GENOCEA BIOSCIENCES, INC.
Form 10-Q
November 05, 2015

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, 2015
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	¨
Non-accelerated filer	x (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 3, 2015, there were 28,115,036 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 GEN-004;
- 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, 2015

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$42,827	$20,058
Investments, current portion	54,784	27,021
Prepaid expenses and other current assets	883	934
Total current assets	98,494	48,013
Property and equipment, net	3,674	1,956
Restricted cash	316	316
Investments, non-current portion	14,934	—
Other non-current assets	462	47
Total assets	$117,880	$50,332
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$1,731	$2,692
Accrued expenses and other current liabilities	4,928	2,486
Deferred revenue	457	555
Current portion of long-term debt	1,100	—
Other current liabilities	134	107
Total current liabilities	8,350	5,840
Non-current liabilities:		
Long-term debt	10,558	11,389
Deferred revenue, net of current portion	—	350
Other non-current liabilities	87	246
Total liabilities	18,995	17,825
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock	—	—
Common stock	28	18
Additional paid-in-capital	246,436	147,923
Accumulated other comprehensive income (loss)	17	(7)
Accumulated deficit	(147,596)	(115,427)
Total stockholders' equity	98,885	32,507
Total liabilities and stockholders' equity	$117,880	$50,332

See accompanying notes to unaudited financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Grant revenue	$213	$—	$449	$—
Operating expenses:				
Research and development	6,058	6,115	21,536	15,073
General and administrative	3,645	2,843	10,206	7,167
Total operating expenses	9,703	8,958	31,742	22,240
Loss from operations	(9,490)	(8,958)	(31,293)	(22,240)
Other expense:				
Change in fair value of warrants	—	—	—	(725)
Interest expense, net	(281)	(213)	(876)	(681)
Other expense	(281)	(213)	(876)	(1,406)
Net loss	$(9,771)	$(9,171)	$(32,169)	$(23,646)
Reconciliation of net loss to net loss applicable to common stockholders				
Net loss	$(9,771)	$(9,171)	$(32,169)	$(23,646)
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(180)
Net loss attributable to common stockholders	$(9,771)	$(9,171)	$(32,169)	$(23,826)
Net loss per share attributable to common stockholders-basic and diluted	$(0.37)	$(0.53)	$(1.38)	$(1.60)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	26,610	17,465	23,228	14,918

See accompanying notes to unaudited financial statements.

Genocea Biosciences, Inc.
Condensed Statements of Comprehensive Loss
(unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	$(9,771)	$(9,171)	$(32,169)	$(23,646)
Other comprehensive income (loss):				
Unrealized gain on available-for-sale securities	10	11	24	10
Comprehensive loss	$(9,761)	$(9,160)	$(32,145)	$(23,636)

See accompanying notes to unaudited financial statements.

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

	Nine Months Ended September 30,	
	2015	2014
Operating activities		
Net loss	$(32,169)	$(23,646)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	661	298
Stock-based compensation	2,824	2,146
Net amortization of premium on investments	25	14
Change in fair value of warrants liability	—	725
Non-cash interest expense	269	60
Changes in operating assets and liabilities	20	1,211
Net cash used in operating activities	(28,370)	(19,192)
Investing activities		
Purchases of property and equipment	(1,849)	(1,237)
Proceeds from maturities of investments	16,000	—
Purchase of investments	(58,698)	(27,053)
Net cash used in investing activities	(44,547)	(28,290)
Financing activities		
Proceeds from IPO, net of issuance costs	—	59,974
Proceeds from underwritten public offering, net of issuance costs	95,216	—
Repayment of long-term debt		(212)
Proceeds from exercise of stock options	354	624
Proceeds from the exercise of warrants	—	33
Proceeds from the issuance of common stock under ESPP	119	—
Payments made under capital lease	(3)	—
Net cash provided by financing activities	95,686	60,419
Net increase in cash and cash equivalents	$22,769	$12,937
Cash and cash equivalents at beginning of period	20,058	12,208
Cash and cash equivalents at end of period	$42,827	$25,145
Supplemental cash flow information		
Cash paid for interest	$661	$582
Supplemental disclosure of non-cash investing and financing activities		
Conversion of preferred stock to common stock upon closing of IPO	$—	$81,742
Reclassification of prepaid IPO closing costs from non-current assets to additional paid-in capital	$—	$998
Reclassification of warrants to additional paid-in capital	$—	$1,381
Accretion of redeemable convertible preferred stock to redemption value	$—	$180
Vesting of restricted stock	$8	$8

See accompanying notes to unaudited financial statements.

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

1. Organization and operations

The Company

Genocea Biosciences, Inc. (the "Company") is a clinical stage biopharmaceutical company that was incorporated in Delaware on August 16, 2006 and has a principal place of business in Cambridge, Massachusetts. The Company has one product in active clinical development, GEN-003, an immunotherapy to treat patients with genital herpes that is currently in Phase 2 clinical development. In May 2015, the Company reported initial positive top-line data from a Phase 2 dose optimization trial, which showed that during the 28-day observation period immediately after completion of dosing, the best dose of 60 µg per protein / 75 µg of Matrix-M2™ adjuvant demonstrated a statistically significant ($p < 0.0001$) 55 percent reduction from baseline in the viral shedding rate.

In October 2015, the Company reported positive results from a planned interim analysis of data collected six months after dosing. At its best performing dose of 60µg per protein/75µg of adjuvant, GEN-003 demonstrated a statistically significant 58 percent reduction from baseline in the viral shedding rate ($p < 0.0001$), the primary endpoint of the study.

In a planned secondary analysis to assess the impact on genital lesion rates, a patient-reported measurement of clinical disease, GEN-003 demonstrated sustained and statistically significant reductions from baseline in five of six dose groups ranging from 43 to 69 percent. In addition, the proportion of patients receiving GEN-003 who were lesion-free at six months after dosing ranged from approximately 30 to 50 percent, similar to results reported in clinical trials with oral antiviral therapies. A further secondary analysis measuring the time to first recurrence after completion of dosing showed a range of 152 days to greater than 180 days among dose groups. The Phase 2 trial continues to show that GEN-003 is safe and well tolerated by patients, with no serious adverse events related to the vaccine. Data from the 12-month observation period in this trial is expected in first quarter of 2016.

The Company has another product candidate, GEN-004, a universal vaccine to prevent infections caused by all serotypes of pneumococcus. In October 2015, the Company reported that the Phase 2a clinical trial for GEN-004 showed consistent reductions versus placebo in the pre-specified endpoints of the rate and density of colonization, but that neither of the endpoints achieved statistical significance. Plans for further developing GEN-004 in the near-term have been placed on hold pending further data analysis and consultation with advisors.

The Company has other product candidates in preclinical development and ongoing discovery research activities with a focus on infectious disease and immuno-oncology applications. The Company developed GEN-003, GEN-004 and its preclinical product candidates using its proprietary platform technology called the AnTigen Lead Acquisition System ("ATLAS™"). The ATLAS™ platform mimics the human T cell immune response in the laboratory, which could potentially improve the effectiveness T cell-directed vaccines and immunotherapies in the areas of infectious disease, immuno-oncology and autoimmune disorders.

Underwritten public offerings

On March 17, 2015, the Company completed an underwritten public offering of its common stock, $0.001 par value per share ("Common Stock"), in which it sold 6,272,726 shares of Common Stock, including the exercise in full by the underwriters of their option to purchase an additional 818,181 shares of Common Stock, to the public at a price of $8.25 per share. The offering was completed under the shelf registration statement that was filed on Form S-3 and

declared effective on March 10, 2015. Net proceeds of the underwritten public offering, after deducting the underwriting discounts and commissions, were $48.6 million, excluding offering expenses of $276 thousand incurred by the Company.

On August 4 2015, the Company completed an underwritten public offering of its Common Stock in which it sold an aggregate of 3,850,000 shares of Common Stock to the public at a price of $13.00 per share. The offering was completed under the shelf registration statement that was filed on Form S-3 and declared effective May 14, 2015. Net proceeds of the underwritten public offering, after deducting the underwriting discounts and commissions, were $47.0 million, excluding offering expenses of $169 thousand incurred by the Company.

At-the-market equity offering program

On March 2, 2015, the Company entered into a Sales Agreement with Cowen and Company, LLC (the "Sales Agreement") to establish an at-the-market equity offering program (“ATM”) pursuant to which it was able to offer and sell up to $40 million of its Common Stock at prevailing market prices from time to time. On May 8, 2015, the Sales Agreement was amended to increase the offering amount under the ATM to $50 million of its Common Stock. As of September 30, 2015, the Company had not commenced sales under this program.

2. Summary of significant accounting policies

Basis of presentation and use of estimates

The accompanying unaudited condensed 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, 2015 and results of operations for the three and nine months ended September 30, 2015 and 2014.

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, 2014 and the notes thereto which are included in the Company’s Annual Report on Form 10-K, as filed with the SEC on February 27, 2015.

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, the valuation of common stock warrants and warrants to purchase redeemable securities, 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 expense, net. There were no realized gains or losses recognized for the three and nine months ended September 30, 2015 and 2014.

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, 2015, 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.

Deferred financing costs

Offering costs related to debt and equity financing primarily consist of direct and incremental external expenses. In accordance with ASU No. 2015-03 Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs ("ASU 2015-03") the Company presents debt issuance costs related to a recognized debt liability in the balance sheet as a direct deduction of the carrying value of the debt liability, consistent with the accounting treatment of debt discounts. The adoption of ASU 2015-03 in the quarter ended June 30, 2015 resulted in the reclassification of approximately $99 thousand, as of December 31, 2014, of unamortized capitalized debt issuance costs previously included in both other current and other non-current assets to a direct deduction of the carrying value of the debt liability. The adoption of this standard did not have material impact on the Company's financial conditions, results of operations, or cash flows. The amortization of deferred debt financing costs follows the effective interest rate method and was not impacted by the issuance or adoption of ASU 2015-03.

Offering costs related to the registration statements and the initiation of the ATM are recorded as an asset and are reclassified to equity on a pro-rata basis based upon the successful selling of common shares compared to the available limits in either equity program. The costs are reviewed for impairment and will be recorded to expense if and when the Company determines that future equity offerings are not probable of occurring. At September 30, 2015, the Company had $302 thousand of deferred offering costs recorded as a non-current asset.

Development of Software for Internal Use

The Company accounts for the costs of software developed or obtained for internal use in accordance with ASC 350-40, Internal-Use Software. Costs of materials, consultants, payroll, and payroll-related costs for employees incurred in developing internal-use software are capitalized as incurred. These costs are included in Property and equipment, net. Costs incurred during the preliminary project and post-implementation stages are charged to expense.

Fair value of financial instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC Topic 820, Fair Value Measurement and Disclosures, established a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the financial instrument based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the financial instrument and are developed based on the best information available under the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported or disclosed fair value of the financial instruments and is not a measure of the investment credit quality. Fair value measurements are classified and disclosed in one of the following three categories:

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

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company

in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Financial instruments measured at fair value on a recurring basis include cash equivalents and investments (Note 3) and warrants (Note 5). The Company is also required to disclose the fair value of financial instruments not carried at fair value. The fair value of the Company's debt (Note 4) is determined using current applicable rates for similar instruments as of the balance sheet dates and assessment of the credit rating of the Company. The carrying value of the Company's debt approximates fair value because the Company's interest rate yield is near current market rates for comparable debt instruments. The Company's debt is considered a Level 3 liability within the fair value hierarchy.

For the nine months ended September 30, 2015, 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, 2015.

Recently issued accounting standards

Standard	Description	Effect on the financial statements
ASU 2014-09, Revenue from Contracts with Customers (Topic 606)	The standard will replace existing revenue recognition standards and significantly expand the disclosure requirements for revenue arrangements. It may be adopted either retrospectively or on a modified retrospective basis to new contracts and existing contracts with remaining performance obligations as of the effective date. In July 2015, the FASB affirmed its proposal to defer the effective date of the new revenue standard for all entities by one year. As a result, public business entities will be required to apply the new revenue standard to annual reporting periods beginning after December 15, 2017. The standard will become effective for us on January 1, 2018 (the first quarter of our 2018 fiscal year). Early adoption is not permitted under GAAP.	At this time, the Company has not decided on which method it will use to adopt the new standard, nor has it determined the effects of the new guidelines on its results of operations and financial position. For the foreseeable future, the Company's revenues will be limited to grants received from government agencies or nonprofit organizations. The Company is currently evaluating the method of adoption and the impact of this standard on our financial statements.
ASU No. 2014-15, Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15").	The standard requires a company to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the 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. This ASU is effective for annual and interim periods ending after December 15, 2016 and earlier application is permitted.	The Company is evaluating the effects of the new standard, but does not expect it will have a material impact on its financial conditions, results of operations, or cash flows.

3. Cash, cash equivalents and investments

As of September 30, 2015 and December 31, 2014, cash, cash equivalents, and investments comprised funds in depository, money market accounts, U.S treasury securities, and FDIC insured certificates of deposit.

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

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2015				
Money Market funds, included in cash equivalents	$41,033	$41,033	$—	$—
Certificates of deposit, included in cash equivalents	1,604	—	1,604	—
Investments - U.S. treasuries	38,956	38,956	—	—
Investments - certificates of deposit	30,762	—	$30,762	—
Total	$112,355	$79,989	$32,366	$—
December 31, 2014				
Money Market funds, included in cash equivalents	$18,992	$18,992	$—	$—
Marketable securities - U.S. treasuries	27,021	27,021	—	—
Total	$46,013	$46,013	$—	$—

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, 2015 consist of the following (in thousands):

	Contracted Maturity	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Investments					
U.S. Treasuries	15-184 days	$38,939	$17	$—	$38,956
Certificates of deposit	91-365 days	15,828	—	—	15,828
Certificates of deposit	greater than 365 days	14,934	—	—	14,934
Total		$69,701	$17	$—	$69,718

4. Debt

On November 20, 2014, 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 (“2014 Term Loan”). The first tranche of $17.0 million was available through September 30, 2015, of which $12.0 million was drawn down at loan inception. 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. The Company has the option to draw down the second tranche on or prior to December 15, 2015. The third tranche of $5.0 million is not eligible to draw as the Company did not achieve positive results from its Phase 2a human challenge study of GEN-004.

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 on the 2014 Term Loan.

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 for a six-month period at the Company’s sole election as the eligibility requirements for the

second tranche were met as of June 30, 2015. Thereafter, beginning July 1, 2016, payments will be made monthly in 30 equal installments of principal and interest (subject to recalculation upon a change in prime rates). 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 twelve months following the closing date, 2.0%, if an advance is prepaid between twelve months and twenty four months following the closing date, and 1.0% thereafter. Amounts outstanding during 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 must also pay an end of term charge of 4.95% 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.

The Loan Agreement contains a provision that requires all occurrences that would reasonably be expected to have a material adverse effect ("Material Adverse Effect") 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; (ii) the ability of the Company to perform the secured obligations in accordance with the terms of the loan documents, or the ability of the agent or lender to enforce any of its rights or remedies with respect to the secured obligations; or (iii) the collateral or the agent's liens on the collateral or the priority of such liens. Any event that would reasonably be expected to have a Material Adverse Effect is an event of default under the Loan Agreement and, as such, payment of all or any part of the secured obligations may be accelerated upon and during the continuation of such event.

Events of default under the Loan Agreement include failure to make any payments of principal or interest as due under the Loan Agreement or any other loan document, breach of any covenant (subject to certain additional conditions relating to cure periods and the Company's actual knowledge of default), any representations or warranties being false or misleading in any material respect, insolvency or bankruptcy, any attachment, seizure, levy or judgment on the Company's assets of at least $100,000, or the occurrence of any default under any agreement or obligation of the Company involving indebtedness in excess of $100,000. If an event of default occurs, repayment of all amounts due under the Loan Agreement may be accelerated by the lender, including the applicable prepayment charge.

The 2014 Term Loan is automatically accelerated upon a change in control, such that the Company must prepay the outstanding amount of all principal and accrued interest through the prepayment date and any unpaid agent's and lender's fees and expenses accrued to the date of the repayment (including the end of term charge) and the applicable prepayment charge. If a change in control occurs, repayment of amounts due under the Loan Agreement may be accelerated by the lender.

Upon closing the 2014 Term Loan, the Company drew down $12.0 million under the first tranche of the Loan Agreement using approximately $9.8 million of the proceeds to repay all outstanding indebtedness under the Company's 2013 loan agreement ("2013 Term Loan").

In connection with the Loan Agreement, 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 Loan Agreement, 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 "Initial Equity Investment"). 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.

In connection with the issuance of the 2014 Term Loan, the Company incurred $103 thousand of debt issuance costs which were recorded as an off-set to the outstanding principal balance. The Company also reimbursed the lenders $210 thousand for debt financing costs which has been recorded as a debt discount. The 2014 Term Loan included various embedded features which were evaluated for separate accounting as derivatives under ASC Topic 815, Derivatives and Hedging ("ASC 815"). In accordance with ASC 815, it was determined that none of these embedded features required separate accounting from the debt host. The debt discount is being amortized to interest expense over the life of the 2014 Term Loan using the effective interest method.

Future principal payments due on the 2014 Term Loan are as follows (in thousands):

	September 30, 2015
2015	$—
2016	2,223
2017	4,700
2018	5,058
2019	19
Total	$12,000

5. Warrants

As of September 30, 2015 and December 31, 2014, 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 IPO.

Hercules warrants

In accordance with ASC 815, the Company determined the common stock warrant issued to Hercules to be equity classified. The Company estimated the fair value of this warrant as of the issuance date using a Black-Scholes option pricing model (with a 10% discount for lack of marketability) with the following assumptions:

	November 20, 2014	
Fair value of underlying instrument	$9.05	
Expected volatility	70.0	%
Expected term (in years)	5.00	
Risk-free interest rate	1.64	%
Expected dividend yield	0.0	%

The Company utilized this fair value in its allocation of debt proceeds between debt and the warrants which was performed on a relative fair value basis. The Company allocated $334 thousand to the Hercules warrants and recognized this amount in additional paid-in capital during the year ended December 31, 2014.

At September 30, 2015, all of the common stock warrants issued to Hercules remained outstanding.

6. Commitments and contingencies

In February 2014, the Company signed an operating lease for office and laboratory space that commenced in March 2014 and expires in February 2017 (the "2014 Lease"). In June 2015, the Company signed a second operating lease for office space in the same building as the 2014 Lease, which also expires in February 2017 (the "2015 Lease"). The minimum future lease payments under both the 2014 Lease and the 2015 Lease are as follows (in thousands):

	September 30, 2015
2015	$337
2016	1,379
2017	231
Total	$1,947

At September 30, 2015 and December 31, 2014, the Company has an outstanding letter of credit of $316 thousand with a financial institution related to a security deposit for the 2014 Lease, which is secured by cash on deposit and expires on February 28, 2017. An additional unsecured deposit was required for the 2015 Lease.

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 entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. These agreements may require payments to be made by the Company upon the occurrence of certain development milestones and certain commercialization milestones for each distinct product covered by the licensed patents (in addition to certain royalties to be paid on marketed products or sublicense income) contingent upon the occurrence of future events that cannot be reasonably estimated.

In March 2014, the Company announced a joint research collaboration with Dana-Farber Cancer Institute to characterize anti-tumor T cell responses in melanoma patients. This collaboration extends the use of the Company's proprietary ATLAS platform for the rapid discovery of T cell antigens to cancer immunotherapy approaches. Under this agreement, the Company recognized no revenue and $30 thousand for the three and nine months ended September 30, 2015, respectively, and none for the three and nine months ended September 30, 2014.

In September 2014, the Company received $1.2 million in the form of a grant entered into with the Bill & Melinda Gates Foundation for the identification of protective T-cell antigens for malaria vaccines. The grant will allow for the continued expansion of the Company’s malaria antigen library and aid in the identification of novel protein antigens to facilitate the development of highly efficacious anti-infection malarial vaccines. The Company recognized revenue under the agreement of $213 thousand and $419 thousand for the three and nine months ended September 30, 2015.

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 fee for project management services are charged over the duration of the arrangement. In addition, clinical and manufacturing contracts generally require reimbursement to suppliers for certain set-up, production, travel, and other related costs as they are incurred. In some manufacturing contracts, the Company also may be responsible for the payment of a reservation fee, which will equal a percentage of the expected production fees, to reserve manufacturing slots in the production timeframe. Generally, the Company is liable for actual effort expended by these organizations at any point in time during the contract through the notice period. To the extent amounts paid to a supplier exceed the milestones achieved, the Company records a prepaid asset, and to the extent milestones achieved exceed amounts billed or billable under a contract, an accrual for the estimate of services rendered is recorded.

In February 2014, the Company entered into a supply agreement with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. (“Fujifilm”) for the manufacture and supply of antigens for future GEN-003 clinical trials. Under the agreement, the Company is obligated to pay Fujifilm manufacturing milestones, in addition to reimbursement of certain material production related costs. Additionally, the Company is responsible for the payment of a reservation fee, which will equal a percentage of the expected production fees, to reserve manufacturing slots in the production

timeframe. The Company incurred expenses under this agreement of $357 thousand and $3.9 million for the three and nine months ended September 30, 2015, respectively, and $769 thousand and $1.1 million for the three and nine months ended September 30, 2014, respectively.

Litigation

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

7. Equity and net loss per share

At September 30, 2015, the Company has authorized 25,000,000 shares of preferred stock at $0.001 par value per share. As of September 30, 2015 and December 31, 2014, there were no shares of preferred stock issued or outstanding.

At September 30, 2015, the Company has authorized 175,000,000 shares of common stock at $0.001 par value per share. As of September 30, 2015 and December 31, 2014, there were 28,127,110 and 17,869,235 shares of common stock issued. As of September 30, 2015 and December 31, 2014, there were 28,114,158 and 17,852,389 shares of common stock outstanding.

The Company computes basic and diluted earnings (loss) per share using a methodology that gives effect to the impact of outstanding participating securities (the “two-class method”). As the three and nine months ended September 30, 2015 and 2014 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.

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,	
	2015	2014
Warrants	78	4
Outstanding options	2,716	2,077
Total	2,794	2,081

Reverse stock split

On January 20, 2014, the Board of Directors and stockholders approved a 1-for-11.9 reverse stock split of the Company’s Common Stock, which was effected on January 21, 2014. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares upon the completion of our initial public offering (“IPO”) on February 17, 2014. The Company’s historical share and per share information were retroactively adjusted to give effect to this reverse stock split. Shares of Common Stock underlying outstanding stock option were proportionately reduced and the respective exercise prices proportionately increased.

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 December 31, 2014 and September 30, 2015, the Company had issued 35,964 shares of restricted Common Stock. The Company had 16,840 and 11,008 shares of nonvested restricted stock that were subject to repurchase by the Company as of December 31, 2014 and September 30, 2015, respectively.

8. Stock-based compensation

The Company's Board of Directors adopted the 2014 Equity Incentive Plan (the "2014 Equity Plan"), which was approved by its stockholders and became effective prior to the commencement of our IPO on February 10, 2014. The 2014 Equity Plan replaced the 2007 Equity Incentive Plan (the "2007 Equity Plan").

The 2014 Equity Plan provides for the grant of incentive stock options, non-qualified stock options and restricted stock awards to key employees and directors of, and consultants and advisors to, the Company. The maximum number of shares of Common Stock that may be delivered in satisfaction of awards under the 2014 Equity Plan is 903,494 shares, plus 219,765 shares that were available for grant under the 2007 Equity Plan on the date the 2014 Equity Plan was adopted. The 2014 Equity Plan provides that the number of shares available for issuance will automatically increase annually on each January 1, from January 1, 2015 through January 1, 2024, in amount equal to the lesser of 4.0% of the outstanding shares of the

Company's outstanding Common Stock as of the close of business on the immediately preceding December 31 or the number of shares determined the Company's Board of Directors. Pursuant to this provision, on January 1, 2015, the shares available under the 2014 Equity Plan increased by 714,769 shares of Common Stock. The 2014 Equity Plan also allows for shares of Common Stock underlying awards that are cancelled, forfeited, repurchased, expire or are otherwise terminated to be added to the shares of Common Stock available for issuance under the 2014 Equity Plan.

Outstanding option awards granted under the 2007 Equity Plan, at the time of the adoption of the 2014 Equity Plan, remain outstanding and effective. As of September 30, 2015, 234,369 shares remain available for future grants under the 2014 Equity Plan. Including options outstanding as of September 30, 2015, under both the 2007 Equity Plan and the 2014 Equity Plan and including shares still available for future awards under the 2014 Equity Plan, 2,950,584 of common shares may be issued under option award 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,	
	2015	2014	2015	2014
Research and development	$380	$291	$1,245	$1,139
General and administrative	498	306	1,579	1,007
Total	$878	$597	$2,824	$2,146

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, 2014	2,290	$7.26	8.08	$5,332
Granted	659	$9.34		
Exercised	(113)	$3.13		
Canceled	(120)	$14.07		
Outstanding at September 30, 2015	2,716	$7.64	7.83	$4,687
Exercisable at September 30, 2015	1,272	$5.28	6.71	$3,996
Vested or expected to vest at September 30, 2015	2,584	$7.56	7.79	$4,598

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, 2015, and accordingly did not recognize stock-based compensation expense for these periods. No stock-based compensation was recorded for the three months ended September 30, 2014 and $435 thousand was recorded for the nine months ended September 30, 2014. The stock-based compensation recorded for the nine months ended September 30, 2014 was due to the achievement of milestones and subsequent vesting of 96,988 performance-based options in first quarter of 2014. As of September 30, 2015, 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 our 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. The first offering period under the 2014 ESPP began on July 1, 2014. During the nine months ended September 30, 2015, 20,069 shares were issued under the 2014 ESPP, with 165,085 shares remaining for future issuance under the plan as of September 30, 2015. The Company incurred stock-based compensation expense related to the 2014 ESPP of $30 thousand and $83 thousand for the three and nine months ended September 30, 2015, respectively, and $21 thousand for both the three and nine months ended September 30, 2014.

9. Income taxes

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. There were no significant income tax provisions or benefits for the three and nine months ended September 30, 2015 and 2014. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has provided a full valuation allowance against its deferred tax assets.

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

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

Overview

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

We have one product candidate in active Phase 2 clinical development, GEN-003, an immunotherapy for the treatment of genital herpes. We have another product candidate, GEN-004, a universal vaccine for the prevention of pneumococcal infections for which we have suspended development pending further data analysis and consultation with our advisers after we did not achieve statistically significant results in our Phase 2a human challenge study. We also have active research and pre-clinical development programs for diseases including genital herpes, chlamydia and malaria. We are also investigating the application of ATLAS to immuno-oncology target discovery.

GEN-003 — Phase 2 immunotherapy for genital herpes

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

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

Having identified a dose that, according to company-sponsored market research, delivers clinically meaningful efficacy in magnitude and durability, we are now conducting a 310-subject Phase 2 dose optimization trial. The objective of this trial is to confirm the results of the best performing dose in the Phase 1/2a trial and to test six other combinations of proteins and adjuvant to determine the optimal dose for future trials and potentially improve on the current profile of GEN-003.

In May 2015, we announced positive top-line data from the Phase 2 trial. 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. During the 28-day observation period immediately after completion of dosing, the best dose of 60µg per protein/75µg of Matrix-M2™ adjuvant demonstrated a highly statistically significant ($p<0.0001$) 55% reduction from baseline in the viral shedding rate, the primary endpoint of the trial and a measure of anti-viral activity. All dose combinations tested, including the successful 30µg per protein/50µg of adjuvant dose from the prior Phase 1/2a trial, demonstrated a statistically significant viral shedding rate reduction versus baseline and only the lowest dose combination did not demonstrate a statistically significant reduction versus placebo. In a planned secondary analysis to assess impact on patient reported genital lesion rates, all dose groups, including the placebo group, demonstrated a statistically significant reduction from baseline. Furthermore, there was no difference in discontinuations in patient dosing due to adverse events across the different treatment arms.

In October 2015, we announced positive results from a planned interim analysis of data collected six months after dosing. At its best performing dose of 60 µg per protein / 75 µg of Matrix-M2™ adjuvant, GEN-003 demonstrated a

statistically significant 58 percent reduction from baseline in the viral shedding rate ($p < 0.0001$). In a planned secondary analysis to assess the impact on patient reported genital lesion rates, GEN-003 also demonstrated sustained and statistically significant reductions from baseline in five of six dose groups ranging from 43 to 69 percent. In addition, the proportion of patients receiving GEN-003 who were lesion-free at six months after dosing ranged from approximately 30 to 50 percent, similar to results reported in clinical trials with oral antiviral therapies. A further secondary analysis measuring the time to first recurrence after completion of dosing showed a range of 152 days to greater than 180 days among dose groups. The Phase 2 trial continues to show that GEN-003 is safe and well tolerated by patients, with no serious adverse events related to the vaccine. Data from the 12-month observation period in this trial is expected in the first quarter of 2016.

Following improvements that we have made to the manufacturing process for GEN-003, we intend to commence a small Phase 2b bridging study in the fourth quarter of 2015. Top-line viral shedding and genital lesion rate data from the 28-day observation period immediately after dosing from this bridging study is expected in the second quarter of 2016.

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

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

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

We also have a second T cell-stimulating vaccine candidate, GEN-004, a potential universal Streptococcus pneumoniae, or pneumococcus, vaccine to protect against the 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 June 2014, we announced top-line data from a Phase 1 clinical trial for GEN-004. This trial met its safety, tolerability and immunogenicity goals including measurable increases in the blood of Th17 cells. We initiated a 98-subject Phase 2a trial in September 2014 to demonstrate that GEN-004 can reduce the frequency, magnitude and duration of colonization of pneumococcus in the nasopharynx in healthy adults.

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 colonization, but that neither of the endpoints achieved statistical significance. GEN-004 was safe and well tolerated by subjects. GEN-004 reduced the colonization rate, measured by microbiological culture, by between 22 and 25 percent versus placebo across those measurement time points. When measured by the presence of pneumococcal DNA, the reductions ranged between 18 and 36 percent. Additionally the median density of colonization measured by microbiological culture for GEN-004 treated subjects ranged from zero to two colony forming units ("CFUs") per mL of nasal wash compared to one to 11 CFUs per mL for the placebo group. When measured by the presence of pneumococcal DNA, the median densities ranged from zero to 10 copies per mL in treated subjects and 19 to 52 copies per mL in placebo subjects. None of the differences were statistically significant. There was no difference in the duration of colonization between GEN-004 and placebo.

While we did not hit statistical significance in this study, the consistent apparent effect gives us confidence in the vaccine concept and in the potential for GEN-004. We believe it is possible that future trials would require a change in some combination of dose, adjuvant or trial population to confirm any effect. Pending further data analysis and consultation with our advisors to determine next steps for this program, we are removing the development of GEN-004 from our near-term plans to focus our resources on the ongoing GEN-003 program, and on maximizing the potential of our preclinical pipeline and our ATLAS technology for T cell target discovery.

Research and non-clinical development in oncology

We initiated 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 cancer 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. While 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 checkpoint inhibitor 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 checkpoint inhibitors against the complete repertoire of patient-specific putative cancer neoantigens. The goals of the collaboration are to identify signatures of T cell response in cancer patients associated with response or non-response to CPI therapy and to discover new T cell cancer vaccine antigens. ATLAS will be used in conjunction with Memorial Sloan Kettering’s patient-specific cancer neoantigen sequences and blood samples from the same cancer patients.

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

Research and non-clinical development in infectious disease

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

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, 2015, we had received an aggregate of $223.7 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At September 30, 2015, our cash and cash equivalents and marketable securities were $112.5 million.

Since inception, we have incurred significant operating losses. Our net losses were $9.8 million and $32.2 million for the three and nine months ended September 30, 2015, respectively, and our accumulated deficit was $147.6 million as of September 30, 2015. We expect to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We will need to generate significant revenue to achieve profitability, and we may never do so.

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

We believe that our cash, cash equivalents and investments at September 30, 2015 are sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2017. Through this timeframe, we expect to have results from multiple Phase 2 GEN-003 studies including the twelve month data from our ongoing dose optimization clinical trial, a bridging study, a dose regimen clinical trial, and a study to investigate the potential benefits of using GEN-003 in combination with oral antiviral medicines. In late 2016, we also expect to have conducted our FDA end of Phase 2 meeting for GEN-003 for genital herpes such that a Phase 3 study may begin in the second half of 2017. However, costs related to clinical trials can be unpredictable and therefore there can be no guarantee that our current balances of cash, cash equivalents and investments, and any proceeds received from other sources, will be sufficient to fund our studies or operations through this period. These funds will not be sufficient to enable us to conduct pivotal clinical trials for, seek marketing approval for or commercially launch GEN-003 or any other product candidate. Accordingly, to obtain marketing approval for and to commercialize these or any other product candidates, we will be required to obtain further funding through public or private equity offerings, debt

financings, collaboration and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital when needed would have a negative effect on our financial condition and our ability to pursue our business strategy.

Financial Overview

Grant revenue

Grant revenue consists of revenue earned to conduct vaccine development research. We have received grants from private not-for-profit organizations and federal agencies. These grants have related to the discovery and development of several of our product candidates, including product candidates for the prevention of pneumococcus, chlamydia, and malaria. 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, or CROs, contract manufacturing organizations, or 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,

	2015	2014	2015	2014
Genital herpes (GEN-003)(1)	$2,955	$4,020	$12,582	$8,622
Pneumococcus (GEN-004)(1)	595	1,210	2,572	3,600
Other research and development (2)	2,508	885	6,382	2,851
Total research and development	$6,058	$6,115	$21,536	$15,073

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

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

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

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.

Interest expense, net

Interest expense, net consists primarily of interest expense on our long-term debt facilities and non-cash interest related to the amortization of debt discount and issuance costs, partially offset by interest earned on our cash, cash equivalent and investment portfolio.

Change in fair value of warrants

This expense consists of fair value adjustments on warrants to purchase preferred stock. Upon completion of our IPO on February 10, 2014, warrants to purchase preferred stock were converted to warrants to purchase common stock and as a result, the Company no longer recorded fair value adjustments for its warrants.

Accretion of redeemable convertible preferred stock

Certain classes of our preferred stock were redeemable beginning in 2017 at the original issuance price plus any declared or accrued but unpaid dividends upon written election of the preferred stockholders in accordance with the terms of our articles of incorporation. Accretion of preferred stock reflects the accretion of issuance costs and, for Series B preferred stock, cumulative dividends based on their respective redemption values. On February 10, 2014, we completed our IPO and all shares of preferred stock were converted into 11,466,479 shares of our Common Stock. No accretion of preferred stock is recorded after this date as no shares of preferred stock are outstanding.

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, common stock warrants, warrants to purchase redeemable securities, 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, 2014 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 27, 2015.

Results of Operations

Comparison of the Three Months Ended September 30, 2015 and September 30, 2014

	Three Months Ended September 30,		Increase
(in thousands)	2015	2014	(Decrease)
Grant revenue	$213	$—	$213
Operating expenses:			
Research and development	6,058	6,115	(57)
General and administrative	3,645	2,843	802
Total operating expenses	9,703	8,958	745
Loss from operations	(9,490)	(8,958)	(532)
Other expense:			
Interest expense, net	—	—	—
Other expense	(281)	(213)	(68)
Net loss	$(9,771)	$(9,171)	$(600)

Grant revenue

Grant revenue was $0.2 million for the three months ended September 30, 2015, an increase of $0.2 million from none for the three months ended September 30, 2014. The increase was due to current period activities performed on a $1.2 million grant entered into with the Bill & Melinda Gates Foundation in September 2014.

Research and development expenses

Research and development expenses were unchanged at $6.1 million for three months ended September 30, 2015 compared to the three months ended September 30, 2014. Increases in compensation, consulting and professional services (approximately $0.7 million) and lab-related costs (approximately $0.5 million) were offset by reductions in manufacturing costs (approximately $0.8 million) and licensing fees (approximately $0.4 million). On a program basis, GEN-003 and GEN-004 costs decreased by $1.1 million and $0.6 million, respectively, offset by increases in pre-clinical research and development for other product candidates and the development of the ATLAS technology platform.

General and Administrative Expenses

General and administrative expense increased $0.8 million to $3.6 million for the three months ended September 30, 2015 from $2.8 million for the three months ended September 30, 2014. The increase was due largely to higher compensation costs due to increases in headcount along with increases in depreciation costs due to capital additions.

Interest Expense, Net

Interest expense, net increased $0.1 million to $0.3 million for the three months ended September 30, 2015 from $0.2 million for the three months ended September 30, 2014. The increase was due primarily to higher average principal balances on the Company’s outstanding debt for the third quarter of 2015 as compared to the same period in 2014.

24

Results of Operations

Comparison of the Nine Months Ended September 30, 2015 and September 30, 2014

	Nine Months Ended September 30,		Increase
(in thousands)	2015	2014	(Decrease)
Grant revenue	$449	$—	$449
Operating expenses:			
Research and development	21,536	15,073	6,463
General and administrative	10,206	7,167	3,039
Total operating expenses	31,742	22,240	9,502
Loss from operations	(31,293)	(22,240)	(9,053)
Other expense:			
Other expense, net	—	(725)	725
Interest expense, net	(876)	(681)	(195)
Other expense	(876)	(1,406)	530
Net loss	$(32,169)	$(23,646)	$(8,523)

Grant revenue

Grant revenue increased $0.4 million for the nine months ended September 30, 2015 from none for the nine months ended September 30, 2014. The increase was due to current period activities performed on a $1.2 million grant entered into with the Bill & Melinda Gates Foundation in September 2014.

Research and development expenses

Research and development expenses increased approximately $6.5 million to $21.5 million for the nine months ended September 30, 2015 from $15.1 million for the nine months ended September 30, 2014. Increases in clinical and manufacturing costs (approximately $3.9 million), compensation, consulting and professional services (approximately $1.7 million) and lab-related and facilities costs (approximately $1.1 million) were generally offset by reductions in licensing fees (approximately $0.4 million). On a program basis, GEN-003 costs increased approximately $4.0 million and pre-clinical research and development for other product candidates and the development of the ATLAS technology platform increased approximately $3.5 million. Offsetting these increases, GEN-004 costs decreased by approximately $1.0 million.

General and administrative expenses

General and administrative expense increased $3.0 million to $10.2 million for the nine months ended September 30, 2015 from $7.2 million for the nine months ended September 30, 2014. The increase was due largely to additional personnel costs of $1.8 million attributable to higher headcount along with increases in depreciation costs of approximately $0.3 million due to capital additions. The remaining $1.0 million increase is generally attributable to higher public company overhead costs.

Other expense, net

Other expense decreased $0.7 million to none for the nine months ended September 30, 2015 from $0.7 million for the nine months ended September 30, 2014. The decrease was due to a non-recurring adjustment recorded in the first quarter ended March 31, 2014 to the fair value of warrants to purchase preferred stock as a result of an increase in the fair value of the underlying stock both before and on the date of the completion of our IPO on February 10, 2014.

Interest expense, net

Interest expense, net increased $0.2 million to $0.9 million for the nine months ended September 30, 2015 from $0.7 million for the nine months ended September 30, 2014. The increase was due primarily to higher average principal balances on the Company's outstanding debt for the year to date period in 2015 as compared to the same period in 2014.

Liquidity and Capital Resources

Overview

Since our inception through September 30, 2015, we have received an aggregate of $223.7 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At September 30, 2015, our cash, cash equivalents and investment securities were $112.5 million, comprising cash and cash equivalents of $42.8 million and current and non-current investment securities of $69.7 million.

In February 2014, we completed an IPO of 5.5 million shares of our Common Stock at a price of $12.00 per share for an aggregate offering price of $66.0 million. We received net proceeds from the offering of approximately $61.4 million, after deducting approximately $4.6 million in underwriting discounts and commission, excluding offering costs payable by us.

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 $101.8 million, after deducting approximately $6.1 million in underwriting discounts and commissions, excluding offering costs payable by us.

Debt Financings

On November 20, 2014, the 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 ("2014 Term Loan"). The first tranche of $17.0 million was available through September 30, 2015, of which $12.0 million was drawn down at loan inception. 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. The Company has the option to draw down the second tranche on or prior to December 15, 2015. The third tranche of $5.0 million is not eligible to draw as the Company did not achieve positive results from its Phase 2a human challenge study of GEN-004.

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 on the 2014 Term Loan.

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 for a six-month period at the Company's sole election as the eligibility requirements for the second tranche were met as of September 30, 2015. Thereafter, beginning July 1, 2016, payments will be made monthly in 30 equal installments of principal and interest (subject to recalculation upon a change in prime rates).

Upon closing the 2014 Term Loan, the Company used approximately $9.8 million of the initial draw down under the first tranche of the loan and security agreement to repay all outstanding indebtedness under the Company's 2013 loan agreement.

Operating Capital Requirements

Our primary uses of capital are, and we expect will continue to be for the near future, compensation and related expenses, manufacturing costs for pre-clinical and clinical materials, third party clinical trial research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

We believe that our cash, cash equivalents and investment securities at September 30, 2015 are sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2017. Through this timeframe, we expect to

have results from multiple Phase 2 GEN-003 studies, including the twelve month data from our ongoing dose optimization clinical trial, a bridging study, a dose regimen clinical trial, and a study to investigate the potential benefits of using GEN-003 in combination with oral antiviral medicines. In the second half of 2016, we also expect to have conducted our FDA end of Phase 2 meeting for GEN-003 for genital herpes such that a Phase 3 study may begin in the second half of 2017. We are removing the development of GEN-004 from our near-term plans to focus our resources on the ongoing Phase 2 program for GEN-003 and on maximizing the potential of our preclinical pipeline and our ATLAS technology for T cell target discovery. 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,	
	2015	2014
Net cash used in operating activities	$(28,370)	$(19,192)
Net cash used in investing activities	(44,547)	(28,290)
Net cash provided by financing activities	95,686	60,419
Net increase in cash and cash equivalents	$22,769	$12,937

Operating Activities

Net cash used in operations increased $9.3 million to $28.4 million for the nine months ended September 30, 2015 from $19.2 million for the nine months ended September 30, 2014. The increase in net cash used was due primarily to a larger net loss of approximately $8.5 million and a decrease of $1.2 million in our working capital accounts.

Investing Activities

Net cash used in investing activities was $44.5 million for the nine months ended September 30, 2015 compared to $28.3 million for the nine months ended September 30, 2014. The $16.3 million increase was due largely to investing proceeds from the March and August 2015 Offerings, purchasing activity of $25.7 million, offset by $10.0 million in investment maturities. The remaining increase was due to higher levels of capital investment.

Financing Activities

Net cash provided by financing activities increased $35.3 million to $95.7 million for the nine months ended September 30, 2015 from $60.4 million for the nine months ended September 30, 2014. The increase was mostly due to higher net proceeds from the March 2015 Offering and the August 2015 Offering compared to the IPO in February 2014.

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 27, 2015.

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, 2015 and December 31, 2014, we had cash, cash equivalents and investments of $112.5 million and $47.1 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, 2015 and December 31, 2014, 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, 2015 (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, 2015, 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, 2015, 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, 2015, 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 27, 2015 other than as set forth below.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our founding in 2006 and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biotechnology company, and we have not yet generated significant revenues. We have incurred net losses each year since our inception, including net losses of $35.3 million, $20.8 million and $13.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. For the nine months ended September 30, 2015, we have incurred a net loss of $32.2 million. As of September 30, 2015 and December 31, 2014, we had accumulated deficits of $147.6 million and $115.4 million, respectively. To date, we have not commercialized any products or generated any revenues from the sale of products and have financed our operations primarily through private placements of our preferred stock, debt financing, our initial public offering completed in February 2014, and secondary public offerings in March 2015 and August 2015 and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate product revenues or become profitable.

We have devoted most of our financial resources to research and development, including our clinical and non-clinical technology development and development activities. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or additional grants. We have not completed pivotal clinical studies for any product candidate and it will be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payors and other factors.

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

- continue our Phase 2 clinical trial of GEN-003, our most advanced product candidate that we are developing for the treatment of genital herpes infections, and commence a planned Phase 2b bridging clinical trial in late 2015 following improvements that we have made to the manufacturing process for GEN-003;

- initiate additional non-clinical, clinical or other studies for our other product candidates;
- manufacture material for clinical trials and for commercial sale;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to discover and develop additional product candidates;
- acquire or in-license other product candidates and technologies;

- make royalty milestone or other payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing non-clinical studies and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or the European Medicines Agency to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed would force us to delay, limit, reduce or terminate our product development or commercialization efforts.

As of September 30, 2015, our cash, cash equivalents and investments were $112.5 million. We believe that we will continue to expend substantial resources for the foreseeable future developing GEN-003 and our non-clinical product candidates. These expenditures will include costs associated with research and development, potentially acquiring new technologies, potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the progress, results and costs of our current Phase 2 dose optimization clinical trial along with future Phase 2 trials, including a bridging study, a dose regimen study, and a study to investigate the potential benefits of using GEN-003 in combination with oral antiviral medicines;

- the number and development requirements of other product candidates that we pursue;

- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful and the outcome of regulatory review of our product candidates;

- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;

- the cost of our general and administrative functions;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the cost of manufacturing our product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting patent applications, maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation;
- the timing, receipt, and amount of sales of, or royalties or milestone payments on, our future products, if any; and
- the extent to which we acquire or in-license other products or technologies.

Based on our current operating plan, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our projected operating expenses and capital expenditure requirements into the second half of 2017, by which time we anticipate that we will have had an end of Phase 2 meeting with the FDA for our ongoing GEN-003 clinical study and a Phase 3 trial will have commenced. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us when needed, we would be required to delay, limit, reduce or terminate non-clinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

Risks Related to Clinical Development, Regulatory Review and Approval of Our Product Candidates

We are substantially dependent on the success of the clinical development of GEN-003, our only product candidate currently in an active clinical trial. Any failure to successfully develop or commercialize the GEN-003 vaccine, or any significant delays in doing so, will have a material adverse effect on our business, result of operations and financial condition.

We have invested a significant portion of our efforts and financial resources in the development of the GEN-003 vaccine for genital herpes, the only product candidate we have that is currently in an active clinical development following the suspended development for our product candidate GEN-004 in October 2015. Our ability to generate product revenue depends heavily on the successful development and commercialization of GEN-003. The successful development and commercialization of GEN-003 will depend on several factors, including the following:

- Successful completion of our ongoing and additional clinical studies of GEN-003;
- Obtaining marketing approvals from regulatory authorities for GEN-003;
- Establishing manufacturing and commercialization arrangements between ourselves and third parties;
- A continued acceptable safety and efficacy profile of GEN-003; and

- The availability of reimbursement to patients from healthcare payors for GEN-003.

Any failure to successfully develop or commercialize GEN-003 or any significant delays in doing so will have a material adverse effect on our business, results of operations and financial condition.

Because our product candidate is in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenue.

Our early encouraging non-clinical and clinical results for GEN-003 are not necessarily predictive of the final results of our ongoing or future clinical trials. Success in non-clinical studies may not be predictive of similar results in humans during clinical trials, and successful results from early or small clinical trials of a vaccine candidate may not be replicated in later and larger clinical trials. Among other reasons for the potential failure of earlier, smaller clinical trials to be replicated in later, larger clinical trials is the fact that manufacturing scale up is necessary to prepare for Phase 3 development and commercialization. Because our products require complex manufacturing processes, scaling up these processes can cause changes in the product that may not be apparent until the product is tested in humans.

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

Risks Related to Our Indebtedness

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

In November 2014 we entered into a secured credit facility consisting of a working capital term loan facility with Hercules Technology Growth Capital, Inc. providing for term loans of up to an aggregate of $27.0 million in three separate tranches, an initial $17.0 million tranche and two additional $5.0 million tranches. On November 20, 2014, we drew down an initial $12.0 million under our secured credit facility and paid off our then-existing secured credit facility. We did not borrow the remaining $5.0 million from the first tranche, which expired 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. The second tranche remains available for us to draw through December 15, 2015. We are not eligible for the remaining $5.0 million from the third tranche since we did not achieve positive results from our Phase 2a human challenge study for GEN-004. All obligations under our secured credit facility are secured by substantially all of our existing property and assets, excluding our intellectual property and licensed-in technology. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds from Unregistered Securities

None.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Quarterly Report on Form 10-Q.

Use of Proceeds from Registered Equity Securities

Initial Public Offering

In February 2014, we completed our IPO of 5.5 million shares of our Common Stock at a price of $12.00 per share for an aggregate offering price of $66.0 million. The offer and sale of all of the shares in the offering were registered under the Securities Act of 1933, as amended, (the “Securities Act”) pursuant to a registration statement on Form S-1 (File No. 333-193043), which was declared effective by the SEC on February 4, 2014. Citigroup Global Markets, Inc. and Cowen and Company, LLC ("Cowen") acted as joint book-running managers of the offering and as representatives of the underwriters. Stifel, Nicolaus & Company, Incorporated ("Stifel") and Needham & Company, LLC ("Needham") acted as co-managers for the offering. The offering commenced on February 4, 2014 and did not terminate until the sale of all of the shares offered.

We received net proceeds from the offering of approximately $61.4 million, after deducting approximately $4.6 million in underwriting discounts and commissions, excluding approximately $2.4 million of offering costs payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours.

March 2015 Public Offering

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 offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-3 (File No. 333-202406), which was declared effective by the SEC on March 10, 2015. Cowen and Piper Jaffray ("Piper") acted as joint book-running managers of the offering and as representatives of the underwriters. Stifel acted as a lead manager and Needham acted as a co-manager for the offering. The offering commenced on March 11, 2015 and did not terminate until the sale of all of the shares offered.

We received net proceeds from the offering of approximately $48.6 million, after deducting approximately $3.1 million in underwriting discounts and commissions, excluding approximately $276 thousand of offering costs payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours.

August 2015 Public Offering

In August 2015, we completed an 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 offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-3 (File No. 333-203981), which was declared effective by the SEC on May 14, 2015. Cowen, Piper, and Stifel acted as joint book-running managers of the offering and as representatives of the underwriters. Needham acted as a co-manager for the offering. The offering commenced on July 30, 2015.

We received net proceeds from the offering of approximately $47.0 million, after deducting approximately $3.0 million in underwriting discounts and commissions, excluding $169 thousand of offering costs payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours.

Use of Proceeds

As of September 30, 2015, we have used the net proceeds mentioned above primarily to fund the preclinical and clinical development of our product candidates and other general corporate purposes. We have not used any of the net proceeds from the offerings to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10% or more of our Common Stock or to any affiliate of ours. We have invested the balance of the net proceeds from the offerings in a variety of capital preservation investments, including investment grade, interest bearing instruments, U.S. government securities, and certificates of deposits. Other than the suspension of development of GEN-004 pending further

data analysis and expert consultations, there has been no material change in our planned use of the balance of the net proceeds from the offerings as described in our final prospectuses filed with the SEC pursuant to Rule 424(b) under the Securities Act.

Item 6. Exhibits

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

Exhibit Number	Exhibit
31.1	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Chief Executive Officer
31.2	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Chief Financial Officer
32.1	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Executive Officer
32.2	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Financial Officer
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Balance Sheets as of September 30, 2015 and December 31, 2014, (ii) Condensed Statements of Operations for the three and nine months ended September 30, 2015 and 2014, (iii) Condensed Statements of Comprehensive Loss for the three and nine months ended September 30, 2015 and 2014, (iv) Condensed Statements of Cash Flows for the nine months ended September 30, 2015 and 2014 and (v) Notes to Unaudited Condensed Financial Statements

SIGNATURES

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

Genocea Biosciences, Inc.

Date: November 5, 2015	By:	/s/ WILLIAM D. CLARK William D. Clark President and Chief Executive Officer and Director (Principal Executive Officer)
Date: November 5, 2015	By:	/s/ JONATHAN POOLE Jonathan Poole Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)