UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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** x **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** x **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	x
Non-accelerated filer	☐	(Do not check if a smaller reporting company)	Smaller reporting company	☐
			Emerging growth company	x

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. x

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

As of May 4, 2017, there were 28,504,775 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:

- the timing of results of our ongoing and planned clinical trials;
- our planned clinical trials for GEN-003;
- our estimates regarding the amount of funds we require to complete our clinical trials for GEN-003 and to continue our investments in immuno-oncology;
- our estimate for when we will require additional funding;
- our plans to commercialize GEN-003 and our other vaccine candidates;
- the timing of, and our ability to, obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- the potential benefits of strategic partnership agreements and our ability to enter into strategic partnership arrangements;
- our ability to quickly and efficiently identify and develop product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position; and
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing.

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 March 31, 2017

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 34,138	$ 27,424
Investments, current portion	14,537	35,938
Prepaid expenses and other current assets	1,443	926
Total current assets	50,118	64,288
Property and equipment, net	4,782	4,871
Restricted cash	316	316
Other non-current assets	429	421
Total assets	$ 55,645	$ 69,896
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,875	$ 3,043
Accrued expenses and other current liabilities	2,440	4,178
Current portion of long-term debt	4,771	3,149
Total current liabilities	10,086	10,370
Non-current liabilities:		
Long-term debt	12,312	13,809
Other non-current liabilities	163	176
Total liabilities	22,561	24,355
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Common stock	29	28
Additional paid-in-capital	254,276	252,996
Accumulated other comprehensive loss	(3)	—
Accumulated deficit	(221,218)	(207,483)
Total stockholders' equity	33,084	45,541
Total liabilities and stockholders' equity	$ 55,645	$ 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 March 31,	
	2017	**2016**
Grant revenue	$ —	$ 235
Operating expenses:		
Research and development	9,742	7,332
General and administrative	3,634	3,924
Refund of research and development expense	—	(1,592)
Total operating expenses	13,376	9,664
Loss from operations	(13,376)	(9,429)
Other income and expense:		
Interest income	77	109
Interest expense	(436)	(431)
Total other income and expense	(359)	(322)
Net loss	$ (13,735)	$ (9,751)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities	$ (3)	$ —
Comprehensive loss	$ (13,738)	$ (9,751)
Net loss per share - basic and diluted	$ (0.48)	$ (0.35)
Weighted-average number of common shares used in computing net loss per share	28,496	28,152

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2017	**2016**
Operating activities		
Net loss	$ (13,735)	$ (9,751)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	449	361
Stock-based compensation	1,021	1,063
Non-cash interest expense	127	115
Changes in operating assets and liabilities	(2,521)	(1,967)
Net cash used in operating activities	(14,659)	(10,179)
Investing activities		
Purchases of property and equipment	(282)	(577)
Proceeds from maturities of investments	21,552	33,521
Purchases of investments	(155)	(2,301)
Net cash provided by investing activities	21,115	30,643
Financing activities		
Proceeds from equity offerings, net of issuance costs	246	—
Proceeds from exercise of stock options	12	7
Net cash provided by financing activities	258	7
Net increase in cash and cash equivalents	$ 6,714	$ 20,471
Cash and cash equivalents at beginning of period	27,424	17,259
Cash and cash equivalents at end of period	$ 34,138	$ 37,730
Supplemental cash flow information		
Cash paid for interest	$ 308	$ 316
Property and equipment included in accounts payable and accrued expenses	$ 77	$ 452

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 vaccines and immunotherapies to address diseases with significant unmet needs through its AnTigen Lead Acquisition System ("ATLAS™") proprietary discovery platform. ATLAS is used to rapidly design vaccines and immunotherapies that act, in part, through T cell (or cellular) immune responses, in contrast to approved vaccines and immunotherapies, which are designed to act primarily through B cell (or antibody) immune responses. The Company believes that by harnessing T cells, first-in-class vaccines and immunotherapies can be developed to address diseases where T cells are central to the control of the disease.

The Company has one product candidate in active Phase 2 clinical development, GEN-003, an immunotherapy for the treatment of genital herpes. The Company also has a pre-clinical immuno-oncology program, GEN-009, focused on personalized cancer vaccines. The GEN-009 program leverages ATLAS to identify patient neoantigens, or newly formed antigens that are often found in tumor cells that have not been previously recognized by the immune system. We have other non-active infectious disease programs, including GEN-004, a Phase 2-ready universal vaccine for the prevention of pneumococcal infections, and early stage programs focused on genital herpes prophylaxis, chlamydia, and malaria.

The Company is devoting substantially all of its efforts to product research and development, initial market development, and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other clinical stage companies, including dependence on key individuals, competition from other companies, the need and related uncertainty associated 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 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 March 31, 2017, the Company had an accumulated deficit of approximately $221.2 million. The Company had cash, cash equivalents and investments of $48.7 million at March 31, 2017. The Company expects that existing cash, cash equivalents and investments are sufficient to support operating expenses, capital expenditure requirements, and debt obligations into the first quarter of 2018, without assuming any receipt of proceeds from potential business development partnerships or equity financings. This guidance assumes the Company commences a Phase 3 clinical trial for GEN-003 for genital herpes around the end of 2017 and files an IND for GEN-009 for cancer by the end of 2017; however, it is the Company’s strategy to secure additional sources of financing in advance of starting GEN-003 Phase 3 clinical trials. The Company has the ability to modify its operating plans in order to fund operations through at least one year from the issuance of this quarterly report.

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. For the three months ended March 31, 2016, there were no ATM sales.

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 March 31, 2017 and results of operations for the three months ended March 31, 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 three months ended March 31, 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 March 31, 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 4) 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 three months ended March 31, 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 three months ended March 31, 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 timing of the adoption of ASC 606 and the related 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 March 31, 2017 and December 31, 2016, cash, cash equivalents and investments comprised funds in depository, money market accounts, U.S. treasury securities, and FDIC-insured certificates of deposit.

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

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2017				
Money market funds, included in cash equivalents	$ 33,493	$ 33,493	$ —	$ —
Investments - U.S treasuries	8,999	8,999	—	—
Investments - certificates of deposit	5,538	—	5,538	—
Total	$ 48,030	$ 42,492	$ 5,538	$ —
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 marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. The Company validates the prices provided by its third party pricing services by reviewing their 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 March 31, 2017 and December 31, 2016.

Investments at March 31, 2017 consist of the following (in thousands):

	Contractual Maturity	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasuries	15-91 days	$ 9,002	$ —	$ 3	$ 8,999
Certificates of deposit	5-90 days	5,538	—	—	5,538
Total		$ 14,540	$ —	$ 3	$ 14,537

Cash equivalents and investments at December 31, 2016 consist 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. 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 $17.0 million was outstanding under the amended 2014 Term Loan at March 31, 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.

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 March 31, 2017, the 2014 Term Loan bears an effective interest rate of 10.2%.

As of both March 31, 2017 and December 31, 2016, the Company had outstanding borrowings under the 2014 Term Loan of $17.0 million. Interest expense related to the 2014 Term Loan was $0.4 million each for the three months ended March 31, 2017 and 2016.

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

	March 31, 2017
2017	3,149
2018	6,659
2019	8,034
Total	$ 17,842

5. 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):

	March 31, 2017
2017	$ 1,187
2018	1,607
2019	1,637
2020	274
Total	$ 4,705

At March 31, 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. The Company did not recognize any revenue and recognized revenue of $235 thousand under this agreement for the three months ended March 31, 2017 and 2016, respectively.

The Company relies on research institutions, contract research organizations, 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 payment of a reservation fee, which will equal a

percentage of the expected production 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. The Company incurred expenses under the agreement of $1.1 million and $158 thousand for the three months ended March 31, 2017 and 2016, respectively.

Litigation

The Company is not a party to any litigation and 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.

6. Equity and net loss per share

At March 31, 2017, the Company authorized 175,000,000 shares of common stock at $0.001 par value per share. As of March 31, 2017, 28,502,470 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 three-month periods ended March 31, 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 March 31, 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):

	Three Months Ended March 31,	
	2017	2016
Warrants	78	78
Outstanding options	4,968	3,675
Outstanding ESPP	24	16
Total	5,070	3,769

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 March 31, 2017, all shares of common stock were fully vested.

7. Stock and employee benefit plans

Stock-based compensation expense

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

	Three Months Ended March 31,	
	2017	2016
Research and development	$ 387	$ 463
General and administrative	634	600
Total	$ 1,021	$ 1,063

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	1,266	$ 4.68		
Exercised	(4)	$ 2.86		
Canceled	(101)	$ 7.74		
Outstanding at March 31, 2017	4,968	$ 5.58	7.96	$ 8,783
Exercisable at March 31, 2017	2,021	$ 6.16	6.32	$ 4,039
Vested or expected to vest at March 31, 2017	4,968	$ 5.58	7.96	$ 8,783

Performance-based stock options

The Company granted stock options to certain employees, executive officers and consultants, which contain performance-based vesting criteria. Milestone events are specific to the Company's corporate goals, which include, but are not limited to, certain clinical development milestones, business development agreements and capital fundraising events. Stock-based compensation expense associated with these performance-based stock options is recognized if the performance conditions are considered probable of being achieved, using management's best estimates. The Company determined that none of the performance-based milestones were probable of achievement during the three months ended March 31, 2017, and accordingly did not recognize stock-based compensation expense for these periods. As of March 31, 2017, there are 56,336 performance-based common stock options 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 March 31, 2017, 73,468 shares remain for future issuance under the plan. The Company incurred stock-based compensation expense related to the 2014 ESPP of $38 thousand and $33 thousand for the three months ended March 31, 2017 and 2016, respectively.

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 discovers and develops novel vaccines and immunotherapies to address diseases with significant unmet needs. We use our proprietary discovery platform, ATLAS™, to rapidly design vaccines and immunotherapies that act, in part, through T cell (or cellular) immune responses, in contrast to approved vaccines and immunotherapies, which are designed to act primarily through B cell (or antibody) immune responses. We believe that by harnessing T cells we can develop first-in-class vaccines and immunotherapies to address diseases where T cells are central to the control of the disease.

We have one product candidate in active Phase 2 clinical development, GEN-003, an immunotherapy for the treatment of genital herpes. We also have a pre-clinical immuno-oncology program, GEN-009, focused on personalized cancer vaccines. 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 have other non-active infectious disease programs, including GEN-004, a Phase 2-ready universal vaccine for the prevention of pneumococcal infections, and early stage programs focused on genital herpes prophylaxis, chlamydia, and malaria.

GEN-003 — Phase 2 immunotherapy for genital herpes

Our lead program is GEN-003, a Phase 2 candidate therapeutic vaccine, or immunotherapy, that we are developing to treat genital herpes infections. We have completed two positive clinical trials and have a third clinical trial currently underway which has also demonstrated positive interim efficacy results. Key data from those clinical trials is described below.

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 safe and 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 have already 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 an ongoing Phase 2b

efficacy trial, from which positive six-month, placebo-controlled clinical efficacy data were announced in January 2017 (see Phase 2b trial below).

The efficacy of GEN-003 at these two dose levels over the course of the Phase 2 dose optimization trial, including the extension period, is as follows:

	60/50 Dose				60/75 Dose			
Endpoint	**Post dose 3**	**6 months**	**12 months**	**24 months**	**Post dose 3**	**6 Months**	**12 months**	**24 months**
n	42	38	36	21	41	39	34	25
Viral shedding rate reduction*	41% (p<0.01)	47% (p<0.0004)	66% (p<0.0001)	58% NA**	55% (p<0.006)	58% (p<0.0001)	55% (p<0.01)	69% NA**
Genital lesion rate reduction*	69% (p<0.0005)	50% (p<0.01)	65% (p<0.003)	77% NA**	60% (p<0.02)	43% (p<0.03)	47% (p<0.02)	39% NA**
% patients lesion free	68%	36%	30%	NA**	68%	30%	21%	NA**

* Mean rate reduction vs. pre-dosing baseline levels. Statistical analysis performed using a Poisson mixed effect model with empirical variance : Magaret, Amalia, "Models for HSV shedding must account for two levels of overdispersion" ((January 2016). UW Biostatistics Working Paper Series. Working Paper 410)

** Per prospectively defined clinical trial protocol, descriptive results only, no statistical testing performed.

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 January 2017, we announced further positive clinical results from the ongoing Phase 2b clinical trial. At six months after dosing, GEN-003 demonstrated statistically significant improvements versus placebo across multiple clinical endpoints. The 60/50 Dose significantly reduced the median rate of genital lesions during the six months following dosing compared to placebo (52% 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. GEN-003 also consistently demonstrated significant benefits versus placebo across several other clinical endpoints across the dose groups as summarized in the following table:

Secondary clinical endpoint	**Placebo (n=44)**	**60/50 Dose (n=43)**	**60/75 Dose (n=44)**
Median genital lesion rate	5.6%	2.7%	1.9%
Mean genital lesion rate (percent of days with lesions over six months)	7.9%	4.5%	4.6%
p-value versus placebo[(1)]	NA	0.03	0.03
Median duration of recurrences	4.2	2.8	4.0
Mean duration of recurrences (days)	4.8	3.3	4.3
p-value versus placebo[(1)]	NA	0.01	0.64
Median number of recurrences over six months	2.0	1.0	1.5
Mean number of recurrences over six months	2.7	2.1	1.9
p-value versus placebo[(1)]	NA	0.08	0.02
Kaplan-Meier estimate of percent recurrence free after first dose	10%	29%	31%
p-value versus placebo[(2)]	NA	0.03	0.03
Kaplan-Meier estimate of percent recurrence free after last dose	13%	22%	36%
p-value versus placebo[(2)]	NA	0.17	0.02

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

The clinical efficacy data versus placebo at twelve-months post dosing and the viral shedding rate reduction data at six-months and twelve-months post dosing is expected in the middle of 2017.

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 and discontinuations due to adverse events 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 FDA, the outcome of which was aligned with our previously disclosed Phase 3 design expectations. We continue to expect that GEN-003 will be Phase 3-ready in the fourth quarter of 2017. We plan to commence a clinical trial exploring the potential additive effects of GEN-003 on top of daily administration of valacyclovir in parallel with the Phase 3 program. We retain all rights to GEN-003 and if GEN-003 successfully completes clinical development and is approved, we believe it would represent an important new treatment option for patients with genital herpes.

Our Immuno-Oncology Program

Guided by our positive clinical results for GEN-003 received to date, and our belief in the ATLAS platform, 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, or newly formed antigens unique to each patient, that are associated with that individual's tumor. We anticipate filing a personalized cancer vaccine IND application with the FDA in 2017. We are also applying the results from ATLAS, and its potential utility as a diagnostic tool, to identify patients that could benefit from checkpoint blockade therapy. Our strategy in immuno-oncology combines our own internal development programs with a focus on partnering ATLAS with 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 Epstein-Barr Virus (“EBV”). EBV infection has been linked to cancers with high unmet needs such as non-Hodgkin’s lymphoma, nasopharyngeal carcinoma and gastric carcinoma. We believe the ATLAS platform is highly suited to the creation of a new immunotherapy for EBV given that T cell responses are understood to be crucial for protection against EBV. Furthermore, EBV is part of the herpesvirus family, in which we have deep experience through our development of GEN-003. We are currently conducting ATLAS screens for EBV and plan to select antigen candidates for further study in 2017.

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 March 31, 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 March 31, 2017, our cash and cash equivalents and investments were $48.7 million.

Since inception, we have incurred significant operating losses. Our net losses were $13.7 million and $9.8 million for the three months ended March 31, 2017 and 2016, respectively, and our accumulated deficit was $221.2 million as of March 31, 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 three months ended March 31, 2017, we have sold 52 thousand shares under our ATM program and received $0.2 million in net proceeds after deducting commissions. There were no ATM sales for the three months ended March 31, 2016.

We believe that our cash, cash equivalents and investments at March 31, 2017 are sufficient to support our operating expenses, capital expenditure requirements, and debt obligations into the first quarter of 2018, without assuming any receipt of proceeds from potential business development partnerships or equity financings. This guidance assumes commencing Phase 3 trials for GEN-003 for genital herpes around the end of 2017 and filing an IND for GEN-009 for cancer by the end of the year; however it is our strategy to secure additional sources of financing in advance of starting GEN-003 Phase 3 clinical trials.

Costs related to clinical trials can be unpredictable and therefore there can be no guarantee that our current balances of cash, cash equivalents and investments, and any proceeds received from other sources, will be sufficient to fund our studies or operations through this period. These funds will not be sufficient to enable us to conduct pivotal clinical trials for, seek marketing approval for or commercially launch GEN-003 or any other product candidate. Accordingly, to obtain marketing approval for and to commercialize these or any other product candidates, we will be required to obtain further funding through public or private equity offerings, debt financings, collaboration and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital when needed would have a negative effect on our financial condition and our ability to pursue our business strategy.

Financial Overview

Grant revenue

Grant revenue consists of revenue earned to conduct vaccine development research. We have received grants from private not-for-profit organizations and federal agencies. These grants have related to the discovery and development of several of our product candidates, including product candidates for the prevention of pneumococcus, chlamydia, 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. We will not receive any revenue from any product candidates that we develop until we obtain regulatory approval and commercialize such products or until we potentially enter into agreements with third parties for the development and commercialization of product candidates. If our development efforts for any of our product candidates result in regulatory approval or we enter into collaboration agreements with third parties, we may generate revenue from product sales or from such third parties.

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

Research and development expenses

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

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

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

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

	Three Months Ended March 31,	
	2017	2016
Genital herpes (GEN-003)(1)	$ 6,359	$ 3,215
Immuno-oncology program (2)	1,988	512
Other research and development (3)	1,395	3,605
Total research and development	$ 9,742	$ 7,332

(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 research and development expenses will increase as we continue the manufacture of clinical materials and manage the clinical trials of, and seek regulatory approval for, GEN-003, and advance our preclinical development pipeline.

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

Refund of research and development expenses

The refund of research and development expenses recorded in the three months ended March 31, 2016 related to a one-time payment received from Novavax pursuant to contractual obligations under the Novavax Agreement that existed to refund research and development expenses paid to Novavax between 2009 and 2011.

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 March 31, 2017 and March 31, 2016

(in thousands)	Three Months Ended March 31, 2017	2016	Increase (Decrease)
Grant revenue	$ —	$ 235	$ (235)
Operating expenses:			
Research and development	9,742	7,332	2,410
General and administrative	3,634	3,924	(290)
Refund of research and development expense	—	(1,592)	(1,592)
Total operating expenses	13,376	9,664	3,712
Loss from operations	(13,376)	(9,429)	3,947
Other income and expenses:			
Interest income	77	109	(32)
Interest expense	(436)	(431)	5
Total other income and expense	(359)	(322)	37
Net loss	$ (13,735)	$ (9,751)	$ 3,984

Grant revenue

We did not record any grant revenue in the three months ended March 31, 2017 as compared to $0.2 million in the three months ended March 31, 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 $2.4 million in the three months ended March 31, 2017 as compared to the three months ended March 31, 2016. The increase was due largely to increases in compensation, consulting and professional services (approximately $1.5 million), external manufacturing (approximately $1.3 million) and office and facility costs (approximately $0.1 million), offset by decreased clinical related costs (approximately $0.5 million).

On a program basis, GEN-003 costs increased by $3.1 million for the three months ended March 31, 2017 driven by increases in headcount related expenses (approximately $1.7 million), increased external manufacturing related expenses (approximately $1.1 million) to support the Phase 3 clinical drug supply, and higher consulting and professional service costs in advance of the expected Phase 3 trials. Spending increases on GEN-009 and immuno-oncology programs (approximately $1.5 million) were more than offset by lower costs on deprioritized infectious disease programs.

General and Administrative Expenses

General and administrative expenses decreased $0.3 million in the three months ended March 31, 2017 reflecting improved operating leverage.

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 2011.

Interest Income

Interest income of approximately $0.1 million for the three months ended March 31, 2017 was generally consistent with the same quarter in the prior year due to rising investment yields offset by lower investment 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.

Liquidity and Capital Resources

Overview

Since our inception through March 31, 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 March 31, 2017, our cash, cash equivalents and investment securities were $48.7 million, comprising cash and cash equivalents of approximately $34.2 million and current investment securities of approximately $14.5 million.

For the quarter ended March 31, 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 $17.0 million was outstanding under the amended 2014 Term Loan at March 31, 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 believe that our cash, cash equivalents and investments at March 31, 2017 are sufficient to support our operating expenses, capital expenditure requirements, and debt obligations into the first quarter of 2018, without assuming any receipt of proceeds from potential business development partnerships or equity financings. This guidance assumes commencing Phase 3 trials for GEN-003 for genital herpes around the end of 2017 and filing an IND for GEN-009 for cancer by the end of the year; however it is our strategy to secure additional sources of financing in advance of starting GEN-003 Phase 3 clinical trials.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and costs of our ongoing and planned clinical trials for GEN-003;
- the progress, timing and costs of manufacturing GEN-003 for current and planned clinical trials;
- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our other product candidates and potential product candidates;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for GEN-003 and other product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- the receipt of marketing approval;
- revenue received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, grants, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the extent to which we in-license or acquire other products and technologies.

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

Cash Flows

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

	Three Months Ended March 31,	
	2017	2016
Net cash used in operating activities	$ (14,659)	$ (10,179)
Net cash provided by investing activities	21,115	30,643
Net cash provided by financing activities	258	7
Net increase in cash and cash equivalents	$ 6,714	$ 20,471

Operating Activities

Net cash used in operations increased by approximately $4.5 million to $14.7 million for the three months ended March 31, 2017 from $10.2 million for the three months ended March 31, 2016. The increase in net cash used was due primarily to a higher net loss of approximately $4.0 million and a $0.6 million increase in our working capital accounts.

Investing Activities

Net cash provided by investing activities was $21.1 million for the three months ended March 31, 2017 compared to $30.6 million for the three months ended March 31, 2016. The $9.5 million decrease was due to a $12.0 million reduction in net proceeds from maturities and sales of investments offset by decreases in investment purchases of approximately $2.2 million and capital expenditures of $0.3 million.

Financing Activities

Net cash provided by financing activities increased $0.3 million for the three months ended March 31, 2017 compared to the three months ended March 31, 2016 due to $0.2 million in net proceeds from equity offerings under the ATM in the three months ended March 31, 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 March 31, 2017 and December 31, 2016, we had cash, cash equivalents and investments of $48.7 million and $63.4 million, respectively, consisting primarily of money market funds, U.S Treasury securities, and FDIC insured certificates of deposits. The investments in these financial instruments are made in accordance with an investment policy approved by our Board of Directors, which specifies the categories, allocations and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments in which we invest could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio that may include cash, cash equivalents and investment securities available-for-sale in a variety of securities, which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations or our financial position would be materially affected by an immediate change of 10% in interest rates.

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

We are also exposed to market risk related to change in foreign currency exchange rates. We contract with certain vendors that are located in Europe which have contracts denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign exchange rate risk. As of March 31, 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 March 31, 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 March 31, 2017, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the three months ended March 31, 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. While the outcome of these proceedings and claims cannot be predicted with certainty, as of March 31, 2017, we were not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on our financial position or profitability. No governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

Item 1A. Risk Factors

There have been no material changes from the risk factors set forth in the Company's Annual Report on Form 10-K, as filed with the SEC on February 17, 2017.

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 March 31, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of March 31, 2017 and December 31, 2016, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income for the three months ended March 31, 2017 and 2016, (iii) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 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: May 5, 2017

By: /s/ WILLIAM D. CLARK

William D. Clark

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

Date: May 5, 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, 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: May 5, 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: May 5, 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 March 31, 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: May 5, 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 March 31, 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: May 5, 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.