GENOCEA BIOSCIENCES, INC.
Form 10-Q
May 06, 2016

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, 2016
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, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	¨	Accelerated filer	x
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

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

As of May 4, 2016, there were 28,293,583 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”, 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 our immuno-oncology and infectious disease pipeline;
- our estimate for when we will require additional funding;
- our plans to commercialize GEN-003 and our other vaccine candidates;
- the timing of, and our ability to, obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- the potential benefits of strategic partnership agreements and our ability to enter into strategic partnership arrangements;
- our ability to quickly and efficiently identify and develop product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position; and
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing.

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, 2016

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$37,730	$17,259
Investments, current portion	57,926	77,069
Prepaid expenses and other current assets	1,561	865
Restricted cash	316	—
Total current assets	97,533	95,193
Property and equipment, net	4,751	4,083
Restricted cash	—	316
Investments, net of current portion	—	12,104
Other non-current assets	371	446
Total assets	$102,655	$112,142
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$2,151	$1,757
Accrued expenses and other current liabilities	2,911	3,975
Deferred revenue	—	235
Total current liabilities	5,062	5,967
Non-current liabilities:		
Long-term debt	16,592	16,477
Other non-current liabilities	11	37
Total liabilities	21,665	22,481
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock	—	—
Common stock	28	28
Additional paid-in-capital	248,623	247,550
Accumulated other comprehensive loss	—	(7)
Accumulated deficit	(167,661)	(157,910)
Total stockholders' equity	80,990	89,661
Total liabilities and stockholders' equity	$102,655	$112,142

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,	
	2016	2015
Grant revenue	$235	$121
Operating expenses:		
Research and development	7,332	8,509
General and administrative	3,924	3,389
Refund of research and development expense	(1,592)	—
Total operating expenses	9,664	11,898
Loss from operations	(9,429)	(11,777)
Other income and expense:		
Interest income	109	12
Interest expense	(431)	(319)
Total other income and expense	(322)	(307)
Net loss	$(9,751)	$(12,084)
Other comprehensive income (loss):		
Unrealized gain on available-for-sale securities	—	11
Comprehensive loss	$(9,751)	$(12,073)
Net loss per share - basic and diluted	$(0.35)	$(0.64)
Weighted-average number of common shares used in computing net loss per share	28,152	18,834

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,	
	2016	2015
Operating activities		
Net loss	$(9,751)	$(12,084)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	361	180
Stock-based compensation	1,063	915
Net amortization of premium on investments	—	10
Non-cash interest expense	115	101
Changes in operating assets and liabilities	(1,967)	130
Net cash used in operating activities	(10,179)	(10,748)
Investing activities		
Purchases of property and equipment	(577)	(232)
Proceeds from maturities of investments	33,521	—
Purchases of investments	(2,301)	—
Net cash provided by (used in) investing activities	30,643	(232)
Financing activities		
Proceeds from underwritten public offering, net of issuance costs	—	48,367
Proceeds from exercise of stock options	7	26
Net cash provided by financing activities	7	48,393
Net increase in cash and cash equivalents	$20,471	$37,413
Cash and cash equivalents at beginning of period	17,259	20,058
Cash and cash equivalents at end of period	$37,730	$57,471
Supplemental cash flow information		
Cash paid for interest	$316	$218
Property and equipment, included in accounts payable and accrued expenses	$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. The Company's development pipeline consists of candidates discovered using ATLAS™, a proprietary discovery platform which enables the identification of clinically relevant T cell antigens for novel vaccines and immunotherapies targeting infectious disease and oncology applications. 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, in GEN-004, a Phase 2-ready universal vaccine for the prevention of pneumococcal infections. While internal development of GEN-004 has been suspended, the Company is currently seeking partners to advance GEN-004 into a Phase 1/2 clinical trial targeting toddler and infant populations. The Company also has active research and pre-clinical development programs for diseases including genital herpes, chlamydia, and malaria and is investigating the application of ATLAS to immuno-oncology target discovery.

The Company is devoting substantially all of its efforts to product research and development, initial market development, and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other clinical stage companies, including dependence on key individuals, competition from other companies, the need and related uncertainty associated 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.

Liquidity

As of March 31, 2016, the Company had an accumulated deficit of approximately $167.7 million. The Company had cash, cash equivalents and investments of $95.7 million at March 31, 2016. The Company believes that its existing cash, cash equivalents and investments will be sufficient to fund projected operating expenses and capital expenditure requirements into the second half of 2017.

Underwritten public offerings

On March 17, 2015, the Company completed an underwritten public offering of its common stock, $0.001 par value per share ("Common Stock"), in which it sold 6,272,726 shares of Common Stock, including the exercise in full by the underwriters of their option to purchase an additional 818,181 shares of Common Stock, to the public at a price of

$8.25 per share. The offering was completed under the shelf registration statement that was filed on Form S-3 and declared effective on March 10, 2015. Net proceeds of the underwritten public offering, after deducting the underwriting discounts and commissions, were $48.6 million, excluding offering expenses of $276 thousand incurred by the Company.

On August 4 2015, the Company completed an underwritten public offering of its Common Stock in which it sold an aggregate of 3,850,000 shares of Common Stock to the public at a price of $13.00 per share. The offering was completed under the shelf registration statement that was filed on Form S-3 and declared effective May 14, 2015. Net proceeds of the underwritten public offering, after deducting the underwriting discounts and commissions, were $47.0 million, excluding offering expenses of $233 thousand incurred by the Company.

At-the-market equity offering program

On March 2, 2015, the Company entered into a Sales Agreement with Cowen and Company, LLC (the "Sales Agreement") to establish an at-the-market equity offering program (“ATM”) pursuant to which it was able to offer and sell up to $40 million of its Common Stock at prevailing market prices from time to time. On May 8, 2015, the Sales Agreement was amended to increase the offering amount under the ATM to $50 million of its Common Stock. As of March 31, 2016, the Company had not commenced sales under this program.

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, 2016 and results of operations for the three months ended March 31, 2016 and 2015.

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, 2015 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, 2016.

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, 2016 and 2015.

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, 2016, 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) and warrants (Note 6). 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 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, 2016, 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, 2016.

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). Early adoption is not permitted under GAAP.	At this time, the Company has not decided on which method it will use to adopt the new standard, nor has it determined the effects of the new guidelines on its results of operations and financial position. For the foreseeable future, the Company's revenues will be limited to grants received from government agencies or nonprofit organizations. The Company is currently evaluating the method of adoption and the impact of this standard on its consolidated financial statements.
ASU 2014-15, Presentation of Financial Statements — Going Concern (Subtopic 205-40)	In August 2014, the FASB issued ASU 2014-15, Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern. The standard requires an evaluation of whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued. ASU 2014-15 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018.	Management has evaluated ASU 2014-15 and believes it could have an impact on the Company's financial statement disclosures in future reporting periods. Refer to the Liquidity section in Footnote 1 for further details regarding the Company's liquidity.
ASU 2016-02, Leases (Topic 842)	In February 2016, the FASB issued ASU 2016-02, which replaces the existing lease accounting standards.	The Company generally does not finance purchases of equipment or other capital, but it does lease office and lab facilities. The Company is evaluating the effect that this ASU will have on its consolidated

	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.	financial statements and related disclosures.
ASU 2016-09, Compensation — Stock Compensation (Topic 718)	In March 2016, the FASB issued ASU 2016-09, which provides for improvements to employee share-based payment accounting. The areas for simplification in this update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016.	The Company is evaluating the impact that this new guidance will have on the consolidated financial statements, but the effect of adoption is not expected to have a material impact to the balance sheet, statement of operations or cash flows.

3. Cash, cash equivalents and investments

As of March 31, 2016 and December 31, 2015, cash, cash equivalents, and investments comprised funds in depository, money market accounts, and FDIC insured certificates of deposit. At December 31, 2015, the Company's cash equivalents and investments also included U.S treasury securities.

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, 2016					
Money Market funds, included in cash equivalents	$37,465	$37,465	$ —	$	—
Investments - certificates of deposit	57,926	—	57,926	—	
Total	$95,391	$37,465	$ 57,926	$	—
December 31, 2015					
Money Market funds, included in cash equivalents	$14,207	$14,207	$ —	$	—
U.S treasuries, included in cash equivalents	2,203	2,203	—	—	
Investments - U.S. treasuries	27,924	27,924	—	—	
Investments - certificates of deposit	61,249	—	61,249	—	
Total	$105,583	$44,334	$ 61,249	$	—

Cash equivalents and investments are valued using third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income-based and market-based approaches and observable market inputs to determine value.

Investments at March 31, 2016 consist of the following (in thousands):

	Contracted Maturity	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Certificates of deposit	91-365 days	$ 57,926	$ —	$ —	$ 57,926
Total		$ 57,926	$ —	$ —	$ 57,926

4. Long-term debt

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 Company was 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, 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 the Company to draw two additional $5.0 million tranches. One $5.0 million tranche is immediately available to draw through December 15, 2016 and a second $5.0 million tranche is available to draw 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. As of March 31, 2016, the second $5.0 million tranche is not yet available to the Company. At March 31, 2016, $17.0 million was outstanding under the amended 2014 Term Loan.

2014 Term Loan

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

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

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

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

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

The Loan Agreement contains a material adverse effect provision ("Material Adverse Effect") 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 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.

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 per share). The exercise price and the number of shares are subject to adjustment upon a merger event, reclassification of the shares of Common Stock, subdivision or combination of the shares of Common Stock or certain dividends payments. The warrant is exercisable until November 20, 2019 and will be exercised automatically on a net issuance basis if not exercised prior to the expiration date and if the then-current fair market value of one share of Common Stock is greater than the exercise price then in effect. The warrant has been classified as equity for all periods it has been outstanding.

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

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

The Company incurred $280 thousand in debt financing costs related to the First Amendment, which was recorded as a debt discount and will be amortized over the remaining loan term. In connection with the issuance of the 2014 Term Loan, the Company incurred $103 thousand of financing costs and also reimbursed Hercules $210 thousand for debt financing costs, which has been recorded as a debt discount and will be amortized over the remaining loan term. The End of Term Charge is amortized ratably over the term loan period based upon the outstanding debt amount. The increase in the 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, 2016, the 2014 Term Loan bears an effective interest rate of 10.2%.

As of both March 31, 2016 and December 31, 2015, 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 and $0.3 million for the three months ended March 31, 2016 and 2015, respectively.

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

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

5. Commitments and contingencies

Lease commitments

In February 2014, the Company signed an operating lease for office and laboratory space that commenced in March 2014 and expires in February 2017 (the "2014 Lease"). In June 2015, the Company signed a second operating lease for

office space in the same building as the 2014 Lease, which also expires in February 2017 (the "2015 Lease"). The 2015 Lease has one three-year renewal period.

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

	March 31, 2016
2016	$1,039
2017	231
Total	$1,270

At March 31, 2016 and December 31, 2015, the Company has an outstanding letter of credit of $316 thousand with a financial institution related to a security deposit for the 2014 Lease, which is secured by cash on deposit and expires on February 28, 2017. An additional unsecured deposit was required for the 2015 Lease.

Significant Contracts and Agreements

In addition to lease commitments, the Company enters into contractual arrangements that obligate it to make payments to the contractual counterparties upon the occurrence of future events. In the normal course of operations, the Company enters into license and other agreements and intends to continue to seek additional rights 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 March 2014, the Company announced a joint research collaboration with Dana-Farber Cancer Institute to characterize anti-tumor T cell responses in melanoma patients. This collaboration extends the use of the Company's proprietary ATLAS platform for the rapid discovery of T cell antigens to cancer immunotherapy approaches. Under this agreement, the Company recognized no revenue and $21 thousand for the three months ended March 31, 2016 and 2015, respectively.

In September 2014, the Company received $1.2 million in the form of a grant entered into with the Bill & Melinda Gates Foundation for the identification of protective T-cell antigens for malaria vaccines. The grant will allow for the continued expansion of the Company’s malaria antigen library and aid in the identification of novel protein antigens to facilitate the development of highly efficacious anti-infection malarial vaccines. The Company recognized revenue under the agreement of $235 thousand and $100 thousand for the three months ended March 31, 2016 and 2015, 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 milestones achieved, the Company records a prepaid asset, and to the extent milestones achieved exceed amounts billed or billable under a contract, an accrual for the estimate of services rendered is recorded.

In February 2014, the Company entered into a supply agreement with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. (“Fujifilm”) for the manufacture and supply of antigens for future GEN-003 clinical trials. Under the agreement, the Company is obligated to pay Fujifilm manufacturing milestones, in addition to reimbursement of certain material production related costs. Additionally, the Company is responsible for the payment of a reservation fee, which will equal a percentage of the expected production fees, to reserve manufacturing slots in the production timeframe. The Company incurred expenses under this agreement of $158 thousand and $2.5 million for the three months ended March 31, 2016 and 2015, 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, 2016, the Company has authorized 25,000,000 shares of preferred stock at $0.001 par value per share. As of March 31, 2016 and December 31, 2015, there were no shares of preferred stock issued or outstanding.

At March 31, 2016, the Company has authorized 175,000,000 shares of Common Stock at $0.001 par value per share. As of March 31, 2016 and December 31, 2015, there were 28,161,010 and 28,161,313 shares of Common Stock issued. As of March 31, 2016 and December 31, 2015, there were 28,155,302 and 28,151,596 shares of Common Stock 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”). As the three months ended March 31, 2016 and 2015 resulted in net losses, 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, 2016 and December 31, 2015, 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,	
	2016	2015
Warrants	78	78
Outstanding options	3,675	2,763
Outstanding ESPP	16	11
Total	3,769	2,852

Restricted stock

During 2013, a Company director exercised stock options and received 31,092 shares of Common Stock that were subject to a Stock Restriction and Repurchase Agreement with the Company. Under the terms of the agreement, shares of Common Stock issued are subject to a vesting schedule and unvested shares are subject to repurchase by the Company. Vesting occurs periodically at specified time intervals and specified percentages. All shares of Common Stock become fully vested within four years of the date of grant.

As of both March 31, 2016 and December 31, 2015, the Company had issued 35,964 shares of restricted Common Stock. The Company had 7,773 and 9,717 shares of nonvested restricted stock that were subject to repurchase by the Company as of March 31, 2016 and December 31, 2015, respectively.

7. Stock and employee benefit plans

The Company’s Board of Directors adopted the 2014 Equity Incentive Plan (the “2014 Equity Plan”), which was approved by its stockholders and became effective prior to the commencement of the Company's IPO. The 2014 Equity Plan replaced the 2007 Equity Incentive Plan (the “2007 Equity Plan”).

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

Outstanding options awards granted from the 2007 Equity Plan, at the time of the adoption of the 2014 Equity Plan, remain outstanding and effective. The shares of Common Stock underlying awards that are cancelled, forfeited, repurchased, expire or are otherwise terminated under the 2007 Equity Plan are added to the shares of Common Stock available for issuance under the 2014 Equity Plan. As of March 31, 2016, the number of options available for grant is 694,119 shares and the total number of Common Stock shares that may be issued is 4,369,469.

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,	
	2016	2015
Research and development	$463	$415
General and administrative	600	500
Total	$1,063	$915

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, 2015	2,723	$ 7.60	7.61	$ 2,840
Granted	1,042	$ 3.12		
Exercised	(3)	$ 2.83		
Canceled	(87)	$ 8.68		
Outstanding at March 31, 2016	3,675	$ 6.31	7.94	$ 10,383
Exercisable at March 31, 2016	1,557	$ 5.97	6.47	$ 5,046
Vested or expected to vest at March 31, 2016	3,675	$ 6.31	7.94	$ 10,383

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, 2016, and accordingly did not recognize stock-based compensation expense for these periods. As of March 31, 2016, there are 56,336 performance-based common stock options outstanding for which the probability of achievement was not deemed probable.

Employee stock purchase plan

In connection with the completion of the Company's IPO 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, 2016, 144,242 shares remain for future issuance under the plan. The Company incurred stock-based compensation expense related to the 2014 ESPP of $33 thousand for the three months ended March 31, 2016 and $26 thousand for the three months ended March 31, 2015.

8. Income taxes

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company’s history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. There were no significant income tax provisions or benefits for the three months ended March 31, 2016 and 2015. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has provided a full valuation allowance against its deferred tax assets.

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 have another product candidate, GEN-004, a universal vaccine for the prevention of pneumococcal infections, for which we are actively seeking partnership opportunities to conduct a Phase 2 infant and toddler study. We also have active research and pre-clinical development programs for diseases including genital herpes, chlamydia, malaria, Epstein-Barr virus infections and related cancers, and we are actively investigating the application of ATLAS to immuno-oncology target discovery.

GEN-003 — Phase 2 immunotherapy for genital herpes

Our lead program is GEN-003, a Phase 2 candidate therapeutic vaccine, or immunotherapy, that we are developing to treat genital herpes infections. Data in 2014 from our double-blind, placebo-controlled, dose-escalating Phase 1/2a trial for GEN-003 represented the first reported instance of a therapeutic vaccine working against an infectious disease, and we have since identified two doses in our Phase 2 trial which has showed an even greater magnitude and duration of reduction in viral shedding than the best dose in the Phase 1/2a trial.

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

We recently completed a 310-subject Phase 2 dose optimization trial. 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 (25µg, 50µg, or 75µg). A seventh group received placebo. Subjects received three doses of GEN-003 or placebo at 21-day intervals. Baseline viral shedding and genital lesion rates were established for each subject in a 28-day observation period prior to the commencement of dosing by collecting 56 genital swab samples (two per day), which were analyzed for the presence of HSV-2 DNA, and by recording the days on which genital lesions were present. 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 6 active combinations of GEN-003 and Matrix-M2 under a separate protocol.

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 percent of patients who were recurrence free from lesions up to six and 12 months after dosing, the time to first recurrence of lesions after dosing and the reduction in genital lesion rates.

The two most promising doses from this dose optimization study were 60 μg per protein combined with either 50 or 75 μg of Matrix-M2 adjuvant. The efficacy of GEN-003 at these two dose levels over the course of the Phase 2 dose optimization trial is as follows:

Endpoint	60 µg per protein / 50 µg of Matrix-M2 Post dose 3	6 months	12 months	60 µg per protein / 75 µg of Matrix-M2 Post dose 3	6 months	12 months
Viral shedding rate reduction*	41% (p<0.0001)	46% (p<0.0001)	64% (p<0.0001)	55% (p<0.0001)	58% (p<0.0001)	52% (p<0.0001)
% patients lesion free	68%	36%	30%	68%	30%	21%
Genital lesion rate reduction*	69% (p<0.0001)	50% (p<0.0001)	65% (p<0.0001)	60% (p<0.0001)	43% (p<0.0001)	47% (p<0.0001)

Notes:
* Rate reduction vs. pre-dosing baseline levels. Poisson mixed effect model analysis.

These two doses have been advanced to our ongoing Phase 2b efficacy trial. GEN-003 continues to be safe and well tolerated by patients, with no serious adverse events related to the vaccine in the dose optimization trial.

Following improvements that we made to the manufacturing process for GEN-003, we commenced a 135-subject Phase 2b efficacy study in the fourth quarter of 2015. Top-line viral shedding data from the 28-day observation period immediately after dosing is expected in the third quarter of 2016 and clinical efficacy data versus placebo against potential Phase 3 endpoints at six months post dosing is expected around the end of 2016.

In the second half of 2016, we intend to commence a Phase 2b study to investigate the potential benefits of using GEN-003 in combination with oral antiviral medicines. We also intend to conduct an end-of-Phase 2 meeting with the FDA in early 2017. We retain all rights to GEN-003 and plan to advance this program through regulatory approval and, if approved, commercialize this vaccine through a focused commercial effort in the United States. Outside the United States, we intend to evaluate partnerships for GEN-003 opportunistically.

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

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

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

In 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, the consistent apparent effect gives us confidence in the vaccine concept and in the potential for GEN-004. While internal development of GEN-004 has been suspended, the we continue to seek partners to advance GEN-004 into a Phase 1/2 clinical trial targeting toddler and infant populations.

Research and non-clinical development in oncology

We announced a research collaboration with the Dana-Farber Cancer Institute ("DFCI") in 2014 to apply the ATLAS platform in immuno-oncology. This collaboration centered on ATLAS's potential to identify patterns of T cell response in melanoma patients receiving checkpoint inhibitor ("CPI") therapy. By analyzing the immune responses of both responders and non-responders to CPI therapy, ATLAS successfully identified the cancer antigens to which

either (or both) CD4+ or CD8+ T cells became activated. Although this research was not powered to draw firm conclusions, the analysis of T cell responses in patients receiving CPI therapy revealed a pattern indicating a greater breadth of T cell activation for responders than non-responders. The study also revealed preliminary evidence that different characteristics of T cell responses emerge when comparing patients who respond and those who do not. Some T cell responses did not correspond with improved patient outcomes, and may be classified as “decoys,” further validating the ability of ATLAS to distinguish clinically relevant targets of T cell response. The collaboration with Dana-Farber is ongoing as we continue to analyze more tumor samples to characterize T cell response profiles that may be prognostic of CPI efficacy, and to identify T cell antigens that may be included in novel immunotherapies.

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

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

Research and non-clinical development in infectious disease

We have ongoing non-clinical development programs in chlamydia and HSV-2 prophylaxis and a research program funded by the Bill & Melinda Gates Foundation in malaria.

Company background

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, 2016, we had received an aggregate of $223.7 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, 2016, our cash and cash equivalents and investments were $95.7 million.

Since inception, we have incurred significant operating losses. Our net losses were $9.8 million for the three months ended March 31, 2016, respectively, and our accumulated deficit was $167.7 million as of March 31, 2016. We expect to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We will need to generate significant revenue to achieve profitability, and we may never do so.

In March 2015, we completed an underwritten public offering of 6.3 million shares of our Common Stock at a public offering price of $8.25 per share for an aggregate offering price of $51.7 million (the "March 2015 Offering"). In August 2015, we completed another underwritten public offering of 3.9 million shares of our Common Stock at a public offering price of $13.00 per share for an aggregate offering price of $50.1 million (the "August 2015 Offering"). We received net proceeds from these offerings of approximately $101.8 million, after deducting approximately $6.1 million in underwriting discounts and commissions, excluding offering costs payable by us.

We believe that our cash, cash equivalents and investments at March 31, 2016 are sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2017. Through this timeframe, we expect to have results from multiple Phase 2 GEN-003 studies including the virological and clinical efficacy from our ongoing Phase 2b efficacy study, and a study to investigate the potential benefits of using GEN-003 in combination with oral antiviral medicines. In early 2017, we also expect to have conducted our FDA end of Phase 2 meeting for GEN-003 for genital herpes such that a Phase 3 study may begin in the second half of 2017. However, costs related to clinical

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

Financial Overview

Grant revenue

Grant revenue consists of revenue earned to conduct vaccine development research. We have received grants from private not-for-profit organizations and federal agencies. These grants have related to the discovery and development of several of our product candidates, including product candidates for the prevention of pneumococcus, chlamydia, 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 plan to continue to pursue grant funding, but there can be no assurance we will be successful in obtaining such grants in the future.

We have no products approved for sale. We will not receive any revenue from any product candidates that we develop until we obtain regulatory approval and commercialize such products or until we potentially enter into agreements with third parties for the development and commercialization of product candidates. If our development efforts for any of our product candidates result in regulatory approval or we enter into collaboration agreements with third parties, we may generate revenue from product sales or from such third parties.

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

Research and development expenses

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

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

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

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

	Three Months Ended March 31,	
	2016	2015
Genital herpes (GEN-003)(1)	$3,215	$5,585
Other research and development (2)	4,117	2,924
Total research and development	$7,332	$8,509

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

(2) Includes costs related to other product candidates and certain technology platform development costs related to ATLAS.

We expect our research and development expenses will increase as we continue the manufacture of 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 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 first quarter of 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, 2015 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, 2016.

Results of Operations

Comparison of the Three Months Ended March 31, 2016 and March 31, 2015

(in thousands)	Three Months Ended March 31, 2016	2015	Increase (Decrease)
Grant revenue	$235	$121	$ 114
Operating expenses:			
Research and development	7,332	8,509	(1,177)
General and administrative	3,924	3,389	535
Refund of research and development expense	(1,592)	—	(1,592)
Total operating expenses	9,664	11,898	(2,234)
Loss from operations	(9,429)	(11,777)	2,348
Other income and expenses:			
Interest income	109	12	97
Interest expense	(431)	(319)	(112)
Total other income and expense	(322)	(307)	(15)
Net loss	$(9,751)	$(12,084)	$ 2,333

Grant revenue

Grant revenue was $0.2 million for the three months ended March 31, 2016, an increase of $0.1 million from $0.1 million for the three months ended March 31, 2015. The increase was due to a higher level of research activity performed under a $1.2 million grant entered into with the Bill & Melinda Gates Foundation in September 2014.

Research and development expenses

Research and development expenses decreased $1.2 million for the three months ended March 31, 2016 compared to the three months ended March 31, 2015. Increases in compensation, consulting and professional services (approximately $1.1 million), lab-related costs (approximately $0.7 million), and office and facility costs (approximately $0.3 million) were offset by reductions in manufacturing costs (approximately $2.4 million) and clinical costs (approximately $1.1 million).

On a program basis, costs to advance our pre-clinical product candidates and develop our ATLAS platform for immuno-oncology increased by $1.2 million. The decrease in clinical costs is driven by the completion of the GEN-004 Phase 2a trial, which was ongoing in the first quarter of 2015, and the conduct of a smaller Phase 2 trial for GEN-003 in the first quarter of 2016 compared to the same period in 2015. GEN-003 manufacturing costs also decreased due to the timing of activities in support of clinical trials.

General and Administrative Expenses

General and administrative expense increased $0.5 million to $3.9 million for the three months ended March 31, 2016 from $3.4 million for the three months ended March 31, 2015. The increase was due largely to higher compensation costs due to increases in headcount, consulting and professional services, and in depreciation costs due to additional office space.

Refund of research and development expense

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 increased $0.1 million to $0.1 million for the three months ended March 31, 2016 due to both higher levels of investing activity and a higher interest rate environment.

Interest Expense

Interest expense increased $0.1 million to $0.4 million for the three months ended March 31, 2016 from $0.3 million for the three months ended March 31, 2015. The increase was due primarily to the $5.0 million increase in principal borrowings under our 2014 Term Loan as a result of the First Amendment entered into in the fourth quarter of fiscal year 2015.

Liquidity and Capital Resources

Overview

Since our inception through March 31, 2016, we have received an aggregate of $278.8 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At March 31, 2016, our cash, cash equivalents and investment securities were $95.7 million, comprising cash and cash equivalents of $37.7 million and current investment securities of $57.9 million.

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

Debt Financings

On November 20, 2014 (the "Closing Date"), we entered into a loan and security agreement (the “Loan Agreement”) with Hercules Technology Growth Capital, Inc. (“Hercules”), which provided up to $27.0 million in debt financing in three separate tranches (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 permits us to draw two additional $5.0 million tranches. One $5.0 million tranche is immediately available to draw through December 15, 2016 and a second $5.0 million tranche becomes available through December 15, 2016, subject to us demonstrating sufficient evidence of continued clinical progression of our GEN-003 product candidate and making favorable progress in applying our proprietary technology platform toward the development of novel immunotherapies with application in oncology. As of March 31, 2016, the second $5.0 million tranche is not yet available to us. At March 31, 2016, $17.0 million was outstanding under the amended 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 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, and we expect will continue to be for the near future, compensation and related expenses, manufacturing costs for pre-clinical and clinical materials, third party clinical trial research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

We believe that our cash, cash equivalents and investment securities at March 31, 2016 are sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2017. Through this timeframe, we expect to have results from multiple Phase 2 GEN-003 studies including a Phase 2b efficacy study and a study to investigate the potential benefits of using GEN-003 in combination with oral antiviral medicines. In early 2017, we also expect to conduct our FDA end of Phase 2 meeting for GEN-003 for genital herpes such that a Phase 3 study may begin in the second half of 2017. We are focused on maximizing the potential of our preclinical pipeline and our ATLAS technology for T cell target discovery, including enabling new immuno-oncology therapies. We expect that these funds will not be sufficient to enable us to seek marketing approval or commercialize any of our product candidates.

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

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

We expect that we will need to obtain substantial additional funding in order to commercialize GEN-003 and our other product candidates in order to receive regulatory approval. To the extent that we raise additional capital through the sale of Common Stock, convertible securities or other equity securities, the ownership interests of our existing stockholders may be

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

Cash Flows

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

	Three Months Ended March 31,	
	2016	2015
Net cash used in operating activities	$(10,179)	$(10,748)
Net cash provided by (used in) investing activities	30,643	(232)
Net cash provided by financing activities	7	48,393
Net increase in cash and cash equivalents	$20,471	$37,413

Operating Activities

Net cash used in operations decreased approximately $0.6 million to $10.2 million for the three months ended March 31, 2016 from $10.7 million for the three months ended March 31, 2015. The decrease in net cash used was due primarily to a reduction in net loss of approximately $2.3 million offset by an increase of $2.0 million in our working capital accounts.

Investing Activities

Net cash provided by investing activities was $30.6 million for the three months ended March 31, 2016 compared to net cash used in investing activities of $0.2 million for the three months ended March 31, 2015. The $30.9 million increase was due largely to the receipt of proceeds from maturities and sales of investments, totaling $33.5 million, offset by investments made of $2.3 million. The remaining impact was due to higher levels of capital investment.

Financing Activities

Net cash provided by financing activities decreased $48.4 million for the three months ended March 31, 2016 compared to the three months ended March 31, 2015 as there were no proceeds from follow-on offerings similar to the $48.4 million in net proceeds from the March 2015 Offering.

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, 2016.

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, 2016 and December 31, 2015, we had cash, cash equivalents and investments of $95.7 million and $106.4 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, 2016 and December 31, 2015, 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, 2016 (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, 2016, 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, 2016, 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, 2016, 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, 2016.

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, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of March 31, 2016 and December 31, 2015, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income for the three months ended March 31, 2016 and 2015, (iii) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2016 and 2015 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, 2016 By: /s/ WILLIAM D. CLARK
William D. Clark
President and Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 5, 2016 By: /s/ JONATHAN POOLE
Jonathan Poole
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)