GENOCEA BIOSCIENCES, INC.
Form 10-Q
November 04, 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 September 30, 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 November 2, 2016, there were 28,381,959 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 immuno-oncology;
- our estimate for when we will require additional funding;
- our plans to commercialize GEN-003 and our other vaccine candidates;
- the timing of, and our ability to, obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- the potential benefits of strategic partnership agreements and our ability to enter into strategic partnership arrangements;
- our ability to quickly and efficiently identify and develop product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position; and
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing.

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

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

Genocea Biosciences, Inc.
Form 10-Q
For the Quarter Ended September 30, 2016

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 26,417	$ 17,259
Investments, current portion	49,044	77,069
Prepaid expenses and other current assets	950	865
Total current assets	76,411	95,193
Property and equipment, net	5,034	4,083
Restricted cash	316	316
Investments, net of current portion	—	12,104
Other non-current assets	1,108	446
Total assets	$ 82,869	$ 112,142
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,888	$ 1,757
Accrued expenses and other current liabilities	3,641	3,975
Deferred revenue	—	235
Current portion of long-term debt	1,559	—
Total current liabilities	7,088	5,967
Non-current liabilities:		
Long-term debt	15,274	16,477
Other non-current liabilities	158	37
Total liabilities	22,520	22,481
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock	—	—
Common stock	28	28
Additional paid-in-capital	251,762	247,550
Accumulated other comprehensive income (loss)	8	(7)
Accumulated deficit	(191,449)	(157,910)
Total stockholders' equity	60,349	89,661
Total liabilities and stockholders' equity	$ 82,869	$ 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Grant revenue	$—	$213	$235	$449
Operating expenses:				
Research and development	8,811	6,058	22,821	21,536
General and administrative	3,619	3,645	11,569	10,206
Refund of research and development expense	—	—	(1,592)	—
Total operating expenses	12,430	9,703	32,798	31,742
Loss from operations	(12,430)	(9,490)	(32,563)	(31,293)
Other income and expense:				
Interest income	103	39	323	70
Interest expense	(438)	(320)	(1,299)	(946)
Total other income and expense	(335)	(281)	(976)	(876)
Net loss	$(12,765)	$(9,771)	$(33,539)	$(32,169)
Other comprehensive income (loss):				
Unrealized (loss) gain on available-for-sale securities	(9)	10	15	24
Comprehensive loss	$(12,774)	$(9,761)	$(33,524)	$(32,145)
Net loss per share - basic and diluted	$(0.45)	$(0.37)	$(1.18)	$(1.38)
Weighted-average number of common shares used in computing net loss per share	28,370	26,610	28,267	23,228

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	$ (33,539)	$ (32,169)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,309	661
Stock-based compensation	3,113	2,824
Net amortization of premium on investments	—	25
Non-cash interest expense	356	269
Changes in operating assets and liabilities	(1,342)	17
Net cash used in operating activities	(30,103)	(28,373)
Investing activities		
Purchases of property and equipment	(1,968)	(1,849)
Proceeds from maturities of investments	58,891	16,000
Purchases of investments	(18,755)	(58,698)
Net cash provided by (used in) investing activities	38,168	(44,547)
Financing activities		
Proceeds from equity offerings, net of issuance costs	815	95,216
Proceeds from exercise of stock options	166	354
Proceeds from the issuance of common stock under ESPP	112	119
Net cash provided by financing activities	1,093	95,689
	$ 9,158	$ 22,769

Net increase in cash and cash equivalents	17,259		20,058	
Cash and cash equivalents at beginning of period				
Cash and cash equivalents at end of period	$	26,417	$	42,827
Supplemental cash flow information				
Cash paid for interest	$	943	$	661
Property and equipment included in accounts payable and accrued expenses	$	293	$	531

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. Although 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. In November 2016, the Company announced its intention to focus all near-term research and pre-clinical resources to accelerate its progress in immuno-oncology, specifically cancer vaccines. As a result of this decision, it has paused all work on early stage infectious disease programs in genital herpes, chlamydia, and malaria. Progress made and data generated to date in these infectious disease research programs remains valuable to Genocea for the future.

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 for 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 September 30, 2016, the Company had an accumulated deficit of approximately $191.4 million. The Company had cash, cash equivalents and investments of $75.5 million at September 30, 2016. On the basis of current operating plans, including the plan to focus research investments on immuno-oncology and the planned commencement of Phase 3 trials for GEN-003 in the second half of 2017, it expects that these funds will be sufficient to fund operating expenses and capital expenditure requirements into the first quarter of 2018, without assuming any receipt of proceeds from potential business development partnerships, equity financings or debt drawdowns.

At-the-market equity offering program

On March 2, 2015, the Company entered into a Sales Agreement with Cowen and Company, LLC (the "Sales Agreement") to establish an at-the-market equity offering program (“ATM”) pursuant to which it was able to offer and sell up to $40 million of its Common Stock at prevailing market prices from time to time. On May 8, 2015, the Sales Agreement was amended to increase the offering amount under the ATM to $50 million of its Common Stock. In April 2016, the Company sold 136 thousand shares and received $0.8 million in net proceeds after deducting commissions. For the three months ended September 30, 2016, there were no additional ATM sales.

2. Summary of significant accounting policies

Basis of presentation and use of estimates

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and the instructions of Form 10-Q and Article 10 of Regulation S-X. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These interim condensed financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position as of September 30, 2016 and results of operations for the three and nine months ended September 30, 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 nine months ended September 30, 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 September 30, 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). The Company is also required to disclose the fair value of financial instruments not carried at fair value. The fair value of the Company's debt (Note 4) is determined using current applicable rates for similar instruments as of the balance sheet dates and an assessment of the credit rating of the Company. The carrying value of the Company's debt approximates fair value because the Company's interest rate yield is near current market rates for comparable debt instruments. The Company's debt is considered a Level 3 liability within the fair value hierarchy.

For the nine months ended September 30, 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 nine months ended September 30, 2016.

Recently adopted accounting standards

Standard	Description	Effect on the financial statements
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 early adopted ASU 2016-09 as of June 30, 2016. In connection with the early adoption, the Company elected an accounting policy to record forfeitures as they occur. There was no financial statement impact upon adoption as the Company had estimated a forfeiture rate of zero given that most options awards vest on a monthly basis. ASU 2016-09 also provides that companies no longer record excess tax benefits or certain tax deficiencies in additional paid-in capital (APIC). Instead, all excess tax benefits and tax deficiencies are recorded as income tax expense or benefit in the income statement. There was no financial statement impact of adopting this provision of the ASU as the Company is in a net operating loss (NOL) position and all excess tax benefits that exist from options previously exercised require a full valuation allowance. As such, the adoption of this standard did not have a material impact on the financial statements. For the nine month period ending September 30, 2016, the Company did not record an income statement benefit for excess tax benefits as a valuation allowance is also required on these amounts.

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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).	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 as the Company does not currently have any arrangements that would be impacted by the new standard. As a result, the Company is continuing to evaluate 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, 2016.	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 new standard requires a dual approach for lessee accounting under which a lessee	The Company generally does not finance purchases of equipment but it does lease office and lab facilities. The Company is in the process of evaluating the effect that this ASU will have on its consolidated financial statements and related disclosures.

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.

3. Cash, cash equivalents and investments

As of September 30, 2016 and December 31, 2015, cash, cash equivalents, and investments comprised funds in depository, money market accounts, U.S. treasuries, and FDIC insured certificates of deposit.

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

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2016				
Money market funds, included in cash equivalents	$24,460	$24,460	$ —	$ —
Investments - U.S treasuries	16,523	16,523	—	—
Investments - certificates of deposit	32,521	—	32,521	—
Total	$73,504	$40,983	$ 32,521	$ —
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 September 30, 2016 consist of the following (in thousands):

	Contracted Maturity	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasuries	123-273 days	$ 16,515	$ 8	$ —	$ 16,523
Certificates of deposit	3-182 days	32,521	—	—	32,521
Total		$ 49,036	$ 8	$ —	$ 49,044

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 September 30, 2016, the second $5.0 million tranche is not yet available to the Company. At September 30, 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 on January 1, 2019.

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

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

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

The Loan Agreement contains a material adverse effect 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.

The 2014 Term Loan is automatically accelerated upon a change in control wherein the Company must prepay the outstanding principal and any accrued and unpaid interest through the prepayment date, including any unpaid agent's and lender's fees and expenses accrued to the date of the repayment, the End of Term Charge, and a prepayment charge. If a change in control occurs, repayment of amounts due under the Loan Agreement may be accelerated by Hercules. The Company believes acceleration of the repayment of amounts outstanding under the loan is remote.
In connection with the 2014 Term Loan, the Company issued a common stock warrant to Hercules on November 20, 2014. The warrant is exercisable for 73,725 shares of the Company's Common Stock (equal to $607,500 divided by the

exercise price of $8.24 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 September 30, 2016, the 2014 Term Loan bears an effective interest rate of 10.2%.

As of both September 30, 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 $1.3 million for the three and nine months ended September 30, 2016, respectively, and $0.3 million and $0.9 million for the three and nine months ended September 30, 2015, respectively.

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

	September 30, 2016
2016	$ —
2017	3,149
2018	6,659
2019	8,034
Total	$ 17,842

5. Commitments and contingencies

Lease commitments

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

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

	September 30, 2016
2016	$ 316
2017	1,550
2018	1,607
2019	1,637
2020	274
Total	$ 5,384

At September 30, 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 2016 Lease, which is secured by cash on deposit and expires on February 29, 2020. An additional unsecured deposit was required for the 2015 Lease.

Significant Contracts and Agreements

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

In 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. In September 2014, the Company received $1.2 million in the form of a grant entered into with the Bill & Melinda Gates Foundation for the identification of protective T-cell antigens for malaria vaccines. This grant provided for the continued expansion of the Company’s malaria antigen library to aid in the identification of novel protein antigens to facilitate the development of highly efficacious anti-infection malarial vaccines. The Company recognized revenue under these agreements of $213 thousand and $449 thousand for the three and nine months ended September 30, 2015, respectively. The Company recognized revenue of none and $235 thousand for the three and nine months ended September 30, 2016, respectively.

The Company relies on research institutions, contract research organizations, clinical investigators as well as clinical and commercial material manufacturers of our product candidates. Under the terms of these agreements, the Company is obligated to make milestone payments upon the achievement of manufacturing or clinical milestones defined in the contracts. In some cases, monthly service fees for project management services are charged over the duration of the arrangement. In addition, clinical and manufacturing contracts generally require reimbursement to suppliers for certain set-up, production, travel, and other related costs as they are incurred. In some manufacturing contracts, the Company also may be responsible for the payment of a reservation fee, which will equal a percentage of the expected production fees, to reserve manufacturing slots in the production timeframe. Generally, the Company is liable for actual effort expended by these organizations at any point in time during the contract through the notice period. To the extent amounts paid to a supplier exceed the 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. In June and September 2016, the Company entered into new statements of work under the agreement with Fujifilm for the manufacture and supply of antigens for the Company's Phase 3 clinical trials. The Company incurred expenses under the agreement of $0.4 million and $3.9 million for the three and nine months ended September 30, 2015, respectively. The Company incurred expenses under the agreement of $0.5 million and $0.8 million for the three and nine months ended September 30, 2016, respectively.

Litigation

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 September 30, 2016, the Company has authorized 25,000,000 shares of preferred stock at $0.001 par value per share. As of September 30, 2016 and December 31, 2015, there were no shares of preferred stock issued or outstanding.

At September 30, 2016, the Company has authorized 175,000,000 shares of Common Stock at $0.001 par value per share. As of September 30, 2016 and December 31, 2015, there were 28,384,548 and 28,161,313 shares, respectively, of Common Stock issued. As of September 30, 2016 and December 31, 2015, there were 28,380,663 and 28,151,596 shares, respectively, 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 and nine months ended for both September 30, 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 September 30, 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):

	Nine Months Ended September 30,	
	2016	2015
Warrants	78	78
Outstanding options	3,794	2,716
Outstanding ESPP	21	13
Total	3,893	2,807

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 September 30, 2016 and December 31, 2015, the Company had issued 35,964 shares of restricted Common Stock. The Company had 3,885 and 9,717 shares of nonvested restricted stock that were subject to repurchase by the Company as of September 30, 2016 and December 31, 2015, respectively.

7. Stock and employee benefit plans

Stock-based compensation expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	$428	$380	$1,234	$1,245
General and administrative	691	498	1,879	1,579
Total	$1,119	$878	$3,113	$2,824

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	1,472	$ 3.51		
Exercised	(56)	$ 2.96		
Canceled	(345)	$ 8.46		
Outstanding at September 30, 2016	3,794	$ 6.01	7.74	$ 4,708
Exercisable at September 30, 2016	1,763	$ 6.09	6.47	$ 2,627
Vested or expected to vest at September 30, 2016	3,794	$ 6.01	7.74	$ 4,708

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 and nine months ended September 30, 2016, and accordingly did not recognize stock-based compensation expense for these periods. As of September 30, 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 September 30, 2016, 112,073 shares remain for future issuance under the plan. The Company incurred stock-based compensation expense related to the 2014 ESPP of $45 thousand and $110 thousand for the three and nine months ended September 30, 2016, respectively, and $30 thousand and $83 thousand for the three and nine months ended September 30, 2015, respectively.

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

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

Overview

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

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. Although 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. In November 2016, the Company announced its intention to focus all near-term research and pre-clinical resources to accelerate its progress in immuno-oncology, specifically cancer vaccines. As a result of this decision, it has paused all work on early stage infectious disease programs in genital herpes, chlamydia, and malaria. Progress made and data generated to date in these infectious disease research programs remains valuable to Genocea for the future.

GEN-003 — Phase 2 immunotherapy for genital herpes

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

Phase 1/2 Trial

Final analysis of the data from the Phase 1/2a trial showed that, for the best performing 30µg dose group, there was a sustained reduction in the viral shedding rate. After completion of dosing for this group, the viral shedding rate was reduced 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.

Phase 2 Dose Optimization Trial

A 310-subject Phase 2 dose optimization trial was completed in March 2016. The objective of this trial was to confirm the results of the Phase 1/2a trial and to test six combinations of proteins and adjuvant to determine the optimal dose for future trials and potentially improve on the profile of GEN-003. Subjects were randomized to one of six dosing groups of either 30µg or 60µg per protein paired with one of three adjuvant doses (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:

	Placebo	60 µg per protein / 50 µg of Matrix-M2			60 µg per protein / 75 µg of Matrix-M2		
Endpoint	Post dose 3	Post dose 3	6 months	12 months	Post dose 3	6 months	12 months
Viral shedding rate reduction[1]	-4%	41%	47%	66%	55%	58%	55%
Poisson mixed effect model (Old Model)[2]							
p-value vs baseline	0.48	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
p-value vs placebo	NA	<0.0001	NA	NA	<0.0001	NA	NA
Poisson mixed effect model with Empirical Variance (New Model)[3]							
p-value vs baseline	0.88	0.01	0.0004	<0.0001	0.006	<0.0001	0.01
p-value vs placebo	NA	0.04	NA	NA	0.01	NA	NA
% patients lesion free	NA	68%	36%	30%	68%	30%	21%
Genital lesion rate reduction[1]	60%	69%	50%	65%	60%	43%	47%
Poisson mixed effect model (Old Model)[2]							
p-value vs baseline	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
p-value vs placebo	NA	0.3	NA	NA	0.79	NA	NA
Poisson mixed effect model with Empirical Variance (New Model)[3]							
p-value vs baseline	0.0002	0.0005	0.01	0.003	0.02	0.03	0.02
p-value vs placebo	NA	0.59	NA	NA	0.85	NA	NA

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

(2) Generalized Linear Model with “Standard” Poisson distribution as pre-specified in the Phase 2 trial statistical analysis plan, formerly a widely adopted model developed by the University of Washington (“UW”) and which was used in both the GEN-003 Phase 1/2 and Phase 2 trials (the “Old Model”).

(3) Statistical analysis performed using a modified Poisson model (the “New Model”) reflecting advances in the field since the start of the Phase 2 dose optimization trial: Magaret, Amalia, "Models for HSV shedding must account for two levels of overdispersion" ((January 2016). UW Biostatistics Working Paper Series. Working Paper 410). UW developed the New Model as clinical trial data which accumulated over the years indicated that the Old Model assumptions around the distribution of data did not fit this actual genital herpes clinical trial data. The New Model corrects the assumption of data distribution by an empiric variance method which better reflects this clinical trial experience. Critically, the results of the GEN-003 clinical trials analyzed with the New Model remain statistically significant and the estimated magnitude of the effect, confidence intervals around that effect and durability of effect are unchanged.

Genocea considers it important to reflect advances in the field of genital herpes research in its approach to the conduct of clinical trials and the analysis of clinical trial data and adopted the New Model as the primary statistical model for the viral shedding rate and genital lesion rate data in its ongoing Phase 2b trial. Results shown above from the Phase 2 trial using the New Model are provided for comparative purposes, but were not part of the original pre-specified statistical analysis plan for this trial.

Phase 2b Trial

In December 2015, a Phase 2b trial was initiated as our first study testing potential Phase 3 endpoints with a Phase 3-ready formulation of GEN-003, one manufactured with commercially-scalable processes. The trial enrolled 131

subjects that were randomized to one of three dose groups - placebo, 60 µg per protein / 50 µg of Matrix-M2 (the "60/50 Dose") and 60 µg per protein / 75 µg of Matrix-M2 (the "60/75 Dose"). All subjects received three injections at 21-day intervals.

In September 2016, we announced positive viral shedding rate reductions from the ongoing Phase 2b study. The study achieved its primary endpoint, with GEN-003 demonstrating a statistically significant (versus placebo and baseline) 40%

reduction in the viral shedding rate compared to baseline immediately after dosing in the 60/50 Dose group, using a new Phase 3-ready formulation. This result was consistent with a statistically significant (versus placebo and baseline) viral shedding rate reduction of 41% at this same dose and time point in a prior Phase 2 trial. In addition, the reactogenicity profile of this dose, an indication of the strength of the immune response to GEN-003, was consistent between the trials. This same dose in the prior Phase 2 trial subsequently demonstrated virologic and clinical efficacy durable through at least one year after dosing.

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

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

	Placebo	60/50 Dose	60/75 Dose
Viral shedding rate reduction[(1)]	6%	-40%	-27%
Poisson mixed effect model with Empirical Variance (New Model)[(2)(3)]			
p-value vs. baseline	0.76	0.03	0.16
p-value vs. placebo	NA	0.05	0.20

(1) Rate reduction vs. pre-dosing levels.
(2) The New Model (see note above under “Phase 2 Dose Optimization Trial”), as pre-specified in the Phase 2b statistical analysis plan.
(3) Under the Old Model (see note above under “Phase 2 Dose Optimization Trial”), p-values for the 60/50 Dose were <0.0001 vs. both baseline and placebo and for the 60/75 Dose were 0.001 vs. baseline and 0.004 vs. placebo.

The trial will also compare GEN-003 efficacy to placebo for the clinical endpoints of: the proportion of patients who are lesion recurrence free at six and 12 months after dosing; the time to first lesion recurrence after dosing; and, the impact on percentage of days with genital herpes lesions at six and 12 months after dosing. All subjects will be followed for 12 months after the last dose. The clinical efficacy data versus placebo against potential Phase 3 endpoints at six-months post dosing is expected in January 2017. The viral shedding rate reduction data at six-months post dosing is expected in the first half of 2017.

Safety in the trial was continuously reviewed by an independent Data Safety Monitoring Board. There was no grade 4 reactogenicity or related serious adverse events and discontinuations due to adverse events were low and similarly distributed across active dose groups and placebo.

We intend to conduct an end-of-Phase 2 meeting with the FDA in early 2017. We now plan to conduct a clinical trial exploring the potential additive effects of GEN-003 on top of daily administration of VALTREX®, an oral antiviral therapy, as part of the GEN-003 Phase 3 program. We believe that this will increase the chances that positive results in this trial could be included in GEN-003’s label, if approved. 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. We intend to evaluate partnerships for the future development and commercialization of GEN-003.

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, 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.

We continue to advance our collaborations with Memorial Sloan Kettering Cancer Center and Dana-Farber Cancer Center and we expect to announce further data from these collaborations later in the fourth quarter of 2016.

Research and non-clinical development in infectious disease

We have paused activities on our non-clinical development programs in chlamydia, HSV-2 prophylaxis and malaria in order to focus all of our internal research and pre-clinical resources on our immune-oncology investments. Progress made and data generated to date in these infectious disease research programs remains valuable to Genocea for the future.

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 September 30, 2016, we had received an aggregate of $279.6 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At September 30, 2016, our cash and cash equivalents and investments were $75.5 million.

Since inception, we have incurred significant operating losses. Our net losses were $12.8 million and $33.5 million for the three and nine months ended September 30, 2016, respectively, and our accumulated deficit was $191.4 million as of September 30, 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.

As of September 30, 2016, we sold 136 thousand shares under our ATM program and received $0.8 million in net proceeds after deducting commissions.

On the basis of current operating plans, including the plan to focus research investments on immuno-oncology and the planned commencement of Phase 3 trials for GEN-003 in the second half of 2017, Genocea expects that these funds will be sufficient to fund its operating expenses and capital expenditure requirements into the first quarter of 2018, without assuming any receipt of proceeds from potential business development partnerships, equity financings or debt drawdowns. We expect to report six-month placebo-controlled clinical efficacy results from the ongoing Phase 2b trial in January 2017 and we anticipate conducting an FDA end-of-Phase 2 meeting for GEN-003 in the first quarter 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Genital herpes (GEN-003)(1)	$4,979	$2,955	$11,339	$12,582
Other research and development (2)	3,832	3,103	11,482	8,954
Total research and development	$8,811	$6,058	$22,821	$21,536

(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. Additionally, costs that are not specifically allocated by project including facilities costs, depreciation expense, and non-project specific costs incurred by R&D personnel, are included in this line item.

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

General and administrative expenses

General and administrative expenses consist principally of salaries and related costs for personnel, including stock-based compensation and travel expenses, in executive 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 nine months ended September 30, 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 September 30, 2016 and September 30, 2015

	Three Months Ended September 30,		Increase
(in thousands)	2016	2015	(Decrease)
Grant revenue	$—	$213	$ (213)
Operating expenses:			
Research and development	8,811	6,058	2,753
General and administrative	3,619	3,645	(26)
Total operating expenses	12,430	9,703	2,727
Loss from operations	(12,430)	(9,490)	(2,940)
Other income and expenses:			
Interest income	103	39	64
Interest expense	(438)	(320)	(118)
Total other income and expense	(335)	(281)	(54)
Net loss	$(12,765)	$(9,771)	$ (2,994)

Grant revenue

We did not record any grant revenue in the three months ended September 30, 2016 as compared to $0.2 million in the three months ended September 30, 2015. The $0.2 million decrease was due to the completion of work related to a $1.2 million grant entered into with the Bill & Melinda Gates Foundation in September 2014. The full amount of the grant was recognized as of March 31, 2016.

Research and development expenses

Research and development expenses increased $2.8 million in the three months ended September 30, 2016. The increase was due largely to increases in compensation, consulting and professional services (approximately $1.8 million), clinical costs (approximately $0.6 million), and office and facility costs (approximately $0.2 million).

On a program basis, GEN-003 costs increased by $2.0 million compared to the three months ended September 30, 2015, driven by increases in headcount related expenses and clinical expenses to support the GEN-003 program, and higher consulting and professional service costs in advance of the expected Phase 3 trials. GEN-004 costs decreased by approximately

$0.5 million following the suspension of development of the program in the fourth quarter of 2015. Other costs, including those to advance our pre-clinical product candidates and develop our ATLAS platform for immuno-oncology increased by approximately $1.3 million.

General and Administrative Expenses

General and administrative expenses were unchanged at approximately $3.6 million from the same three month period in 2015. Expenditures across various activities also remained consistent with the same quarter in the prior year.

Interest Income

Interest income increased $0.1 million for the three months ended September 30, 2016 due to both higher levels of investing activity and a higher interest rate environment.

Interest Expense

Interest expense increased $0.1 million in the three months ended September 30, 2016. 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.

Comparison of the Nine Months Ended September 30, 2016 and September 30, 2015

	Nine Months Ended September 30,		Increase
(in thousands)	2016	2015	(Decrease)
Grant revenue	$235	$449	$ (214)
Operating expenses:			
Research and development	22,821	21,536	1,285
General and administrative	11,569	10,206	1,363
Refund of research and development expense	(1,592)	—	(1,592)
Total operating expenses	32,798	31,742	1,056
Loss from operations	(32,563)	(31,293)	(1,270)
Other income and expenses:			
Interest income	323	70	253
Interest expense	(1,299)	(946)	(353)
Total other income and expense	(976)	(876)	(100)
Net loss	$(33,539)	$(32,169)	$ (1,370)

Grant revenue

Grant revenue for the nine months ended September 30, 2016 decreased by $0.2 million from the same nine month period in 2015. We entered into a $1.2 million grant with the Bill & Melinda Gates Foundation in September 2014. Grant activities occurred throughout the nine-month period in 2015 and were largely completed in the first quarter of 2016.

Research and development expenses

Research and development expenses increased $1.3 million for the nine months ended September 30, 2016. The increases in compensation, consulting and professional services (approximately $3.6 million), lab-related costs (approximately $1.5 million), facility costs (approximately $0.7 million), and depreciation expense (approximately $0.3 million), were partially offset by decreases in manufacturing costs (approximately $4.5 million) and clinical costs (approximately $0.7 million). The remaining increases, all insignificant by spending category, are attributable to the overall growth of the research and development function.

On a program basis, GEN-003 costs decreased $1.2 million in the nine months ended September 30, 2016, driven by lower manufacturing costs offset by increases in headcount and related expenses to support the GEN-003 program and an increase in clinical trial activities for ongoing and anticipated trials GEN-004 costs decreased by $2.0 million following the suspension of development of the program in the fourth quarter of 2015. Other costs, including those to advance our pre-clinical product candidates and develop our ATLAS platform for immuno-oncology increased by $4.5 million.

General and Administrative Expenses

General and administrative expense increased $1.4 million in the nine months ended September 30, 2016. The increase was due largely to GEN-003 market research costs and higher depreciation costs from facility expansion.

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 $0.3 million in the nine months ended September 30, 2016 due to both higher levels of investing activity and a higher interest rate environment.

Interest Expense

Interest expense increased $0.4 million in the nine months ended September 30, 2016. 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 September 30, 2016, we have received an aggregate of $279.6 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At September 30, 2016, our cash, cash equivalents and investment securities were $75.5 million, comprising cash and cash equivalents of $26.4 million and current investment securities of approximately $49.1 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.

As of September 30, 2016, we sold 136 thousand shares under our ATM program and received $0.8 million in net proceeds after deducting commissions.

Debt Financings

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

In December 2015, we entered into an amendment to the Loan Agreement (the "First Amendment") with Hercules. The First Amendment required us to draw an additional $5.0 million and 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 September 30, 2016, the second $5.0 million tranche is not yet available to us. At September 30, 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, manufacturing costs for pre-clinical and clinical materials, third party clinical trial research and development services, laboratory and related supplies, clinical costs, compensation and related expenses, legal and other regulatory expenses and general overhead costs.

On the basis of current operating plans, including the plan to focus research investments on immuno-oncology and the planned commencement of Phase 3 trials for GEN-003 in the second half of 2017, Genocea expects that its cash, cash equivalents and marketable securities as at September 30, 2016 will be sufficient to fund its operating expenses and capital expenditure requirements into the first quarter of 2018, without assuming any receipt of proceeds from potential business development partnerships, equity financings or debt drawdowns. Through this timeframe, we expect to report six-month placebo-controlled clinical efficacy results from the ongoing Phase 2b study and we anticipate meeting the FDA in an end-of-Phase 2 meeting for GEN-003 in the first quarter 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):

	Nine Months Ended September 30,	
	2016	2015
Net cash used in operating activities	$(30,103)	$(28,373)
Net cash provided by (used in) investing activities	38,168	(44,547)
Net cash provided by financing activities	1,093	95,689
Net increase in cash and cash equivalents	$9,158	$22,769

Operating Activities

Net cash used in operations increased by approximately $1.7 million to $30.1 million for the nine months ended September 30, 2016 from $28.4 million for the nine months ended September 30, 2015. The increase in net cash used was due primarily to a higher net loss of approximately $1.3 million and a $1.4 million decrease in our working capital accounts both offset by increases in depreciation and amortization (approximately $0.6 million) and

stock-based compensation expense (approximately $0.3 million).

Investing Activities

Net cash provided by investing activities was $38.2 million for the nine months ended September 30, 2016 compared to net cash used of $44.5 million for the nine months ended September 30, 2015. The $82.7 million increase was due largely to an increase of $42.8 million in net proceeds from maturities and sales of investments and a decrease in investment purchases of $39.9 million.

Financing Activities

Net cash provided by financing activities decreased $94.6 million for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 due to $0.8 million in net proceeds from equity offerings under the ATM in the nine months ended September 30, 2016 compared to $95.2 million in net proceeds from the follow-on equity offerings in March and August of 2015.

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 September 30, 2016 and December 31, 2015, we had cash, cash equivalents and investments of $75.5 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 September 30, 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 September 30, 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 September 30, 2016, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the nine months ended September 30, 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 September 30, 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
10.1*	Amended and Restated Exclusive License Agreement between Children's Medical Center Corporation and Genocea Biosciences, Inc., dated March 23, 2012.
10.2*	Amended and Restated License Agreement between Genocea Biosciences, Inc. and President and Fellows of Harvard College, dated November 19, 2013.
10.3*	License and Collaboration Agreement between Genocea Biosciences, Inc. and Isconova AB, dated August 5, 2009, as amended on March 19, 2010, June 18, 2010, August 17, 2010, October 19, 2011, February 6, 2012 and October 21, 2014.
10.4*	Exclusive License Agreement for Escherichia Coli K12 to Deliver Protein to the Macrophage Cytosol between Genocea Biosciences, Inc. and the Regents of the University of California, dated August 18, 2006.
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
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The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2016 and 2015, (iii) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015 and (iv) Notes to Unaudited Condensed Consolidated Financial Statements

*Confidential treatment has been granted by, or is being requested from, the Securities and Exchange Commission as to certain portions of this exhibit (indicated by asterisks), which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities Act of 1933, as amended and the Securities Exchange Act of 1934, as amended, as applicable.

SIGNATURES

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

Genocea Biosciences, Inc.

Date: November 4, 2016 By: /s/ WILLIAM D. CLARK
William D. Clark
President and Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 4, 2016 By: /s/ JONATHAN POOLE
Jonathan Poole
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)