

GENOCEA BIOSCIENCES, INC.

Form 10-Q

August 06, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 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

Genoccea Biosciences, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	51-0596811
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
100 Acorn Park Drive	
Cambridge, Massachusetts	02140
(Address of Principal Executive Offices)	(Zip Code)
(617) 876-8191	
(Registrant's Telephone Number, Including Area Code)	

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>

(Do not check if a 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 ☒

As of August 4, 2015, there were 28,060,240 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 and GEN-004;
- 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.

Genoce Biosciences, Inc.
Form 10-Q
For the Quarter Ended June 30, 2015

TABLE OF CONTENTS

	Page
<u>PART I. FINANCIAL INFORMATION</u>	<u>4</u>
<u>Item 1.</u> <u>Financial Statements (unaudited)</u>	<u>4</u>
<u>Condensed Balance Sheets as of June 30, 2015 and December 31, 2014</u>	<u>4</u>
<u>Condensed Statements of Operations for the three and six months ended June 30, 2015 and 2014</u>	<u>5</u>
<u>Condensed Statements of Comprehensive Loss for the three and six months ended June 30, 2015 and 2014</u>	<u>6</u>
<u>Condensed Statements of Cash Flows for the six months ended June 30, 2015 and 2014</u>	<u>7</u>
<u>Notes to Unaudited Condensed Financial Statements</u>	<u>8</u>
<u>Item 2.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>18</u>
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>27</u>
<u>Item 4.</u> <u>Controls and Procedures</u>	<u>27</u>
<u>PART II. OTHER INFORMATION</u>	<u>28</u>
<u>Item 1</u> <u>Legal Proceedings</u>	<u>28</u>
<u>Item 1A.</u> <u>Risk Factors</u>	<u>28</u>
<u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>28</u>
<u>Item 6.</u> <u>Exhibits</u>	<u>29</u>

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$49,580	\$20,058
Marketable securities	25,015	27,021
Prepaid expenses and other current assets	770	934
Total current assets	75,365	48,013
Property and equipment, net	2,557	1,956
Restricted cash	316	316
Other non-current assets	478	47
Total assets	\$78,716	\$50,332
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$1,411	\$2,692
Accrued expenses and other current liabilities	4,160	2,486
Deferred revenue	670	555
Other current liabilities	125	107
Total current liabilities	6,366	5,840
Non-current liabilities:		
Long-term debt	11,564	11,389
Deferred revenue, net of current portion	—	350
Other non-current liabilities	124	246
Total liabilities	18,054	17,825
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock	—	—
Common stock	24	18
Additional paid-in-capital	198,456	147,923
Accumulated other comprehensive income (loss)	7	(7)
Accumulated deficit	(137,825) (115,427)
Total stockholders' equity	60,662	32,507
Total liabilities and stockholders' equity	\$78,716	\$50,332

See accompanying notes to unaudited financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Grant revenue	\$115	\$—	\$236	\$—
Operating expenses:				
Research and development	6,969	4,551	15,478	8,958
General and administrative	3,172	2,358	6,561	4,324
Total operating expenses	10,141	6,909	22,039	13,282
Loss from operations	(10,026)	(6,909)	(21,803)	(13,282)
Other expense:				
Change in fair value of warrants	—	—	—	(725)
Interest expense, net	(288)	(237)	(595)	(468)
Other expense	(288)	(237)	(595)	(1,193)
Net loss	\$(10,314)	\$(7,146)	\$(22,398)	\$(14,475)
Reconciliation of net loss to net loss applicable to common stockholders				
Net loss	\$(10,314)	\$(7,146)	\$(22,398)	\$(14,475)
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(180)
Net loss attributable to common stockholders	\$(10,314)	\$(7,146)	\$(22,398)	\$(14,655)
Net loss per share attributable to common stockholders-basic and diluted	\$(0.43)	\$(0.41)	\$(1.04)	\$(1.08)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	24,154	17,346	21,510	13,623

See accompanying notes to unaudited financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net loss	\$(10,314)	\$(7,146)	\$(22,398)	\$(14,475)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	3	(1)	14	(1)
Comprehensive loss	\$(10,311)	\$(7,147)	\$(22,384)	\$(14,476)

See accompanying notes to unaudited financial statements.

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

	Six Months Ended June 30,	
	2015	2014
Operating activities		
Net loss	\$(22,398)	\$(14,475)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	391	160
Stock-based compensation	1,946	1,549
Net amortization of premium on investments	20	4
Change in fair value of warrants liability	—	725
Non-cash interest expense	175	40
Changes in operating assets and liabilities	(206)	(970)
Net cash used in operating activities	(20,072)	(12,967)
Investing activities		
Purchases of property and equipment	(993)	(202)
Proceeds from maturities of marketable securities	2,000	—
Purchase of marketable securities	—	(27,053)
Net cash provided by (used in) investing activities	1,007	(27,255)
Financing activities		
Proceeds from IPO, net of issuance costs	—	59,974
Proceeds from underwritten public offering, net of issuance costs	48,369	—
Proceeds from exercise of stock options	101	135
Proceeds from the exercise of warrants	—	33
Proceeds from the issuance of common stock under ESPP	119	—
Payments made under capital lease	(2)	—
Net cash provided by financing activities	48,587	60,142
Net increase in cash and cash equivalents	\$29,522	\$19,920
Cash and cash equivalents at beginning of period	20,058	12,208
Cash and cash equivalents at end of period	\$49,580	\$32,128
Supplemental cash flow information		
Cash paid for interest	\$438	\$378
Supplemental disclosure of non-cash investing and financing activities		
Conversion of preferred stock to common stock upon closing of IPO	\$—	\$81,774
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	\$5	\$5

See accompanying notes to unaudited financial statements.

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

1. Organization and operations

The Company

Genoce 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 two products in clinical development:

GEN-003, an immunotherapy to treat patients with genital herpes, currently in Phase 2 clinical development. The Company reported positive top-line data from an ongoing Phase 2 dose optimization trial from the immediate post dosing 28-day observation period in May 2015. The Company identified an improved dose of 60µg per protein/75µg of adjuvant, which demonstrated a highly statistically significant reduction ($p < 0.0001$) from baseline in the viral shedding rate (55%) and genital lesion rate (60%). Data from the six-month and 12-month observation periods in this trial is expected in the fourth quarter of 2015 and the first quarter of 2016, respectively.

GEN-004, a universal vaccine which is being developed to prevent infections caused by all serotypes of pneumococcus. The Company has completed enrollment in a Phase 2 human challenge clinical trial and expects to report top-line proof-of-efficacy data in the fourth quarter of 2015.

The Company also has other product candidates that are currently in preclinical development and ongoing discovery research activities in 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 underwriters have a 30-day option, from the commencement date of July 30, 2015, to purchase an additional 577,500 shares of Common Stock. The offering was completed under the shelf registration statement that was filed on Form S-3 and declared effective May 14, 2015 (the “Registration Statement”). Net proceeds of the underwritten public offering, after deducting the underwriting discounts and commissions, were \$47.0 million, excluding estimated offering expenses of \$146 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 June 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 June 30, 2015 and results of operations for the three and six months ended June 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.

Deferred financing costs

Offering costs related to debt and equity financing primarily consist of direct and incremental external expenses. In April 2015, the FASB issued ASU No. 2015-03 Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs ("ASU 2015-03"). ASU 2015-03 requires a company to present 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. This new standard also requires adoption on a retrospective basis, wherein the balance sheet of each individual period presented should be adjusted to reflect the period-specific effects of applying the new guidance. This ASU is effective for public entities for annual and interim periods beginning after December 15, 2015 and early adoption is permitted.

As of June 30, 2015, the Company early adopted the provisions of ASU 2015-03. Approximately \$85 thousand, as of June 30, 2015, and \$99 thousand, as of December 31, 2014, of unamortized capitalized debt issuance costs previously included in both other current and other non-current assets was reclassified 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 Statement 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 or the Registration Statement and ATM are no longer available. At June 30, 2015, the Company had \$293 thousand of deferred offering costs recorded as a non-current asset.

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. FASB 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 marketable securities (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 long-term 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 long-term debt approximates fair value because the Company's interest rate yield is near current market rates for comparable debt instruments. The Company's long-term debt is considered a Level 3 liability within the fair value hierarchy.

For the six months ended June 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 six months ended June 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	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	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,

Concern (“ASU 2014-15”). concern exists when relevant conditions and events, or cash flows. 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.

3. Cash, cash equivalents and marketable securities

As of June 30, 2015 and December 31, 2014, cash, cash equivalents and marketable securities comprised funds in depository, money market accounts and U.S treasury securities.

The following table presents the cash, cash equivalents and marketable securities 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)
June 30, 2015				
Money Market funds, included in cash equivalents	\$49,009	\$49,009	—	—
Marketable securities - U.S. treasuries	25,015	25,015	—	—
Total	\$74,024	\$74,024	\$—	\$—
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 marketable securities 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.

Marketable securities at June 30, 2015 consist of the following (in thousands):

	Contracted Maturity	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current					
U.S. Treasuries	15-184 days	\$25,008	\$7	\$—	\$25,015
Total		\$25,008	\$7	\$—	\$25,015

4. Long-term 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 June 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 Company would be eligible to draw down the third tranche of \$5.0 million provided that favorable data from the ongoing Phase 2a human challenge study for GEN-004 is achieved prior to December 15, 2015. The Company has not achieved the requirements to draw down the third tranche as of June 30, 2015.

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. The Company elected to extend the maturity date on the 2014 Term Loan as of June 30, 2015.

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 No. 815, “Derivatives and Hedging”. In accordance with Topic No. 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):

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

5. Warrants

As of June 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 represent warrants to purchase redeemable securities that were automatically converted to warrants exercisable into Common Stock upon the completion of our IPO on February 10, 2014.

Hercules warrants

In accordance with ASC Topic No. 815, “Derivatives and Hedging”, 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 June 30, 2015, all of the common stock warrants issued to Hercules remained outstanding.

Warrants to purchase redeemable securities

As of December 31, 2013, the Company had outstanding warrants to purchase 2,291,512 shares of redeemable convertible preferred stock. On January 29, 2014, 21,695 warrants to purchase Series A preferred stock were exercised for cash. On February 4, 2014, an additional 28,926 warrants to purchase Series A preferred stock were exercised for cash. Prior to the completion of our IPO on February 10, 2014, warrants to purchase 987,840 shares of Series A preferred stock were exercised in a cashless exercise for 316,932 shares of Series A preferred stock, which automatically converted into 26,633 shares of Common Stock upon the completion of our IPO. Also upon the completion of our IPO, warrants exercisable for 1,253,051 shares of redeemable convertible preferred stock were automatically converted into warrants exercisable for 105,297 shares of

Common Stock. On February 12, 2014, 43,465 warrants were exercised in a cashless exercise for 16,593 shares of Common Stock. On April 23, 2014, 57,954 warrants were exercised in a cashless exercise for 37,250 shares of Common Stock. As of June 30, 2015 and December 31, 2014, 3,878 of these common stock warrants 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):

	June 30, 2015
2015	\$675
2016	1,379
2017	231
Total	\$2,285

At June 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 and Harvard Medical School to characterize anti-tumor T cell responses in melanoma patients. This collaboration extends the use of our proprietary ATLAS platform for the rapid discovery of T cell antigens to cancer immunotherapy approaches. The Company recognized revenue under the agreement of \$9 thousand and \$30 thousand for the three and six months ended June 30, 2015, respectively, and none for the three and six months ended June 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 \$115 thousand and \$236 thousand for the three and six months ended June 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 \$1.1 million and \$3.6 million for the three and six months ended June 30, 2015, respectively and \$412 thousand and \$437 thousand for the three and six months ended June 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 June 30, 2015, the Company has authorized 25,000,000 shares of preferred stock at \$0.001 par value per share. As of June 30, 2015 and December 31, 2014, there were no shares of preferred stock issued or outstanding.

At June 30, 2015, the Company has authorized 175,000,000 shares of common stock at \$0.001 par value per share. As of June 30, 2015 and December 31, 2014, there were 24,204,463 and 17,869,235 shares of common stock issued. As of June 30, 2015 and December 31, 2014, there were 24,191,511 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 six months ended June 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):

	Six Months Ended June 30,	
	2015	2014
Warrants	78	4
Outstanding options	2,760	2,234
Total	2,838	2,238

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 June 30, 2015, the Company had issued 35,964 shares of restricted Common Stock. The Company had 16,840 and 12,952 shares of nonvested restricted stock that were subject to repurchase by the Company as of December 31, 2014 and June 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 June 30, 2015, 284,913 shares remain available for future grants under the 2014 Equity Plan. Including options outstanding as of June 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, 3,044,717 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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Research and development	\$450	\$371	\$865	\$848
General and administrative	581	297	1,081	701
Total	\$1,031	\$668	\$1,946	\$1,549

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	588	\$9.31		
Exercised	(42)	\$2.38		
Canceled	(76)	\$15.61		
Outstanding at June 30, 2015	2,760	\$7.55	7.88	\$18,061

Exercisable at June 30, 2015	1,248	\$4.87	6.52	\$11,372
Vested or expected to vest at June 30, 2015	2,611	\$7.45	7.83	\$17,345

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 six months ended June 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 June 30, 2014 and \$435 thousand was recorded for the six months ended June 30, 2014. The stock-based compensation recorded for the six months ended June 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 June 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 six months ended June 30, 2015, 15,622 shares were issued under the 2014 ESPP, with 165,085 shares remaining for future issuance under the plan as of June 30, 2015. The Company incurred stock-based compensation expense related to the 2014 ESPP of \$26 thousand and \$53 thousand for the three and six months ended June 30, 2015, respectively, and none for the three and six months ended June 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 six months ended June 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 two product candidates in Phase 2 clinical development: GEN-003, an immunotherapy for the treatment of genital herpes and GEN-004, a universal vaccine for the prevention of pneumococcal infections. 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. The study showed the GEN-003 was well tolerated, with no serious adverse events related to the vaccine. Furthermore, there was no difference in discontinuations in patient dosing due to adverse events across the different treatment arms. Data from the six-month and 12-month observation periods in this trial is expected in the fourth quarter of 2015 and the first quarter of 2016, respectively.

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. Viral shedding and genital lesion rate data from this bridging study is expected in the early 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 — Phase 2 universal vaccine for the prevention of pneumococcal infections

We are also developing 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. This trial is fully enrolled and we expect to announce top-line results from this trial in the fourth quarter of 2015.

Products in research and non-clinical development

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. Additionally, we have an ongoing immuno-oncology collaboration with Dana Farber Cancer Institute and Harvard Medical School.

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 June 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 June 30, 2015, our cash and cash equivalents and marketable securities were \$74.6 million.

Since inception, we have incurred significant operating losses. Our net losses were \$10.3 million and \$22.4 million for the three and six months ended June 30, 2015, respectively, and our accumulated deficit was \$137.8 million as of June 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 marketable securities at June 30, 2015, together with the recent net proceeds from the August 2015 Offering, 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 six and 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. Furthermore we expect to have top-line data from our current Phase 2a clinical trial for GEN-004 for pneumococcus and to have commenced our planned toddler study for GEN-004 by this time. However, costs related to clinical trials can be unpredictable and therefore there can be no guarantee that our current balances of cash, and cash equivalents and marketable securities, along with the net proceeds from the August 2015 Offering, and any proceeds received from other sources, will be sufficient to fund these studies or our 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, GEN-004 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

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):

20

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
HSV-2 (GEN-003)(1)	\$4,042	\$2,679	\$9,627	\$4,602
Pneumococcus (GEN-004)(1)	900	977	1,977	2,388
Other research and development (2)	2,027	895	3,874	1,968
Total research and development	\$6,969	\$4,551	\$15,478	\$8,958

(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 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, our product candidates.

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 and cash equivalents.

Other (Expense) Income

Other (expense) income 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 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 June 30, 2015 and June 30, 2014

(in thousands)	Three Months Ended June 30,		Increase
	2015	2014	(Decrease)
Grant revenue	\$115	\$—	\$115
Operating expenses:			
Research and development	6,969	4,551	2,418
General and administrative	3,172	2,358	814
Total operating expenses	10,141	6,909	3,232
Loss from operations	(10,026)	(6,909)	(3,117)
Other expense:			
Interest expense, net	(288)	(237)	(51)
Other expense	(288)	(237)	(51)
Net loss	\$(10,314)	\$(7,146)	\$(3,168)

Grant Revenue

Grant revenue was \$0.1 million for the three months ended June 30, 2015, an increase from none for the three months ended June 30, 2014. The increase was largely due to the recognition of revenue from a \$1.2 million grant entered into with the Bill & Melinda Gates Foundation in September 2014.

Research and Development Expenses

Research and development expenses increased \$2.4 million to \$7.0 million for the three months ended June 30, 2015 from \$4.6 million for the three months ended June 30, 2014. The increase was attributable to: an increase of \$1.4 million in GEN-003 costs, reflecting increased manufacturing and clinical trial costs, and an increase of \$1.1 million in pre-clinical research costs partially offset by a decrease of \$0.1 million in GEN-004 costs, largely driven by lower manufacturing costs.

General and Administrative Expenses

General and administrative expense increased \$0.8 million to \$3.2 million for the three months ended June 30, 2015 from \$2.4 million for the three months ended June 30, 2014. The increase was due largely to additional personnel

costs of \$0.5 million, including \$0.3 million in increased stock-based compensation, due to an increase in headcount; \$0.2 million in increased audit, legal and consulting expenses; and \$0.1 million in public company overhead costs.

Interest Expense, Net

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

Results of Operations

Comparison of the Six Months Ended June 30, 2015 and June 30, 2014

(in thousands)	Six Months Ended June 30,		Increase
	2015	2014	(Decrease)
Grant revenue	\$236	\$—	\$236
Operating expenses:			
Research and development	15,478	8,958	6,520
General and administrative	6,561	4,324	2,237
Total operating expenses	22,039	13,282	8,757
Loss from operations	(21,803)	(13,282)	(8,521)
Other expense:			
Other expense, net	—	(725)	725
Interest expense, net	(595)	(468)	(127)
Other expense	(595)	(1,193)	598
Net loss	\$(22,398)	\$(14,475)	\$(7,923)

Grant Revenue

Grant revenue increased \$0.2 million to \$0.2 million for the six months ended June 30, 2015 from none for the six months ended June 30, 2014. The increase was largely due to the recognition of revenue from 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 \$6.5 million to \$15.5 million for the six months ended June 30, 2015 from \$9.0 million for the six months ended June 30, 2014. The increase was attributable to: an increase of \$5.0 million in GEN-003 costs, reflecting increased manufacturing and clinical trial costs, and an increase of \$1.9 million in pre-clinical research costs partially offset by a decrease of \$0.4 million in GEN-004 costs, largely driven by lower manufacturing costs.

General and Administrative Expenses

General and administrative expense increased \$2.2 million to \$6.5 million for the six months ended June 30, 2015 from \$4.3 million for the six months ended June 30, 2014. The increase was due largely to additional personnel costs of \$1.1 million, including \$0.4 million in increased stock-based compensation, due to an increase in headcount; \$0.4 million in increased audit, legal and consulting expenses; and \$0.7 million in public company overhead costs.

Other Expense

Other expense decreased \$0.7 million to none for the six months ended June 30, 2015 from \$0.7 million for the six months ended June 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 \$0.1 million to \$0.6 million for the six months ended June 30, 2015 from \$0.5 million for the six months ended June 30, 2014. The increase was due primarily to higher average principal balances on the Company's outstanding debt for the first half of 2015 as compared to the same period in 2014.

Liquidity and Capital Resources

Overview

Since our inception through June 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 June 30, 2015, our cash and cash equivalents and marketable securities were \$74.6 million, comprising cash and cash equivalents of \$49.6 million and marketable securities of \$25.0 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 June 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 Company would be eligible to draw down the third tranche of \$5.0 million provided that favorable data from the ongoing Phase 2a human challenge study for GEN-004 is achieved prior to December 15, 2015. We have not achieved the requirements to draw down the third tranche as of June 30, 2015.

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. The Company elected to extend the maturity date on the 2014 Term Loan as of June 30, 2015.

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).

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 marketable securities at June 30, 2015, along with the recent net proceeds from the August 2015 Offering, 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 six and 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. Furthermore we expect to have top-line data from our current Phase 2a clinical trial for GEN-004 for pneumococcus and to have commenced our planned toddler study for GEN-004 by this

time. 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 and GEN-004;
- the progress, timing and costs of manufacturing GEN-003 and GEN-004 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, GEN-004 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, GEN-004 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, GEN-004 or our other product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to GEN-003, GEN-004 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):

	Six Months Ended June 30,	
	2015	2014
Net cash used in operating activities	\$(20,072)	\$(12,967)
Net cash provided by (used in) investing activities	1,007	(27,255)
Net cash provided by financing activities	48,587	60,142
Net increase in cash and cash equivalents	\$29,522	\$19,920

Operating Activities

Net cash used in operations increased \$7.1 million to \$20.1 million for the six months ended June 30, 2015 from \$13.0 million for the six months ended June 30, 2014. The increase was due primarily to an increase in the net loss of approximately \$7.9 million, a decrease in change in fair value of warrant liability of \$0.7 million, which was partially offset by an increase in stock based compensation of \$0.4 million, an increase in depreciation expense of \$0.2 million, an increase in non-cash interest expense of \$0.1 million and a decrease of \$0.8 million in our working capital accounts.

Investing Activities

Net cash provided by investing activities was \$1.0 million for the six months ended June 30, 2015 and net cash used in investing activities was \$27.3 million for the six months ended June 30, 2014. The \$28.3 million decrease was due largely to the purchase of \$27.1 million of marketable securities in the second quarter of 2014 compared to the maturity of marketable securities of \$2.0 million in the second quarter of 2015, which was partially offset by an increase in cash used to purchase property and equipment of \$0.8 million.

Financing Activities

Net cash provided by financing activities decreased \$11.6 million to \$48.6 million for the six months ended June 30, 2015 from \$60.1 million for the six months ended June 30, 2014. The decrease was due largely to the net proceeds of \$60.0 million from our IPO in February 2014, which was partially offset by net proceeds of \$48.4 million from our underwritten public offering in March 2015.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K, as filed with the SEC on February 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 June 30, 2015 and December 31, 2014, we had cash, cash equivalents and marketable securities of \$74.6 million and \$47.1 million, respectively, consisting primarily of money market funds and U.S Treasury securities. 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 June 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 June 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 June 30, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the six months ended June 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 June 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.

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. The underwriters have a 30-day option from the commencement date to purchase an additional 577,500 shares of Common Stock.

We received net proceeds from the offering of approximately \$47.0 million, after deducting approximately \$3.0 million in underwriting discounts and commissions, excluding approximately \$146 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 June 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 short-term, investment grade, interest bearing instruments and U.S. government securities. 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 June 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Balance Sheets as of June 30, 2015 and December 31, 2014, (ii) Condensed Statements of Operations for the three and six months ended June 30, 2015 and 2014, (iii) Condensed Statements of Comprehensive Loss for the

three and six months ended June 30, 2015 and 2014, (iv) Condensed Statements of Cash Flows for the six months ended June 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.

Genoce Biosciences, Inc.

Date: August 6, 2015

By: /s/ WILLIAM D. CLARK
William D. Clark
President and Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 6, 2015

By: /s/ JONATHAN POOLE
Jonathan Poole
Chief Financial Officer (Principal Financial Officer
and Principal Accounting Officer)