vendors that conduct our clinical trials and preclinical activities;
- costs of acquiring, developing, and manufacturing clinical trial materials and lab supplies; and
- facility costs, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies.

We expense internal research and development costs to operations as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

The following table identifies research and development expenses for our product candidates as follows (in thousands):

	Years ended December 31,		Increase
	2019	2018	(Decrease)
Phase 1/2a programs	$ 16,462	$ 6,234	$ 10,228
Discovery and pre-IND	7,141	14,888	(7,747)
Other research and development	3,349	4,087	(738)
Total research and development	$ 26,952	$ 25,209	$ 1,743

Phase 1/2a programs are Phase 1 or Phase 2 development activities. Discovery and pre-IND includes costs incurred to support our discovery research and translational science efforts up to the initiation of Phase 1 development. Other research and

development includes costs that are not specifically allocated to active product candidates, including facilities costs, depreciation expense, and other costs.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related expenses for personnel in executive and other administrative functions. Other general and administrative expenses include facility costs, and professional fees associated with consulting, corporate and intellectual property legal expenses, and accounting services.

Other income (expense)

Other income (expense) consists of the change in warrant liability, interest expense, net of interest income, and other expense for miscellaneous items, such as the transaction expenses.

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 judgments that affect the amounts of assets, liabilities and expenses reported in the consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from those estimates or assumptions.

While our significant accounting policies are described in more detail in**Note 2. Summary of significant accounting policies** appearing in Item 8 in this Annual Report on Form 10-K, we believe the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our consolidated financial statements.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our research and development expenses. This process involves a thorough review of open contracts and purchase orders and an evaluation by internal personnel to identify services received that have been performed for us and estimating the associated cost incurred for these services for which we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued research and development expenses 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 accrued research and development expenses include fees paid to CROs in connection with clinical trials, CMOs with respect to preclinical 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 patients 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 patients enrolled, number of sites, or extent 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. 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.

Warrants to Purchase Redeemable Securities

We have recorded the warrants issued in a 2018 public offering to purchase redeemable securities (the "2018 Public Offering Warrants") as a liability on our balance sheets. As the 2018 Public Offering Warrants are liability-classified, we remeasure the fair value of the 2018 Public Offering Warrants at each reporting date. We calculated the estimated fair value of the 2018 Public

Offering Warrants using a Monte Carlo simulation. The Monte Carlo simulation requires the input of assumptions, including our stock price, the volatility of our stock price, remaining term in years, expected dividend yield, and risk-free rate. In addition, the valuation model considers our probability of being acquired during each annual period within the 2018 Public Offering Warrant term, as an acquisition event can potentially impact the settlement of the 2018 Public Offering Warrants. Changes to the assumptions used in determining the fair value of the 2018 Public Offering Warrants could result in materially different fair values of the 2018 Public Offering Warrants.

Results of Operations

Comparison of the Years Ended December 31, 2019 and December 31, 2018

	Years Ended December 31,		Increase
(in thousands)	**2019**	**2018**	**(Decrease)**
Operating expenses:			
Research and development	$ 26,952	$ 25,209	$ 1,743
General and administrative	12,037	14,309	(2,272)
Total operating expenses	38,989	39,518	(529)
Loss from operations	(38,989)	(39,518)	(529)
Other income (expense):			
Change in fair value of warrant	986	14,757	(13,771)
Interest expense, net	(946)	(1,021)	(75)
Other expense	(1)	(2,029)	(2,028)
Total other income	39	11,707	(11,668)
Net loss	$ (38,950)	$ (27,811)	$ 11,139

Research and development expenses

Research and development expenses increased $1.7 million to $27.0 million for the year ended December 31, 2019 from $25.2 million for the year ended December 31, 2018. The increase was due largely to increased external manufacturing costs of approximately $2.2 million, increased headcount-related costs of approximately $0.6 million, and increased clinical costs of approximately $0.3 million, offset by decreased consulting and professional services costs of approximately $1.3 million.

We expect that 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. We also expect to incur costs related to the preparation and submission of an investigational new drug ("IND") application and subsequent initiation of a clinical trial for the advancement of GEN-011.

General and administrative expenses

General and administrative expense decreased approximately $2.3 million to $12.0 million for the year ended December 31, 2019 from $14.3 million for the year ended December 31, 2018. The decrease was primarily due to reduced legal costs of approximately $2.2 million. In 2018, the Company incurred significant legal fees related to shareholder litigation, which was settled in 2019.

We anticipate that our general and administrative expenses will increase in the future to support the expected growth in our business, expand our operations and organizational capabilities. Additionally, if and when we believe regulatory approval of our first product candidate appears likely, we anticipate that we will increase costs in preparation for commercial launch.

Change in fair value of warrants

Change in fair value of warrants reflects the non-cash change in the fair value of the 2018 Public Offering Warrants, which 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 income is attributed to a smaller decrease in our stock price than that in the prior year.

Interest expense, net

Interest expense, net, consists primarily of interest expense on our long-term debt facilities, offset by interest earned on our cash equivalents.

Other income (expense)

Other income (expense) decreased $2.0 million for the year ended December 31, 2019, as compared to the year ended December 31, 2018. For the year ended December 31, 2018, other expense included $2.2 million of transaction costs allocated to the warrants related to the 2018 Public Offering Warrants.

Liquidity and Capital Resources

Overview

Since our inception in 2006, we have funded operations primarily through proceeds from public issuances of common stock, our long-term debt and the private placement of our common stock.

As of December 31, 2019, we had approximately $40.1 million in cash and cash equivalents.

In April 2018, we entered into an amended and restated loan and security agreement with Hercules Capital, Inc. ("Hercules"), which was subsequently amended in November 2019 (as amended, the "2018 Term Loan"). The 2018 Term Loan provides a $14.0 million term loan. The 2018 Term Loan will mature on May 1, 2021 and accrues interest at a floating rate per annum equal to the greater of (i) 8.00% or (ii) the sum of 3.00% plus the prime rate. The 2018 Term Loan provides for interest-only payments until January 1, 2021. Thereafter, payments will include equal installments of principal and interest through maturity. The 2018 Term Loan may be prepaid subject to a prepayment charge. We are also obligated to pay an end of term charge of $1.0 million at maturity. As of December 31, 2019, the Company had outstanding borrowings of $13.4 million.

In October 2019, we entered into a purchase agreement with LPC pursuant to which LPC purchased $2.5 million of our common stock at a purchase price of $2.587 per share. In addition, for a period of 30 months, we have the right, at our sole discretion, to sell up to an additional $27.5 million of our common stock based on prevailing market prices of our common stock at the time of each sale. In consideration for entering into the purchase agreement, we issued 289,966 shares of our common stock to LPC as a commitment fee. The purchase agreement limits our sales of shares of common stock to LPC to 5,227,323 shares of common stock, representing 19.99% of the shares of common stock outstanding on the date of the purchase agreement. The purchase agreement also prohibits us from directing LPC to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by LPC and its affiliates, would result in LPC and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of our common stock.

In June 2019, we entered into an underwriting agreement relating to the underwritten public offering of 10,500,000 shares of our common stock, par value $0.001 per share, at a price to the public of $3.50 per share, for gross proceeds of approximately $36.8 million (the “2019 Public Offering”). We also granted the underwriters an option to purchase up to an additional 1,575,000 shares of common stock (“Overallotment Option”). In June 2019, the underwriters exercised this option in full. We received approximately $5.5 million in gross proceeds from the underwriter’s exercise of the Overallotment Option. In connection with the 2019 Public Offering, inclusive of the Overallotment Option, we incurred approximately $3.9 million of offering-related expenses, resulting in total net proceeds of $38.4 million.

In February 2019, we completed a private placement financing transaction (the “Private Placement”). We issued 3,199,998 shares (the “Shares”) of common stock, prefunded warrants (the “Pre-Funded Warrants”) to purchase 531,250 shares of common stock (the “Pre-Funded Warrant Shares”), and warrants (the “Private Placement Warrants”) to purchase up to 932,812 shares of common stock (the “Warrant Shares”). The Shares, Pre-Funded Warrants and Private Placement Warrants (collectively, the “Units”) were sold at a purchase price of $4.02 per Unit. We received net cash proceeds of approximately $13.8 million for the purchase of the Shares, Pre-Funded Warrant Shares and Warrant Shares.

Cash Flows

The following table summarizes our sources and uses of cash for the years ended December 31, 2019 and 2018 (in thousands):

	Years ended December 31,		Increase
	2019	2018	(Decrease)
Net cash used in operating activities	$ (37,734)	$ (41,235)	$ (3,501)
Net cash used in investing activities	(1,087)	(131)	956
Net cash provided by financing activities	52,901	55,455	(2,554)
Net increase in cash and cash equivalents	$ 14,080	$ 14,089	$ (9)

Operating Activities

Net cash used in operations decreased $3.5 million to $37.7 million for the year ended December 31, 2019 from $41.2 million for the year ended December 31, 2018. The decrease in net cash used was due to favorable changes in working capital attributable to accounts payable and accrued expenses.

Investing Activities

Net cash used in investing activities increased $1.0 million to $1.1 million of cash used in investing activities for the year ended December 31, 2019 compared to $0.1 million of cash used in investing activities for the year ended December 31, 2018. The increase in cash used in investing activities was due to increased purchases of property and equipment.

Financing Activities

Net cash provided by financing activities decreased $2.6 million to $52.9 million for the year ended December 31, 2019 from $55.5 million of cash provided by financing activities for the year ended December 31, 2018. In 2018, we generated net proceeds of $51.7 million from a 2018 public offering of common stock and warrants and we generated net proceeds of $2.9 million from the sale of shares of common stock issued pursuant to our ATM facility, whereas in 2019, the Private Placement generated net proceeds of $13.8 million, the 2019 Public Offering generated net proceeds of $38.4 million, and the transactions pursuant to the purchase agreement with LPC generated net proceeds of $2.5 million. During the years ended December 31, 2019 and 2018, we made payments of $1.9 million and $0.5 million on our long term debt.

Operating Capital Requirements

Our primary uses of capital are for compensation and related expenses, manufacturing costs for preclinical and clinical materials, third party clinical trial services, laboratory and related supplies, legal and other regulatory expenses, and general overhead costs. We expect these costs will continue to be the primary operating capital requirements for the near future.

We expect that our existing cash and cash equivalents are sufficient to support our operations into the first quarter of 2021. As reflected in the consolidated financial statements, we had available cash and cash equivalents of $40.1 million at December 31, 2019. In addition, we had cash used in operating activities of $37.7 million for the year ended December 31, 2019. These factors, combined with our forecast of cash required to fund operations for a period of at least one year from the date of issuance of these financial statements, raise substantial doubt about our ability to continue as a going concern. We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and costs of our planned clinical trials for GEN-009;
- the progress, timing, and costs of manufacturing GEN-009 for planned clinical trials;
- the outcome, timing, and costs of seeking regulatory approvals, including an IND application for GEN-011;
- the initiation, progress, timing, costs, and results of preclinical studies and clinical trials for our other product candidates and potential product candidates;
- the terms and timing of any future collaborations, grants, licensing, consulting, or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents, or other intellectual property rights, including

milestone payments, royalty payments, and patent prosecution fees that we are obligated to pay pursuant to our license agreements;

- the costs of preparing, filing, and prosecuting patent applications, maintaining and protecting our intellectual property rights, and defending against intellectual property related claims;
- the extent to which we in-license or acquire other products and technologies;
- the receipt of marketing approval;
- the costs of commercialization activities for GEN-009 and other product candidates, if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution, and manufacturing capabilities; and
- revenue received from commercial sales of our product candidates.

We will need to obtain substantial additional funding in order to complete clinical trials and receive regulatory approval for GEN-009, GEN-011 and our other product candidates. To the extent that we raise additional capital through the sale of our common stock, convertible securities, or other equity securities, the ownership interests of our existing stockholders may be materially diluted and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. In addition, debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends, that could adversely affect our ability to conduct our business. If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back, or discontinue the development of GEN-009, GEN-011 or our other product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to GEN-009, GEN-011 or our other product candidates that we otherwise would seek to develop or commercialize ourselves.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 7A. Qualitative and Quantitative Disclosures About Market Risk

We had cash and cash equivalents of approximately $40.1 million as of December 31, 2019. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk relates to fluctuations in interest rates, which are affected by changes in the general level of U.S. interest rates. Given the short-term nature of our cash and cash equivalents, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations. We do not own any derivative financial instruments.

We do not believe that our cash, cash equivalents and marketable securities have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash, cash equivalents and marketable securities at one or more financial institutions that are in excess of federally insured limits.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our results of operations during the year ended December 31, 2019.

Item 8. Financial Statements and Supplementary Data

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

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019 (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded, based upon the evaluation described above that, as of December 31, 2019, our disclosure controls and procedures were effective at the reasonable-assurance level.

Management's Annual Report on Internal Controls Over Financial Reporting

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

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

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

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2019, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On February 12, 2020, our board of directors (the "Board") elected Gisela M. Schwab, M.D., age 63, to the Board as an independent director, effective February 14, 2020. Ms. Schwab will be a Class II director of the Company and will be nominated for re-election at the annual meeting of our stockholders to be held in 2022.

Dr. Schwab has served as President, Product Development and Medical Affairs and Chief Medical Officer of Exelixis, Inc. ("Exelixis") since February 2016. Previously she served as Executive Vice President and Chief Medical Officer of Exelixis from January 2008 to February 2016 and as Senior Vice President and Chief Medical Officer of Exelixis from September 2006 to January 2008. From 2002 to 2006, she held the position of Senior Vice President and Chief Medical Officer at Abgenix, Inc. ("Abgenix"), a human antibody-based drug development company. She also served as Vice President, Clinical Development, at Abgenix from 1999 to 2001. Prior to working at Abgenix, from 1992 to 1999, she held positions of increasing responsibility at Amgen Inc., most recently as Director of Clinical Research and Hematology/Oncology Therapeutic Area Team Leader. From August 2011 through July 2014, Dr. Schwab served as a member of the board of directors of Topotarget A/S, a publicly-held biopharmaceutical company. Since June 2012 she has served as a member of the board of directors of Cellerant Therapeutics, Inc. a privately-held biopharmaceutical company and since March 2015, she has served as a member of the board of directors of Nordic Nanovector A.S., a Norwegian biotechnology company. She received her Doctor of Medicine degree from the University of Heidelberg, trained at the University of Erlangen-Nuremberg and the National Cancer Institute and is board certified in internal medicine and hematology and oncology. We believe that Dr. Schwab's scientific expertise, which includes advancing product candidates through development and regulatory approval to commercial launch, qualifies her to serve as a member of our Board.

Dr. Schwab will receive compensation for her service as a director in accordance with our non-employee director compensation policy, including an annual director fee of $35,000. Pursuant to our non-employee director compensation policy and our Amended and Restated 2014 Equity Incentive Plan and non-qualified stock option award agreement, Dr. Schwab will receive an award of stock options to purchase 9,375 shares of our common stock on February 14, 2020.

In accordance with our customary practice, we have entered into an indemnification agreement with Dr. Schwab, which requires us to indemnify her against certain liabilities that may arise in connection with her status or service as a director. The indemnification agreement also provides for an advancement of expenses incurred by Dr. Schwab in connection with any proceeding

relating to her status as a director. The foregoing description is qualified in its entirety by the full text of the form of indemnification agreement, which was filed with the Securities and Exchange Commission as Exhibit 10.1 to our Registration Statement on Form S-1 (Registration No. 333-197247), and which is incorporated herein by reference.

There is no arrangement or understanding between Dr. Schwab and any other person pursuant to which Dr. Schwab was selected as a director. Other than as described above, there are no transactions involving Dr. Schwab requiring disclosure under Item 404(a) of Regulation S-K of the Securities and Exchange Commission.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Other than the information regarding our executive officers provided in Part I of this report under the heading "Business—Information about our Executive Officers," the information required to be furnished pursuant to this item is incorporated herein by reference to our definitive proxy statement for the 2020 Annual Meeting of the Stockholders.

Item 11. Executive and Director Compensation

The information required by this Item 11 is incorporated herein by reference from our definitive proxy statement for the 2020 Annual Meeting of Stockholders.

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

The information required by this Item 12 is incorporated herein by reference from our definitive proxy statement for the 2020 Annual Meeting of Stockholders.

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

The information required by this Item 13 is incorporated herein by reference from our definitive proxy statement for the 2020 Annual Meeting of Stockholders.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 is incorporated herein by reference from our definitive proxy statement for the 2020 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statements

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2019 and 2018

Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2019 and 2018

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019 and 2018

Consolidated Statements of Cash Flows for each of the years ended December 31, 2019 and 2018

Notes to Consolidated Financial Statements

Item 16. Form 10-K Summary

None.

Financial Statement Schedules

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

Exhibits

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

Genocea Biosciences, Inc.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
Genocea Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Genocea Biosciences, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for the years ended December 31, 2019 and 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2019 and 2018, and the consolidated results of its operations and its cash flows for the years ended December 31, 2019 and 2018, in conformity with U.S. generally accepted accounting principles.

Adoption of New Accounting Standards

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases as a result of the adoption of Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842), and the related amendments effective January 1, 2019.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2009
Boston, Massachusetts
February 13, 2020

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 40,127	$ 26,361
Prepaid expenses and other current assets	1,457	696
Total current assets	41,584	27,057
Property and equipment, net	2,617	2,582
Right of use assets	6,306	—
Restricted cash	631	316
Other non-current assets	1,473	1,160
Total assets	$ 52,611	$ 31,115
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 553	$ 1,659
Accrued expenses and other current liabilities	4,611	3,816
Lease liabilities	1,117	—
Current portion of long-term debt	—	5,257
Total current liabilities	6,281	10,732
Non-current liabilities:		
Long-term debt, net of current portion	13,407	9,565
Warrant liability	2,486	3,472
Lease liabilities, net of current portion	5,395	—
Other non-current liabilities	—	11
Total liabilities	27,569	23,780
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; (shares authorized of 25,000,000 at December 31, 2019 and 2018; 1,635 shares issued and outstanding at December 31, 2019 and 2018)	701	701
Common stock, $0.001 par value; (shares authorized of 85,000,000 and 250,000,000 at December 31, 2019 and 2018; 27,452,900 shares issued and outstanding at December 31, 2019 and 10,846,397 shares issued and outstanding at December 31, 2018)	27	11
Additional paid-in capital	355,268	298,627
Accumulated deficit	(330,954)	(292,004)
Total stockholders' equity	25,042	7,335
Total liabilities and stockholders' equity	$ 52,611	$ 31,115

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 26,952	$ 25,209
General and administrative	12,037	14,309
Total operating expenses	38,989	39,518
Loss from operations	(38,989)	(39,518)
Other income (expense):		
Change in fair value of warrant	986	14,757
Interest expense, net	(946)	(1,021)
Other expense	(1)	(2,029)
Total other income	39	11,707
Net loss	$ (38,950)	$ (27,811)
Comprehensive loss	$ (38,950)	$ (27,811)
Net loss per share - basic and diluted	$ (1.89)	$ (2.69)
Weighted-average number of common shares used in computing net loss per share	20,644	10,321

See accompanying notes to consolidated financial statements.

Genocea Biosciences, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands)

	Common Shares		Preferred Shares	Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Amount	Capital	Deficit	Equity (Deficit)
Balance at December 31, 2017	3,592	$ 3	$ —	$ 258,140	$ (264,193)	$ (6,050)
Issuance of common stock, net	7,230	8	701	38,077	—	38,786
Issuance of common Stock; ESPP purchase	25	—	—	67	—	67
Stock-based compensation expense	—	—	—	2,153	—	2,153
Issuance of warrants in connection with debt modification	—	—	—	190	—	190
Net loss	—	—	—	—	(27,811)	(27,811)
Balance at December 31, 2018	10,847	$ 11	$ 701	$ 298,627	$ (292,004)	$ 7,335
Issuance of common stock, net	16,530	16	—	54,653	—	54,669
Issuance of common stock; ESPP purchase	71	—	—	130	—	130
Exercise of stock options	5	—	—	21	—	21
Stock-based compensation expense	—	—	—	1,837	—	1,837
Net loss	—	—	—	—	(38,950)	(38,950)
Balance at December 31, 2019	27,453	$ 27	$ 701	$ 355,268	$ (330,954)	$ 25,042

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,	
	2019	**2018**
Operating activities		
Net loss	$ (38,950)	$ (27,811)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,097	1,088
Stock-based compensation	1,837	2,153
Allocation of proceeds to transaction expenses	—	2,115
Change in fair value of warrant liability	(986)	(14,757)
Gain on sale of equipment	(29)	(78)
Write-off of deferred financing fees	110	355
Non-cash interest expense	504	643
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(803)	53
Right of use assets, net of lease liabilities	206	—
Other non-current assets	(423)	(989)
Accounts payable	(1,106)	(2,103)
Accrued expenses and other liabilities	809	(1,904)
Net cash used in operating activities	(37,734)	(41,235)
Investing activities		
Purchases of property and equipment	(1,135)	(241)
Proceeds from sale of equipment	48	110
Net cash used in investing activities	(1,087)	(131)
Financing activities		
Proceeds from equity offerings, net of issuance costs	54,669	55,458
Payment of deferred financing costs	—	(127)
Proceeds from long-term debt	—	592
Repayment of long-term debt	(1,919)	(535)
Proceeds from exercise of stock options	21	—
Proceeds from the issuance of common stock under ESPP	130	67
Net cash provided by financing activities	52,901	55,455
Net increase in cash, cash equivalents and restricted cash	$ 14,080	$ 14,089
Cash, cash equivalents and restricted cash at beginning of period	26,678	12,589
Cash, cash equivalents and restricted cash at end of period	$ 40,758	$ 26,678
Non-cash financing activities and supplemental cash flow information		
Cash paid in connection with operating lease liabilities	$ 1,637	$ —
Cash paid for interest	$ 1,103	$ 1,074
Warrants issued in connection with debt modification	$ —	$ 190

See accompanying notes to consolidated financial statements.

1. Organization and operations

The Company

Genocea Biosciences, Inc. (the "Company") is a biopharmaceutical company that was incorporated in Delaware on August 16, 2006 and has a principal place of business in Cambridge, Massachusetts. The Company seeks to discover and develop novel cancer immunotherapies using its ATLAS™ proprietary discovery platform. The ATLAS platform profiles each patient's $CD4^+$ and $CD8^+$ T cell immune responses to every potential target or "antigen" in that patient's tumor. The Company believes that this approach optimizes antigen selection for immunotherapies such as cancer vaccines and cellular therapies. Consequently, the Company believes that ATLAS could lead to more immunogenic and efficacious cancer immunotherapies.

The Company's most advanced program is GEN-009, a personalized neoantigen cancer vaccine, for which it is conducting a Phase 1/2a clinical trial. The GEN-009 program uses ATLAS to identify neoantigens, or immunogenic tumor mutations unique to each patient, for inclusion in each patient's GEN-009 vaccine. The Company is also advancing GEN-011, a neoantigen-specific adoptive T cell therapy program that also relies on ATLAS, and is targeting an IND filing for GEN-011 in the second quarter of 2020.

The Company is devoting substantially all of its efforts to product research and development, initial market development, and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks and uncertainties common to companies in the biotech and pharmaceutical industry, including, but not limited to, the risks associated with the uncertainty of success of its preclinical and clinical trials; the challenges associated with gaining regulatory approval of product candidates; the risks associated with commercializing pharmaceutical products, if approved for marketing and sale; the potential for development by third parties of new technological innovations that may compete with the Company's products; the dependence on key personnel; the challenges of protecting proprietary technology; the need to comply with government regulations; the high costs of drug development; compliance with government regulations, competition from companies with greater financial, technological and other resources; and the uncertainty of being able to secure additional capital when needed to fund operations.

Accounting Standards Update ("ASU"), 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40)*, also referred to as Accounting Standards Codification ("ASC") 205-40 ("ASC 205-40"), requires the Company to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the financial statements are issued. As of December 31, 2019, the Company had an accumulated deficit of $331.0 million and anticipates that it will continue to incur significant operating losses for the foreseeable future as it continues to develop its product candidates. Until such time, if ever, as the Company can generate substantial product revenue and achieve profitability, the Company expects to finance its cash needs through a combination of equity offerings, strategic transactions, and other sources of funding. If the Company is unable to raise additional funds when needed, the Company may be required to implement further cost reduction strategies, including ceasing development of GEN-009, GEN-011, and other corporate programs and activities.

As reflected in the consolidated financial statements, the Company had available cash and cash equivalents of $40.1 million at December 31, 2019. In addition, the Company had cash used in operating activities of $37.7 million for the year ended December 31, 2019. These factors, combined with the Company's forecast of cash required to fund operations for a period of at least one year from the date of issuance of these consolidated financial statements, raise substantial doubt about the Company's ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Effective May 22, 2019, the Company effected a reverse stock split of its issued and outstanding common stock, par value $0.001, at a ratio of one-for-eight, and decreased the number of authorized shares of common stock from 250,000,000 shares to 85,000,000 shares. The share and per share information presented in these financial statements and related notes have been retroactively adjusted to reflect the one-for-eight reverse stock split.

2. Summary of significant accounting policies

The following is a summary of significant accounting policies followed in the preparation of these financial statements.

Basis of presentation and principles of consolidation

The accompanying consolidated financial statements include those accounts of the Company and a wholly-owned subsidiary after elimination of all intercompany accounts and transactions. The Company operates as one segment, which is discovering, researching, developing and commercializing novel cancer immunotherapies.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, estimates related to clinical trial accruals, estimates related to prepaid and accrued research and development expenses, stock-based compensation expense, and warrants to purchase redeemable securities. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Cash and cash equivalents

The Company considers only those investments which are highly liquid, readily convertible to cash and that mature within three months from date of purchase to be cash equivalents. The carrying values of money market funds approximate fair value due to their short-term maturities.

Prepaid research and development

Cash advances paid by the Company prior to receipt of preclinical or clinical material and preclinical and clinical trial services are recorded as prepaid research and development costs. The prepayments are applied against future research and development costs. The Company expects the carrying value of prepaid research and development costs to be fully realized.

Property and equipment

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

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

Development of software for internal use

The Company accounts for the costs of software developed or obtained for internal use in accordance with ASC 350-40,*Internal-Use Software* ("ASC 350-40"). Costs of materials, consultants, payroll, and payroll-related costs for employees incurred in developing internal-use software are capitalized as incurred. These costs are included in property and equipment, net on the consolidated balance sheet. Costs incurred during the preliminary project and post-implementation stages are charged to expense. Amortization is recorded using the straight-line method over the estimated useful lives of the respective asset which is three to five years.

Impairment of long-lived assets

The Company evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset, the assets are written down to their estimated fair values. Long-lived assets to be disposed are reported at the lower of the carrying amount or fair value less cost to sell. The Company recognized no asset impairment losses in the years ended December 31, 2019 and 2018.

Deferred financing costs

Offering costs primarily consist of direct and incremental expenses incurred related to debt and equity financing in accordance with ASU 2015-03, *Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"). The Company presents debt issuance costs related to a recognized debt liability in the balance sheet as a direct deduction of the carrying value of the debt liability, consistent with the accounting treatment of debt discounts in accordance with ASU 2015-03. The amortization of deferred debt financing costs follows the effective interest rate method.

Fair value of financial instruments

The Company has certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

- Level 1—Fair values are determined by utilizing quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access;
- Level 2—Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates, yield curves and foreign currency spot rates; and
- Level 3—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The Company's financial assets consist of cash equivalents and the Company's financial liabilities consist of a warrant liability.

The fair value of the Company's cash equivalents is determined using quoted prices in active markets. The Company's cash equivalents consist of money market funds that are classified as Level 1.

The fair value of the Company's warrant liability is determined using a Monte Carlo simulation. See **Note 9. Warrants** for assumptions used and methodologies utilized in calculating the estimated fair value. The Company's warrant liability is classified as Level 3.

Leases

At the inception of the contract, the Company determines if an arrangement is a lease and has a lease term greater than 12 months. A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset to the Company by the end of the lease term, (ii) the Company holds an option to purchase the leased asset that it is reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, or (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term. All other leases are recorded as operating leases. All leases that are concluded to be in accordance with ASU No. 2018-11, *Leases* (Topic 842): *Targeted Improvements* are included in lease right-of-use ("ROU") assets and lease liabilities in the consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. The Company uses the implicit rate when readily determinable. The operating lease ROU asset is reduced by deferred lease payments and unamortized lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for fixed lease payments on operating leases are recognized over the expected term on a straight-line basis, while lease expense for fixed lease payments on financing leases are recognized using the effective interest

method over the lease term. The Company has lease agreements with lease and non-lease components, which are generally accounted for separately. The non-lease components generally consist of common area maintenance that is expensed as incurred.

Research and development expenses

Research and development costs are expensed as incurred. The Company has entered into various research and development contracts with research institutions and other companies. Nonrefundable advanced payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed or when the goods have been received rather than when the payment is made. When evaluating the adequacy of the related accrued liabilities, the Company analyzes progress of the studies and/or services performed, including the phase or completion of events, invoices received and contracted costs.

Stock-based compensation expense

The Company accounts for its stock-based compensation to employees in accordance with ASC 718,*Compensation-Stock Compensation* and adjusts the amounts recorded each period to reflect actual forfeitures.

Effective January 1, 2019, the Company recognizes stock-based compensation expense for stock-based awards, including grants of stock options and restricted stock, made to non-employee consultants based on the estimated fair value on the date of grant, over the requisite service period. Through December 31, 2018, the Company recognized stock-based compensation expense for stock-based awards granted to non-employee consultants based on the fair value of the awards on each date on which the awards vest. Stock-based compensation expense was recognized over the vesting period, provided that services were rendered by such non-employee consultants during that time. At the end of each financial reporting period, the fair value of unvested options was re-measured using the then-current fair value of the common stock of the Company and updated assumptions in the Black-Scholes option-pricing model.

For awards that vest or begin vesting upon achievement of a performance condition, the Company recognizes stock-based compensation expense when achievement of the performance condition is deemed probable using an accelerated attribution model over the implicit service period. Certain of the Company's awards that contain performance conditions also require the Company to estimate the number of awards that will vest, which the Company estimates when the performance condition is deemed probable of achievement.

Income taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using the enacted tax rates in effect for the year in which these temporary differences are expected to recovered or settled. Valuation allowances are provided if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

Basic and diluted net loss per share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding for the period. For periods in which the Company has reported net losses, diluted net loss per share is the same as basic net loss per share, because dilutive common shares are not assumed to have been issued if their effect is antidilutive. The Company reported a net loss for the years ended December 31, 2019 and 2018.

New Accounting Pronouncements

The following new accounting pronouncements were adopted by the Company on January 1, 2019:

In February 2016, the FASB issued ASU No. 2016-02,*Leases*, which replaced existing guidance in ASC 840, "Leases", and in July 2018, the FASB issued ASU No. 2018-11, *Leases* (Topic 842): *Targeted Improvements*. The new standard establishes a ROU that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The adoption of ASC 842 resulted in the Company recognizing ROU assets and related operating lease liabilities of $1.7 million and $1.8 million, respectively, in the consolidated balance sheet as of January 1, 2019. The Company used the modified retrospective method of adoption, with January 1, 2019 as the effective date of initial application.

The Company elected the short-term lease recognition exemption for all leases that qualify. The Company also elected the package of practical expedients for leases that commenced prior to January 1, 2019, allowing it not to reassess (i) whether any expired or existing contracts contain leases, (ii) the lease classification for any expired or existing leases and (iii) the initial indirect costs for any existing leases.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share Based Payment Accounting*. The new standard largely aligns the accounting for share-based payment awards issued to employees and nonemployees by expanding the scope of ASC 718 to apply to nonemployee share-based transactions, as long as the transaction is not effectively a form of financing. The Company adopted the provisions of ASU No. 2018-17 effective January 1, 2019, which did not have a material impact on the Company's consolidated financial statements for the year ended December 31, 2019.

The following new accounting pronouncements have been issued but are not yet effective as of December 31, 2019:

In June 2016, the FASB issued *ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. The new standard is effective beginning January 1, 2020. Based on the composition of the Company's investment portfolio, which includes only money market funds, and the insignificance of the Company's other financial assets, current market conditions, and historical credit loss activity, the Company does not expect the adoption of this standard to have a material impact on the consolidated financial position and results of operations and related disclosures.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*. The new standard requires public entities to disclose certain new information and modifies some disclosure requirements. The new standard is effective beginning January 1, 2020. The Company does not expect that the adoption of this standard will have a material impact on its disclosures.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in Accounting Standards Codification 350-40 to determine which implementation costs to defer and recognize as an asset. The new standard is effective beginning January 1, 2020. The Company does not expect that the adoption of this standard will have a material impact on its consolidated financial position and results of operations and related disclosures.

3. Fair value of financial instruments

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2019 and 2018 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2019				
Assets				
Cash equivalents	39,971	39,971	—	—
Total assets	$ 39,971	$ 39,971	$ —	$ —
Liabilities				
Warrant liability	2,486	—	—	2,486
Total liabilities	$ 2,486	$ —	$ —	$ 2,486
December 31, 2018				
Assets				
Cash equivalents	24,651	24,651	—	—
Total assets	$ 24,651	$ 24,651	$ —	$ —
Liabilities				
Warrant liability	3,472	—	—	3,472
Total liabilities	$ 3,472	$ —	$ —	$ 3,472

The following table reflects the change in the Company's Level 3 warrant liability (in thousands):

	Warrant liability
Balance at Issuance (January 2018)	$ 18,231
Change in fair value	(14,757)
Warrants exercised	(2)
Balance at December 31, 2018	$ 3,472
Change in fair value	(986)
Balance at December 31, 2019	$ 2,486

4. Property and equipment, net

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

	December 31,	
	2019	2018
Laboratory equipment	$ 4,125	$ 3,761
Internally developed software	2,547	1,970
Leasehold improvements	1,524	1,524
Furniture and office equipment	456	447
Computer hardware	338	338
Internally developed software in progress	97	—
Total property and equipment	9,087	8,040
Accumulated depreciation and amortization	(6,470)	(5,458)
Property and equipment, net	$ 2,617	$ 2,582

Depreciation expense was $0.7 million for both the years ended December 31, 2019 and 2018, respectively. Amortization related to the Company's internally developed software was $0.4 million for both the years ended December 31, 2019 and 2018, respectively.

5. Accrued expenses and other current liabilities

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

	December 31,	
	2019	2018
Payroll and employee-related costs	$ 2,245	$ 2,147
Research and development costs	1,607	759
Other current liabilities	759	910
Total	$ 4,611	$ 3,816

6. Commitments and contingencies

Operating Leases

As of January 1, 2019, the Company has entered into two lease agreements for two floors of lab and office space in a multi-tenant building in Cambridge, Massachusetts.

In March 2019, the Company entered into a sublease agreement for a portion of office space lease through February 2020. Since the Company retained its obligations under the sublease, it did not adjust the lease liability, however the sublease is being reflected as a reduction of lease expense.

In May 2019, the Company entered into a lease extension for office and lab space through February 2025. As a result of the lease term extension, the Company recognized an increase in the ROU assets of $5.4 million and associated lease liabilities of $5.3 million. The associated lease obligation for the extension is included in the Company's ROU assets and associated lease liabilities as of December 31, 2019. The Company has the option to extend the lease terms for an additional five years, which is not included in the Company's ROU assets and associated lease liabilities as of December 31, 2019.

In July 2019, the Company exercised an option for additional office and lab space from March 2020 through February 2025. As the Company does not have the right to use or control the office space, the Company has not included the associated lease obligation in its determination of ROU assets and associated lease liabilities as of December 31, 2019. The Company's lease obligation associated with the additional lab and office space is $7.2 million and will be reflected as a lease liability upon it's right to use the office space in March 2020.

For the year ended December 31, 2019, lease expense, net of sublease income, was $1.5 million.

The weighted average remaining lease term and weighted average discount rate of the Company's operating leases are as follows:

	December 31, 2019
Weighted average remaining lease term in years	5.12
Weighted average discount rate	8.27%

Finance Lease

In December 2019, the Company entered into an agreement to lease lab equipment for a term of 15 months. The Company determined that the agreement qualifies as a finance lease based on the criteria that the Company holds the option to purchase the asset and is reasonably certain to exercise at the end of the lease term. The ROU asset and lease liability were calculated using an incremental borrowing rate of 7.95%. Lease payments on this lease begin in January 2020.

The following table summarizes the presentation in the Company's consolidated balance sheets:

Leases (in thousands)	Classification	December 31, 2019
Assets		
Operating	Lease right-of-use asset	$ 6,156
Finance	Lease right-of-use asset	150
Total leased assets		$ 6,306
Liabilities		
Current		
Operating	Lease liabilities	$ 990
Finance	Lease liabilities	127
Non-current		
Operating	Lease liabilities, net of current portion	5,373
Finance	Lease liabilities, net of current portion	22
Total lease liabilities		$ 6,512

The minimum lease payments related to the Company's operating leases in accordance with ASC 842 as of December 31, 2019 were as follows (in thousands):

	Operating Leases	Finance Leases	Total
2020	$ 1,477	$ 134	$ 1,611
2021	1,473	23	1,496
2022	1,511	—	1,511
2023	1,548	—	1,548
2024 and thereafter	1,853	—	1,853
Total lease payments	$ 7,862	$ 157	$ 8,019
Less imputed interest	(1,500)	(7)	(1,507)
Total	$ 6,362	$ 150	$ 6,512

The following information is disclosed in accordance with ASC 840, which was applicable until the adoption of ASC 842 as of January 1, 2019. As of December 31, 2018, future minimum commitments under the Company's operating leases with initial terms of more than one year were as follows (in thousands):

	Total Lease Commitments
2019	$ 1,637
2020	274
Total	$ 1,911

For the year ended December 31, 2018, under ASC 840, the Company paid $1.5 million in rent expense.

At December 31, 2019 and 2018, the Company has an outstanding letter of credit of $0.6 million and $0.3 million, respectively, with a financial institution related to a security deposit for the office and lab space lease. The amount is secured by cash on deposit and expires on February 28, 2025.

Contractual obligations

The Company has entered into certain agreements with various contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), which generally include cancellation clauses.

Harvard University License Agreement

The Company has an exclusive license agreement with Harvard University ("Harvard"), granting the Company 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 related to the ATLAS discovery platform. The Company is also obligated to pay Harvard milestone payments up to $1.6 million in the aggregate upon the achievement of certain development and regulatory milestones. As of December 31, 2019, the Company has paid $0.3 million in aggregate milestone payments. The Company is obligated under this license agreement to use commercially reasonable efforts to develop, market and sell licensed products in compliance with an agreed upon development plan. In addition, the Company is obligated to achieve specified development milestones and in the event the Company is unable to meet its 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.

Upon commercialization of our products covered by the licensed patent rights or discovered using the licensed methods, the Company is obligated to pay Harvard royalties on the net sales of such products and services sold by the Company, the Company's affiliates, and the Company's 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 the Company's 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 the Company receives 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 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 the Company receives any additional revenue (cash or non-cash) under any sublicense, the Company 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.

This license agreement with Harvard will expire on a product-by-product or service-by-service and country-by-country basis until the expiration of the last-to-expire valid claim under the licensed patent rights. The Company 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 the Company that remains uncured; in the event of our insolvency, bankruptcy, or similar circumstances; or if the Company challenges the validity of any patents licensed to us.

Oncovir License and Supply Agreement

In January 2018, the Company 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 the Company for use in connection with the research, development, use, sale, manufacture, commercialization and marketing of products combining Hiltonol with the Company's technology (the "Combination Product"). Hiltonol is the adjuvant component of GEN-009, which will consist of synthetic long peptides or neoantigens identified using the Company's proprietary ATLAS platform, formulated with Hiltonol.

Oncovir granted the Company 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 will 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 the Company under the agreement expires.

Under this agreement, the Company is obligated to pay Oncovir low to mid six figure milestone payments upon the achievement of certain clinical trial milestones for each Combination Product and the first marketing approval for each Combination Product in certain territories, as well as tiered royalties in the low-single digits on a product-by-product basis based on the net sales of Combination Products.

The Company may terminate the agreement upon a decision to discontinue the development of the Combination Product or upon a determination by the Company 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.

7. Long-term debt

In April 2018, the Company entered into an amended and restated loan and security agreement with Hercules Capital, Inc. ("Hercules"), which was subsequently amended in November 2019 (as amended, the "2018 Term Loan"). The 2018 Term Loan provides a $14.0 million term loan. The 2018 Term Loan matures on May 1, 2021 and accrues interest at a floating rate per annum equal to the greater of (i) 8.00%, or (ii) the sum of 3.00% plus the prime rate. The 2018 Term Loan provides for interest-only payments until January 1, 2021. Thereafter, payments will include equal installments of principal and interest through maturity. The 2018 Term Loan may be prepaid subject to a prepayment charge. The Company is obligated to pay an end of term charge of $1.0 million at maturity. The Company evaluated the November 2019 amendment to the 2018 Term Loan and concluded that it was a modification pursuant to ASC 470-50, *Debt* (Topic 470).

The 2018 Term Loan is secured by a lien on substantially all assets of the Company, other than intellectual property. Hercules has a perfected first-priority security interest in certain cash, cash equivalents and investment accounts. The 2018 Term Loan contains non-financial covenants, representations and a Material Adverse Effect provision. There are no financial covenants. A "Material Adverse Effect" means a material adverse effect upon: (i) the business, operations, properties, assets or condition (financial or otherwise) of the Company; (ii) the ability of the Company to perform the secured obligations in accordance with the terms of the loan documents, or the ability of agent or lender to enforce any of its rights or remedies with respect to the secured obligations; or (iii) the collateral or agent's liens on the collateral or the priority of such liens. Any event that has a Material Adverse Effect or would reasonably be expected to have a Material Adverse Effect is an event of default under the Loan Agreement and repayment of amounts due under the Loan Agreement may be accelerated by Hercules under the same terms as an event of default. As of December 31, 2019, the Company was in compliance with all covenants of the 2018 Term Loan. The 2018 Term Loan is automatically redeemable upon a change in control. The Company believes acceleration of the repayment of amounts outstanding under the loan is remote, and therefore, the debt balance is classified according to the contractual payment terms at December 31, 2019.

In connection with a previously issued term loan in 2014 the Company issued common stock warrants to Hercules which expired unexercised in November 2019. In connection with the 2018 Term Loan, the Company issued common stock warrants to Hercules (the "Hercules Warrant"). See **Note 9. Warrants**.

As of December 31, 2019 and 2018, the Company had outstanding borrowings of $13.4 million and $14.8 million, respectively. During the years ended December 31, 2019 and 2018, the Company made payments of $1.9 million and $0.5 million on its long term debt. Interest expense was $1.6 million and $1.7 million for the years ended December 31, 2019 and 2018, respectively.

Future principal payments, including the End of Term Charges, are as follows (in thousands):

	December 31, 2019
2020	$ —
2021	13,960
Total	$ 13,960

8. Stockholders' equity

2019 Public Offering

In June 2019, the Company entered into an underwriting agreement relating to the public offering of 10,500,000 shares of the Company's common stock, par value $0.001 per share, at a price of $3.50 per share, for gross proceeds of approximately $36.8 million (the "2019 Public Offering"). The Company also granted the underwriters an option to purchase up to an additional 1,575,000 shares of common stock ("Overallotment Option"). On June 26, 2019, the underwriters exercised this option in full. The Company received approximately $5.5 million in gross proceeds from the underwriter's exercise of the Overallotment Option. In connection with the 2019 Public Offering, inclusive of the Overallotment Option, the Company received net proceeds of $38.4 million.

Private Placement

In February 2019, the Company completed a private placement financing transaction (the "Private Placement"). The Company issued 3,199,998 shares of common stock, prefunded warrants (the "Pre-Funded Warrants") to purchase 531,250 shares of common stock (the "Pre-Funded Warrant Shares"), and warrants (the "Private Placement Warrants") to purchase up to 932,812 shares of common stock (the "Warrant Shares"). The Shares, Pre-Funded Warrants and Private Placement Warrants (collectively, the "Units") were sold at a purchase price of $4.02 per Unit. The Company received net cash proceeds of approximately $13.8 million for the purchase of the Shares, Pre-Funded Warrant Shares and Warrant Shares. See **Note 9. Warrants**.

The Company had the option to issue additional shares of common stock in a second closing (the "Second Closing") for gross proceeds of up to $24.2 million. The occurrence of the Second Closing was conditioned on top-line results from Part A of the Company's Phase 1/2a clinical trial for GEN-009 and a decision by the Company's board of directors to proceed with the Second Closing. In June 2019, the Company announced top-line results from this trial but elected not to proceed with the Second Closing. In lieu of the Second Closing, the Company proceeded with the 2019 Public Offering.

2018 Public Offering

In January 2018, the Company entered into two underwriting agreements, the first relating to the public offering of 6,670,625 shares of the Company's common stock, par value $0.001 per share, and accompanying warrants to purchase up to 3,335,313 shares of common stock ("2018 Public Offering Warrants"), at a combined price of $8.00 per share, for gross proceeds of approximately $53.4 million (the "2018 Common Stock Offering") and the second relating to the public offering of 1,635 shares of the Company's Series A convertible preferred stock ("Preferred Stock"), par value $0.001 per share, which are convertible into 204,375 shares of common stock, and accompanying warrants to purchase up to 102,188 shares of common stock for gross proceeds of approximately $1.6 million (the "Preferred Stock Offering," and together with the 2018 Common Stock Offering, the "January 2018 Financing"). The Company received approximately $1.0 million in gross proceeds and issued 119,718 shares of common stock and warrants to purchase up to 179,757 shares of common stock from the underwriters' exercise of their overallotment option.

Preferred Stock

Each share of preferred stock is convertible into 125 shares of common stock, subject to certain adjustments upon stock dividends and stock splits. The holders of preferred stock shall be entitled to receive dividends in the same form as dividends actually paid on shares of common stock when, as and if such dividends are declared by the Board of Directors and paid on shares of the common stock, on an as-if-converted-to-common stock basis.

Issuance costs

In connection with the January 2018 Financing, the Company incurred approximately $4.0 million of issuance costs. The Company allocated approximately $2.6 million of the issuance costs to the common and preferred stock within additional paid-in capital and immediately expensed approximately $1.4 million of the issuance costs allocated to the liability classified 2018 Public Offering Warrants.

Warrants

See **Note 9. Warrants**.

Hercules

In connection with the 2018 Loan Agreement with Hercules, the Company also entered into an amendment to the November 2014 equity rights letter agreement (the "Amended Equity Rights Letter Agreement"). Hercules has the right to participate in any one or more subsequent private placement equity financings of up to $2.0 million on the same terms and conditions as purchases by the other investors in each subsequent equity financing. The Amended Equity Rights Letter Agreement will terminate upon the earlier of (1) such time when Hercules has purchased $2.0 million of subsequent equity financing securities in the aggregate, and (2) the later of (a) the repayment of all indebtedness under the 2018 Term Loan, or (b) the expiration or termination of the exercise period for the Hercules Warrant. See **Note 9. Warrants**.

Agreement with Lincoln Park Capital

In October 2019, the Company entered into a purchase agreement with Lincoln Park Capital ("LPC") pursuant to which LPC purchased shares of the Company's common stock at a purchase price of $2.587 per share and received net proceeds of approximately $2.5 million. In addition, for a period of thirty months, the Company has the right, at its sole discretion, to sell up to an additional $27.5 million of the Company's common stock based on prevailing market prices of its common stock at the time of each sale. In consideration for entering into the purchase agreement, the Company issued 289,966 shares of its common stock to LPC as a commitment fee. The purchase agreement limits our sales of shares of common stock to LPC to 5,227,323 shares of common stock, representing 19.99% of the shares of common stock outstanding on the date of the purchase agreement. The purchase agreement also prohibits us from directing LPC to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by LPC and its affiliates, would result in LPC and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of our common stock. The Company determined that the right to sell additional shares represents a freestanding put option that meets the criteria

of a derivative pursuant to ASC 815 *Derivatives and Hedging*, but has a fair value of zero, and therefore no additional accounting was required.

At-the-market equity offering program

In 2015, the Company entered into an agreement, as amended, with Cowen and Company, LLC to establish an at-the-market equity offering program ("ATM") pursuant to which it was able to offer and sell shares of its common stock at prevailing market prices from time to time. Through December 31, 2019, the Company has sold an aggregate of 463,887 shares under the ATM and received approximately $4.0 million in net proceeds.

9. Warrants

As of December 31, 2019, the Company had the following potentially issuable shares of common stock related to unexercised warrants outstanding:

	Shares	Exercise price	Expiration date	Classification
Hercules Warrant	41,177	$ 6.80	Q2 2023	Equity
2018 Public Offering Warrants	3,616,944	$ 9.60	Q1 2023	Liability
Private Placement Warrants	932,812	$ 4.52	Q1 2024	Equity
Pre-Funded Warrants	531,250	$ 0.08	Q1 2039	Equity
	5,122,183			

Hercules Warrant

The exercise price and the number of shares are subject to adjustment upon a merger event, reclassification of the shares of common stock, subdivision or combination of the shares of common stock or certain dividends payments. The Company determined that the Hercules Warrant should be equity classified in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") for all periods presented.

2018 Public Offering Warrants

The exercise price and the number of shares are subject to adjustment upon a merger event, reclassification of the shares of common stock, subdivision or combination of the shares of common stock or certain dividends payments. 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 2018 Public Offering Warrants, the Company will be obligated to use its best efforts to ensure that the holders of the 2018 Public Offering 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 2018 Public Offering 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 2018 Public Offering 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.

The Company determined that the 2018 Public Offering Warrants should be liability classified in accordance with ASC 480. As the 2018 Public Offering Warrants are liability-classified, the Company remeasures the fair value at each reporting date. The Company initially recorded the 2018 Public Offering Warrants at their estimated fair value of approximately $18.2 million. In connection with the Company's remeasurement of the 2018 Public Offering Warrants to fair value, the Company recorded income of $1.0 million and $14.8 million for the years ended December 31, 2019 and 2018, respectively. The fair value of the warrant liability is approximately $2.5 million and $3.5 million as of December 31, 2019 and 2018, respectively.

The following table details the assumptions used in the Monte Carlo simulation models used to estimate the fair value of the Warrant Liability as of December 31, 2019 and 2018, respectively:

	December 31, 2019	December 31, 2018
Stock Price	$ 2.07	$ 2.32
Volatility	50.0% - 116.6%	50.0% - 111.3%
Remaining term (years)	3.1	4.1
Expected dividend yield	—%	—%
Risk-free rate	1.6%	2.4% - 2.5%
Range of annual acquisition event probability	20.0%	0.0% - 30.0%

Private Placement and Prefunded Warrants

The exercise price of the warrants is subject to appropriate adjustment in the event of stock dividends, subdivisions, stock splits, stock combinations, reclassifications, reorganizations or a change of control affecting our common stock. The Company determined that the Private Placement Warrants and the Pre-Funded Warrants should be equity classified in accordance with ASC 480 for the period ended December 31, 2019. The Company also determined that the Pre-Funded Warrants should be included in the determination of basic earnings per share in accordance with ASC 260, *Earnings per Share.*

10. Stock and employee benefit plans

The Company issues stock options with service conditions, which are generally the vesting of the awards. The Company has also issued stock options that vest upon the satisfaction of certain performance conditions.

The 2014 Equity Incentive Plan ("2014 Equity Plan"), which was subsequently amended and restated in June 2018, provides for the grant of incentive stock options, non-qualified stock options, restricted stock, and other awards to key employees and directors of, and consultants and advisors to, the Company. The 2014 Equity Plan, as amended, provides that the number of shares available for issuance will automatically increase annually on each January 1, in amount equal to the lesser of 4.0% of the outstanding shares of the Company's outstanding common stock as of the close of business on the immediately preceding December 31 or the number of shares determined the Company's board of directors. On January 1, 2020, the total number of shares available for issuance under the 2014 Equity Plan, as amended. increased by 1,098,116 for shares under this provision.

At December 31, 2019, 1,568,535 option awards are reserved for issuance under the Company's equity plans and245,430 awards remain available for future grants.

Determining the Fair Value of Stock Options

The Company measures the fair value of stock options with service-based and performance-based vesting criteria to employees, consultants and directors on the date of grant using the Black-Scholes option pricing model.

The Company does not have sufficient history to support a calculation of volatility and expected term using only its historical data. As such, the Company has used a weighted-average volatility considering the Company's own volatility since its initial public offering and the volatilities of several guideline companies. For purposes of identifying similar entities, the Company considered characteristics such as industry, length of trading history, and stage of life cycle. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The average expected life was determined according to the "simplified method" as described in SAB 110, which is the mid-point between the vesting date and the end of the contractual term. The risk-free interest rate is determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant.

The weighted-average assumptions used in the Black-Scholes option-pricing model are as follows:

	Years ended December 31,	
	2019	2018
Expected volatility	79.7%	78.6%
Risk-free interest rate	2.3%	2.8%
Expected term (in years)	6.0	6.0
Expected dividend yield	0%	0%

The following table summarizes stock option activity for employees and non-employees (shares in thousands):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	893	$ 18.79		
Granted	679	$ 4.36		
Exercised	(5)	$ 4.32		
Canceled	(244)	$ 17.64		
Outstanding at December 31, 2019	1,323	$ 11.65	8.0	$ —
Exercisable at December 31, 2019	522	$ 20.09	6.6	$ —

During the years ended December 31, 2019 and 2018, the Company granted stock options to purchase an aggregate of 678,710 and 657,375 shares of its common stock, respectively, with weighted-average grant date fair values of $4.36 and $6.96, respectively.

As of December 31, 2019, there was $3.0 million of total unrecognized compensation cost, related to employee and non-employee stock options granted under the Company's equity plans. The Company expects to recognize that cost over a remaining weighted-average period of 2.65 years.

Stock-based compensation expense

Total stock-based compensation expense is recognized for stock options and restricted stock granted to employees and non-employees and has been reported in the Company's consolidated statements of operations as follows (in thousands):

	Years ended December 31,	
	2019	2018
Research and development	$ 725	$ 620
General and administrative	1,112	1,533
Total	$ 1,837	$ 2,153

Employee Stock Purchase Plan

In February 2014, the Company's board of directors adopted the 2014 Employee Stock Purchase Plan (the "2014 ESPP"), which was subsequently amended in June 2018. The 2014 ESPP, as amended, authorizes the issuance of up to 337,597 shares of common stock to participating eligible employees. The 2014 ESPP, as amended, provides for six-month option periods commencing on January 1 and ending June 30, and commencing July 1 and ending December 31 of each calendar year. The Company issued 71,118 and 23,417 shares under the 2014 ESPP, as amended, for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, there were 217,985 shares remaining for future issuance under the plan.

401(k) Savings plan

In 2007, the Company established a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code ("401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pretax basis. Beginning January 1, 2015, the Company began making matching contributions to participants in this plan. The Company made matching contributions to participants in this plan which totaled $0.2 million and $0.1 million for the years ended December 31, 2019 and 2018, respectively.

11. Net loss per share

Basic and diluted net loss per share was calculated as follows for the years ended December 31, 2019 and 2018:

	Years ended December 31,	
	2019	2018
Basic net loss per share:		
Numerator:		
Net loss (in thousands)	$ (38,950)	$ (27,811)
Denominator:		
Weighted average common stock outstanding - basic (in thousands)	20,644	10,321
Dilutive effect of shares of common stock equivalents resulting from common stock options and restricted stock units	—	—
Weighted average common stock outstanding - diluted	20,644	10,321
Net loss per share - basic and diluted	$ (1.89)	$ (2.69)

The following common stock equivalents outstanding as of December 31, 2019 and 2018, presented on an as converted basis, were excluded from the calculation of net loss per share for the periods presented, due to their anti-dilutive effect (in thousands):

	Years ended December 31,	
	2019	2018
Stock options	1,323	893
Warrants	4,591	3,668
Total	5,914	4,561

Stock options that are outstanding and contain performance-based vesting criteria for which the performance conditions have not been met are excluded from the calculation of common stock equivalents outstanding.

12. Income taxes

For the years ended December 31, 2019 and 2018, the Company did not record a current or deferred income tax expense or benefit. The Company's losses before income taxes consist solely of domestic losses. The significant components of the Company's deferred tax assets are comprised of the following:

	December 31,	
	2019	2018
Deferred tax assets:		
U.S. and state net operating loss carryforwards	$ 56,906	$ 49,614
Capitalized R&D	28,427	25,366
Research and development credits	11,717	10,445
Lease liability	1,779	—
Stock-based compensation	1,053	1,989
Depreciation and amortization	545	640
Accrued expenses	507	450
Other temporary differences	38	85
Total deferred tax assets	100,972	88,589
Less valuation allowance	(99,249)	(88,589)
Deferred tax assets less valuation allowance	$ 1,723	$ —
Deferred tax liabilities:		
ROU asset	$ (1,723)	$ —
Total deferred tax liabilities	(1,723)	—
Net deferred tax assets (deferred tax liabilities)	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2019 and 2018. The valuation allowance increased approximately $10.7 million during the year ended December 31, 2019 due primarily to the generation of net operating losses.

A reconciliation of income tax expense computed at the statutory federal income tax rate to income taxes as reflected in the consolidated financial statements is as follows:

	Years ended December 31,	
	2019	2018
Federal income tax expense at statutory rate	21.0 %	21.0 %
State income tax, net of federal benefit	6.3 %	8.9 %
Permanent differences	0.0 %	9.0 %
Research and development credit	3.3 %	6.7 %
Change in valuation allowance	(27.4)%	(43.1)%
Other, net	(3.2)%	(2.5)%
Effective tax rate	0.0 %	0.0 %

As of December 31, 2019 and 2018, the Company had U.S. federal net operating loss carryforwards of approximately $211.5 million and $184.8 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2038. The federal net operating losses generated in tax years after December 31, 2017 can be carried forward indefinitely. As of December 31, 2019 and 2018, the Company also had U.S. state net operating loss carryforwards of approximately $197.7 million and $171.1 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2039.

As of December 31, 2019 and 2018, the Company had federal research and development tax credit carryforwards of approximately $8.9 million and $7.8 million, respectively, available to reduce future tax liabilities which expire at various dates through 2039. As of December 31, 2019 and 2018, the Company had state research and development tax credit carryforwards of approximately $3.5 million and $3.2 million, respectively, available to reduce future tax liabilities which expire at various dates through 2034.

Under the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net

operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financings since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Code, or could result in a change in control in the future.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2019 and 2018, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations and comprehensive loss.

For all years through December 31, 2019, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards. However, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position for these years. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

The Company files income tax returns in the United States and the Commonwealth of Massachusetts. The federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2015 through December 31, 2019. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, state, or foreign tax authorities to the extent utilized in a future period.

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

	Three Months Ended,			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Operating expenses	$ 9,477	10,066	9,584	9,862
Net income (loss)	(15,567)	(6,495)	(7,532)	(9,356)
Net loss per share - basic and diluted	$ (1.22)	$ (0.42)	$ (0.28)	$ (0.34)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	12,713	15,344	26,681	27,620

	Three Months Ended,			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Operating expenses	$ 10,384	9,788	10,460	$ 8,886
Net loss	(15,890)	(4,438)	(7,833)	350
Net loss per share - basic and diluted	$ (1.78)	$ (0.42)	$ (0.72)	$ 0.03
Weighted-average number of common shares used in computing net loss per share - basic and diluted	8,905	10,693	10,829	10,847

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on February 13, 2020.

GENOCEA BIOSCIENCES, INC.

By: /s/ William Clark

William Clark
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ William Clark William Clark	President and Chief Executive Officer and Director (Principal Executive Officer)	February 13, 2020
/s/ Diantha Duvall Diantha Duvall	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 13, 2020
/s/ Kenneth Bate Kenneth Bate	Director	February 13, 2020
/s/ Ali Behbahani Ali Behbahani	Director	February 13, 2020
/s/ Katrine Bosley Katrine Bosley	Director	February 13, 2020
/s/ Ronald Cooper Ronald Cooper	Director	February 13, 2020
/s/ Michael Higgins Michael Higgins	Director	February 13, 2020
/s/ Howard Mayer Howard Mayer, M.D.	Director	February 13, 2020
/s/ George Siber George Siber, M.D.	Director	February 13, 2020

Exhibit Number	Exhibit
3.1	Fifth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on February 12, 2014)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on June 25, 2018)
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on May 21, 2019)
3.4	Amended and Restated By-laws (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on February 12, 2014)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
4.2	Fourth Amended and Restated Registration Rights Agreement (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
4.3	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, File No. 001-36289 filed on January 19, 2018)
4.4	Form of Class A Warrant to Purchase Shares of Common Stock of Genocea Biosciences, Inc. (incorporated by reference to Exhibit 4.5 to the Company's Annual Report on Form 8-K, File No. 001-36289, filed on February 16, 2018)
4.5	Warrant Agreement between the Company and Hercules Capital, Inc., dated April 24, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on April 30, 2018)
4.6	Form of Pre-Funded Warrant to Purchase Shares of Common Stock of Genocea Biosciences, Inc. (incorporated by reference to Exhibit 4.1 to the Company's Form 8-K, File No. 001-36289, filed on February 12, 2019)
4.7	Form of Class B Warrant to Purchase Shares of Common Stock of Genocea Biosciences, Inc. (incorporated by reference to Exhibit 4.8 to the Company's Annual Report on Form 10-K, File No. 001-36289, filed on February 28, 2019)
4.8*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1	Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.2++*	Amended and Restated License Agreement between Genocea Biosciences, Inc. and President and Fellows of Harvard College, dated November 19, 2012
10.3	Lease, dated as of July 3, 2012 between TBCI, LLC and Genocea Biosciences, Inc. (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1, File No. 333-193043, dated December 23, 2013)
10.4	Agreement Regarding Sublease, dated as of July 9, 2012, by TBCI, LLC, FoldRx Pharmaceuticals, Inc., Pfizer Inc. and Genocea Biosciences, Inc. (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.5†	Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan, as amended on June 24, 2013 (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.6†	Amended and Restated Employment Letter Agreement between William Clark and Genocea Biosciences, Inc., dated January 16, 2014 (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1, File No. 333-193043, as amended on January 23, 2014)

Exhibit Number	Exhibit
10.7†	Genocea Biosciences, Inc. Amended and Restated 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on June 25, 2018)
10.8†	Genocea Biosciences, Inc. Cash Incentive Plan (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.9†	Form of Nonstatutory Stock Option Granted under the Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.10†	Form of Incentive Stock Option Granted under the Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1, File No. 333-193043, filed on December 23, 2013)
10.11†	Form of Incentive Stock Option under the Genocea Biosciences, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.12†	Form of Nonstatutory Stock Option under the Genocea Biosciences, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.13†	Genocea Biosciences, Inc. 2014 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on June 25, 2018)
10.14†	Nonstatutory Stock Option granted under the Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan to Katrine Bosley, dated May 13, 2013 (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.15†	Nonstatutory Stock Option granted under the Genocea Biosciences, Inc. Amended and Restated 2007 Equity Incentive Plan to Katrine Bosley, dated November 5, 2013 (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-1, File No. 333-193043, as amended on January 13, 2014)
10.16	Equity Rights Letter Agreement between the Company and Hercules Technology Growth Capital, Inc., dated November 20, 2014 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on November 21, 2014)
10.17	Sublease Agreement between the Company and the Smithsonian Institution, dated June 15, 2015 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on June 19, 2015)
10.18	First Amendment to Lease, dated May 16, 2016, between 100 Discovery Park DE, LLC, a Delaware limited liability company (as successor in interest to TBCI, LLC, as Trustee of 100 Discovery Park Realty Trust) and Genocea Biosciences, Inc. (incorporated by reference to Exhibit 10.30 to the Company's Form 10-Q, filed on August 5, 2016, File No. 001-36289)
10.19+	License and Supply Agreement, between the Company and Oncovir, Inc., dated January 26, 2018 (incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K, File No. 001-36289, filed on February 16, 2018).
10.20+	Amended and Restated Loan and Security Agreement between the Company, the several banks and other financial institutions or entities from time to time parties thereto and Hercules Capital, Inc., dated April 24, 2018 (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, File No. 001-36289, filed on August 3, 2018)
10.21	Amendment to Equity Rights Letter Agreement between the Company, Hercules Capital, Inc. (f/k/a Hercules Technology Growth Capital, Inc.), dated April 24, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on April 30, 2018)

Exhibit Number	Exhibit
10.22	First Amendment to Amended and Restated Loan and Security Agreement between the Company, the several banks and other financial institutions or entities from time to time parties thereto and Hercules Capital, Inc., dated November 14, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on November 19, 2019)
10.23*	Second Amendment to the Lease, dated May 1, 2019, between 100 Discovery Park DE, LLC, a Delaware limited liability company (as successor in interest to TBCI, LLC, as Trustee of 100 Discovery Park Realty Trust) and Genocea Biosciences, Inc.
21.1	List of Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Form 10-K, filed on February 17, 2016, File No. 001.36289)
23.1*	Consent of Ernst & Young LLP
31.1*	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Chief Executive Officer
31.2*	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Principal Financial Officer
32.1**	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Executive Officer
32.2**	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Principal Financial Officer
101. INS*	XBRL Instance Document
101. SCH*	XBRL Taxonomy Extension Schema
101. CAL*	XBRL Taxonomy Extension Calculation Linkbase
101. DEF*	XBRL Taxonomy Extension Definition Linkbase
101. LAB*	XBRL Taxonomy Extension Label Linkbase
101. PRE*	XBRL Taxonomy Extension Presentation Linkbase

* Filed herewith.
** Furnished herewith.
† Indicates a management contract or compensatory plan.
+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been submitted separately to the Securities and Exchange Commission.
++ Portions of this exhibit (indicated by asterisks) have been omitted because the Registrant has determined they are not material and would likely cause competitive harm to the Registrant if publicly disclosed.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, Genocea Biosciences Inc. ("Genocea," "we," "our," or "us") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, $0.001 par value per share.

DESCRIPTION OF CAPITAL STOCK

The following summary of the terms of our capital stock is based upon our fifth amended and restated certificate of incorporation, as amended (the "Certificate of Incorporation"), and our amended and restated bylaws (the "Bylaws"). The summary is not complete, and is qualified by reference to our Certificate of Incorporation and our Bylaws, which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our Certificate of Incorporation, our Bylaws, and the applicable provisions of the Delaware General Corporation Law for additional information.

Authorized Shares of Capital Stock

Our authorized capital stock consists of 85,000,000 shares of our common stock, par value $0.001 per share, and 25,000,000 shares of our preferred stock, par value $0.001 per share. As of January 31, 2020, we had 27,643,773 shares of our common stock issued and outstanding and 1,635 shares of our preferred stock issued and outstanding.

Listing

Our common stock is listed and principally traded on The Nasdaq Capital Market under the symbol "GNCA."

Voting Rights

Each holder of shares of our common stock is entitled to one (1) vote for each share held of record by such holder on the applicable record date on all matters submitted to a vote of shareholders. Pursuant to our Certificate of Incorporation, shareholders do not have the right to vote cumulatively.

Dividend Rights.

Subject to preferences that may apply to shares of preferred stock outstanding at the time, holders of outstanding shares of common stock are entitled to receive dividends out of assets legally available at the times and in the amounts as the board of directors may from time to time determine.

Conversion or Redemption Rights.

Our common stock is neither convertible nor redeemable.

Liquidation Rights.

Upon our liquidation, dissolution or winding up, the holders of our common stock are entitled to receive pro rata our assets which are legally available for distribution, after payment of all debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences.

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and

registrar's address is 144 Fernwood Ave, Edison, New Jersey 08837.

Warrants

As of January 31, 2020, we had the following warrants outstanding:

- warrants exercisable for an aggregate of 3,616,944 shares of our common stock at an exercise price of $9.60 per share that expire on January 18, 2023 and may be exercised at any time and from time to time, in whole or in part.
- warrants exercisable for an aggregate of 41,177 shares of our common stock at an exercise price of $6.80 per share that expire on April 24, 2023 and may be exercised at any time and from time to time, in whole or in part.
- warrants exercisable for an aggregate of 932,812 shares of our common stock at an exercise price of $4.52 per share that expire on February 14, 2024 and may be exercised at any time and from time to time, in whole or in part.
- warrants exercisable for an aggregate of 531,250 shares of our common stock for which the aggregate exercise price was partially paid by the holders of the warrants on or prior to the date of issuance, which warrants expire on February 14, 2039 and may be exercised at any time and from time to time, in whole or in part, by payment of the remaining aggregate exercise price.

Each of the foregoing warrants have a net exercise provision under which their holders may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our stock at the time of exercise of the warrants after deduction of the aggregate exercise price. These warrants contain provisions for adjustment of the exercise price and number of shares issuable upon the exercise of warrants in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations.

Except for the right to participate in certain dividends and distributions and as otherwise provided in the warrants or by virtue of such holder's ownership of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants.

Our warrant agent is Computershare Trust Company, N.A.

Anti-Takeover Effects of Our Certificate of Incorporation and Our By-Laws

Our Certificate of Incorporation and Bylaws contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of the company unless such takeover or change in control is approved by the board of directors.

These provisions include:

Classified Board. Our Certificate of Incorporation provides that our board of directors is divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our board. Our Certificate of Incorporation also provides that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors.

Action by Written Consent; Special Meetings of Stockholders. Our Certificate of Incorporation provides that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our Certificate of Incorporation and Bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors. Except as described above, stockholders are not be permitted to call a special meeting or to require the board of directors to call a special meeting.

Removal of Directors. Our Certificate of Incorporation provides that our directors may be removed only for cause by the affirmative vote of at least 75% of the voting power of our outstanding shares of capital stock, voting together as a single class. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board.

Advance Notice Procedures. Our Bylaws establish an advance notice procedure for stockholder proposals to be brought

before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting are only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the Bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the by-laws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

Super Majority Approval Requirements. The Delaware General Corporation Law generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. Our Certificate of Incorporation and Bylaws provide that the affirmative vote of holders of at least 75% of the total votes eligible to be cast in the election of directors is required to amend, alter, change or repeal the by-laws. This requirement of a supermajority vote to approve amendments to our by-laws could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but Unissued Shares. Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive Forum. Our Certificate of Incorporation provides that, subject to limited exceptions, the state or federal courts located in the State of Delaware are the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) 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, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our Certificate of Incorporation or our Bylaws, or (iv) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Certificate of Incorporation described above. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or by-laws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or

change in control attempts of us may be discouraged or prevented.

EXHIBIT 10.2

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO GENOCEA BIOSCIENCES, INC. IF PUBLICLY DISCLOSED.

AMENDED AND RESTATED LICENSE AGREEMENT

This Amended and Restated License Agreement ("Agreement") is entered into as of this 19th day of November, 2012 (the "Amended and Restated Effective Date"), by and between Genocea Biosciences, Inc., a company formed under the laws of the State of Delaware, having a place of business at Cambridge Discovery Park, 100 Acorn Park Drive, 5th Floor, Cambridge, MA 02140 ("Licensee") and President and Fellows of Harvard College, an educational and charitable corporation existing under the laws and the constitution of the Commonwealth of Massachusetts, having a place of business at Holyoke Center, Suite 727, 1350 Massachusetts Avenue, Cambridge, Massachusetts 02138 ("Harvard").

WHEREAS, Harvard is the owner of the Patent Rights and Harvard Technology Transfer Materials (as defined below) and has the right to grant licenses thereunder; and

WHEREAS, Harvard desires to have products developed and commercialized under such patent rights and materials to benefit the public; and

WHEREAS, Licensee has represented to Harvard, in order to induce Harvard to enter into this Agreement, that Licensee shall commit itself to commercially reasonable efforts to develop and commercialize products based on the Patent Rights and Harvard Technology Transfer Materials;

WHEREAS, Harvard and Licensee previously entered into that certain License Agreement, dated November 30, 2007 (the "Original Effective Date"), pursuant to which Licensee obtained a license under the Patent Rights and Harvard Technology Transfer Materials (the "Original Agreement"); and

WHEREAS, the parties now desire to modify their arrangements under the Original Agreement, all on the terms and conditions set forth herein.

NOW, THEREFORE, the parties hereto, intending to be legally bound, hereby agree as follows:

0. Amendment and Restatement.

Licensee and Harvard hereby agree that, effective as of the Amended and Restated Effective Date, the Original Agreement is hereby amended and restated in its entirety as set forth in this Agreement, and the Original Agreement shall be of no further force or effect from and after the Amended and Restated Effective Date, except as expressly provided herein, provided, that nothing in this Agreement shall affect the rights and obligations of the parties under the Original Agreement with respect to periods prior to the Amended and Restated Effective Date, all of which shall survive in accordance with their terms.

1. Definitions.

Whenever used in this Agreement with an initial capital letter, the terms defined in this Article 1, whether used in the singular or the plural, shall have the meanings specified below.

1.1 "Affiliate" shall mean, with respect to an entity, any person, organization or entity controlling, controlled by or under common control with, such entity. For purposes of this definition only, "control" of another person, organization or entity shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the activities, management or policies of such person, organization or entity, whether through the ownership of voting securities, by contract or otherwise. Without limiting the foregoing, control shall be presumed to exist when a person, organization or entity (i) owns or directly controls fifty percent (50%) or more of the outstanding voting stock or other ownership interest of the other organization or entity, or (ii) possesses, directly or indirectly, the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the organization or other entity. The parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such cases such lower percentage shall be substituted in the preceding sentence.

1.2 "Calendar Quarter" shall mean each of the periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, for so long as this Agreement is in effect.

1.3 "Development Milestones" shall mean the development and commercialization milestones set forth in Exhibit 1.3 hereto, as such milestones may be adjusted pursuant to Section 3.4.

1.4 "Development Plan" shall mean the plan for the development and commercialization of Licensed Products attached hereto as Exhibit 1.4, as such plan may be adjusted from lime to time pursuant to Section 3.2.

1.5 "Direct Development Costs" shall mean the costs incurred, on a cash basis, by Licensee with respect to the development of Licensed Products in accordance with the Development Plan, such as:

1.5.1 Costs for development activities conducted to procure data necessary for regulatory filings to obtain marketing approval from a Regulatory Authority, including, but not limited to, research, formulation development and testing, clinical development activities, data management, toxicology and planning and execution of clinical trials;

1.5.2 costs for regulatory filings necessary to obtain marketing approval from a Regulatory Authority;

1.5.3 insurance premiums paid for commercial insurance to the extent such insurance directly relates to development activities conducted pursuant to the Development Plan (i.e., if insurance covers risks other than risks related to development of the Licensed Product, then only an appropriate portion of such premiums shall be included); and

1.5.4 capital expenditures to the extent directly attributable to the development of Licensed Products.

1.5.5 the fully burdened costs of labor for the percentage of the individuals' time spent on such development activities.

To the extent a cost is associated with activities in addition to development of Licensed Products then only the appropriate portion of such costs devoted to the development of Licensed Products shall be included as Direct Development Costs.

1.6 "FDA" shall mean the United States Food and Drug Administration.

1.7 "Harvard Technology Transfer Materials" shall mean the protocols and other materials listed in Exhibit 1.7 hereto, as such Exhibit may be supplemented and updated from time to time by mutual written agreement of the parties. Effective upon each such agreement by the parties, Exhibit 1.7 shall be amended automatically to include any such additional protocols and other materials. Within thirty (30) days after the Original Effective Date, Harvard shall deliver the initial set of Harvard Technology Transfer Materials to Licensee.

1.8 "IND" shall mean an investigational new drug application, clinical study application, clinical trial exemption or similar application or submission for approval to conduct human clinical investigations filed with a Regulatory Authority.

1.9 "Infringed Patent" shall mean (a) an issued and unexpired patent that has not been abandoned, held invalid, revoked, held or rendered unenforceable or lost through an interference proceeding, and (b) a pending claim of a pending patent application that (i) has been asserted and continues to be prosecuted in good faith, (ii) has not been abandoned or finally rejected without the possibility of appeal or refiling, and (iii) has not been pending for more than five (5) years; which in either case would be infringed by the identification, discovery, development, manufacture, use or sale of a Licensed Product.

1.10 "Initiation" or **"Initiate"** shall mean, with respect to a Phase I Clinical Trial, a Phase II Clinical Trial or a Phase III Clinical Trial, the administration of the first dose to the first patient in such clinical trial.

1.11 "Licensed Method" shall mean any method, the practice of which would, but for the grant of rights hereunder, infringe a Valid Claim (in the case of a Valid Claim that has not yet issued, assuming that such Valid Claim has issued).

1.12 "Licensed Product" shall mean any Type I Licensed Product or any Type II Licensed Product.

1.13 "Licensed Services" shall mean any service provided for or on behalf of a third party on a fee-for-service basis that entails the practice of a Licensed Method.

1.14 "Net Sales" shall mean the gross amount invoiced by or on behalf of Licensee, its Affiliates and Sublicensees (in each case, the "Invoicing Entity") on sales, leases or other transfers of Licensed Products, less the following to the extent applicable on such sales, leases or other transfers of Licensed Products and not previously deducted from the gross invoice price: (a) customary trade, quantity or cash discounts to the extent actually allowed and taken; (b) amounts actually repaid or credited by reason of rejection or return of any previously sold, leased or otherwise transferred Licensed Products; (c) customer freight charges that are paid by or on behalf of the Invoicing Entity; and (d) to the extent separately stated on purchase orders, invoices or other documents of sale, any sales, value added or similar taxes, custom duties or other similar governmental charges levied directly on the production, sale, transportation, delivery or use of a Licensed Product that are paid by or on behalf of the Invoicing Entity, but not including any tax levied with respect to income; provided that:

1.14.1 in the event that an Invoicing Entity receives non-cash consideration for any Licensed Products or in the case of transactions not at arm's length with a non-Affiliate of Invoicing

Entity, Net Sales shall be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business; and

1.14.2 sales of Licensed Products by an Invoicing Entity to its Affiliate or Sublicensee for resale by such Affiliate or Sublicensee shall not be deemed Net Sales. Instead, Net Sales shall be determined based on the gross amount invoiced by such Affiliate or Sublicensee on resale of Licensed Products to a third party purchaser.

Notwithstanding the foregoing, the following shall not be included in Net Sales: (1) Licensed Products provided by Licensee, its Affiliates or Sublicensees for administration to patients enrolled in clinical trials or distributed through a not-for-profit foundation at no charge to eligible patients provided that Licensee, its Affiliates, or Sublicensees receive no consideration from such clinical trials or not-for-profit foundation for such use of Licensed Products and (2) Licensed Products used as samples to promote additional Net Sales, in amounts consistent with normal business practices of Licensee, its Affiliates or Sublicensees, provided that Licensee, its Affiliates, or Sublicensees receive no consideration for such samples.

Further, Net Sales shall be adjusted as follows:

In the event a Licensed Product is [* * *] as defined below, Net Sales of the [* * *], where [* * *]. If, in a specific country, the relevant Licensed Product is [* * *] in such country. As used above, the term [* * *] means [* * *]. Without limiting any of the foregoing, Net Sales shall be determined in accordance with normally accepted accounting principles, such as GAAP, IFRS or similar accounting principles, on a basis consistent with the audited consolidated financial statements of Licensee, its Affiliates, or its Sublicensees, as applicable.

1.15 "Non-Royalty Sublicense Income" shall mean any payments or other consideration that Licensee or any of its Affiliates receives in connection with a Sublicense, other than royalties based on Net Sales or Service Income or the receipt of a portion of profits derived from the sale of Licensed Products or the performance of Licensed Services. In the event that Licensee or an Affiliate of Licensee receives non-cash consideration in connection with a Sublicense or in the case of transactions not at arm's length, Non-Royalty Sublicense Income shall be calculated based on the fair market value of such consideration or transaction, at the time of the transaction, assuming an arm's length transaction made in the ordinary course of business. Non-Royalty Sublicense Income shall not include (a) amounts received from a Sublicensee that are committed to cover future industry standard, fully burdened costs to be incurred by Licensee or any of its Affiliates in the performance of research and development activities to be performed by Licensee or any of its Affiliates under a Sublicense agreement in connection with a Licensed Product or a product expected to become a Licensed Product, (b) equity investments in Licensee to the extent such payment reflects the fair market value of such securities, (c) amounts received from a Sublicensee in connection with a bona fide, fully repayable, market rate loan made by Sublicensee to Licensee, (d) the attributed value of any cross-license granted by a Sublicensee to

Licensee to the extent such cross-license provides Licensee with freedom to operate with respect to a Licensed Product or a product expected to become a Licensed Product (but not excluding any consideration actually received from such Sublicensee on account of such cross-license), (e) payments made to reimburse Licensee for any amounts paid by it to Harvard under Section 6.2 of this Agreement or (1) payments made to reimburse Licensee for the costs of Licensee's full time equivalents who market and promote Licensed Products and Licensed Services and sell Licensed Products, which reflect the fair market value of such services and are substantiated by any report delivered by Licensee to any such Sublicensee to claim such reimbursement.

1.16 "Patent Rights" shall mean, in each case to the extent owned and controlled by Harvard: (a) the patent applications listed on Exhibit 1.15; (b) any patent or patent application that claims priority to and is a divisional, continuation, reissue, renewal, reexamination, substitution or extension of any patent application identified in (a); (c) any patents issuing on any patent application identified in (a) or (b), including any reissues, renewals, reexaminations, substitutions or extensions thereof; (d) any claim of a continuation-in-part application or patent that is entitled to the priority date of, and is directed specifically to subject matter specifically described in, at least one of the patents or patent applications identified in (a), (b) or (c); and (e) any foreign counterpart (including PCTs) of any patent or patent application identified in (a), (b) or (c) or of the claims identified in (d).

1.17 "Phase I Clinical Trial" shall mean a clinical trial in any country involving the initial introduction of an investigational new drug into humans, typically designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the United States, "Phase I Clinical Trial" means a human clinical trial that satisfies the requirements of 21 C.F.R. § 312.21(a).

1.18 "Phase II Clinical Trial" shall mean a human clinical trial in any country conducted to evaluate the effectiveness of a drug for a particular indication or indications in patients with the disease or condition under study and, possibly, to determine the common short-term side effects and risks associated with the drug. In the United States, "Phase II Clinical Trial" means a human clinical trial that satisfies the requirements of 21 C.F.R. § 312.21(b).

1.19 "Phase III Clinical Trial" shall mean a human clinical trial in any country, whether controlled or uncontrolled, that is performed after preliminary evidence suggesting effectiveness of the drug under evaluation has been obtained, and intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the

drug and to provide an adequate basis for physician labeling. In the United Slates, "Phase III Clinical Trial means a human clinical trial that satisfies the requirements of 21 C.F.R. § 312.21(c).

1.20 "Regulatory Authority" shall mean any applicable government regulatory authority involved in granting approvals for the manufacturing and/ marketing of a Licensed Product, including, in the United States, the FDA.

1.21 "Service Income" shall mean the gross amount invoiced by or on behalf of an Invoicing Entity (as defined in Section 1.14) for the performance of Licensed Services; provided that:

1.21.1 in any performance of Licensed Services by an Invoicing Entity for its Affiliate, Service Income shall be equal to the fair market value of the Licensed Services performed, assuming an arm's length transaction made in the ordinary course of business; and

1.21.2 in the event that an Invoicing Entity received non-case consideration for any Licensed Services or in the case of transactions not at arm's length with a non-Affiliate of Invoicing Entity, Service Income shall be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business.

1.22 "Sublicense" shall mean: (a) any right granted, license given or agreement entered into by Licensee to or with any other person or entity (or by a Sublicensee to or with a further Sublicensee in accordance with Section 2.3.2.4), under or with respect to or authorizing any use of any of the Patent Rights, or otherwise authorizing the development, manufacture, marketing, distribution, use and/or sale of Licensed Products or the performance of Licensed Services; or (b) any option or other right granted by Licensee to any other person or entity (or by a Sublicensee to or with a further Sublicensee in accordance with Section 2.3.2.4) to negotiate for or receive any of the rights described under clause (a), including in connection with a standstill agreement; in each case regardless of whether such grant of rights, license given or agreement entered into is referred to or is described as a sublicense.

1.23 "Sublicensee" shall mean any person or entity granted a Sublicense, other than an Affiliate.

1.24 "Third Party Proposed Product" shall mean a Type II Licensed Product for vaccination against or treatment of an organism or disease for which Licensee is not developing or commercializing a Licensed Product.

1.25 "Type I Licensed Product" shall mean any product, the manufacture, use, sale, marketing or importation of which falls within the scope of a Valid Claim in the country in which it is manufactured, used, sold, marketed or imported.

1.26 "Type II Licensed Product" shall mean any product that is not a Type I Licensed Product, but is identified or discovered through the use of a Licensed Method.

1.27 "Valid Claim" shall mean: (a) a claim of an issued and unexpired patent within the Patent Rights that has not been (i) held permanently revoked, unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, (ii) rendered unenforceable through disclaimer or otherwise, (iii) abandoned or (iv) lost through an interference proceeding; or (b) a pending claim of a pending patent application within the Patent Rights that (i) has been asserted and continues to be prosecuted in good faith, (ii) has not been abandoned or finally rejected without the possibility of appeal or refiling, and (iii) has not been pending for more than five (5) years from the date of issuance of the first substantive patent office action considering the patentability of such claim by the applicable patent office in such country (at which time such pending claim shall cease to be a Valid Claim for purposes of this Agreement unless and until such claim becomes a claim of an issued patent).

2. License Grants.

2.1 Licenses.

2.1.1 Exclusive License. Subject to the terms and conditions set forth in this Agreement, Harvard hereby grants to Licensee an exclusive, worldwide, royalty-bearing license, sublicensable solely in accordance with Sections 2.2 and 2.3, under the Patent Rights solely (a) to identify, discover, develop, make, have made, use, market, offer for sale, sell, have sold and import Type I and Type II Licensed Products and (b) to perform Licensed Services; provided, however, that:

2.1.1.1 Harvard shall retain the right to make and use Type I and Type II Licensed Products, and to grant licenses to other not-for-profit research organizations the right to make and use Type I Licensed Products, for internal research, teaching and other educational purposes and not for the purpose of commercial manufacture, distribution or provision of services for a fee; and

2.1.1.2 the United States federal government shall retain rights in the Patent Rights pursuant to 35 U.S.C. §§ 200-212 and 37 C.F.R. § 401 et seq., and any right granted in this

Agreement greater than that permitted under 35 U.S.C. §§ 200-212 or 37 C.F.R. § 401 et seq. shall be subject to modification as may be required to conform to the provisions of those statutes and regulations.

2.1.2 Non-Exclusive License. Subject to the terms and conditions set forth in this Agreement, Harvard hereby grants to Licensee a non-exclusive, worldwide, license under its rights in and to the Harvard Technology Transfer Materials solely for use in identifying, discovering, developing, making, having made, using, marketing, offering for sale, selling, having sold and importing any Type I Licensed Product or Type II Licensed Product. Notwithstanding anything contained herein or in any other agreement to the contrary, ownership of inventions discovered or invented using the Harvard Technology Transfer Materials shall follow inventorship and inventorship shall be determined in accordance with United States patent law; provided, however, that Licensee's ownership of any such discovery or invention shall not affect its obligations under this Agreement, including its obligations under Section 4.5.2.

2.2 Sublicenses to Affiliates. The licenses granted to Licensee under Section 2.1 shall include the right to have some or all of Licensee's rights or obligations under this Agreement performed or exercised by one or more of Licensee's Affiliates (for so long each such Affiliate remains an Affiliate of Licensee), provided that:

2.2.1 no such Affiliate shall be entitled to grant, directly or indirectly, to any third party any right of whatever nature under, or with respect to, or permitting any use or exploitation of, any of the Patent Rights or the Harvard Technology Transfer Materials, including any right to develop, manufacture, market or sell Licensed Products or to practice Licensed Methods unless Licensee has assigned the rights under this Agreement to such Affiliate pursuant to Section 11.12 because, in such event, such Affiliate will be the Licensee under this Agreement; and

2.2.2 any act or omission taken or made by an Affiliate of Licensee under this Agreement shall be deemed an act or omission by Licensee under this Agreement.

2.3 Other Sublicenses.

2.3.1 Sublicense Grant. Licensee shall be entitled to grant Sublicenses to Sublicensees under the license granted pursuant to Section 2.1.1 subject to the terms of this Section 2.3. Any such Sublicense shall be on terms and conditions in compliance with and not inconsistent with the terms of this Agreement. Such Sublicenses shall only be made for consideration and in bona-fide arm's length transactions.

2.3.2 Sublicense Agreements. Sublicenses under this Section 2.3 shall be granted only pursuant to written agreements, which shall be subject to and consistent with the terms and

conditions of this Agreement. Such Sublicense agreements shall contain, among other things, provisions to the following effect:

2.3.2.1 all provisions necessary to ensure Licensee's ability to comply with Licensee's obligation under or not violate the provisions of Sections 4.4, 4.5, 4.6, 5.1, 5.3, 5.4, 8.1 and 11.1;

2.3.2.2 a section substantially the same as Article 9 (Indemnification), which also shall state that the Indemnitees (as defined in Section 9.1) are intended third party beneficiaries of such Sublicense agreement for the purpose of enforcing such indemnification;

2.3.2.3 in the event of termination of the license set forth in Section 2.1.1 above (in whole or in part (e.g., termination of the license as to a Licensed Product or in a particular country)), any existing Sublicense shall terminate to the extent of such terminated license; provided, however, that, for each Sublicensee, upon termination of the license, if the Sublicensee is not then in breach of the Sublicense agreement such that Licensee would have the right to terminate such Sublicense agreement, such Sublicensee shall have the right to obtain a license from Harvard on the same terms and conditions as set forth herein, which shall not impose any representations, warranties, obligations or liabilities on Harvard that are not included in this Agreement, provided that (a) the scope of the license granted directly by Harvard to such Sublicensee shall be coextensive with the scope of the license granted by Licensee to such Sublicensee, (b) if the Sublicense granted to such Sublicensee was non-exclusive, such Sublicensee shall not have the right to participate in the prosecution or enforcement of the Patent Rights under the license granted to it directly by Harvard and (c) if there are more than one Sublicensee, each Sublicensee that is granted a direct license shall be responsible for a pro rata share of the reimbursement due under Section 6.2.3 of this Agreement (based on the number of direct licenses under the Patent Rights in effect on the date of reimbursement);

2.3.2.4 the Sublicensee shall only be entitled to sublicense its rights under such Sublicense agreement on the terms set forth in this Section 2.3; and

2.3.2.5 the Sublicensee shall not be entitled to assign the Sublicense agreement without the prior written consent of Harvard, except that Sublicensee may assign the Sublicense agreement to a successor in connection with the merger, consolidation or sale of all or substantially all of its assets or that portion of its business to which the Sublicense agreement relates; provided, however, that any permitted assignee agrees in writing in a manner reasonably satisfactory to Harvard to be bound by the terms of such Sublicense agreement.

2.3.3 Delivery of Sublicense Agreement. Licensee shall furnish Harvard with a fully executed copy, redacted with respect to matters not relevant to Harvard's interests, of any such

Sublicense agreement or further Sublicense agreement under Section 2.3.2.4, promptly after its execution. Harvard shall keep all such Sublicense agreements and their terms confidential and shall use them solely for the purpose of monitoring Licensee's and Sublicensees' compliance with their obligations hereunder and enforcing Harvard's rights under this Agreement.

2.3.4 Breach by Sublicensee. During the term of this Agreement, Licensee shall be responsible for any breach of a Sublicense agreement by a Sublicensee (or further Sublicense agreement under Section 2.3.2.4) that results in a material breach of this Agreement. Licensee may elect (a) to cure such breach in accordance with Section 10.2.3.1 of this Agreement or (b) to enforce its rights by terminating such Sublicense agreement in accordance with the terms thereof. Licensee shall indemnify Harvard for, and hold it harmless from, any and all damages or losses caused to Harvard as a result of any such breach by a Sublicensee or further Sublicensee.

2.4 Improvements. In the future event that Harvard owns and controls patents and/or patent applications (a) for which one of the inventors is Dr. Darren Higgins or Dr. Michael Starnbach, (b) that are not Patent Rights and (c) that include claims that are dominated by any Valid Claims, Licensee may notify Harvard in writing that it wishes to obtain a license under such patents and/or patent applications solely with respect to those claims that are dominated by such Valid Claims. Harvard will grant Licensee a license under such claims by amending this Agreement to include such claims in the definition of Patent Rights if (i) Harvard is not, at the time of its receipt of Licensee's notice, subject to any legal or pre-existing contractual obligations or restraints that would prevent it from granting the requested license and (ii) the inventor(s) do(es) not reasonably object to the grant of the requested license. Licensee shall not be required to pay any additional upfront consideration for such license, except for a license issuance fee to be agreed upon by the parties. The other financial terms of this Agreement (e.g., maintenance fees, milestone payments, royalty payments and payments on account of Non-Royalty Sublicense Income) will apply to the requested license.

2.5 [†].

2.6 No Other Grant of Rights. Except as expressly provided in this Agreement, nothing in this Agreement shall be construed to confer any ownership interest, license or other rights upon Licensee by implication, estoppel or otherwise as to any technology, intellectual property rights, products or biological materials of Harvard or any other entity, regardless of whether such technology, intellectual property rights, products or biological materials are dominant, subordinate or otherwise related to any Patent Rights.

3. Development and Commercialization.

3.1 Diligence. Licensee shall use commercially reasonable efforts and shall cause its Sublicensees to use commercially reasonable efforts: (a) to develop Licensed Products in accordance with the Development Plan; (b) to introduce Licensed Products into the commercial market; and (c) to market Licensed Products following such introduction into the market. In addition, Licensee, by itself or through its Affiliates or Sublicensees, also shall achieve each of the Development Milestones referenced in the then-current version of Exhibit 1.3 within the time periods specified therein. Harvard's right to take any action against Licensee in connection with a failure to achieve any such Development Milestones shall be limited to those rights set forth in Section 3.4 or, if and to the extent applicable, Section 10.2.3. The parties acknowledge and agree that if Licensee, by itself or through its Affiliates or Sublicensees, meets its obligations in the preceding sentence then Licensee will be deemed to have also met its development obligations under (a) above.

3.2 Modification of Development Plan. Licensee may modify the then applicable Development Plan from time to time to improve Licensee's ability to meet the Development Milestones.

3.3 Reporting. Within sixty (60) days after the end of each calendar year. Licensee shall furnish Harvard with a written report summarizing its, its Affiliates' and its Sublicensees' efforts during the prior year to develop and commercialize Licensed Products, including without limitation: (a) research and development activities; (b) commercialization efforts; and (c) marketing efforts. Each report shall contain a description of Licensee's efforts in compliance with its obligations under Section 3.1, and a discussion of intended efforts for the then current year. Together with each report. Licensee shall provide Harvard with a copy of the then current Development Plan.

3.4 Failure. If Licensee believes that it will not achieve one or more Development Milestones with respect to Licensed Products, it may notify Harvard in writing in advance of the relevant deadline. Licensee shall include with such notice an explanation of the reasons for such failure, a proposal for extending and/or amending the relevant milestone(s), and a detailed written plan for promptly achieving such extended and/or amended milestone(s). If Licensee does not provide Harvard with a reasonable explanation of its failure to meet the relevant Development Milestone(s) (and lack of finances shall not constitute reasonable basis for such failure) or does not provide Harvard with a reasonable proposed extension and/or amendment, Harvard may notify Licensee in writing of Licensee's failure to meet the relevant Development Milestone(s) and, in such event, shall allow Licensee ninety (90) days to cure such failure. Subject to the last sentence of this section, Licensee's failure to cure within such ninety (90) day period shall constitute a material breach of this Agreement (a ''Development Breach") entitling Harvard to proceed solely under this Section 3.4. In the event of a Development Breach where the relevant Development Milestone pertains to

a Type I Licensed Product, Harvard shall have the right, in lieu of its rights under Section 10.2.3, to terminate the licenses granted in this Agreement only as they apply to Type I Licensed Products. In the event Licensee (a) commits a Development Breach with respect to two Type II Licensed Products or (b) commits a Development Breach with respect to one Type II Licensed Product after already having committed a Development Breach with respect to a Type I Licensed Product, Harvard shall have the right, in lieu of its rights under Section 10.2.3, only to convert the license granted in Section 2.1.1 as it applies to Type II Licensed Products and Licensed Services into a non-exclusive, non-transferable, worldwide license (without the right to sublicense). Notwithstanding the foregoing, if Licensee does provide Harvard with an explanation of its failure to meet the relevant Development Milestone(s) and a proposed extension and/or amendment that is reasonably acceptable to Harvard, Exhibit 1.3 shall be amended automatically to incorporate such extension and/or amendment, as applicable. For clarity, if and only if Licensee fails to achieve a Development Milestone and does not avail itself of any aspect of the procedure set forth in this Section 3.4 (e.g., by failing to notify Harvard in accordance with the first sentence of this Section 3.4), such failure to achieve the Development Milestone shall be a material breach that entitles Harvard to proceed under Section 10.2.3.

4. Consideration for Grant of License

4.1 Equity.

4.1.1 Grant. As partial consideration for the licenses granted hereunder, within thirty (30) days after the Original Effective Date, Licensee shall issue to Harvard such amount of common stock of Licensee that constitutes [* * *] of the outstanding common stock of Licensee, on a Fully Diluted Basis, after giving effect to such issuance (the "Shares"). "Fully Diluted Basis" shall mean, as of the Original Effective Date, the number of shares of common stock of Licensee then outstanding (assuming conversion of all outstanding stock other than common stock into common stock) plus the number of shares of common stock of Licensee issuable upon exercise or conversion of then outstanding convertible securities, options, rights or warrants of Licensee (which shall be determined without regard to whether such securities arc then vested, exercisable or convertible). Harvard acknowledges that all certificates representing the shares described in this Section may bear customary securities legends requiring compliance with the Securities Act of 1933 and related slate securities laws upon any transfer of such shares.

4.1.2 Representations and Warranties. Licensee hereby represents and warrants to Harvard that:

4.1.2.1 the capitalization table attached hereto as Exhibit 4.1.2.1 (the "Cap Table") sets forth all of the outstanding capital stock of Licensee on a Fully-Diluted Basis as of the Original Effective Date;

4.1.2.2 other than as set forth in the Cap Table, as of the Original Effective Date, there were no outstanding shares of capital stock, convertible securities, outstanding warrants, options or other rights to subscribe for, purchase or acquire from Licensee any capital stock of Licensee and there were no contracts or binding commitments providing for the issuance of, or the granting of rights to acquire, any capital stock of Licensee or under which Licensee was obligated to issue any of its securities; and

4.1.2.3 the Shares, when issued pursuant to the terms of the Original Agreement, became, upon such issuance, duly authorized, validly issued, fully paid and nonassessable.

4.2 License Fee. As partial consideration for the licenses granted hereunder, Licensee shall pay Harvard a non-refundable license fee of [* * *] within thirty (30) days after the Original Effective Date. The license fee paid under this Section 4.2 shall be creditable against any amount that is payable to Harvard under Section 4.6 on account of an upfront sublicense fee or milestone payment paid by a Sublicensee to Licensee.

4.3 License Maintenance Fees. As partial consideration for the licenses granted hereunder, Licensee shall pay Harvard non-refundable annual license maintenance fees as follows:

4.3.1 [* * *] due and payable on the first anniversary of the Original Effective Date;

4.3.2 [* * *] due and payable on the second anniversary of the Original Effective Date;

4.3.3 [* * *] due and payable on the third anniversary of the Original Effective Date; and

4.3.4 [* * *] for Type I Licensed Products and [* * *] for Type II Licensed Products due and payable on the fourth anniversary of the Original Effective Date and on each subsequent anniversary of the Original Effective Date during the Term.

Each license maintenance fee paid under this Section 4.3 shall be creditable against the royalties that are payable to Harvard under Section 4.5.

4.4 Milestones.

4.4.1 As partial consideration for the licenses granted hereunder, Licensee shall pay Harvard the following milestone payments as specified in Section 4.4.2, regardless of whether such milestone is achieved by Licensee, its Affiliate or a Sublicensee:

4.4.1.1 [* * *] upon [* * *] with respect to the first Type I Licensed Product;

4.4.1.2 [* * *] upon [* * *] with respect to the first Type I Licensed Product;

4.4.1.3 [* * *] upon [* * *] with respect to the first Type I Licensed Product; and

4.4.1.4 [* * *] upon the [* * *] with respect to the first Type I Licensed Product.

With respect to the first three (3) Type II Licensed Products to achieve a milestone set forth above, Licensee shall pay Harvard thirty three percent (33%) of the amount due with respect to a Type I Licensed Product for meeting the same milestone. With respect to each subsequent Type II Licensed Product to achieve such milestone, Licensee shall pay Harvard sixteen and one half percent (16.5%) of the amount due with respect to a Type I Licensed Product for meeting the same milestone.

4.4.2 Licensee shall notify Harvard in writing within thirty (30) days following the achievement of each milestone described in Section 4.4.1, and shall make the appropriate milestone payment within thirty (30) days after the achievement of such milestone.

4.4.3 The milestones set forth in Section 4.4 are intended to be successive. In the event that a Licensed Product is not required to undergo the testing or other event associated with a particular milestone ("Skipped Milestone"), such Skipped Milestone shall be deemed to have been achieved upon the achievement by such Licensed Product of the next successive milestone ("Achieved Milestone"). Subject to Section 4.4.2, payment for any Skipped Milestone that is owed in accordance with the provisions of this Section 4.4.3 shall be due within thirty (30) days after the achievement of the Achieved Milestone.

4.4.4 Each milestone payment made under this Section 4.4 shall be creditable against any amount that is payable to Harvard under Section 4.6 on account of any amount paid by a Sublicensee to Licensee for upfront or milestone payments.

4.5 Royalties.

4.5.1 Type I Licensed Products. As partial consideration for the license granted under Section 2.1.1, Licensee shall pay Harvard an amount equal to the following percentages of Net Sales with respect to Type I Licensed Products and of Service Income:

4.5.1.1 for Net Sales and Service Income by Licensee and its Affiliates, [* * *] of such Net Sales and Service Income: and

4.5.1.2 for Net Sales and Service Income by a Sublicensee, the greater of (a) [* * *] of such Net Sales and Service Income and (b) [* * *] of royalties payable by such Sublicensee to Licensee on account of such Net Sales and Service Income.

4.5.2 Type II Licensed Products. As partial consideration for the license granted under Section 2.1.2, Licensee shall pay Harvard an amount equal to the following percentages of Net Sales with respect to Type II Licensed Products:

4.5.2.1 for Net Sales by Licensee and its Affiliates, [* * *] of such Net Sales; and

4.5.2.2 for Net Sales by a Sublicensee, the greater of (a) [* * *] of such Net Sales and (b) [* * *] of royalties payable by such Sublicensee to Licensee on account of such Net Sales.Such royalties shall be payable under this Agreement on a Licensed Product by Licensed Product and country by country basis until [* * *] have passed since the date of [* * *] in each such country.

4.5.3 Third Party Royalty Set Off. In the event that Licensee or a Sublicensee is required to obtain a license from a third party to an Infringed Patent in order to identify, discover, develop, manufacture, use or sell a Type I or Type II Licensed Product, and Licensee or a Sublicensee obtains such a license after arm's length negotiations, Licensee may offset [* * *] of any royalties paid under such third party license with respect to sales of Type I or Type II Licensed Products against the royalty payments that are due to Harvard pursuant to Section 4.5.1 or 4.5.2 with respect to sales of such Type I or Type II Licensed Product in such country. Notwithstanding the above, (a) the royalty payments to Harvard with respect to a Licensed Product that is the subject of an offset under this Section 4.5.3 may not be reduced by more than [* * *] of the amount otherwise due with respect to such Type I or Type II Licensed Product, (b) the offset that Licensee is entitled to make against royalty payments due to Harvard may not be greater than any offset that Licensee or a Sublicensee, as applicable, is entitled to make against royalty payments due to a third party licensee on account of royalty payments made under or by virtue of this Agreement and (c) in the event that a Sublicensee is required to obtain a license from a third party as described above, the percentage offset that Licensee is entitled to make against royalty payments due to Harvard with respect to Net

Sales by such Sublicensee may not be greater than any percentage offset that such Sublicensee actually makes against royalty payments due to Licensee with respect to such Net Sales.

4.5.4 Bad Debt. If, after exercising good faith, commercially reasonable collection efforts, Licensee is unable to collect any amount related to the sale, lease or other transfer of Licensed Products and/or related to the performance of Licensed Services for which it has previously paid royalties hereunder, Licensee shall be entitled to deduct any royalty previously paid with respect to such uncollected amount from the royalty payment due by Licensee in the next Calendar Quarter, which deduction shall be set forth in the corresponding report under Section 5.1 below. If, at any time after such deduction Licensee does collect any of such amounts, such collected amounts shall be included as Net Sales or Service Income in the Calendar Quarter in which they are collected and Licensee shall pay Harvard royalties thereon accordingly.

4.6 Non-Royalty Sublicense Income. As partial consideration for the licenses granted hereunder. Licensee shall pay Harvard an amount equal to [* * *] of all Non-Royalty Sublicense Income. Notwithstanding the foregoing, if a Sublicense is part of a transaction in which [* * *] to be attributed to the Sublicense as part of the overall transaction. In such event, the amount payable to Harvard under this Section 4.6 with respect to Non-Royalty Sublicense Income received in connection with such transaction shall be determined by the following equation:

(x)(y) [* * *] = A
where:
(x) is the [* * *];
(y) is the [* * *];

and A is the amount to be paid to Harvard.

4.7 No Multiple Payments. Only a single royalty shall be due and payable by Licensee under this Agreement with respect to a Licensed Product or Licensed Service regardless of whether the Licensed Product or Licensed Service is covered by more than one Valid Claim.

5. Reports; Payments; Records.

5.1 Reports and Payments.

5.1.1 Reports. Within sixty (60) days after the conclusion of each Calendar Quarter commencing with the first Calendar Quarter in which Net Sales or Service Income are generated or Non-Royalty Sublicense Income is received, Licensee shall deliver to Harvard a report containing

the following information (in each instance, with a Licensed Product-by-Licensed Product and Licensed Service-by-Licensed Service breakdown):

5.1.1.1 the number of units of Licensed Products sold, leased or otherwise transferred by Licensee, its Affiliates and Sublicensees for the applicable Calendar Quarter (with a breakdown by type of Licensed Products - i.e., Type I Licensed Products and Type II Licensed Products);

5.1.1.2 the gross amount invoiced for Licensed Products sold, leased or otherwise transferred by Licensee, its Affiliates and Sublicensees during the applicable Calendar Quarter (with a breakdown by type of Licensed Products) and Licensed Services performed;

5.1.1.3 a calculation of Net Sales and Service Income for the applicable Calendar Quarter, including an itemized listing of applicable deductions;

5.1.1.4 a detailed accounting of all Non-Royalty Sublicense Income received during the applicable Calendar Quarter and amounts received from Sublicenses that Licensee excluded from Non-Royalty Sublicense Income pursuant to Section 1.14 (a) - (f); and

5.1.1.5 the total amount payable to Harvard in U.S. Dollars in Net Sales, Service Income, and Non-Royalty Sublicense Income for the applicable Calendar Quarter, together with the exchange rates used for conversion.

Each such report shall be certified on behalf of Licensee by its Chief Financial Officer, President or Chief Executive Officer as true, correct and complete in all material respects. If no amounts are due to Harvard for a particular Calendar Quarter, the report shall so state.

5.1.2 Payment. Within sixty (60) days after the end of each Calendar Quarter. Licensee shall pay Harvard all amounts due with respect to Net Sales, Service Income, and Non- Royalty Sublicense Income for the applicable Calendar Quarter.

5.2 Payment Currency. All payments due under this Agreement shall be payable in U.S. Dollars. Conversion of foreign currency to U.S. Dollars shall be made at the conversion rate existing in the United States (as reported in the Wall Street Journal) on the last working day of the applicable Calendar Quarter. Such payments shall be without deduction of exchange, collection or other charges.

5.3 Records. Licensee shall maintain, and shall cause its Affiliates and Sublicensees to maintain, complete and accurate records of Licensed Products that are made, used or sold and Licensed Services that are performed under this Agreement, any amounts payable to Harvard in

relation to such Licensed Products and Licensed Services, and all Non-Royalty Sublicense Income received by Licensee, which records shall contain sufficient information to permit Harvard to confirm the accuracy of any reports or notifications delivered to Harvard under Section 5.1. Licensee, its Affiliates and/or its Sublicensees, as applicable, shall retain such records relating to a given Calendar Quarter for at least five (5) years after the conclusion of that Calendar Quarter, during which time Harvard shall have the right, at its expense, to cause an independent, certified public accountant to inspect such records during normal business hours for the sole purpose of verifying any reports and payments delivered under this Agreement. Such accountant shall not disclose to Harvard any information other than information relating to the accuracy of reports and payments delivered under this Agreement. The parties shall reconcile any underpayment or overpayment within thirty (30) days after the accountant delivers the results of the audit. In the event that any audit performed under this Section 5.3 reveals an underpayment in excess of five percent (5%) in any calendar year, the audited entity shall bear the full cost of such audit. Harvard may exercise its rights under this Section 5.3 only once every year per audited entity and only with reasonable prior notice to the audited entity.

5.4 Late Payments. Any payments by Licensee that are not paid on or before the date such payments are due under this Agreement shall bear interest at the lower of (a) one and one half percent (1.5%) per month and (b) the maximum rate allowed by law. Interest shall accrue beginning on the first day following the due date for payment and shall be compounded quarterly. Payment of such interest by Licensee shall not limit, in any way. Harvard's right to exercise any other remedies Harvard may have as a consequence of the lateness of any payment.

5.5 Payment Method. Each payment due to Harvard under this Agreement shall be paid by check or wire transfer of funds to Harvard's account in accordance with written instructions provided by Harvard. If made by wire transfer, such payments shall be marked so as to refer to this Agreement.

5.6 Withholding and Similar Taxes. All amounts to be paid to Harvard pursuant to this Agreement shall be without deduction of exchange, collection, or other charges, and, specifically, without deduction of withholding or similar taxes or other government imposed fees or taxes, except as permitted in the definition of Net Sales.

6. Intellectual Property.

6.1 Title. The entire right, title and interest in the Patent Rights and Harvard Technology Transfer Materials shall be owned solely by Harvard.

6.2 Patent Filing, Prosecution and Maintenance.

6.2.1 Patent Rights. Harvard shall be responsible for the preparation, filing, prosecution, protection and maintenance of and, subject to Licensee meeting its payment obligations under Section 6.2.3, shall prepare, file, prosecute, protect and maintain all Patent Rights, using patent counsel reasonably acceptable to Licensee. With respect to Patent Rights, Harvard shall: (a) use independent patent counsel reasonably acceptable to Licensee and instruct such patent counsel to furnish the Licensee with copies of all correspondence relating to the Patent Rights from the United States Patent and Trademark Office (USPTO) and any other patent office, as well as copies of all proposed responses to such correspondence in time for Licensee to review and comment on such response; (b) give Licensee an opportunity to review' the text of each patent application before filing; (c) consult with Licensee with respect thereto; (d) supply Licensee with a copy of the application as filed, together with notice of its filing date and serial number; (e) keep Licensee advised of the status of actual and prospective patent filings; and (f) provide advance copies of any papers related to the filing, prosecution, protection and maintenance of such patent filings. Harvard shall give Licensee the opportunity to provide comments on and make requests of Harvard concerning the preparation, filing, prosecution, protection and maintenance of the Patent Rights, and shall consider such comments and requests in good faith.

6.2.2 Past Expenses. Within thirty (30) days after its receipt of an invoice from Harvard, Licensee shall reimburse Harvard for all documented, out-of-pocket expenses incurred by Harvard through the end of the last full Calendar Quarter before the Original Effective Date (the "Past Expense Period") with respect to the preparation, filing, prosecution, protection and maintenance of the Patent Rights.

6.2.3 Future Expenses. Subject to Section 6.2.4 below, within thirty (30) days after its receipt of each invoice from Harvard, Licensee shall reimburse Harvard for all documented, out-of-pocket expenses inclined by Harvard pursuant to Section 6.2.1, including those incurred between the end of the Past Expense Period and the Original Effective Date.

6.2.4 Abandonment. Should Licensee decide that it does not wish to pay for the preparation, filing, prosecution, protection or maintenance of any Patent Rights in a country ("Abandoned Patent Rights"), Licensee shall provide Harvard with prompt written notice of such election. Ninety (90) days after receipt of such notice by Harvard, Licensee shall be released from its obligation to reimburse Harvard for the expenses incurred thereafter as to such Abandoned Patent Rights. In the event of Licensee's abandonment of any Patent Rights, Harvard may terminate (at any time upon written notice) the license granted to Licensee hereunder with respect to such Abandoned Patent Rights. In such case, Licensee will have no rights whatsoever to exploit such Abandoned Patent Rights and the claims of such Abandoned Patent Rights shall cease to constitute

Valid Claims. Harvard shall then be free, without further notice or obligation to Licensee, to grant rights in and to such Abandoned Patent Rights to third parties.

6.2.5 Small Entity Designation. If Licensee, its Affiliates, any Sublicensee and/or any holder of an option to obtain a Sublicense does not qualify, or at any point during the term of this Agreement ceases to qualify, as an entity entitled to pay lesser fees as provided by the USPTO (i.e., a "small entity") or the patent office of any other country. Licensee shall so notify Harvard immediately, in order to enable Harvard to comply with regulations regarding payment of fees with respect to Patent Rights.

6.2.6 Marking. Licensee, its Affiliates and Sublicensees shall mark all Licensed Products sold or otherwise disposed of in such a manner as to conform with the patent laws and practice of the country to which such products arc shipped or in which such products are sold.

7. Enforcement of Patent Rights.

7.1 Notice. In the event either party becomes aware of any possible or actual infringement of any Patent Rights relating to Licensed Products or a Licensed Service that are not solely within the scope of rights granted to a third party under Section 2.5 (an "Infringement"), that party shall promptly notify the other party and provide it with details regarding such Infringement.

7.2 Suit by Licensee. Licensee shall have the first right, but not the obligation, to take action in the prosecution, prevention or termination of any Infringement. Before Licensee commences an action with respect to any Infringement, Licensee shall consider in good faith the views of Harvard and potential effects on the public interest in making its decision whether to sue. Should Licensee elect to bring suit against an infringer, Licensee shall keep Harvard reasonably informed of the progress of the action and shall give Harvard a reasonable opportunity in advance to consult with Licensee and offer its views about major decisions affecting the litigation. Licensee shall give careful consideration to those views, but shall have the right to control the action; provided, however, that if Licensee fails to defend in good faith the validity and/or enforceability of the Patent Rights in the action or, or if Licensee's license to a Valid Claim in the suit terminates, Harvard may elect to take control of the action pursuant to Section 7.3. Should Licensee elect to bring suit against an infringer and Harvard is joined as party plaintiff in any such suit, Harvard shall have the right to approve the counsel selected by Licensee to represent Licensee and Harvard, such approval not to be unreasonably withheld. The expenses of such suit or suits that Licensee elects to bring, including any expenses of Harvard reasonably incurred in conjunction with the prosecution of such suits or the settlement thereof, shall be paid for entirely by Licensee and Licensee shall hold Harvard free, clear and harmless from and against any and all costs of such litigation, including attorney's fees.

Licensee shall not compromise or settle such litigation without the prior written consent of Harvard, which consent shall not be unreasonably withheld or delayed. In the event Licensee exercises its right to sue pursuant to this Section 7.2, it shall first reimburse itself out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorney's fees, necessarily incurred in the prosecution of any such suit. If, after such reimbursement, any funds shall remain from said recovery, then Harvard shall receive an amount equal to twenty percent (20%) of such funds and the remaining eighty percent (80%) of such funds shall be retained by Licensee.

7.3 Suit by Harvard. If Licensee does not lake action in the prosecution, prevention, or termination of any Infringement pursuant to Section 7.2 above, and has not commenced negotiations with the infringer for the discontinuance of said Infringement, within ninety (90) days after receipt of notice to Licensee by Harvard of the existence of an Infringement, Harvard may elect to do so. Should Harvard elect to bring suit against an infringer and Licensee is joined as party plaintiff in any such suit, Licensee shall have the right to approve the counsel selected by Harvard to represent Harvard, such approval not to be unreasonably withheld. The expenses of such suit or suits that Harvard elects to bring, including any expenses of Licensee reasonably incurred in conjunction with the prosecution of such suits or the settlement thereof, shall be paid for entirely by Harvard and Harvard shall hold Licensee free, clear and harmless from and against any and all costs of such litigation, including attorney's fees. Harvard shall not compromise or settle such litigation without the prior written consent of Licensee, which consent shall not be unreasonably withheld or delayed. In the event Harvard exercises its right to sue pursuant to this Section 7.3, it shall first reimburse itself out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorney's fees, necessarily incurred in the prosecution of any such suit. If, after such reimbursement, any funds shall remain from said recovery, then Licensee shall receive an amount equal to twenty percent (20%) of such funds and the remaining eighty percent (80%) of such funds shall be retained by Harvard.

7.4 Own Counsel. Each party shall always have the right to be represented by counsel of its own selection and at its own expense in any suit instituted under this Article 7 by the other party for Infringement.

7.5 Cooperation. Each party agrees to cooperate fully in any action under this Article 7 that is controlled by the other party, provided that the controlling party reimburses the cooperating party promptly for any costs and expenses incurred by the cooperating party in connection with providing such assistance.

7.6 Standing. If a party lacks standing and the other party has standing to bring any such suit, action or proceeding, then such other party shall do so at the request of and at the expense of

the requesting party. If either party determines that it is necessary or desirable for another party to join any such suit, action or proceeding, the other party shall execute all papers and perform such other acts as may be reasonably required in the circumstances.

7.7 Declaratory Judgment. If a declaratory judgment action is brought naming Licensee and/or any of its Affiliates or Sublicensees as a defendant and alleging invalidity or unenforceability of any claims within the Patent Rights, Licensee shall promptly notify Harvard in writing and Harvard may elect, upon written notice to Licensee within thirty (30) days after Harvard receives notice of the commencement of such action, to take over the sole defense of the invalidity or unenforceability aspect of the action at its own expense and shall reasonably consider all comments of Licensee concerning such action.

8. Warranties; Limitation of Liability.

8.1 Compliance with Law. Licensee represents and warrants that it will comply, and will ensure that its Affiliates and Sublicensees comply, with all local, state, and international laws and regulations relating to the development, manufacture, use, sale and importation of Licensed Products and the performance of Licensed Services. Without limiting the foregoing, Licensee represents and warrants that it will comply, and will ensure that its Affiliates and Sublicensees comply, with all United States export control laws and regulations.

8.2 No Warranty.

8.2.1 NOTHING CONTAINED HEREIN SHALL BE DEEMED TO BE A WARRANTY BY HARVARD THAT IT CAN OR WILL BE ABLE TO OBTAIN PATENTS ON PATENT APPLICATIONS INCLUDED IN THE PATENT RIGHTS, OR THAT ANY OF THE PATENT RIGHTS WILL AFFORD ADEQUATE OR COMMERCIALLY WORTHWHILE PROTECTION.

8.2.2 HARVARD MAKES NO REPRESENTATION THAT THE PRACTICE OF THE PATENT RIGHTS OR USE OF THE HARVARD TECHNOLOGY TRANSFER MATERIALS OR THE DEVELOPMENT, MANUFACTURE, USE, SALE OR IMPORTATION OF ANY LICENSED PRODUCT OR THE PRACTICE OF ANY LICENSED METHOD, OR ANY ELEMENT THEREOF, WILL NOT INFRINGE THE PATENT OR PROPRIETARY RIGHTS OF ANY THIRD PARTY.

8.2.3 EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY TECHNOLOGY, PATENTS, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER

OF THIS AGREEMENT AND HEREBY DISCLAIMS WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WI TH RESPECT TO ANY AND ALL OF THE FOREGOING.

8.3 Limitation of Liability.

8.3.1 Except with respect to Licensee's indemnification obligations under Article 9, neither party will be liable to the other with respect to any subject matter of this Agreement under any contract, negligence, strict liability or other legal or equitable theory for (a) any indirect, incidental, consequential or punitive damages or lost profits or (b) cost of procurement of substitute goods, technology or services.

8.3.2 Harvard's aggregate liability for all damages of any kind arising out of or relating to this Agreement or its subject matter shall not exceed the amounts paid to Harvard under this Agreement.

9. Indemnification.

9.1 Indemnity.

9.1.1 Licensee shall indemnify, defend and hold harmless Harvard and its current or former directors, governing board members, trustees, officers, faculty, medical and professional staff, employees, students, and agents and their respective successors, heirs and assigns (collectively, the "Indemnitees") from and against any claim, liability, cost, expense, damage, deficiency, loss or obligation or any kind or nature (including, without limitation, reasonable attorney's fees and other costs and expenses of litigation) by or owed to a third party (collectively, "Claims"), based upon, arising out of, (a) practice by Licensee, its Affiliates and Sublicensees of the Patent Rights or (b) the development, manufacture, distribution, sale or use of Licensed Products or the performance of Licensed Services, including without limitation any cause of action relating to product liability concerning any product, process, or service made, used or sold pursuant to any right or license granted under this Agreement; provided, however, that the above indemnification shall not apply to any Claim to the extent that it is directly attributable to the gross negligence or intentional misconduct of any Indemnitee.

9.1.2 Licensee shall, at its own expense, provide attorneys reasonably acceptable to Harvard to defend against any actions brought or filed against any Indemnitee hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought. Any Indemnitee seeking indemnification hereunder shall promptly notify Licensee of such Claim;

provided, however, that failure to so notify Licensee will relieve Licensee from liability for indemnification only if and to the extent Licensee did not otherwise promptly learn of such Claim and such failure results in additional costs, expenses or liability of Licensee or the inability to defend any such Claim under Section 9.1. The Indemnitees shall provide Licensee, at Licensee's expense, with reasonable assistance and full information with respect to such Claim and give Licensee sole control of the defense or settlement of any Claim for which Licensee acknowledges full responsibility under this Section 9.1; provided, however, that (a) Licensee shall not settle any such Claim which will adversely impact Harvard's interest in the Patent Rights, admit any liability on the part of an Indemnitee or impose any obligations on any Indemnitee without the prior written consent of Harvard, which consent shall not be unreasonably withheld, and (b) any Indemnitee shall have the right to retain its own counsel, at the expense of Licensee, if representation of such Indemnitee by the counsel retained by Licensee would be inappropriate because of actual or potential differences in the interests of such Indemnitee and any other party represented by such counsel. Notwithstanding the foregoing, in no event shall Licensee be required to pay the expenses of more than one counsel for the Indemnitees in addition to counsel retained by Licensee. Licensee agrees to keep Harvard informed of the progress in the defense and disposition of such claim, suit or action and to consult with Harvard with regard to any proposed settlement. Notwithstanding the foregoing, Licensee shall have no obligations for any Claim if the Indemnitee seeking indemnification makes any admission, settlement or other communication regarding such Claim without the prior written consent of Licensee, in its sole discretion.

9.2 Insurance.

9.2.1 Beginning at the time any Licensed Product is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) or any Licensed Service is being performed by Licensee, or by an Affiliate, Sublicensee or agent of Licensee, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than $5,000,000 per incident and $5,000,000 annual aggregate and naming the Indemnitees as additional insureds. During clinical trials of any such Licensed Product, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than $3,000,000 per incident and $3,000,000 annual aggregate, naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide: (a) product liability coverage and (b) broad form contractual liability coverage for Licensee's indemnification under this Agreement.

9.2.2 If Licensee elects to self-insure all or part of the limits described above in Section 9.2.1 (including deductibles or retentions which are in excess of $250,000 annual aggregate) such self-insurance program must be acceptable to Harvard and the Risk Management Foundation

of the Harvard Medical Institutions, Inc. in their commercially reasonable discretion. The minimum amounts of insurance coverage required shall not be construed to create a limit o! Licensee's liability with respect to its indemnification under this Agreement.

9.2.3 Licensee shall provide Harvard with written evidence of such insurance upon request of Harvard. Licensee shall provide Harvard with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if Licensee does not obtain replacement insurance providing comparable coverage within thirty (30) days after such notice, Harvard shall have the right to terminate this Agreement effective at the end of such thirty (30) day period without notice or any additional waiting periods.

9.2.4 Licensee shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during: (a) the period that any Licensed Product is being commercially distributed or sold or any Licensed Service is being performed by Licensee, or an Affiliate, Sublicensee or agent of Licensee; and (b) a reasonable period after the period referred to in (a) above which in no event shall be less than five (5) years.

10. Term and Termination.

10.1 Term. The term of this Agreement shall commence on the Original Effective Date and, unless earlier terminated as provided in this Article 10, shall continue in full force and effect on a Licensed Product by Licensed Product, Licensed Service by Licensed Service and country by country basis until the expiration of the last to expire Valid Claim.

10.2 Termination.

10.2.1 Termination Without Cause. Licensee may terminate this Agreement upon ninety (90) days prior written notice to Harvard, as to Type I or Type II Licensed Products, or as to both. All rights and licenses granted herein shall survive such termination as to the type of Licensed Product that is not terminated. In the event of a termination with respect to Type II Licensed Products, Licensee's obligations under Sections 4.4, 4.5.2, 4.6 and Articles 5 and 9 shall survive such termination with respect to Type II Licensed Products that were identified or discovered through the use of a Licensed Method, which use was made prior to such termination.

10.2.2 Termination for Patent Challenge. Harvard may terminate this Agreement immediately, as to Type I or Type II Licensed Products or both, upon written notice to Licensee if Licensee commences an action in which it challenges the validity, enforceability or scope of any of the Patent Rights. All rights and licenses granted herein shall survive such termination as to the Licensed Product that is not terminated.

10.2.3 Termination for Default.

10.2.3.1 Subject to Section 3.4, in the event that cither party commits a material breach of its obligations under this Agreement and fails to cure that breach within ninety (90) days after receiving written notice thereof, the other party may terminate this Agreement in its entirety immediately upon written notice to the party in breach; provided, however, that in the event that Licensee has materially breached its obligations under this Agreement (such as a failure to achieve an applicable Development Milestone without availing itself of any aspect of the procedure set forth in Section 3.4) solely with respect any given Type I Licensed Product and not with respect to any Type II Licensed Products, then Harvard shall consider in good faith, but in its sole discretion, terminating only the rights and licenses granted herein with respect to Type I Licensed Products, and either leaving as is or converting to non-exclusive the rights and licenses granted herein with respect to Type II Licensed Products and Licensed Services.

10.2.3.2 If Licensee defaults in its obligations under Section 9.2 to procure and maintain insurance or, if Licensee has in any event failed to comply with the notice requirements contained therein, then Harvard may terminate this Agreement immediately without notice or additional waiting period.

10.2.4 Bankruptcy. Harvard may terminate this Agreement upon notice to Licensee if Licensee becomes judicially declared insolvent, is adjudged bankrupt, applies for judicial or extra judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee (or the like) in bankruptcy appointed by reason of its insolvency, or in the event an involuntary bankruptcy action is filed against Licensee and not dismissed within ninety (90) days, or if the other party becomes the subject of liquidation or dissolution proceedings or otherwise discontinues business.

10.3 Effect of Termination.

10.3.1 Termination of Rights. Upon termination of this Agreement in whole or in part by either party pursuant to any of the provisions of Sections 3.4 or 10.2: (a) the rights and licenses granted to Licensee under Article 2 with respect to the terminated Licensed Products and/or Licensed Services, as applicable, shall terminate and, in the event that the Agreement is terminated in whole, all rights in and to and under the Patent Rights shall revert to Harvard; and (b) any existing agreements that contain a Sublicense with respect to the terminated Licensed Products shall terminate to the extent of such Sublicense; provided, however, that, for each Sublicensee, upon termination of the Sublicense agreement with such Sublicensee, if the Sublicensee is not then in breach of its Sublicense agreement with Licensee such that Licensee would have the right to terminate such Sublicense, such Sublicensee shall have the right to obtain a license from Harvard

on the same terms and conditions as set forth herein, which shall not impose any representations, warranties, obligations or liabilities on Harvard that arc not included in this Agreement provided that (a) the scope of the license granted directly by Harvard to such Sublicensee shall be co-extensive with the scope of the license granted by Licensee to such Sublicensee, (b) if the Sublicense granted to such Sublicensee was non-exclusive, such Sublicensee shall not have the right to participate in the prosecution or enforcement of the Patent Rights under the license granted to it directly by Harvard and (c) if there are more than one Sublicensee, each Sublicensee that is granted a direct license shall be responsible for a pro rata share of the reimbursement due under Section 6.2.3 of this Agreement (based on the number of direct licenses under the Patent Rights in effect on the date of reimbursement).

10.3.2 Accruing Obligations. Termination or expiration of this Agreement shall not relieve the parties of obligations accruing prior to such termination or expiration, including obligations to pay amounts accruing hereunder up to the date of termination or expiration. After the date of termination or expiration (except in the case of termination by Harvard pursuant to Section 10.2.2, 10.2.3 or 10.2.4), Licensee, its Affiliates and Sublicensees (a) may sell Licensed Products then in stock and (b) may complete the production of Licensed Products then in the process of production and sell the same; provided that, in the case of both (a) and (b), Licensee shall pay the applicable royalties and payments to Harvard in accordance with Article 4, provide reports and audit rights to Harvard pursuant to Article 5 and maintain insurance in accordance with the requirements of Section 9.2.

10.4 Survival. The parties' respective rights, obligations and duties under Articles 5, 9 and 10 and Section 4.5.2, as well as any rights, obligations and duties which by their nature extend beyond the expiration or termination of this Agreement, shall survive any expiration or termination of this Agreement. In addition, Licensee's obligations under Section 4.6 with respect to Sublicenses granted prior to termination of the Agreement shall survive termination.

11. Miscellaneous.

11.1 Preference for United States Industry. During the period of exclusivity of this license in the United States, Licensee shall comply with 37 C.F.R. § 401.14(i) or any successor rule or regulation. Upon Licensee's request. Harvard agrees to make reasonable efforts to assist Licensee in obtaining a waiver of the requirements imposed by such rules or regulations.

11.2 Security Interest. If Licensee enters into any agreement under which Licensee grants to or otherwise creates in any third party a security interest in this Agreement or any of the rights granted to Licensee herein ("Security Agreement"), and there occurs a default under the terms of

such Security Agreement, if such default is not cured within any applicable cure period that may be provided under such Security Agreement, and any such third party takes any action under the Security Agreement to take title to the secured property, such action shall be deemed a default under this Agreement and be subject to the terms of Section 10.2.3.

11.3 Use of Name. Licensee shall not, and shall ensure that its Affiliates and Sublicensees shall not, use the name or insignia of Harvard or the name of any of Harvard officers, faculty, other researchers or students, or any adaptation of such names, in any advertising, promotional or sales literature, including without limitation any press release or any document employed to obtain funds, without the prior written approval of Harvard. This restriction shall not apply to any information required by law to be disclosed to any governmental entity.

11.4 Entire Agreement. This Agreement is the sole agreement with respect to the subject matter hereof and except as expressly set forth herein, supersedes all other agreements and understandings between the parties with respect to the same.

11.5 Notices. Unless otherwise specifically provided, all notices required or permitted by this Agreement shall be in writing and may be delivered personally, or may be sent by facsimile, overnight delivery or certified mail, return receipt requested, to the following addresses, unless the parties arc subsequently notified of any change of address in accordance with this Section 11.5:

If to Licensee:	Genocea Biosciences, Inc. Cambridge Discovery Park 100 Acorn Park Drive, 5th Floor Cambridge, Massachusetts 02140 Attn: President
If to Harvard:	Office of Technology Development Harvard University Holyoke Center 727 1350 Massachusetts Avenue Cambridge, Massachusetts 02138 Attn.: Chief Technology Development Officer

Any notice shall be deemed to have been received as follows: (a) by personal delivery, upon receipt; (b) by facsimile or overnight delivery, one business day after transmission or dispatch; (c) by certified mail, as evidenced by the return receipt. If notice is sent by facsimile, a confirming copy of the same shall be sent by mail to (lie same address.

11.6 Governing Law and Jurisdiction. This Agreement will be governed by, and construed in accordance with, the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. Any action, suit or other proceeding arising under or relating to this Agreement (a "Suit") shall be brought in a court of competent jurisdiction in the Commonwealth of Massachusetts, and the Parties hereby consent to the sole jurisdiction of the state and federal courts sitting in the Commonwealth of Massachusetts. Each party agrees not to raise any objection at any time to the laying or maintaining of the venue of any Suit in any of the specified courts, irrevocably waives any claim that Suit has been brought in any inconvenient forum and further irrevocably waives the right to object, with respect to any Suit, that such court does not have any jurisdiction over such party.

11.7 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the parties and their respective legal representatives, successors and permitted assigns.

11.8 Headings. Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.

11.9 Counterparts. The parties may execute this Agreement in two or more counterparts, each of which shall be deemed an original.

11.10 Amendment; Waiver. This Agreement may be amended, modified, superseded or canceled, and any of the terms may be waived, only by a written instrument executed by each party or, in the case of waiver, by the party waiving compliance. The delay or failure of either party at any time or times to require performance of any provisions hereof shall in no manner affect the rights at a later time to enforce the same. No waiver by either party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

11.11 No Agency or Partnership. Nothing contained in this Agreement shall give either party the right to bind the other, or be deemed to constitute either party as agent for or partner of the other or any third party.

11.12 Assignment and Successors. This Agreement may not be assigned by either party without the consent of the other, which consent shall not be unreasonably withheld, except that each party may, without such consent, assign this Agreement and the rights, obligations and interests of such party to any of its Affiliates, to any purchaser of all or substantially all of its assets or the

portion of its business to which the subject matter of this Agreement relates, or to any successor corporation resulting from any merger or consolidation of such party with or into such corporation; provided, in each case, that the assignee agrees in writing to be bound by the terms of this Agreement. Any assignment purported or attempted to be made in violation of the terms of this Section 11.12 shall be null and void and of no legal effect.

11.13 Force Majeure. Neither party will be responsible for delays resulting from causes beyond the reasonable control of such party, including, without limitation, fire, explosion, flood, war, strike, or riot, provided that the nonperforming party uses commercially reasonable efforts to avoid or remove such causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.

11.14 Interpretation. Each party hereto acknowledges and agrees that: (a) it and/or its counsel reviewed and negotiated the terms and provisions of this Agreement and has contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to both parties hereto and not in favor of or against either party, regardless of which party was generally responsible for the preparation of this Agreement.

11.15 Severability. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the parties that the remainder of this Agreement shall not be affected.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

President and Fellows of Harvard College	**Genocea Biosciences, Inc.**
By: /s/ Cristin L. Rothfuss_____	By: /s/ Chip Clark _____
Name: Cristin L. Rothfuss _____	Name: Chip Clark _____
Title: Director of Technology Transactions - Office of Technology Development - Harvard University	Title: President and CEO _____

SECOND AMENDMENT OF LEASE

THIS SECOND AMENDMENT OF LEASE (this "Amendment") is made as of the 1st day of May, 2019, by 100 Discovery Park DE, LLC, a Delaware limited liability company (as successor in interest to TBCI, LLC, as Trustee of 100 Discovery Park Realty Trust) ("Landlord"), and Genocea Biosciences, Inc., a Delaware corporation ("Tenant").

Recitals

A. Landlord and Tenant are parties to a Lease dated as of July 3, 2012, as amended by that First Amendment of Lease dated May 16, 2016 (as amended, the "Lease") pursuant to which Landlord has leased to Tenant 23,666 leasable square feet of space on the fifth floor and a portion of the ground floor (the "Existing Premises") of the building located at and commonly known as Building 100, Cambridge Discovery Park, Cambridge, Massachusetts. All capitalized terms used in this Amendment which are defined in the Lease and not otherwise defined in this Amendment shall have the meanings given in the Lease.

B. Landlord and Tenant desire to amend the Lease to: (i) extend the Lease Term for five (5) years beyond February 29, 2020, to February 28, 2025; (ii) expand the Existing Premises by providing for the addition of an agreed upon 22,442 leasable square feet of space, as depicted on Exhibit C hereto (the "Expansion Premises"), as of the Expansion Date (as defined below); and (iii) make certain other changes to the Lease, on and subject to the terms and conditions set forth below.

Statement of Amendment

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. Extension of Term. The term of the Lease is extended for five (5) years beyond February 29, 2020 ("Extension Date") to February 28, 2025.

2. Expansion of Existing Premises. The Expansion Premises shall be added to the Existing Premises as of the date that Landlord delivers possession of the Expansion Premises to Tenant free of all tenants or other occupants and otherwise in the condition set forth in Section 3 of this Amendment (the "Expansion Date"), which date is anticipated to occur on March 1, 2020. All terms and provisions of the Lease, as amended hereby, shall apply to Tenant's leasing of the Expansion Premises from and after the Expansion Date. Notwithstanding the foregoing, Landlord shall use commercially reasonable efforts to deliver the Expansion Premises to Tenant in the condition required by the prior sentence on or before the date that is ninety (90) days after the existing tenant of the Expansion Premises vacates the Expansion Premises and the lease between Landlord and such tenant with respect to the Expansion Premises has been terminated. Notwithstanding the foregoing, if (a) Landlord is unable to deliver possession of the Expansion Premises to Tenant in such condition on or before June 1, 2020, or (b) the Smithsonian institution Astrophysical Observatory ("Smithsonian") exercises its right of first offer to lease the Expansion Premises, which Landlord agrees to offer to Smithsonian within ten (10) days after the date hereof,

and which, under the terms of its lease with Landlord, Smithsonian is required to exercise in writing within ten (10) business days after its receipt of Landlord's offer and if not timely exercised is deemed waived, the Expansion Premises shall not be added to the Existing Premises and the terms of this Amendment related to the Expansion Premises shall be null and void and have no further force or effect (the "Expansion Rescission"). Landlord shall notify Tenant in writing within two (2) business days after Smithsonian exercises or waives (or is deemed to have waived) its right of first offer.

3. Condition of Expansion Premises. Tenant hereby acknowledges and agrees that, with the exception of Landlord's obligation to deliver the Expansion Premises to Tenant on the Expansion Date in compliance with all applicable Legal Requirements, with ail base building systems serving the Expansion Premises in good working order and condition and with the windows watertight, decommissioned in compliance with applicable Legal Requirement, so as to clean and remove any biomedical material or waste or any other Hazardous Materials handled by the previous tenant, and otherwise in so-called "broom clean condition" free of all tenants, occupants and personal property and the trade fixtures of the prior tenant of the Expansion Premises, (a) the Expansion Premises are being leased by Tenant in their condition as of the Expansion Date, "as-is," without representation or warranty by Landlord, and (b) Landlord will not have any obligation to make any alterations or improvements to the Expansion Premises.

4. Expansion Termination Option. Tenant shall have the one time right to elect to terminate the Lease with respect to the Expansion Premises (the "Expansion Termination Option") by written notice to Landlord on or before July 31, 2019. Upon timely exercise of the Expansion Termination Option in accordance with this Section, then the Expansion Premises shall not be added to the Existing Premises on the Expansion Date, and the terms of this Amendment related to the Expansion Premises shall be null and void and have no further force or effect. If Tenant fails to exercise the Expansion Termination Option strictly in accordance with this Section, then the Expansion Termination Option shall automatically lapse and Tenant shall have no further right to terminate the Lease with respect to the Expansion Premises.

5. Tenant's Building Share and Tenant's Project Share . Provided that neither the Expansion Rescission occurred nor is the Expansion Termination Option exercised in accordance with this Amendment, as of the Expansion Date, Tenant's Building Share shall be 35.85% (46,108/128,601) and Tenant's Project Share shall be 13.95% (46,108/330,457).

6. Security Deposit. Provided that Tenant does not exercise the Expansion Termination Option and the Expansion Rescission has not yet occurred, Tenant shall deposit on or before August 1, 2019, an additional $315,546.68 (the "Additional Security Deposit") with the Landlord as an additional security deposit for the Expansion Premises in the form of cash or letter of credit, to be held in accordance with Section 2.5 of the Lease. Additionally, in the event that the Expansion Rescission thereafter occurs, Landlord shall promptly return the Additional Security Deposit to Tenant no later than thirty (30) days immediately following the Expansion Rescission.

7. Specific Amendments of Lease. In furtherance of the above provisions of this Amendment, the Lease is amended as follows, as of the date of this Amendment, unless otherwise expressly stated:

a. Item 5. Item 5 of the Summary of Basic Terms of the Lease is deleted in its entirety and replaced with the following:

"5. Lease Term: From March 1, 2014 through February 28, 2025."

b. Item 8. Effective as of the Extension Date, Item 8 of the Summary of Basic Terms of the Lease is deleted in its entirety and replaced with the following:

"Tenant's Parking Allocation" means 1.5 parking spaces per 1,000 leasable square feet of the Premises, which spaces shall be allocated and available to Tenant throughout the Lease Term in Parking Garage A.

c. Item 9. Item 9 of the Summary of Basic Terms of the Lease is amended by adding the following at the end of the chart showing Base Rent:

"Base Rent for the Existing Premises (23,666 s.f.)

PERIOD	ANNUAL RATE	MONTHLY RATE	PSF RATE
March 1, 2020 - February 28, 2021	$1,443,626.00	$120,302.17	$61.00
March 1, 2021 - February 28, 2022	$1,479,834.98	$123,319.58	$62.53
March 1, 2022 - February 28, 2023	$1,516,753.94	$126,396.16	$64.09
March 1, 2023 - February 29, 2024	$1,554,619.54	$129,551.63	$65.69
March 1, 2024 - February 28, 2025	$1,593,431.78	$132,785.98	$67.33"

d. Definitions. The definition of "Lease Term" in Article I of the Lease is deleted in its entirety and the following is respectively substituted in place thereof:

"Lease Term" means the period beginning at 12:01 a.m. on March 1, 2014 and ending at 11:59 p.m. on February 28, 2025."

e. Lease Term. Section 2.4 of the Lease is deleted in its entirety and replaced with the following:

"Section 2.4. Lease Term: The Lease Term shall commence at 12:01 A.M. on March 1, 2014 and shall end at 11:59 P.M. on February 28, 2025."

8. Additional Specific Amendments of Lease if neither the Expansion Rescission occurs nor the Expansion Termination Option is exercised. In furtherance of the above provisions of this Amendment and provided that neither the Expansion Rescission occurred nor is the Expansion Termination Option exercised in accordance with this Amendment, the Lease is amended as follows as of the Expansion Date:

a. Item 3A. Item 3A of the Summary of Basic Terms of the Lease is deleted in its entirety and replaced with the following:

"3A. Premises: All of the leasable space on the fifth floor (the "Existing Premises") and the sixth floor (the "Expansion Premises") of the Building, as depicted on Exhibit C, and storage rooms on the first floor of the Building, as depicted on Exhibit C-1. The Building and the Other Buildings which are currently part of the Project are depicted on Exhibit B.

b. Item 3D. Item 3D of the Summary of Basic Terms of the Lease is deleted in its entirety and replaced with the following:

"3D. Leasable Square Footage of the Premises (which includes a proportionate share of the Floor Area of the Common Areas of the Building, as provided for in this Lease): An agreed upon 46,108 leasable square feet."

c. Item 7. Item 7 of the Summary of Basic Terms of the Lease is deleted in its entirety and replaced with the following:

"7. "Security Deposit": $631,093.36, in the form of cash or letter of credit."

d. Item 9. Item 9 of the Summary of Basic Terms of the Lease is amended by adding the following at the end thereof:

"Base Rent for the Expansion Premises (22.442 s.f.)

PERIOD	ANNUAL RATE	MONTHLY RATE	PSF RATE
Expansion Date - February 28, 2021	$1,368,962.00	$114,080.17	$61.00
March 1,2021 - February 28, 2022	$1,403,298.26	$116,941.52	$62.53
March 1, 2022 - February 28, 2023	$1,438,307.78	$119,858.98	$64.09
March 1, 2023 - February 29, 2024	$1,474,214.98	$122,851.25	$65.69
March 1, 2024 - February 28, 2025	$1,511,019.86	$125,918.32	$67.33"

e. Exhibit C and Exhibit C-1. Exhibit C and Exhibit C-1 to the Lease are deleted and Exhibit C and Exhibit C-1 attached to this Amendment are substituted in place thereof.

9. Allowance. Landlord will provide an amount up to $25.00 per leasable square foot of the Existing Premises and the Expansion Premises (provided neither the Expansion Rescission occurs nor the Expansion Termination Option is exercised) (the "Additional Allowance") to or for the benefit of Tenant to pay or reimburse Tenant for costs of designing and constructing alterations and improvements to either the Existing Premises and/or the Expansion Premises (provided neither the Expansion Rescission occurs nor the Expansion Termination Option is exercised), including permits, architectural and engineering costs (but excluding costs for Tenant's equipment, furniture, trade fixtures and personal property) performed by or on behalf of Tenant from and after the date

of this Amendment (the "Additional Tenant Improvements"). The Additional Allowance shall be $1,152,700 ($25.00 X 46,108), provided, however; that (i) if either the Expansion Rescission occurs or the Expansion Termination Option is exercised, the Additional Allowance shall be $591,650.00 ($25.00 X 23,666), and (ii) until the Expansion Date occurs, the Additional Allowance shall not exceed $591,650.00 ($25.00 X 23,666). Tenant shall have the right to allocate the Additional Allowance to either the Expansion Premises (provided neither the Expansion Rescission occurs nor the Expansion Termination Option is exercised) or the Existing Premises, or both. Tenant's construction of the Additional Tenant improvements will be performed by contractors approved by Landlord, and pursuant to plans and specifications approved by Landlord in accordance with and otherwise, subject to the provisions of Section 7.5 of the Lease; provided, also, that within thirty (30) days of being invoiced therefor, Tenant will reimburse Landlord for the costs incurred by Landlord to review, inspect and/or approve, as applicable, any such plans or specifications or construction. Disbursement of the Additional Allowance to or at the direction of Tenant shall be conditioned on the subject Additional Tenant Improvements having been performed in accordance with the provisions of this Amendment and the Lease, and shall be subject to Landlord's receipt of a request for payment in form and with backup reasonably satisfactory to Landlord, including but not limited to such certifications, lien waivers and other documents from Tenant, Tenant's contractor and Tenant's architect as Landlord may reasonably require. Landlord may inspect the subject Additional Tenant Improvements as a condition to making any requested disbursement of the Additional Allowance to confirm the status of such Additional Tenant improvements and that such Additional Tenant Improvements have been performed in accordance with the provisions of this Amendment and the Lease, in the event that the cost of any such Additional Tenant Improvements exceeds the amount of the Additional Allowance, Tenant shall be entirely responsible for such excess. Any portion of the Additional Allowance for which Tenant has not qualified for disbursement within twelve (12) months after the first to occur of (i) the Expansion Rescission, or (ii) the Expansion Date for work related to the Expansion Premises, shall be forfeited by Tenant.

10. Extension Option.

(a) Extension Term. Provided that (i) an Event of Default does not exist as of the commencement of the Extension Term (as defined below) or as of the date of Landlord's receipt of the Extension Notice (as defined below), (ii) neither the Expansion Rescission occurred nor the Expansion Termination Option is exercised in accordance with this Amendment and (iii) Tenant has not assigned the Lease (excluding an assignment to a Permitted Transferee) or subleased more than fifty percent (50%) of the Premises (excluding a sublease to a Permitted Transferee), Tenant shall have the right to extend the Lease Term for one (1) period of five (5) years (the "Extension Term") by giving Landlord written notice of extension (the "Extension Notice"), which notice must be received by Landlord not earlier than 18 months, nor later than 12 months, prior to the then-expiration date of the Lease Term, if such extension becomes effective, the Lease Term shall be automatically extended upon the same terms and conditions as are applicable to the current Lease Term, except that (x) Base Rent for the Extension Term shall be as set forth in subsection (b) below, and (y) there shall be no further right to extend or renew the Lease Term beyond the Extension Term. The right of extension provided under this section is personal to Genocea Biosciences, Inc. (or any of its Permitted Transferees) and is not exercisable by any subtenant or assignee permitted under this Lease.

(b) Base Rent for Extension Term.

(i) The Base Rent per square foot for the Extension Term will be the then fair market rent per square foot for the Premises (the "Market Rent"), determined in accordance with this subsection (b); provided, that, in no event shall the Base Rent for the Extension Term be less than the Base Rent in effect during the twelve (12) months immediately preceding the Extension Term. For a period of thirty (30) days after Tenant gives to Landlord the Extension Notice (such period being called the "Negotiation Period"'). Landlord and Tenant shall negotiate in good faith to attempt to agree upon the Market Rent, and, in the course of such negotiations, each party may from time to time submit modified proposals to the other. If the parties agree upon the Market Rent prior to the determination of the arbitrator pursuant to subsection (b)(ii) below, whether such agreement is reached during or after the Negotiation Period, the Market Rent shall be as so agreed.

(ii) If the parties are unable to agree upon the Market Rent within the Negotiation Period, then each party shall, upon selection of an arbitrator pursuant to subsection (b)(iii) below, simultaneously submit to the arbitrator for binding arbitration a proposal as to the Market Rent. The Market Rent shall be determined as of the commencement of the Extension Term at the then current arms- length negotiated base rents being charged for comparable space in comparable buildings located in the market area of the Building, taking into consideration all relevant factors. The Market Rent may include escalations at various points during the Extension Term. The arbitrator shall not have the right to modify any provision of the Lease except Base Rent. Within thirty (30) days after both parties have submitted such proposals to the arbitrator, the arbitrator shall select one of the proposals as more closely approximating the Market Rent appropriate for the Extension Term, and, unless the parties have then agreed upon the Market Rent, the proposed Market Rent set forth in such proposal selected by the arbitrator shall be deemed to be the Market Rent.

(iii) if the parties are unable to agree upon the Market Rent within the Negotiation Period, then the parties shall, within fifteen (15) days after the end of the Negotiation Period (such fifteen (15) day period being herein called the "Selection Period"), attempt to agree upon an arbitrator to whom to submit the determination of Market Rent for binding arbitration pursuant to subsection (b)(ii) above, if the parties are unable to agree upon an arbitrator within the Selection Period, then, at the end of the Selection Period, each party shall select an arbitrator and, within fifteen (15) days after the end of the Selection Period, the arbitrators shall agree upon an arbitrator to whom the determination of Market Rent shall be submitted for binding arbitration pursuant to subsection (b)(ii) above. If such arbitrators are unable to agree promptly upon an arbitrator, an arbitrator shall be selected by the American Arbitration Association. Any arbitrator selected by either party, by the arbitrators selected by the parties or by the American Arbitration Association shall be independent of both parties and shall have such experience, either as a licensed real estate broker or as an appraiser for at least ten years in the market area of the Building, Massachusetts, as would qualify such arbitrator as an expert with respect to leasing terms in the market area of the Building. Such arbitrator shall make the determination required pursuant to subsection (b)(ii) within thirty (30) days after selection. The parties shall share equally the fees and expenses of the arbitrator to whom the determination of Market Rent is submitted. Landlord and Tenant shall each pay the fee of the arbitrator selected by it.

11. Brokers. Each of Landlord and Tenant represents to the other that it has not dealt with any person in connection with this Amendment other than officers or employees of Landlord and Jones Lang LaSalle. Tenant shall indemnify and save Landlord harmless from and against all claims, liabilities, costs and expenses incurred as a result of any breach of the foregoing representation by Tenant. Landlord shall indemnify and save Tenant harmless from and against all claims, liabilities, costs and expenses incurred as a result of any breach of the foregoing representation by Landlord. Landlord shall be solely responsible for the brokerage commission owing to Jones Lang LaSalle in connection with this Amendment in accordance with a separate agreement.

12. Inconsistencies: Continuing Effect of Lease. To the extent that the provisions of this Amendment are inconsistent with the provisions of the Lease, the provisions of this Amendment will control and the Lease will be deemed to be amended hereby. Except as amended by this Amendment, the provisions of the Lease remain in full force and effect.

13. Multiple Counterparts. This Amendment may be executed in multiple counterparts, each of which will be an original, but all of which, taken together, will constitute one and the same Amendment.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment as of the date first set forth above.

LANDLORD:

100 DISCOVERY PARK DE, LLC

By: /s/ Robert A. Schlager
Name: Robert A. Schlager
Title: Vice President

TENANT:

GENOCEA BIOSCIENCES, INC.

By: /s/ Derek Meisner
Name: Derek Meisner
Title: SVP, General Counsel

EXHIBIT C

BUILDING FLOOR PLAN (FIFTH FLOOR)

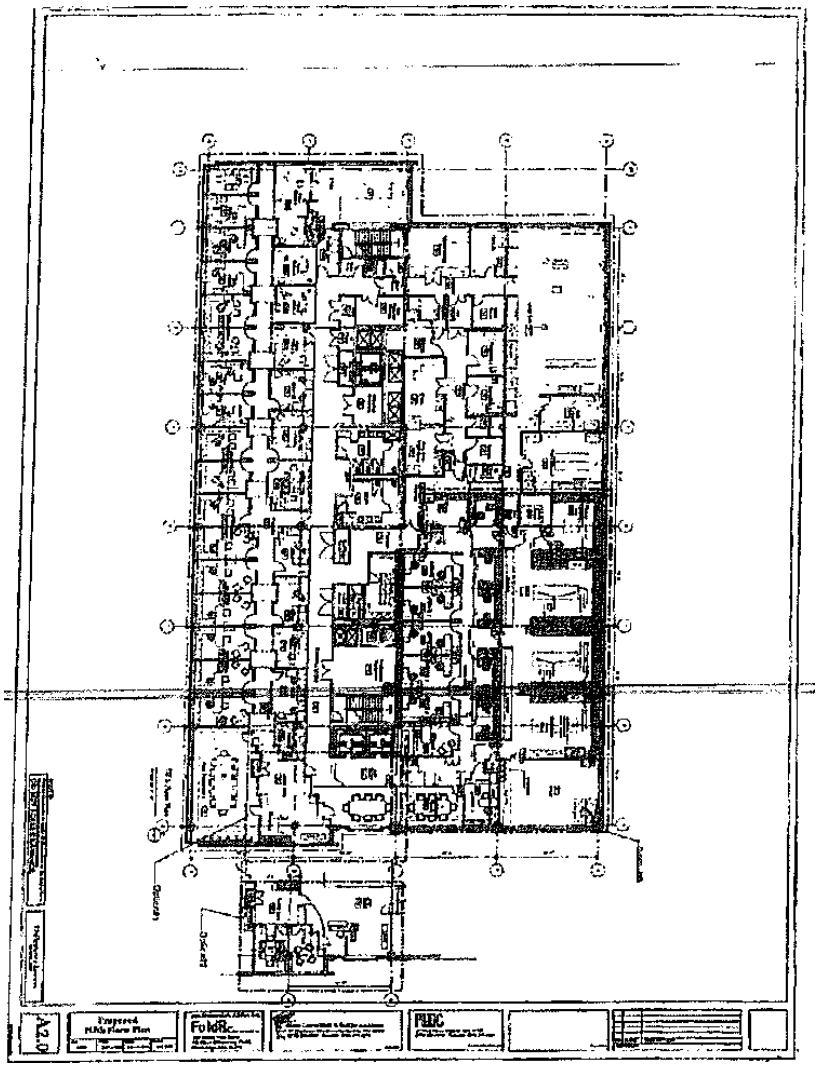

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EXHIBIT C CONT'D.

BUILDING FLOOR PLAN (SIXTH FLOOR)

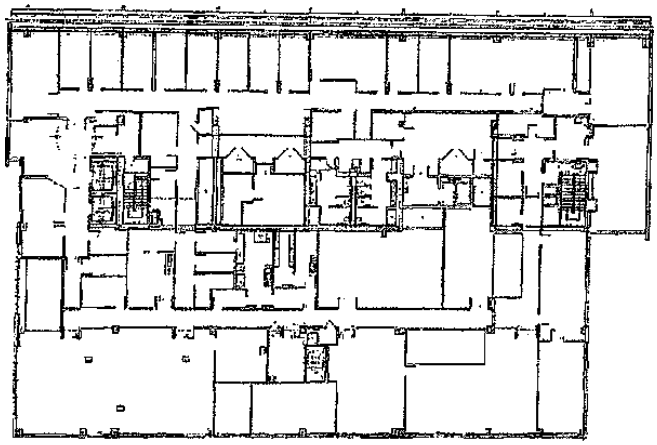

EXHIBIT C-1

BUILDING FLOOR PLAN (FIRST FLOOR)

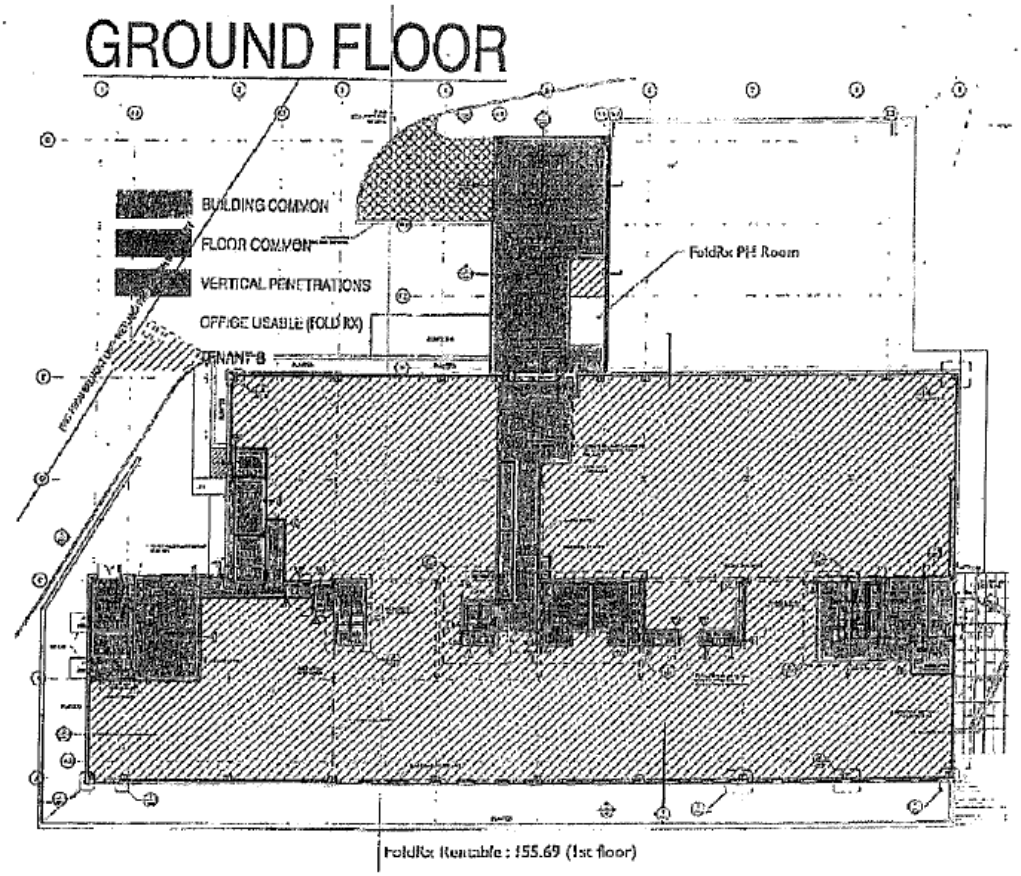

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statements (Form S-3 Nos. 333-225086, 333-230577) of Genocea Biosciences, Inc.
(2) Registration Statements (Form S-8 Nos. 333-230062, 333-223129, 333-216183, 333-209576, 333-202333 and 333-197127) pertaining to the Amended and Restated 2014 Equity Incentive Plan of Genocea Biosciences, Inc.,
(3) Registration Statement (Form S-8 No. 333-226655) pertaining to the Amended and Restated 2014 Equity Incentive Plan, 2014 Employee Stock Purchase Plan, as amended, and common stock issuable pursuant to Narinderjeet Singh Inducement Stock Option Agreement of Genocea Biosciences, Inc.,
(4) Registration Statement (Form S-8 No. 333-194021) pertaining to the Amended and Restated 2007 Equity Incentive Plan and 2014 Equity Incentive Plan of Genocea Biosciences, Inc., and

of our report dated February 13, 2020, with respect to the consolidated financial statements of Genocea Biosciences, Inc. included in this Annual Report (Form 10-K) of Genocea Biosciences, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 13, 2020

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

/s/ WILLIAM D. CLARK

William D. Clark
President and Chief Executive Officer and Director
(Principal Executive Officer)

Date: February 13, 2020

Exhibit 31.2

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

I, Diantha Duvall, Chief Financial Officer (Principal Financial and Accounting Officer), certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ DIANTHA DUVALL

Diantha Duvall
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: February 13, 2020

Exhibit 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Genocea Biosciences, Inc. (the "Company") for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, William D. Clark, as the President and Chief Executive Officer and Director of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

/s/ WILLIAM D. CLARK
William D. Clark*
President and Chief Executive Officer and Director

Date: February 13, 2020

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

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

Exhibit 32.2

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Genocea Biosciences, Inc. (the "Company") for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Diantha Duvall, as the Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

/s/ DIANTHA DUVALL

Diantha Duvall*
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: February 13, 2020

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

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