GENOCEA BIOSCIENCES, INC.

FORM 10-Q
(Quarterly Report)

Filed 11/03/17 for the Period Ending 09/30/17

Address	100 ACORN PARK DRIVE
	CAMBRIDGE, MA, 02140
Telephone	617-876-8191
CIK	0001457612
Symbol	GNCA
SIC Code	2836 - Biological Products, (No Diagnostic Substances)
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2017

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)	(IRS Employer Identification No.)
100 Acorn Park Drive **Cambridge, Massachusetts**	**02140**
(Address of Principal Executive Offices)	(Zip Code)

(617) 876-8191

(Registrant's Telephone Number, Including Area Code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). **Yes** ☒ **No** ☐

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

Large accelerated filer	☐		Accelerated filer	☒
Non-accelerated filer	☐	(Do not check if a smaller reporting company)	Smaller reporting company	☐
			Emerging growth company	☒

If an emerging growth company, indicate by 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** ☒

As of November 1, 2017 , there were 28,704,164 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed in our Annual Report on Form 10-K and other filings with the Securities Exchange Commission (the “SEC”), including the following:

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

Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Information in this Quarterly Report on Form 10-Q that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained any industry, business, market or other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

Genocea Biosciences, Inc.
Form 10-Q
For the Quarter Ended September 30, 2017

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

Genocea Biosciences, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands)

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 21,983	$ 27,424
Investments, current portion	—	35,938
Prepaid expenses and other current assets	1,309	926
Total current assets	23,292	64,288
Property and equipment, net	4,000	4,871
Restricted cash	316	316
Other non-current assets	436	421
Total assets	$ 28,044	$ 69,896
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,129	$ 3,043
Accrued expenses and other current liabilities	6,321	4,178
Current portion of long-term debt	6,538	3,149
Total current liabilities	14,988	10,370
Non-current liabilities:		
Long-term debt	9,244	13,809
Other non-current liabilities	126	176
Total liabilities	24,358	24,355
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock	29	28
Additional paid-in-capital	257,118	252,996
Accumulated deficit	(253,461)	(207,483)
Total stockholders' equity	3,686	45,541
Total liabilities and stockholders' equity	$ 28,044	$ 69,896

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Grant revenue	$ —	$ —	$ —	$ 235
Operating expenses:				
Research and development	10,155	8,811	31,324	22,821
General and administrative	3,750	3,619	10,955	11,569
Restructuring costs	2,591	—	2,591	—
Refund of research and development expense	—	—	—	(1,592)
Total operating expenses	16,496	12,430	44,870	32,798
Loss from operations	(16,496)	(12,430)	(44,870)	(32,563)
Other income and expense:				
Interest income	63	103	211	323
Interest expense	(435)	(438)	(1,319)	(1,299)
Total other income and expense	(372)	(335)	(1,108)	(976)
Net loss	$ (16,868)	$ (12,765)	$ (45,978)	$ (33,539)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	—	(9)	—	15
Comprehensive loss	$ (16,868)	$ (12,774)	$ (45,978)	$ (33,524)
Net loss per share - basic and diluted	$ (0.59)	$ (0.45)	$ (1.61)	$ (1.18)
Weighted-average number of common shares used in computing net loss per share	28,666	28,370	28,568	28,267

See accompanying notes to unaudited condensed consolidated financial statements.

Genocea Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2017	**2016**
Operating activities		
Net loss	$ (45,978)	$ (33,539)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,234	1,309
Stock-based compensation	3,268	3,113
Non-cash interest expense	383	356
Asset impairment	1,001	—
Changes in operating assets and liabilities	667	(1,342)
Net cash used in operating activities	(39,425)	(30,103)
Investing activities		
Purchases of property and equipment	(1,248)	(1,968)
Proceeds from maturities of investments	36,089	58,891
Purchases of investments	(153)	(18,755)
Net cash provided by investing activities	34,688	38,168
Financing activities		
Proceeds from equity offerings, net of issuance costs	246	815
Repayment of long-term debt	(1,559)	—
Proceeds from exercise of stock options	459	166
Proceeds from the issuance of common stock under ESPP	150	112
Net cash (used in) provided by financing activities	(704)	1,093
Net (decrease) increase in cash and cash equivalents	$ (5,441)	$ 9,158
Cash and cash equivalents at beginning of period	27,424	17,259
Cash and cash equivalents at end of period	$ 21,983	$ 26,417
Supplemental cash flow information		
Cash paid for interest	$ 922	$ 943
Property and equipment included in accounts payable and accrued expenses	$ 33	$ 293

See accompanying notes to unaudited condensed consolidated financial statements.

Genocea Biosciences, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

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 vaccines through its AnTigen Lead Acquisition System ("ATLAS ™ ") proprietary discovery platform. The ATLAS platform is designed to recall a patient's pre-existing CD4+ and CD8+ T cell immune responses to their tumor to identify neoantigens and antigens for inclusion in vaccines that are designed to act through T cell (or cellular) immune responses. The Company believes that using ATLAS to identify neoantigens and antigens for inclusion in cancer vaccines could lead to more immunogenic and efficacious cancer vaccines.

In September 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines. Currently, all of the Company’s research programs and product candidates in active development are at the preclinical stage. The Company's most advanced program in active development is its preclinical immuno-oncology program, GEN-009, a neoantigen cancer vaccine. The GEN-009 program leverages ATLAS to identify patient neoantigens, or newly formed antigens unique to each patient, that are associated with that individual's tumor. The Company is also exploring partnering opportunities in the development of cancer vaccines targeting tumor-associated antigens and a vaccine targeting cancers caused by Epstein-Barr Virus ("EBV").

The Company has one Phase 3-ready product candidate, GEN-003, an investigational immunotherapy for the treatment of genital herpes. In September 2017, the Company announced it was exploring strategic alternatives for GEN-003. Consequently, substantially all GEN-003 spending and activities were ceased and the Company reduced its workforce by approximately 40 percent .

The Company is devoting substantially all of its efforts to product research and development, initial market development, and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other preclinical stage companies, including dependence on key individuals, competition from other companies, the need and related uncertainty associated with the development of commercially viable products, and the need to obtain adequate additional financing to fund the development of its product candidates. The Company is also subject to a number of risks similar to other companies in the life sciences industry, including the uncertainty of success of its preclinical and clinical trials, regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability, and dependence on key individuals. The Company anticipates that it will continue to incur significant operating losses for the next several years as it continues to develop its product candidates.

Liquidity

As of September 30, 2017 , the Company had an accumulated deficit of approximately $253.5 million . The Company had cash and cash equivalents of $22.0 million at September 30, 2017 , which it believes is not sufficient to fund the Company’s current operating plan for at least the next twelve months from the date of filing this Quarterly Report on Form 10-Q. The Company expects to seek additional funds through equity or debt financings or proceeds from business development. It may be unable to obtain funds from equity or debt financings or proceeds from business development and, if necessary, the Company will be required to implement further cost reduction strategies, including ceasing development of GEN-009 and all corporate activities. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying condensed 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 condensed 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.

At-the-market equity offering program

On March 2, 2015, the Company entered into a Sales Agreement with Cowen and Company, LLC (the "Sales Agreement") to establish an at-the-market equity offering program (“ATM”) pursuant to which it was able to offer and sell up to

$40 million of its Common Stock at prevailing market prices from time to time. On May 8, 2015, the Sales Agreement was amended to increase the offering amount under the ATM to $50 million of its Common Stock. In January 2017, the Company sold 52 thousand shares and received $0.2 million in net proceeds after deducting commissions. In April 2016, the Company sold 136 thousand shares and received $0.8 million in net proceeds after deducting commissions.

2. Summary of significant accounting policies

Basis of presentation and use of estimates

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and the instructions of Form 10-Q and Article 10 of Regulation S-X. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These interim condensed financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position as of September 30, 2017 and results of operations for the three and nine months ended September 30, 2017 and 2016 .

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full fiscal year. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2016 and the notes thereto which are included in the Company's Annual Report on Form 10-K, as filed with the SEC on February 17, 2017.

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

Cash, cash equivalents and investments

The Company determines the appropriate classification of its investments at the time of purchase. All liquid investments with original maturities of three months or less from the purchase date are considered to be cash equivalents. The Company's current and non-current investments are comprised of certificates of deposit and government agency securities that are classified as available-for-sale in accordance with ASC 320, *Investments—Debt and Equity Securities* . The Company classifies investments available to fund current operations as current assets on its balance sheets. Investments are classified as non-current assets on the balance sheets if (i) the Company has the intent and ability to hold the investments for a period of at least one year and (ii) the contractual maturity date of the investments is greater than one year.

Available-for-sale investments are recorded at fair value, with unrealized gains or losses included in Accumulated other comprehensive income (loss) on the Company's balance sheets. Realized gains and losses are determined using the specific identification method and are included as a component of Interest income or Interest expense, respectively. There were no realized gains or losses recognized for the nine months ended September 30, 2017 and 2016 .

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than-temporary, the Company considers its intent to sell, or whether it is more likely than not that the Company will be required to sell the investment before recovery of the investment's amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, the severity and the duration of the impairment and changes in value subsequent to period end. As of September 30, 2017 , there were no investments with a fair value that was significantly lower than the amortized cost basis or any investments that had been in an unrealized loss position for a significant period.

Fair value of financial instruments

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

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

- Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.
- Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Financial instruments measured at fair value on a recurring basis include cash equivalents and investments (Note 3). The Company is also required to disclose the fair value of financial instruments not carried at fair value. The fair value of the Company's debt (Note 5) is determined using current applicable rates for similar instruments as of the balance sheet dates and an assessment of the credit rating of the Company. The carrying value of the Company's debt approximates fair value because the Company's interest rate yield is near current market rates for comparable debt instruments. The Company's debt is considered a Level 3 liability within the fair value hierarchy.

For the nine months ended September 30, 2017 , there were no transfers among Level 1, Level 2, or Level 3 categories. Additionally, there were no changes to the valuation methods utilized by the Company during the nine months ended September 30, 2017 .

Recently issued accounting standards

Standard	Description	Effect on the financial statements
ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*	The standard will replace existing revenue recognition standards and significantly expand the disclosure requirements for revenue arrangements. It may be adopted either retrospectively or on a modified retrospective basis to new contracts and existing contracts with remaining performance obligations as of the effective date. In July 2015, the FASB affirmed its proposal to defer the effective date of the new revenue standard for all entities by one year. As a result, public business entities will be required to apply the new revenue standard to annual reporting periods beginning after December 15, 2017. The standard will become effective for us on January 1, 2018 (the first quarter of our 2018 fiscal year).	The Company does not currently have and has never had any contracts that are within the scope of ASC 606 or its predecessor guidance, ASC 605 *Revenue Recognition* . The Company will evaluate the ASC 606 accounting considerations when it has a contract that is within its scope.
ASU 2016-02, *Leases (Topic 842)*	In February 2016, the FASB issued ASU 2016-02, which replaces the existing lease accounting standards. The new standard requires a dual approach for lessee accounting under which a lessee would account for leases as finance (also referred to as capital) leases or operating leases. Both finance leases and operating leases will result in the lessee recognizing a right-of-use asset and corresponding lease liability. For finance leases the lessee would recognize interest expense and amortization of the right-of-use asset and for operating leases the lessee would recognize straight-line total lease expense. ASU 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018.	The Company generally does not finance purchases of equipment but it does lease office and lab facilities. The Company is in the process of evaluating the effect that this ASU will have on its consolidated financial statements and related disclosures.
ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*	In November 2016, the FASB issued ASU 2016-18, which requires additional disclosures related to restricted cash. The new standard requires that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017.	The Company does not expect the adoption of this standard to have a material effect on its consolidated financial statements.

3. Cash, cash equivalents and investments

As of September 30, 2017 , cash and cash equivalents comprised of funds in depository and money market accounts. As of December 31, 2016 , cash, cash equivalents and investments comprised of funds in depository, money market accounts, U.S. treasury securities, and FDIC-insured certificates of deposit.

The following table presents the cash equivalents and investments carried at fair value in accordance with the hierarchy defined in Note 2 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2017				
Money market funds, included in cash equivalents	$ 21,282	$ 21,282	$ —	$ —
Total	$ 21,282	$ 21,282	$ —	$ —
December 31, 2016				
Money market funds, included in cash equivalents	$ 25,602	$ 25,602	$ —	$ —
Certificates of deposit, included in cash equivalents	992	—	992	—
Investments - U.S. treasuries	16,508	16,508	—	—
Investments - certificates of deposit	19,429	—	19,429	—
Total	$ 62,531	$ 42,110	$ 20,421	$ —

Cash equivalents and investments have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. The Company validates the prices provided by its third party pricing services by reviewing their methods and obtaining market values from other pricing sources. After completing its validation procedures, the Company did not adjust any fair value measurements provided by the pricing services as of September 30, 2017 and December 31, 2016 .

Cash equivalents and investments at December 31, 2016 consisted of the following (in thousands):

	Contractual Maturity	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasuries	31-181 days	$ 16,508	$ —	$ —	$ 16,508
Certificates of deposit	4-180 days	20,421	—	—	20,421
Total		$ 36,929	$ —	$ —	$ 36,929

4. Accrued expenses and other current liabilities

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

	September 30, 2017	December 31, 2016
Research and development costs	$ 2,670	$ 1,239
Payroll and employee-related costs	2,626	2,090
Other current liabilities	1,025	849
Total	$ 6,321	$ 4,178

5. Long-term debt

2014 Term Loan, First Amendment

On November 20, 2014 (the "Closing Date"), the Company entered into a loan and security agreement (the “Loan Agreement”) with Hercules Technology Growth Capital, Inc. (“Hercules”), which provided up to $27.0 million in debt financing in three separate tranches (the “2014 Term Loan”). The first tranche of $17.0 million was available through June 30, 2015, of which $12.0 million was drawn down at loan inception and for which approximately $9.8 million of the proceeds were used to repay all outstanding indebtedness under the previously existing $10.0 million loan agreement (the "2013 Term Loan"). The option to draw down the remaining $5.0 million under the first tranche expired unused on June 30, 2015. The second tranche of $5.0 million was subject to certain eligibility requirements which were achieved as of June 30, 2015 and the Company had the option to draw down the second tranche on or prior to December 15, 2015. The second tranche expired unused on December 15, 2015. The

third tranche of $5.0 million was not eligible to draw as the Company did not achieve positive results from its Phase 2a human challenge study of GEN-004.

In December 2015, the Company amended the Loan Agreement (the "First Amendment") with Hercules. The First Amendment required the Company to draw an additional $5.0 million and permits it to draw two additional $5.0 million tranches. One $5.0 million tranche was immediately available to draw through December 15, 2016 and a second $5.0 million tranche could have become available through December 15, 2016, subject to the Company demonstrating sufficient evidence of continued clinical progression of its GEN-003 product candidate and making favorable progress in applying its proprietary technology platform toward the development of novel immunotherapies with application in oncology. Both tranches expired unused at December 31, 2016, and $15.4 million was outstanding under the amended 2014 Term Loan at September 30, 2017 .

2014 Term Loan

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

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

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

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

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

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

Events of default under the Loan Agreement include failure to make any payments of principal or interest as due on any outstanding indebtedness, breach of any covenant, any false or misleading representations or warranties, insolvency or bankruptcy, any attachment or judgment on the Company's assets of at least $100 thousand, or the occurrence of any material default of the

Company involving indebtedness in excess of $100 thousand. If an event of default occurs, repayment of all amounts due under the Loan Agreement may be accelerated by Hercules, including the applicable prepayment charge.

The 2014 Term Loan is automatically redeemable upon a change in control. The Company must prepay the outstanding principal and any accrued and unpaid interest through the prepayment date including any unpaid agent's and lender's fees and expenses accrued to the date of the repayment including the End of Term Charge and the applicable Prepayment Charge. If a change in control occurs, repayment of amounts due under the Loan Agreement may be accelerated by Hercules. 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 September 30, 2017.

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

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

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

The Company incurred $0.3 million in debt financing costs related to the First Amendment, which was recorded as a debt discount and will be amortized over the remaining loan term. In connection with the issuance of the 2014 Term Loan, the Company incurred $0.1 million of financing costs and also reimbursed Hercules $0.2 million for debt financing costs, which has been recorded as a debt discount and will be amortized over the remaining loan term. The End of Term Charge is amortized ratably over the term loan period based upon the outstanding debt and the increase in the amount of End of Term Charge due to the additional borrowing from the First Amendment is being amortized from the First Amendment date through maturity. The debt discount is being amortized to interest expense over the life of the 2014 Term Loan using the effective interest method. At September 30, 2017 , the 2014 Term Loan bears an effective interest rate of 10.2% .

As of September 30, 2017 and December 31, 2016 , the Company had outstanding borrowings under the 2014 Term Loan of $15.4 million and $17.0 million , respectively. Interest expense related to the 2014 Term Loan was $0.4 million and $1.3 million for the three and nine months ended September 30, 2017 and 2016 , respectively.

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

	September 30, 2017
2017	$ 1,590
2018	6,659
2019	8,034
Total	$ 16,283

6. Commitments and contingencies

Lease commitments

In May 2016, the Company entered into a lease amendment (the "2016 Lease") for office and laboratory space currently occupied under an original lease that commenced in March 2014 and was set to expire in February 2017 (the "2014 Lease"). The 2016 Lease extended the 2014 Lease by three years through February 2020. In June 2015, the Company signed a second operating lease (the "2015 Lease") for office space in the same building as the 2014 Lease. In August 2016, the Company exercised a three -year renewal option extending the 2015 Lease to February 2020.

The combined minimum future lease payments under both the 2016 Lease and the 2015 Lease are as follows (in thousands):

	September 30, 2017
2017	$ 396
2018	1,607
2019	1,637
2020	274
Total	$ 3,914

At September 30, 2017 and December 31, 2016 , the Company has an outstanding letter of credit of $316 thousand with a financial institution related to a security deposit for the 2016 Lease, which is secured by cash on deposit and expires on February 29, 2020. An additional unsecured deposit was required for the 2015 Lease.

Significant Contracts and Agreements

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

In September 2014, the Company received $1.2 million in the form of a grant entered into with the Bill & Melinda Gates Foundation for the identification of protective T-cell antigens for malaria vaccines. This grant provided for the continued expansion of the Company’s malaria antigen library to aid in the identification of novel protein antigens to facilitate the development of highly efficacious anti-infection malarial vaccines. Activities, and the related grant revenue, were completed under this grant by March 2016.

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

In February 2014, the Company entered into a supply agreement with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. (“Fujifilm”) for the manufacture and supply of antigens for future GEN-003 clinical trials. Under the agreement,
the Company is obligated to pay Fujifilm manufacturing milestones, in addition to reimbursement of certain material
production related costs. Additionally, the Company is responsible for the partial prepayment of manufacturing fees to reserve manufacturing slots in the production timeframe. In June and September 2016, the Company entered into new statements of work

under the agreement with Fujifilm for the manufacture and supply of antigens for the Company's Phase 3 clinical trials for GEN-003. In September 2017, the Company notified Fujifilm to cease all manufacturing activities of antigens for GEN-003. Amounts recorded as of September 30, 2017 represent all liabilities for services completed or in process prior to the cancellation date, charges for terminating the contract within a certain timeframe of expected manufacture activities, and materials purchased which cannot be re-used or re-purposed by Fujifilm.

The Company incurred expenses under the agreement of $1.2 million and $3.4 million for the three and nine months ended September 30, 2017 , respectively. The Company incurred expenses under the agreement of $0.5 million and $0.8 million for the three and nine months ended September 30, 2016 , respectively.

Litigation

On October 31, 2017, a putative class action complaint was filed in the U.S. District Court for the District of Massachusetts, naming Genocea Biosciences, Inc., Chief Executive Officer William D. Clark, and Chief Financial Officer Jonathan Poole as defendants. The complaint alleges violations of the Securities Exchange Act of 1934 and Rule 10b-5 in connection with disclosures made in and subsequent to the Company's Quarterly Report on Form 10-Q for the period ending March 31, 2017, filed with the SEC on May 5, 2017 and the Company's announcement of a strategic shift to immuno-oncology on September 25, 2017. The plaintiff seeks to represent a class of shareholders who purchased or otherwise acquired the Company's securities between May 5, 2017 and September 25, 2017. The complaint seeks unspecified damages and costs. The Company intends to vigorously defend itself against this action. The Company is unable at this time to determine whether the outcome of the litigation would have a material impact on its results of operations, financial condition or cash flows. The Company does not have contingency reserves established for any litigation liabilities.

Refund of research and development expense

In August 2009, the Company entered into an exclusive license and collaboration agreement (the "Novavax Agreement") with Isconova AB, a Swedish company which subsequently was acquired by Novavax, Inc. ("Novavax"). Pursuant to the agreement, Novavax granted the Company a worldwide, sublicensable, exclusive license to two patent families, to import, make, have made, use, sell, offer for sale and otherwise exploit licensed vaccine products containing an adjuvant which incorporates or is developed from Matrix-A, Matrix-C and/or Matrix-M technology, in the fields of HSV and chlamydia. Matrix-M is the adjuvant used in GEN-003.

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

The Company provided the research funding solely to benefit the supply plan for the Matrix-M adjuvant to the point that a Phase 1 clinical trial could be initiated. Because of the benefit received from the research funding payments, an assessment of Novavax's financial ability to repay the research funding at the time of the payments, along with the duration of which amounts could be outstanding, the Company concluded the initial research funding should be recorded as research and development expense at the time of payment. In February 2016, upon receipt of the $1.6 million refund including accrued interest, the Company recorded a gain within operating expenses on the Condensed Consolidated Statements of Operations and Comprehensive Loss.

7. Equity and net loss per share

At September 30, 2017 , the Company authorized 175,000,000 shares of common stock at $0.001 par value per share. As of September 30, 2017 , 28,704,164 shares of common stock were issued and outstanding. At December 31, 2016 , 28,446,461 shares of common stock were issued and 28,444,520 shares of common stock were outstanding.

The Company computes basic and diluted earnings (loss) per share using a methodology that gives effect to the impact of outstanding participating securities (the "two-class method"). For both the three and nine -month periods ended September 30, 2017 and 2016 , there is no income allocation required under the two-class method or dilution attributed to weighted average shares outstanding in the calculation of diluted loss per share.

As of September 30, 2017 and December 31, 2016 , the Company had warrants outstanding that represent the right to acquire 77,603 shares of Common Stock, of which 73,725 represented warrants issued to Hercules and 3,878 represented warrants to purchase Common Stock issued in periods prior to the Company's initial public offering ("IPO").

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

	Nine Months Ended September 30,	
	2017	2016
Stock options	4,400	3,794
Restricted stock units	24	—
Warrants	78	78
Outstanding ESPP	31	21
Total	4,533	3,893

Restricted stock

During 2013, a Company director exercised stock options and received 31,092 shares of common stock that were subject to a Stock Restriction and Repurchase Agreement with the Company. Under the terms of the agreement, shares of common stock issued were subject to a vesting schedule and unvested shares were subject to repurchase by the Company. Vesting occurred periodically at specified time intervals and specified percentages. As of September 30, 2017 , all shares of common stock were fully vested.

In May 2017, the Company granted an officer 47,620 units of Restricted Stock ("RSUs") in accordance with the 2014 Equity Incentive Plan and subject to a Restricted Stock Unit Award Agreement with the Company. On the date of grant, 7,937 units of RSUs vested immediately, and another 23,810 units of RSUs will vest on the eighteen month anniversary of the grant date, subject to the continued employment of the officer. The remaining 15,873 units of RSUs, which contained a performance condition of completing a material financing event on or before September 30, 2017, were canceled as the performance criterion was not achieved. As of September 30, 2017, 23,810 units of RSUs remain unvested.

8. Stock and employee benefit plans

Stock-based compensation expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	$ 322	$ 428	$ 1,060	$ 1,234
General and administrative	771	691	2,208	1,879
Total	$ 1,093	$ 1,119	$ 3,268	$ 3,113

Stock options

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

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2016	3,807	$ 5.94	5.94	$ 2,441
Granted	1,455	$ 4.78		
Exercised	(155)	$ 2.95		
Canceled	(707)	$ 5.80		
Outstanding at September 30, 2017	4,400	$ 5.68	7.06	$ —
Exercisable at September 30, 2017	2,357	$ 6.26	5.88	$ —
Vested or expected to vest at September 30, 2017	4,400	$ 5.68	7.06	$ —

Performance-based awards

The Company granted stock awards to certain employees, executive officers and consultants, which contain performance-based vesting criteria. Milestone events are specific to the Company's corporate goals, which include, but are not limited to, certain clinical development milestones, business development agreements and capital fundraising events. Stock-based compensation expense associated with these performance-based stock options is recognized if the performance conditions are considered probable of being achieved, using management's best estimates. The Company determined that none of the performance-based milestones were probable of achievement during the three and nine months ended September 30, 2017 , and accordingly did not recognize stock-based compensation expense for these periods. As of September 30, 2017 , there are 56,336 performance-based common stock awards outstanding for which the probability of achievement was not deemed probable.

Employee stock purchase plan

On February 10, 2014, the Company's board of directors adopted the 2014 Employee Stock Purchase Plan (the "2014 ESPP"). The 2014 ESPP authorizes the initial issuance of up to a total of 200,776 shares of common stock to participating eligible employees. The 2014 ESPP provides for six-month option periods commencing on January 1 and ending June 30 and commencing July 1 and ending December 31 of each calendar year. As of September 30, 2017 , 30,741 shares remain for future issuance under the plan. The Company incurred stock-based compensation expense related to the 2014 ESPP of $23 thousand and $99 thousand for the three and nine months ended September 30, 2017 , respectively, and $45 thousand and $110 thousand for the three and nine months ended September 30, 2016, respectively.

9. Restructuring costs

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

The following table summarizes the impact of the September 2017 restructuring activities for the three and nine months ended September 30, 2017, along with the current liability recorded in the balance sheet as of September 30, 2017 (in thousands):

	Charges incurred during the nine months ended September 30, 2017	Amount paid through September 30, 2017	Less non-cash charges during the nine months ended September 30, 2017	Amount accrued at September 30, 2017
Employee severance, benefits and related costs	$ 1,064	$ —	$ —	$ 1,064
Contract terminations	526	—	—	526
Asset impairments	1,001	—	1,001	—
Total	$ 2,591	$ —	$ 1,001	$ 1,590

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following information should be read in conjunction with the unaudited consolidated financial information and the notes thereto included in this Quarterly Report on Form 10-Q. The following disclosure contains forward-looking statements that involve risk and uncertainties. Our actual results and timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those discussed in our Annual Report on Form 10-K.

Overview

We are a biopharmaceutical company that seeks to discover and develop novel cancer vaccines through our AnTigen Lead Acquisition System ATLAS proprietary discovery platform. The ATLAS platform is designed to recall a patient's pre-existing CD4+ and CD8+ T cell immune responses to their tumor to identify neoantigens and antigens for inclusion in vaccines that are designed to act through T cell (or cellular) immune responses. We believe that using ATLAS to identify neoantigens and antigens for inclusion in cancer vaccines could lead to more immunogenic and efficacious cancer vaccines.

In September 2017, we announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. Currently, all of our research programs and product candidates in active development are at the preclinical stage. Our most advanced program in active development is our preclinical immuno-oncology program, GEN-009, a neoantigen cancer vaccine. The GEN-009 program leverages ATLAS to identify patient neoantigens, or newly formed antigens unique to each patient, that are associated with that individual's tumor. We are also exploring partnering opportunities in the development of cancer vaccines targeting tumor-associated antigens and a vaccine targeting cancers caused by EBV.

We have one Phase 3-ready product candidate, GEN-003, an investigational immunotherapy for the treatment of genital herpes. In September 2017, we announced that we are exploring strategic alternatives for GEN-003. Consequently, substantially all GEN-003 spending and activities were ceased and we reduced our workforce by approximately 40 percent.

Our Immuno-Oncology Program

We are focused on combining our antigen selection and vaccine development expertise with that of leading cancer innovators to unlock new targets in immuno-oncology. Our potential cancer vaccines will be designed to educate T cells to recognize and attack specific targets and thereby kill cancer cells. We are working to develop personalized cancer vaccines by leveraging ATLAS to identify patient neoantigens that are associated with that individual's tumor.

Neoantigens are personalized tumor mutations that are seen as "foreign" by an individual's immune system. Data published in recent years have indicated that an individual's response to neoantigens drives checkpoint inhibitor efficacy and that it is possible to vaccinate an individual against their own neoantigens. Genocea's lead immuno-oncology program, GEN-009, is an adjuvanted neoantigen peptide vaccine candidate designed to direct a patient's immune system to attack their tumor. GEN-009's neoantigen peptides are identified by Genocea's proprietary ATLAS platform, which recalls a patient's pre-existing CD4+ and CD8+ T cell immune responses to their tumor. Following ATLAS neoantigen identification, Genocea will manufacture a personal vaccine for each patient.

We anticipate filing a personalized cancer vaccine investigational new drug ("IND") application with the FDA in early 2018 for GEN-009. We plan to initiate a Phase 1 clinical trial for GEN-009 in a range of tumor types in the first half of 2018 and expect to report initial immunogenicity data in the first half of 2019.

We are also using ATLAS to develop general cancer vaccines targeting tumor-associated, or shared, antigens and vaccines against cancers of viral origin. Our strategy in immuno-oncology combines our own internal neoantigen vaccine development programs with a focus on partnering ATLAS for these other immuno-oncology applications.

Refer to Part I in our Annual Report on Form 10-K, as filed with the SEC on February 17, 2017, under the heading "Business - Our Immuno-Oncology Program" for additional details on this program, including our current collaborations.

In November 2015, we commenced a new program focused on EBV. EBV infection has been linked to cancers with high unmet needs such as non-Hodgkin's lymphoma, nasopharyngeal carcinoma and gastric carcinoma. We believe that ATLAS is highly suited to the creation of a new immunotherapy for EBV, given that T cell responses are understood to be crucial for protection against EBV. Furthermore, EBV is part of the herpes virus family, in which we have deep experience through our prior development of GEN-003. We are currently seeking a partner to advance the development of this vaccine.

GEN-003 — Phase 2 immunotherapy for genital herpes

Prior to our September 2017 strategic shift announcement, our lead program was GEN-003, a Phase 3-ready investigational immunotherapy for the treatment of genital herpes. We completed three positive clinical trials for which key data from those clinical trials is described below. We are currently exploring strategic alternatives to maximize shareholder value from GEN-003, during which time we have ceased substantially all activities under the GEN-003 program.

Phase 1/2 Trial

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

Phase 2 Dose Optimization Trial

A 310-subject Phase 2 dose optimization trial was completed in March 2016. The objective of this trial was to confirm the results of the Phase 1/2a trial and to test six combinations of proteins and adjuvant to determine the optimal dose for future trials and potentially improve on the profile of GEN-003. Subjects were randomized to one of six dosing groups of either 30µg or 60µg per protein paired with one of three adjuvant doses (25 µg, 50 µg, or 75 µg). A seventh group received placebo. Subjects received three doses of GEN-003 or placebo at 21-day intervals. Baseline viral shedding and genital lesion rates were established for each subject in a 28-day observation period prior to the commencement of dosing by collecting 56 genital swab samples (two per day), which were analyzed for the presence of HSV-2 DNA, and by recording the days on which genital lesions were present. This 28-day observation period was repeated immediately after the completion of dosing, and at six and twelve months following dosing. No maintenance doses were given. After the 28-day observation period immediately after dosing, patients in the placebo arm were rolled over across the six active dose combinations under a separate protocol. Subsequent to March 2016, we extended this clinical trial to include a separate protocol for an extension study which includes a 28-day observation period at 24 months post-dosing to evaluate the reduction versus baseline in both the viral shedding rate and the genital lesion rate.

The primary endpoint of the trial was the reduction in viral shedding rate versus baseline, a measure of anti-viral activity. A number of exploratory secondary endpoints were also studied, including, the reduction in genital lesion rates, the percent of patients who were recurrence free from lesions up to six and 12 months after dosing, and the time to first recurrence of lesions after dosing. We advanced the two most promising doses from this dose optimization study, the 60 µg per protein combined with either 50 or 75 µg of Matrix-M2 adjuvant ("60/50 Dose" and "60/75 Dose" respectively), into a Phase 2b efficacy trial for which positive twelve-month, placebo-controlled clinical efficacy data was announced in July 2017 (see Phase 2b trial below).

Phase 2b Trial

In December 2015, a Phase 2b clinical trial was initiated as our first study testing potential Phase 3 endpoints with a Phase 3-ready formulation of GEN-003, manufactured with commercially-scalable processes. The trial enrolled 131 subjects that were randomized to one of three dose groups - placebo, 60/50 Dose, and 60/75 Dose. All subjects received three injections at 21-day intervals.

In September 2016, we announced positive viral shedding rate reductions from the ongoing Phase 2b study. The study achieved its primary endpoint, with GEN-003 demonstrating a statistically significant (versus placebo and baseline) 40% reduction in the viral shedding rate compared to baseline immediately after dosing in the 60/50 Dose group, using a new Phase 3-ready formulation. This result was consistent with a statistically significant (versus placebo and baseline) viral shedding rate reduction of 41% at this same dose and time point in a prior Phase 2 clinical trial. In addition, the reactogenicity profile of this dose, an indication of the strength of the immune response to GEN-003, was consistent between the trials. This same dose in the prior Phase 2 clinical trial subsequently demonstrated virologic and clinical efficacy that was durable for at least one year after dosing.

The 60/75 Dose group reduced the viral shedding rate by 27%, which is lower than the rate observed in the prior trial, and also showed a less acceptable reactogenicity profile than the prior trial. We believe that the increase in reactogenicity of this dose indicates an overstimulation of the T cell immune system leading to the reduced efficacy with this dose in this trial, as would be expected with the known bell-shaped T cell dose response curve. The likely driver of this effect is a more potent adjuvant formulation following customary manufacturing process changes to prepare for Phase 3 clinical trials and commercialization of GEN-003.

The top-line viral shedding rate reductions for all of the dose groups in the trial are summarized in the following table:

	Placebo	60/50 Dose	60/75 Dose
Viral shedding rate reduction (1)	6%	-40%	-27%
Poisson mixed effect model with Empirical Variance			
p-value vs. baseline	0.76	0.03	0.16
p-value vs. placebo	NA	0.05	0.20

(1) Rate reduction vs. pre-dosing levels.

In July 2017, we announced positive clinical results from the Phase 2b trial. At twelve months after dosing, GEN-003 demonstrated statistically significant improvements versus placebo in both the median genital lesion rate and across multiple clinical endpoints. The 60/50 Dose significantly reduced the median rate of genital lesions during the twelve months following dosing compared to placebo (49% reduction versus placebo). The median genital lesion rate is an important overall measure of disease that captures both the frequency and duration of recurrences, both of which are important to both patients and their caregivers. Importantly, these results were achieved at the Phase 3 dose and expected Phase 3 primary endpoint. GEN-003 also consistently demonstrated significant benefits versus placebo across several other clinical endpoints across the dose groups as summarized in the following table:

Endpoint	**60/50 (n=43)**	**60/75 (n=44)**	**Placebo (n=44)**
Number of subjects contributing clinical data	43	44	44
Median genital lesion rate at baseline*	5.2%	4.4%	10.1%
Mean genital lesion rate at baseline*	10.7%	10.4%	12.0%
Median genital lesion rate (percent of days with lesions over 12 months)	**2.3%**	**2.8%**	**4.5%**
Percent reduction versus placebo	(49)%	(37)%	NA
p-value versus placebo (1)	0.01	0.08	NA
Mean genital lesion rate	3.6%	4.7%	7.3%
Median number of recurrences over 12 months	**1.5**	**2.0**	**4.0**
Percent reduction versus placebo	(63)%	(50)%	NA
p-value versus placebo (1)	0.01	0.07	NA
Mean number of recurrences over 12 months	2.7	3.2	4.4
Median duration of recurrences (days)	**2.7**	**4.0**	**3.6**
Percent reduction versus placebo	-25%	11%	NA
p-value versus placebo (1)	0.02	0.92	NA
Mean duration of recurrences (days)	3.2	4.4	4.8
Kaplan-Meier estimate of percent recurrence free 12 months after first dose	**20%**	**16%**	**7%**
p-value versus placebo (2)	0.04	0.07	NA
Kaplan-Meier estimate of percent recurrence free 12 months after last dose	**20%**	**17%**	**8%**
p-value versus placebo (2)	0.12	0.05	NA
Number of subjects contributing shedding data	30	32	31
Viral Shedding Rate Reduction from Baseline at 12 months	**(42)%**	**(39)%**	**(52)%**
p-value versus baseline (3)	0.02	0.07	0.03
p-value versus placebo (3)	0.67	0.61	NA

* Baseline measurements reflect percent of days with genital lesions captured over a period of only 59-68 days prior to the commencement of dosing. Baseline rates will not be captured or used in the calculation of any of the endpoints in Phase 3 trials where post-treatment comparisons are the approvable standard.

Statistical tests pre-specified in Phase 2b trial protocol as follows:
(1) Wilcoxon Rank Sum test

(2) Log rank test
(3) Poisson mixed effect model with empirical variance
NS = p>0.05

We believe the variability in the shedding data observed at the 28-day observation period twelve months after dosing in this Phase 2b trial is a consequence of the sporadic nature of shedding and the small number of subjects who provided data in this Phase 2b trial.

GEN-003 also continues to demonstrate a safety profile appropriate for its therapeutic setting in the judgment of the trial's independent Drug Monitoring Committee. There was no grade 4 reactogenicity or related serious adverse events ("AEs") and discontinuations due to AEs were low and similarly distributed across active dose groups and placebo.

Around the end of the first quarter of 2017, we had a successful end-of-Phase 2 meeting with the U.S Food and Drug Administration ("FDA"). We believe that progress made and data generated to date in the GEN-003 preclinical and clinical trials remains valuable to the Company for the future.

Other infectious disease programs

Our other infectious disease programs include GEN-004, a potential universal *Streptococcus pneumoniae* , or pneumococcus, vaccine to protect against a leading cause of infectious disease mortality worldwide and early stage programs focused on genital herpes prophylaxis, chlamydia, and malaria. In October 2015, we announced that top-line results from the Phase 2a clinical trial for GEN-004 showed consistent reductions versus placebo in the pre-specified endpoints of the rate and density of upper airway colonization in a human challenge model, but that neither of the endpoints achieved statistical significance. GEN-004 was safe and well tolerated by subjects. Although we did not achieve statistical significance in this study and have suspended the development of the GEN-004 program, the consistent apparent effect gives us confidence in the vaccine concept and in future potential for GEN-004. In November 2016, we paused activities on our other early stage programs focused on genital herpes prophylaxis, chlamydia, and malaria in order to focus all of our internal research and pre-clinical resources on our immuno-oncology investments. We believe that progress made and data generated to date in these infectious disease clinical and research programs remains valuable to the Company for the future.

Financing and business operations

We commenced business operations in August 2006. To date, our operations have been limited to organizing and staffing our company, acquiring and developing our proprietary ATLAS technology, identifying potential product candidates and undertaking preclinical studies and clinical trials for our product candidates. All of our revenue to date has been grant revenue. We have not generated any product revenue and do not expect to do so for the foreseeable future. We have primarily financed our operations through the issuance of our equity securities, debt financings and amounts received through grants. As of September 30, 2017 , we had received an aggregate of $279.8 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At September 30, 2017 , our cash and cash equivalents were $22.0 million .

Since inception, we have incurred significant operating losses. Our net losses were $16.9 million and $46.0 million for the three and nine months ended September 30, 2017 , respectively, and our accumulated deficit was $253.5 million as of September 30, 2017 . 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.

For the nine months ended September 30, 2017 , we sold 52 thousand shares under our ATM program and received $0.2 million in net proceeds after deducting commissions. For the nine months ended September 30, 2016 , we sold 136 thousand shares under our ATM program and received $0.8 million in net proceeds after deducting commissions.

We expect that our existing cash and cash equivalents are sufficient to support our operating expenses and capital expenditure requirements into the middle of 2018. We are currently exploring various avenues to secure capital to advance GEN-009 through our planned IND filing in early 2018 and to initiate a Phase 1 clinical trial for GEN-009 in a range of tumor types in the first half of 2018. If we are able to secure such funding, then we would expect to be able to report initial immunogenicity data in the first half of 2019. In the event that we are unsuccessful in securing capital on acceptable terms for some or all of our programs, then we will review our remaining strategic alternatives to maximize shareholder value including, but not limited to, exploring a potential sale of the company or our assets.

Costs related to clinical trials can be unpredictable and therefore there can be no guarantee that our current balances of cash and cash equivalents, and any proceeds received from other sources, will be sufficient to fund our studies or operations through this period. These funds will not be sufficient to enable us to conduct any preclinical or clinical trials for, seek marketing approval for or commercially launch GEN-009 or any other product candidate. Accordingly, to perform preclinical or clinical trials, obtain marketing approval for and to commercialize these or any other product candidates, we will be required to obtain further funding through public or private equity offerings, debt financings, collaboration and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital when needed would have a negative effect on our financial condition and our ability to pursue our business strategy.

Financial Overview

Grant revenue

Grant revenue consists of revenue earned to conduct vaccine development research. We have received grants from private not-for-profit organizations and federal agencies. These grants have related to the discovery and development of several of our product candidates, including product candidates for the prevention of pneumococcus, chlamydia, malaria, and immunotherapy of cancer. Revenue under these grants is recognized as research services are performed. Funds received in advance of research services being performed are recorded as deferred revenue.

We have no products approved for sale and none of our active product candidates are near the point of commercialization. We will not receive any revenue from any product candidates that we develop until we obtain regulatory approval and commercialize such products or until we potentially enter into agreements with third parties for the development and commercialization of product candidates. If our development efforts for any of our product candidates result in regulatory approval or we enter into collaboration agreements with third parties, we may generate revenue from product sales or from such third parties.

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

Research and development expenses

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

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

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

The following table identifies research and development expenses on a program-specific basis for our product candidates as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Genital herpes (GEN-003)(1)	$ 6,378	$ 4,979	$ 19,724	$ 11,339
Immuno-oncology program (2)	2,655	1,269	8,136	2,437
Other research and development (3)	1,122	2,563	3,464	9,045
Total research and development	$ 10,155	$ 8,811	$ 31,324	$ 22,821

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

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

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

We expect our overall research and development expenses will decrease given the strategic shift and restructuring announced in September 2017 that resulted in our ceasing clinical trials for GEN-003. However, we do expect our research and development costs incurred on our immuno-oncology programs to increase as we continue to develop our supply chain and manufacturing capabilities for our GEN-009 program, prepare an IND, prepare for the initiation of clinical trials for GEN-009, and advance our next generation neoantigen vaccine program, GEN-010, in preclinical development.

General and administrative expenses

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

We anticipate that our general and administrative expenses will decrease in the foreseeable future given the strategic shift and restructuring announced in September 2017, that resulted in our ceasing clinical trials for GEN-003, notwithstanding our requirements to operate as a public company. We expect that costs for insurance, hiring activities, and professional services, such as outside consultants, lawyers and accountants, among other expenses, to remain flat or decrease as we refocus on preclinical and early clinical research and development activities. If and when we believe a regulatory approval of our first product candidate appears likely, we anticipate that we will increase our salary and personnel costs and other expenses as a result of our preparation for commercial operations.

Restructuring costs

On September 25, 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. Consequently, substantially all GEN-003 spending and activities were ceased and the Company reduced its workforce by approximately 40 percent as of the quarter ended September 30, 2017. Charges for employee severance and benefits costs, contract terminations, and impaired assets were recognized and recorded in the three months ended September 30, 2017. Asset impairment charges primarily relate to fixed assets specific to GEN-003 research and development activities.

Refund of research and development expenses

The refund of research and development expenses recorded in the nine months ended September 30, 2016 related to a one-time payment received in February 2016 from Novavax pursuant to contractual obligations under the Novavax Agreement that existed to refund research and development expenses paid to Novavax between 2009 and 2012.

Interest income

Interest income consists of interest earned on our cash, cash equivalent and investment portfolio.

Interest expense

Interest expense consists of interest expense on our long-term debt facilities and non-cash interest related to the amortization of debt discount and issuance costs.

Critical Accounting Policies and Significant Judgments and Estimates

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate estimates, which include, but are not limited to, estimates related to clinical trial accruals, prepaid and accrued research and development expenses, stock-based compensation expense and reported amounts of revenues and expenses during the reported period. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances. Actual results may differ materially from those estimates or assumptions.

The critical accounting policies we identified in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2016 related to prepaid and accrued research and development expenses and stock-based compensation. There have been no material changes to our accounting policies from those described in our Annual Report on Form 10-K. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies disclosed in our Annual Report on Form 10-K, as filed with the SEC on February 17, 2017.

Results of Operations

Comparison of the Three Months Ended September 30, 2017 and September 30, 2016

	Three Months Ended September 30,		Increase
(in thousands)	**2017**	**2016**	**(Decrease)**
Grant revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	10,155	8,811	1,344
General and administrative	3,750	3,619	131
Restructuring costs	2,591	—	2,591
Total operating expenses	16,496	12,430	4,066
Loss from operations	(16,496)	(12,430)	4,066
Other income and expenses:			
Interest income	63	103	(40)
Interest expense	(435)	(438)	(3)
Total other income and expense	(372)	(335)	37
Net loss	$ (16,868)	$ (12,765)	$ 4,103

Research and development expenses

Research and development ("R&D") expenses increased $1.3 million in the three months ended September 30, 2017 as compared to the three months ended September 30, 2016 . The increase was due largely to increases in external manufacturing and research related costs (approximately $1.7 million), offset by decreased clinical costs (approximately $0.3 million).

On a program basis, GEN-003 costs increased by $1.4 million for the three months ended September 30, 2017 driven by increased compensation and external manufacturing related expenses (approximately $2.2 million) to support both the Phase 3 clinical drug supply and clinical planning activities in advance of the previously planned Phase 3 trials, partially offset by reduced clinical costs, due to timing of activities in support of our clinical trials. Spending increases on GEN-009 and immuno-oncology

programs (approximately $1.4 million) were driven primarily by increased manufacturing and compensation, consulting and professional services in anticipation of an IND filing in early 2018. Increased spending on these programs was offset by lower costs on deprioritized infectious disease programs.

General and administrative expenses

General and administrative expenses were $3.8 million for the three months ended September 30, 2017 , a $0.1 million increase from the same three month period in 2016. Increases in consulting and professional services of $0.3 million were offset by a $0.2 million reduction in depreciation expense with all other expenditures across various activities remaining consistent with the same quarter in the prior year.

Restructuring costs

On September 25, 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. Consequently, substantially all GEN-003 spending and activities were ceased and the Company reduced its workforce by approximately 40 percent as of the quarter ended September 30, 2017. We incurred a charge of approximately $1.1 million for employee severance, benefits and related costs in the third quarter of 2017 which will be paid in the fourth quarter of 2017. In addition, we incurred approximately $0.5 million of expense due to contract termination clauses that we anticipate will result in future cash payments and approximately $1.0 million in non-cash asset impairment charges.

Interest Income

Interest income of approximately $0.1 million for the three months ended September 30, 2017 was generally consistent with the same quarter in the prior year due to rising investment yields offset by lower invested balances.

Interest Expense

Interest expense was unchanged from the same three month period in 2016. Interest expense consists of interest expense on our long-term debt facilities and non-cash interest related to the amortization of debt discount and issuance costs.

Comparison of the Nine Months Ended September 30, 2017 and September 30, 2016

	Nine Months Ended September 30,		Increase
(in thousands)	**2017**	**2016**	**(Decrease)**
Grant revenue	$ —	$ 235	$ (235)
Operating expenses:			
Research and development	31,324	22,821	8,503
General and administrative	10,955	11,569	(614)
Restructuring costs	2,591	—	2,591
Refund of research and development expense	—	(1,592)	(1,592)
Total operating expenses	44,870	32,798	12,072
Loss from operations	(44,870)	(32,563)	12,307
Other income and expenses:			
Interest income	211	323	(112)
Interest expense	(1,319)	(1,299)	20
Total other income and expense	(1,108)	(976)	132
Net loss	$ (45,978)	$ (33,539)	$ 12,439

Grant revenue

We did not record any grant revenue in the nine months ended September 30, 2017 as compared to $0.2 million in the nine months ended September 30, 2016 . The $0.2 million decrease was due to the completion of work, as of March 31, 2016, related to a $1.2 million grant entered into with the Bill & Melinda Gates Foundation in September 2014.

Research and development expenses

Research and development expenses increased $8.5 million in the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016 . Higher research and development spending was due largely to increases in external manufacturing and research related costs (approximately $5.3 million), compensation, consulting and professional services (approximately $2.8 million), depreciation and facility costs (approximately $0.4 million), offset by decreased clinical costs (approximately $0.3 million). The remaining increases, all insignificant by spending category, are attributable to the overall growth of the research and development function.

On a program basis, GEN-003 costs increased by $8.4 million for the nine months ended September 30, 2017 driven by increased external manufacturing related expenses (approximately $4.9 million) to support the Phase 3 clinical drug supply and increases in headcount and consulting and professional service costs (approximately $4.4 million) in advance of the previously planned Phase 3 trials. Spending increases on GEN-009 and immuno-oncology programs (approximately $5.7 million) were driven primarily by increased manufacturing (approximately $1.7 million) and compensation, consulting and professional services (approximately $2.5 million) in anticipation of an IND filing in early 2018. Increased spending on these programs was offset by lower costs on deprioritized infectious disease programs.

General and administrative expenses

General and administrative expenses decreased $0.6 million in the nine months ended September 30, 2017 reflecting lower office and facility costs and depreciation costs partially offset by higher compensation, consulting and professional services costs.

Restructuring costs

On September 25, 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. Consequently, substantially all GEN-003 spending and activities were ceased and the Company reduced its workforce by approximately 40 percent as of the quarter ended September 30, 2017. We incurred a charge of approximately $1.1 million for employee severance, benefits and related costs in the third quarter of 2017 which will be paid in the fourth quarter of 2017. In addition, we incurred approximately $0.5 million of expense due to contract termination clauses that we anticipate will result in future cash payments and approximately $1.0 million in non-cash asset impairment charges.

Refund of research and development costs

In February 2016, we recorded a gain upon receipt of $1.6 million, including accrued interest, pursuant to contractual obligations under the Novavax Agreement to refund research and development expenses paid to Novavax between 2009 and 2012.

Interest Income

Interest income decreased approximately $0.1 million for the nine months ended September 30, 2017 due to lower invested balances due to working capital needs to fund operations.

Interest Expense

Interest expense was unchanged from the same nine month period in 2016. Interest expense consists of interest expense on our long-term debt facilities and non-cash interest related to the amortization of debt discount and issuance costs.

Liquidity and Capital Resources

Overview

Since our inception through September 30, 2017 , we have received an aggregate of $279.8 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At September 30, 2017 , our cash and cash equivalents were $22.0 million .

For the nine months ended September 30, 2017 , we sold 52 thousand shares under our ATM program and received $239 thousand in net proceeds after deducting commissions.

Debt Financings

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

In December 2015, we entered into an amendment to the Loan Agreement (the "First Amendment") with Hercules. The First Amendment required us to draw an additional $5.0 million and permitted us to draw two additional $5.0 million tranches. One $5.0 million tranche was immediately available to draw through December 15, 2016 and a second $5.0 million tranche could have become available through December 15, 2016, subject to the Company demonstrating sufficient evidence of continued clinical progression of its GEN-003 product candidate and making favorable progress in applying its proprietary technology platform toward the development of novel immunotherapies with application in oncology. Both tranches expired unused at December 31, 2016, and $15.4 million was outstanding under the amended 2014 Term Loan at September 30, 2017 .

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

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

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

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

Operating Capital Requirements

Our primary uses of capital are for compensation and related expenses, manufacturing costs for pre-clinical and clinical materials, third party clinical trial R&D services, laboratory and related supplies, clinical costs, legal and other regulatory expenses, and general overhead costs. We 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 operating expenses and capital expenditure requirements into the middle of 2018. We are currently exploring various avenues to secure capital to advance GEN-009 through our Phase 1 clinical trial, which we expect to initiate in the first half of 2018. If we are able to secure such funding, then we would expect to be able to report initial immunogenicity data in the first half of 2019. In the event that we are unsuccessful in securing capital on acceptable terms we will review our remaining strategic alternatives to maximize shareholder

value including, but not limited to, exploring a potential sale of the company or our assets and/or a shut-down of company activities. These factors 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 initiation, progress, timing, costs and results of preclinical studies and clinical trials for our other product candidates and potential product candidates;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for GEN-009 and other product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- the receipt of marketing approval;
- revenue received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, grants, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the extent to which we in-license or acquire other products and technologies.

We will need to obtain substantial additional funding in order to commence and complete clinical trials for GEN-009 and our other product candidates in order to receive regulatory approval. To the extent that we raise additional capital through the sale of Common Stock, convertible securities or other equity securities, the ownership interests of our existing stockholders may be materially diluted and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. In addition, debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely affect our ability to conduct our business. If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back or discontinue the development of GEN-009 or our other product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to GEN-003, GEN-009 or our other product candidates that we otherwise would seek to develop or commercialize ourselves. We are currently exploring various avenues to secure capital to advance GEN-009 through its Phase 1 clinical trial, which we expect to initiate in the first half of 2018. If we are able to secure such funding, then we would expect to be able to report initial immunogenicity data in the first half of 2019. We do not intend to commence Phase 1 clinical trials for GEN-009 unless we are able to secure such capital.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods below (in thousands):

	Nine Months Ended September 30,	
	2017	2016
Net cash used in operating activities	$ (39,425)	$ (30,103)
Net cash provided by investing activities	34,688	38,168
Net cash provided by financing activities	(704)	1,093
Net (decrease) increase in cash and cash equivalents	$ (5,441)	$ 9,158

Operating Activities

Net cash used in operations increased by approximately $9.3 million to $39.4 million for the nine months ended September 30, 2017 from $30.1 million for the nine months ended September 30, 2016 . The increase in net cash used was due primarily to a higher net loss of approximately $11.8 million offset by $1.0 million of non-cash asset impairment charges and $1.4 million of changes in our working capital accounts

Investing Activities

Net cash provided by investing activities was $34.7 million for the nine months ended September 30, 2017 compared to $38.2 million for the nine months ended September 30, 2016 as proceeds from maturities of investments, net of investments made, used to fund operations decreased approximately $4.2 million. The decrease in net investment proceeds was offset by a decrease in capital expenditures of $0.7 million.

Financing Activities

Net cash provided by financing activities decreased $1.8 million for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 . Debt principal repayments of $1.6 million combined with $0.2 million in lower net proceeds from other equity transactions resulted in a net cash usage from financing activities at September 30, 2017 .

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K, as filed with the SEC on February 17, 2017.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risk related to changes in interest rates. As of September 30, 2017 , we had cash and cash equivalents of $22.0 million compared to cash, cash equivalents and investments of $63.4 million at December 31, 2016 , consisting primarily of money market funds, U.S Treasury securities, and FDIC insured certificates of deposits. The investments in these financial instruments are made in accordance with an investment policy approved by our Board of Directors, which specifies the categories, allocations and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments in which we invest could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio that may include cash, cash equivalents and investment securities available-for-sale in a variety of securities, which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations or our financial position would be materially affected by an immediate change of 10% in interest rates.

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

We are also exposed to market risk related to change in foreign currency exchange rates. We contract with certain vendors that are located in Europe which have contracts denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign exchange rate risk. As of September 30, 2017 and December 31, 2016 , we had minimal liabilities denominated in foreign currencies.

Item 4. Controls and Procedures

Management's Evaluation of our 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 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2017 (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). 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 September 30, 2017 , our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the nine months ended September 30, 2017 , 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 Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. 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. Except as discussed below, 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.

On October 31, 2017, a putative class action complaint was filed in the U.S. District Court for the District of Massachusetts, naming Genocea Biosciences, Inc., Chief Executive Officer William D. Clark, and Chief Financial Officer Jonathan Poole as defendants. The complaint alleges violations of the Securities Exchange Act of 1934 and Rule 10b-5 in connection with disclosures made in and subsequent to our Quarterly Report on Form 10-Q for the period ending March 31, 2017, filed with the SEC on May 5, 2017 and our announcement of a strategic shift to immuno-oncology on September 25, 2017. The plaintiff seeks to represent a class of shareholders who purchased or otherwise acquired our securities between May 5, 2017 and September 25, 2017. The complaint seeks unspecified damages and costs. We intend to vigorously defend ourselves against this action. We are unable at this time to determine whether the outcome of the litigation would have a material impact on our results of operations, financial condition or cash flows.

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 unaudited condensed consolidated financial statements for the quarter ended September 30, 2017 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. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to obtain necessary capital from outside sources, including obtaining additional capital from the sale of our securities or assets, obtaining loans and grant awards from financial institutions and/or government agencies where possible or entering into partnership arrangements. Our continued net operating losses increase the difficulty in obtaining such capital, and there can be no assurances that we will be able to obtain such capital on favorable terms or at all. If we are unable to obtain sufficient capital from the sale of our securities or from alternative sources, we may be required to reduce, defer, or discontinue certain or all of our research and development activities, including discontinuing development of GEN-009, or we may not be able to continue as a going concern. For example, in September 2017, we ceased substantially all spending and activities related to GEN-003, pending our exploration of strategic alternatives for advancing that product candidate.

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 $46.0 million for the nine months ended September 30, 2017 and $49.6 million and $42.5 million for the years ended December 31, 2016 and 2015, respectively. As of September 30, 2017 and December 31, 2016, we had accumulated deficits of approximately $253.5 million and $207.5 million, respectively. To date, we have not commercialized any products or generated any revenues from the sale of products and have financed our operations primarily through private placements of our preferred stock, debt financing, our initial public offering ("IPO") completed in February 2014, and follow-on public offerings in March 2015 and August 2015 and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate product revenues or become profitable.

We have devoted most of our financial resources to research and development, including our clinical and non-clinical technology development and development activities. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or additional grants. We have not completed pivotal clinical studies for any product candidate and, as we have ceased development of our most advanced clinical-stage product candidate, GEN-003, and are instead focusing on our earlier stage neoantigen cancer vaccine product candidates, 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:

- file an IND application and initiate clinical trials for GEN-009, our most advanced product candidate in active development focused on neoantigen cancer vaccines, and initiate non-clinical or clinical studies for our other product candidates;
- manufacture material for clinical trials and for commercial sale;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to discover and develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- make royalty milestone or other payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

The net losses 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 September 30, 2017, our cash and cash equivalents were $22.0 million. We believe that we will continue to expend substantial resources for the foreseeable future developing GEN-009 and any other neoantigen cancer vaccine product candidates. These expenditures will include costs associated with research and development, potentially acquiring new technologies, potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for

sale, if any. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Furthermore, because of the significant expense associated with conducting clinical trials, we cannot be certain we will have sufficient capital to complete such trials for a given product candidate.

Our future capital requirements depend on many factors, including:

- the costs associated with filing an IND application and initiating our planned Phase 1 program for GEN-009;
- the number and development requirements of other product candidates that we pursue;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful and the outcome of regulatory review of our product candidates;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- the cost of our general and administrative functions;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the cost of manufacturing our product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting patent applications, maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation;
- the timing, receipt, and amount of sales of, or royalties or milestone payments on, our future products, if any; and
- the extent to which we acquire or in-license other products or technologies.

In September 2017, we announced that we are exploring strategic alternatives for GEN-003. Consequently, substantially all GEN-003 spending and activities were ceased and we reduced our workforce by approximately 40 percent. Based on our current operating plan, we believe that our existing cash, cash equivalents and investments are sufficient to support our operating expenses and capital expenditure requirements into the middle of 2018, without assuming any receipt of proceeds from potential business development partnerships, equity financings or debt drawdowns. It is our strategy to secure additional financing in advance of commencing a Phase 1 clinical trial for GEN-009 in the first half of 2018.

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.

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

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and development agreements with strategic partnerships with third parties. In 2015, we raised additional net capital of approximately $95.2 million through follow-on public offerings in March and August along with $4.7 million of net debt financing in December. No significant capital raising activities occurred in 2016. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidates, future revenue streams, research programs or product candidates or grant licenses on terms that are not favorable to us. If we are unable to raise additional capital when needed, we would be required to delay, limit, reduce or terminate our product development or commercialization efforts for GEN-009, our immuno-oncology program, or our other product candidates. For example, in September 2017, we ceased substantially all spending and activities related to GEN-003, pending our exploration of strategic alternatives for advancing that product candidate. If we are unable to raise additional capital when needed, we may also be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

In September 2017, we ceased substantially all spending and activities related to GEN-003, our Phase 3-ready product candidate, pending our exploration of strategic alternatives for advancing that product candidate. We are now currently investing a significant portion of our efforts and financial resources in the development of the GEN-009, a neoantigen cancer vaccine which is currently in pre-clinical development. 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 filing of an IND application for GEN-009;
- 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 development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenue.

We have not conducted any clinical trials for GEN-009. Any successful results in non-clinical studies may not be predictive of similar results in humans during clinical trials, and successful results from early or small clinical trials of a vaccine candidate may not be replicated in later and larger clinical trials. Among other reasons for the potential failure of earlier, smaller clinical trials to be replicated in later, larger clinical trials is the fact that manufacturing scale up is necessary to prepare for Phase 3 development and commercialization. Our product candidates may require complex manufacturing processes, and scaling up these processes can cause changes in the product that may not be apparent until the product is further tested during Phase 3 trials.

If the results of our future clinical trials are inconclusive with respect to the efficacy of our product candidates or if we do not meet our clinical endpoints with statistical significance or if there are safety concerns or AEs associated with our product

candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates. Alternatively, even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy.

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

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

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, clinical trials, manufacturing, import, export and commercialization. In order to obtain regulatory approval for the commercial sale of any product candidate, we must demonstrate through extensive non-clinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Clinical trials are expensive, time-consuming and uncertain as to outcome. We may gain regulatory approval for GEN-009 or our other current or potential future clinical and non-clinical product candidates in some but not all of the territories available or some but not all of the target indications, resulting in limited commercial opportunity for the approved vaccine or immunotherapy, or we may never obtain regulatory approval for these product candidates for any indication in any jurisdiction.

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

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

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

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

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

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

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

- difficulty in establishing or managing relationships with 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 Biologics License Application ("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 by us in reaching a consensus with regulatory agencies on trial design, including the IND for GEN-009 expected to be filed with the FDA in early 2018 and initiation of our Phase 1 clinical trial for GEN-009 expected to occur in the first half of 2018;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required Institutional Review Board ("IRB") approval at each clinical trial site;
- imposition of a clinical hold by regulatory agencies or an IRB for any reason, including safety concerns raised by other clinical trials of similar vaccines that may reflect an unacceptable risk with GEN-009 or after an inspection of clinical operations or trial sites;
- failure to perform in accordance with the FDA’s good clinical practices ("GCPs") or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- delays caused by patients not completing participation in a trial or not returning for post-treatment follow-up;
- clinical trial sites or patients dropping out of a trial or failing to complete dosing;
- occurrence of serious AEs in clinical trials that are associated with the product candidates that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial. We intend to file an IND for GEN-009 in early 2018, but we have experienced clinical holds on IND submissions in the past. For example, our IND for GEN-003 was subject to a clinical hold from January 2012 to July 2012. In our original IND submission, we described a finding of osteonecrosis (microscopic evidence of bone and bone marrow death) in a toxicity study of

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

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

Our active product candidate, GEN-009, and our current and future potential product candidates arising out of our immuno-oncology program, are or will be based on T cell activation, which is a novel approach for vaccines, immunotherapies and medical treatments. Consequently, it may be difficult for us to predict the time and cost of product development. Unforeseen problems with the T cell approach to vaccines and immunotherapies may prevent further development or approval of our current and future product candidates. Because of the novelty of this approach, there may be unknown safety risks associated with the vaccines and immunotherapies that we develop. Regulatory agencies such as the FDA may require us to conduct extensive safety testing prior to approval to demonstrate a low risk of rare and severe 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.

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

Our active development product, GEN-009 includes a novel vaccine adjuvant and our other current and potential future product candidates may include one or more novel adjuvants, which may make it difficult for us to predict the time and cost of product development as well as the requirements the FDA or other regulatory agencies may impose to demonstrate the safety of such product candidates.

Novel vaccine adjuvants, included in some of our product candidates, may pose an increased safety risk to patients. Adjuvants are compounds that are added to vaccine antigens to enhance the activation and improve immune response and efficacy of vaccines. Development of vaccines with novel adjuvants requires evaluation in larger numbers of patients prior to approval than would be typical for therapeutic drugs. Guidelines for evaluation of vaccines with novel adjuvants have been established by the FDA and other regulatory bodies and expert committees. Our product candidates, including GEN-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. Traditionally, regulatory authorities have required extensive study of novel adjuvants. Such extensive study has often included long-term monitoring of safety in large general populations that has at times exceeded 10,000 subjects. This contrasts with the few thousand subjects typically necessary for approval of novel therapeutics. Although GEN-009 is being developed as a treatment, and therefore is not expected to be administered to uninfected subjects, regulators nonetheless may require us to amass a prophylactic vaccine-like safety database.

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

We intend to market our product candidates, if approved, in international markets. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, a vaccine must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our vaccine is also subject to approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our vaccines in any market.

Even if we receive regulatory approval for our product candidates, such immunotherapies will be subject to ongoing regulatory review, which may result in significant additional expense. Additionally, our product candidates, including our active development product, GEN-009, and any other current or potential future immunotherapy product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil, criminal and/or administrative penalties, damages, monetary fines, disgorgement, exclusion from participation in Medicare, Medicaid and other federal health care programs, and curtailment or restructuring of our operations.

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

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct non-clinical studies and clinical trials for our product candidates, including our active development product, GEN-009, and any other current or future product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We intend to rely on third party CROs and other third parties to assist in managing, monitoring and otherwise carrying out our GEN-009 clinical trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. We compete with many other companies for the resources of these third parties. The third parties on whom we rely generally may terminate their engagements at any time, and having to enter into alternative arrangements would delay development and commercialization of our product candidates.

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

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

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

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

We do not have any manufacturing facilities or personnel. We do not expect to independently conduct all aspects of our product manufacturing. We intend to rely on third parties with respect to manufacturing GEN-009. For example, we have relied on third party suppliers and manufacturers to manufacture and supply vaccines for our GEN-003 clinical trials. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

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

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

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the unavailability of a manufacturer that is capable of, or that has the capacity to, manufacture our clinical supply that results in delays or additional manufacturing costs;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how or infringement of third party intellectual property rights by our contract manufacturers; and
- disruptions to the operations of our third party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

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

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

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

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

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

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

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

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

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

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

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

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

A part of our strategy is to evaluate and, as deemed appropriate, enter into partnerships in the future when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other

companies. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

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

If we fail to establish and maintain strategic partnerships related to our product candidates, we will bear all of the risk and costs related to the development of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise which we do not have and for which we have not budgeted. This could negatively affect the development of any unpartnered product candidate. For example, in September 2017, we ceased substantially all spending and activities related to GEN-003, pending our exploration of strategic alternatives for advancing that product candidate.

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

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, patent applications, know-how and confidentiality agreements to protect the intellectual property related to our platform technology and product candidates. The patent position of biotechnology companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the United States Patent and Trademark Office ("U.S. PTO") and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our discovery platform or product candidates in the United States or in other countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or those of our licensors has been found, and prior art that we have not disclosed could be used by a third party to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our discovery platform or product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications, or those of our licensors, may not adequately protect our platform technology, provide exclusivity for our product candidates, prevent others from designing around our patents with similar products, or prevent others from operating in jurisdictions in which we did not pursue patent protection. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If patent applications we hold or have in-licensed with respect to our platform or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates or ATLAS discovery platform, it could dissuade companies from collaborating with us and could limit or destroy our ability to develop or commercialize one or more of our products, or even any product. We or our licensors have filed several patent applications covering aspects of our product candidates. We cannot offer any assurances about which, if any, patents will be issued, the breadth of any such patents or whether any issued patents will be found invalid and unenforceable or will be challenged by third parties. Any successful opposition to these patent applications, or patents that may issue from them, or to any other patent applications or patents owned by or licensed to us, could deprive us of rights necessary for the successful commercialization of any product candidate that we may develop. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate.

In the United States, for patent applications filed prior to March 16, 2013, assuming the other requirements for patentability are met, the first to invent is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. On March 16, 2013, the United States transitioned to a ‘first to file’ system more like that in the rest of the world in that the first inventor to file a patent application is entitled to the patent. Under either the prior system or current one, third parties are allowed to submit prior art prior to the issuance of a patent. Furthermore, both the U.S. and foreign patent systems

permit third parties or, in some cases, the patent authorities themselves, to initiate proceedings challenging the scope and / or validity of issued patents, including for example, opposition, derivation, reexamination, *inter partes* review or interference proceedings. An adverse determination against our or our licensor's patent rights in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position with respect to third parties.

In addition, patents have a limited lifespan. In most countries, including the United States, the natural expiration of a patent is 20 years from the date it is filed. Various extensions of patent term may be available in particular countries, however in all circumstances the life of a patent, and the protection it affords, has a limited term. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. Such possible extensions include those permitted under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States, which permits a patent term extension of up to five years to cover an FDA-approved product. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and non-clinical data, and then may be able to launch their product earlier than might otherwise be the case.

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

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

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

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights, and competitors or other third parties may challenge the validity or enforceability of those rights. To counter infringement or unauthorized use, or to defend against other challenges, litigation may be necessary to enforce or defend our intellectual property rights, to protect our trade secrets and/or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Such litigation can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to litigate intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in contested proceedings, a court or agency may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates, and to use our or our licensors' proprietary technologies without infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination, and *inter partes* review proceedings before the U.S. PTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing

and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

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

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

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

We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages. During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

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

We are a party to a number of license and collaboration agreements that are important to our business, and we may enter into additional license or collaboration agreements in the future. For example, our discovery platform is built, in part, around patents exclusively in-licensed from academic or research institutions. See the "Business - In-License Agreements" and "Business - Other Collaborations" sections of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 for a description of our outstanding license and collaboration agreements with the University of California, Harvard, Children's Medical Center Corporation, Novavax, and the Dana-Farber Cancer Institute. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. In that event, we may be required to expend significant time and resources to redesign our product candidates or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly.

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

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

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

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

Risks Related to Commercialization of Our Product Candidates

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

Even if we obtain marketing approval for GEN-009 or any other products that we may develop or acquire in the future, the product may not gain market acceptance among physicians, third-party payors, patients and others in the medical community. In addition, market acceptance of any approved products depends on a number of other factors, including:

- the efficacy and safety of the product, as demonstrated in clinical trials;
- the clinical indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any warnings that may be required on the label;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety and efficacy of treatment in relation to alternative treatments;
- the availability of adequate course and reimbursement by third-party payors and government authorities;

- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- the effectiveness of our sales and marketing efforts; and
- the restrictions on the use of our products together with other medications, if any.

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

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

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

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

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians;
- the lack of adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

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

- a covered benefit under its health plan;

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

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

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on coverage, prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available vaccines in order to obtain or maintain coverage, reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. There can be no assurance that our vaccine candidates will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

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

In the United States, and in some foreign jurisdictions, the legislative landscape continues to evolve. Our revenue prospects could be affected by changes in health care spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws or judicial decisions, or new interpretations of existing laws or decisions, related to health care availability, the method of delivery or payment for health care products and services could negatively impact our business, operations and financial condition. There is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Patient Protection and Affordable Care Act (the "ACA"), as amended by the Health Care and Education Reconciliation Act in 2010, as well as the pending proposals to eliminate or significantly modify the ACA. It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing health care legislation.

Modifications to or repeal of all or certain provisions of the ACA are expected as a result of the outcome of the recent presidential elections and Republications maintaining control of Congress, consistent with statements made by Donald Trump and members of Congress during the presidential campaign and following the election. We cannot predict the ultimate content, timing or effect of any changes to the ACA or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our business and financial results, and we cannot predict how future federal or state 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.

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 Neon Therapeutics, Gritstone Oncology, Immatics Biotechnologies GmbH, Aduro, Advaxis, Agenus, Moderna, CureVac and BioNTech.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, including recruiting patients, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. Large and established companies such as Merck & Co., Inc., GlaxoSmithKline plc, Novartis, Inc., Sanofi Pasteur, SA, Pfizer Inc. and MedImmune, LLC (a subsidiary of AstraZeneca PLC), among others, compete in the vaccine market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products before we do. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

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

Undesirable side effects caused by our products or even competing products in development that utilize a common mechanism of action could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Serious AEs deemed to be caused by our product candidates could have a material AE on the development of our product candidates and our business as a whole. The most common AEs to date in the clinical trial evaluating the safety and tolerability of GEN-003 have been fatigue, myalgia (muscle pain), pain tenderness and induration (inflammatory hardening of the skin). Our understanding of the relationship between GEN-003 and these events, as well as our understanding of AEs in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected AEs may be observed. We have not yet conducted any clinical trials for GEN-009 and therefore do not yet have any information related to whether GEN-009 may cause AEs or serious AEs.

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

- our clinical trials may be put on hold;

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

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

Risks Related to Our Indebtedness

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

In December 2015, we entered into the First Amendment to the 2014 Term Loan with Hercules. The First Amendment required us to draw an additional $5.0 million and permitted us to draw two additional $5.0 million tranches, which expired unused at December 15, 2016. At September 30, 2017, $15.4 million was outstanding under the amended 2014 Term Loan.

All obligations under our 2014 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:

- we will need to repay our indebtedness by making payments of interest and principal, which will reduce the amount of money available to finance our operations, our research and development efforts and other general corporate activities; and
- our failure to comply with the restrictive covenants in our 2014 Term Loan and the First Amendment could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and Hercules could seek to enforce its security interest in the assets securing such indebtedness.

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

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due. If we do not make scheduled payments when due, or otherwise materially breach or experience an event of default under our 2014 Term Loan, Hercules could accelerate our total loan obligation or enforce its security interest against us.

Failure to satisfy our current and future debt obligations under our 2014 Term Loan could result in an event of default. In addition, other events, including certain events that are not entirely in our control, such as the occurrence of a material adverse event on our business, could cause an event of default to occur. As a result of the occurrence of an event of default, Hercules could accelerate all of the amounts due. In the event of an acceleration of amounts due under our 2014 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 2014 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 2014 Term Loan and have a material adverse effect on our business and prospects.

Our 2014 Term Loan imposes operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things:

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

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 2014 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, Seth Hetherington, M.D., our Chief Medical Officer, Jonathan Poole, our Chief Financial Officer, and Jessica Flechtner, Ph.D., our Chief Scientific Officer. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. We have employment agreements with each of these members of senior management.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms as a result of our recent workforce reduction, the status of our clinical development programs and the competition among numerous pharmaceutical and biotechnology companies for similar personnel. The organizational restructuring we undertook in September 2017 may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause our remaining employees to seek alternate employment. 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.

We may experience difficulties in managing restructurings.

In September 2017, we undertook an organizational restructuring that reduced our workforce by approximately 40%. Effecting any restructuring places significant strains on management, our employees and our operational, financial and other resources. Furthermore, restructurings involve certain additional costs, including severance and benefits payments to terminated employees, and we may also incur liabilities from early termination or assignment of contracts, potential litigation or other effects from such restructuring. Such effects from our restructuring program could have a material adverse affect on our ability to execute on our business plan. There can be no assurance that we will be successful in implementing our restructuring program.

Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to develop our

product candidates, including GEN-009, or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be.

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

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

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

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

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

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

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigations;

- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize any product candidates that we may develop; and
- a decline in our stock price.

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

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

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

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

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

Risks Related to Our Common Stock

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

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

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board providing for supplemental auditor's reports for additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

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

We could be an emerging growth company for up to five years, until December 31, 2019, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" if the market value of our common stock held by non-affiliates is below $75.0 million as of June 30 in any given year, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

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

An inactive market may impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors and, as a result of these and other factors, the price of our common stock may fall.

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

On October 31, 2017, a putative class action complaint was filed in the U.S. District Court for the District of Massachusetts, naming Genocea Biosciences, Inc., Chief Executive Officer William D. Clark, and Chief Financial Officer Jonathan Poole as defendants. The complaint alleges violations of the Securities Exchange Act of 1934 and Rule 10b-5 in connection with disclosures made in and subsequent to our Quarterly Report on Form 10-Q for the period ending March 31, 2017, filed with the SEC on May 5, 2017 and our announcement of a strategic shift to immuno-oncology on September 25, 2017. The plaintiff seeks to represent a class of shareholders who purchased or otherwise acquired our securities between May 5, 2017 and September 25, 2017. The complaint seeks unspecified damages and costs. We intend to vigorously defend ourselves against this action. This lawsuit and this type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

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

If our stock price falls below $1.00 per share, we may not continue to qualify for continued listing on The NASDAQ Global Market ("NASDAQ"). 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. 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.

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

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

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

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

The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our ordinary shares could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on NASDAQ.

We are required to comply with certain of the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment must include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial

reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statement.

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

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

Provisions in our amended and restated certificate of incorporation and amended and restated by-laws contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, our chief executive officer or our president;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our by-laws.

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

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

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

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

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs"), to offset future taxable income. Our existing NOLs 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 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibits Index, which Exhibit Index is incorporated herein by reference.

Exhibit Number	Exhibit
31.1	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Chief Executive Officer
31.2	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Chief Financial Officer
32.1	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Executive Officer
32.2	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Financial Officer
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2017 and December 31, 2016, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2017 and 2016, (iii) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2017 and 2016 and (iv) Notes to Unaudited Condensed Consolidated Financial Statements

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.

Genocea Biosciences, Inc.

Date: November 3, 2017

By: /s/ WILLIAM D. CLARK

William D. Clark

President and Chief Executive Officer and Director (Principal Executive Officer)

Date: November 3, 2017

By: /s/ JONATHAN POOLE

Jonathan Poole

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

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 & Chief Executive Officer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 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 reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

/s/ WILLIAM D. CLARK

William D. Clark

President & Chief Executive Officer

Date: November 3, 2017

Exhibit 31.2

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

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

1. I have reviewed this Quarterly Report on Form 10-Q 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 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 reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

/s/ JONATHAN POOLE

Jonathan Poole

Chief Financial Officer

Date: November 3, 2017

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 Quarterly Report on Form 10-Q of Genocea Biosciences, Inc. (the "Company") for the period ended September 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, William D. Clark, as the President & Chief Executive Officer of the Company, does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

/s/ WILLIAM D. CLARK

William D. Clark*

President &Chief Executive Officer

Date: November 3, 2017

* 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-Q 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 Quarterly Report on Form 10-Q of Genocea Biosciences, Inc. (the "Company") for the period ended September 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Jonathan Poole, as the Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

/s/ JONATHAN POOLE

Jonathan Poole*

Chief Financial Officer

Date: November 3, 2017

*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-Q or as a separate disclosure document.