GENOCEA BIOSCIENCES, INC.
Form 10-Q
November 03, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2017
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-36289

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

Delaware	51-0596811
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
100 Acorn Park Drive Cambridge, Massachusetts	02140
(Address of Principal Executive Offices)	(Zip Code)

(617) 876-8191
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the

Exchange Act. x

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

As of November 1, 2017, there were 28,704,164 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:

- our estimates regarding the timing and amount of funds we require to file our investigational new drug ("IND") application and initiate clinical trials for GEN-009 and to continue our investments in immuno-oncology;
- our estimate for when we will require additional funding;
- our plans to commercialize GEN-009 and our other product candidates;
- the timing of, and our ability to, obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- the potential benefits of strategic partnership agreements and our ability to enter into strategic partnership arrangements;
- our ability to quickly and efficiently identify and develop product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position; and
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing.

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

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

Genocea Biosciences, Inc.
Form 10-Q
For the Quarter Ended September 30, 2017

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 21,983	$ 27,424
Investments, current portion	—	35,938
Prepaid expenses and other current assets	1,309	926
Total current assets	23,292	64,288
Property and equipment, net	4,000	4,871
Restricted cash	316	316
Other non-current assets	436	421
Total assets	$ 28,044	$ 69,896
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable	$ 2,129	$ 3,043
Accrued expenses and other current liabilities	6,321	4,178
Current portion of long-term debt	6,538	3,149
Total current liabilities	14,988	10,370
Non-current liabilities:		
Long-term debt	9,244	13,809
Other non-current liabilities	126	176
Total liabilities	24,358	24,355
Commitments and contingencies (Note 6)		
Stockholders’ equity:		
Common stock	29	28
Additional paid-in-capital	257,118	252,996
Accumulated deficit	(253,461)	(207,483)
Total stockholders’ equity	3,686	45,541
Total liabilities and stockholders’ equity	$ 28,044	$ 69,896

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Grant revenue	$—	$—	$—	$235
Operating expenses:				
Research and development	10,155	8,811	31,324	22,821
General and administrative	3,750	3,619	10,955	11,569
Restructuring costs	2,591	—	2,591	—
Refund of research and development expense	—	—	—	(1,592)
Total operating expenses	16,496	12,430	44,870	32,798
Loss from operations	(16,496)	(12,430)	(44,870)	(32,563)
Other income and expense:				
Interest income	63	103	211	323
Interest expense	(435)	(438)	(1,319)	(1,299)
Total other income and expense	(372)	(335)	(1,108)	(976)
Net loss	$(16,868)	$(12,765)	$(45,978)	$(33,539)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	—	(9)	—	15
Comprehensive loss	$(16,868)	$(12,774)	$(45,978)	$(33,524)
Net loss per share - basic and diluted	$(0.59)	$(0.45)	$(1.61)	$(1.18)
Weighted-average number of common shares used in computing net loss per share	28,666	28,370	28,568	28,267

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30, 2017	2016
Operating activities		
Net loss	$ (45,978)	$ (33,539)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,234	1,309
Stock-based compensation	3,268	3,113
Non-cash interest expense	383	356
Asset impairment	1,001	—
Changes in operating assets and liabilities	667	(1,342)
Net cash used in operating activities	(39,425)	(30,103)
Investing activities		
Purchases of property and equipment	(1,248)	(1,968)
Proceeds from maturities of investments	36,089	58,891
Purchases of investments	(153)	(18,755)
Net cash provided by investing activities	34,688	38,168
Financing activities		
Proceeds from equity offerings, net of issuance costs	246	815
Repayment of long-term debt	(1,559)	—
Proceeds from exercise of stock options	459	166
Proceeds from the issuance of common stock under ESPP	150	112
Net cash (used in) provided by financing activities	(704)	1,093
	$ (5,441)	$ 9,158

Net (decrease) increase in cash and cash equivalents				
Cash and cash equivalents at beginning of period	27,424		17,259	
Cash and cash equivalents at end of period	$	21,983	$	26,417
Supplemental cash flow information				
Cash paid for interest	$	922	$	943
Property and equipment included in accounts payable and accrued expenses	$	33	$	293

See accompanying notes to unaudited condensed consolidated financial statements.

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

1. Organization and operations

The Company

Genocea Biosciences, Inc. (the “Company”) is a biopharmaceutical company that was incorporated in Delaware on August 16, 2006 and has a principal place of business in Cambridge, Massachusetts. The Company seeks to discover and develop novel cancer vaccines through its AnTigen Lead Acquisition System ("ATLAS™") proprietary discovery platform. The ATLAS platform is designed to recall a patient's pre-existing CD4+ and CD8+ T cell immune responses to their tumor to identify neoantigens and antigens for inclusion in vaccines that are designed to act through T cell (or cellular) immune responses. The Company believes that using ATLAS to identify neoantigens and antigens for inclusion in cancer vaccines could lead to more immunogenic and efficacious cancer vaccines.

In September 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines. Currently, all of the Company’s research programs and product candidates in active development are at the preclinical stage. The Company's most advanced program in active development is its preclinical immuno-oncology program, GEN-009, a neoantigen cancer vaccine. The GEN-009 program leverages ATLAS to identify patient neoantigens, or newly formed antigens unique to each patient, that are associated with that individual's tumor. The Company is also exploring partnering opportunities in the development of cancer vaccines targeting tumor-associated antigens and a vaccine targeting cancers caused by Epstein-Barr Virus ("EBV").

The Company has one Phase 3-ready product candidate, GEN-003, an investigational immunotherapy for the treatment of genital herpes. In September 2017, the Company announced it was exploring strategic alternatives for GEN-003. Consequently, substantially all GEN-003 spending and activities were ceased and the Company reduced its workforce by approximately 40 percent.

The Company is devoting substantially all of its efforts to product research and development, initial market development, and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other preclinical stage companies, including dependence on key individuals, competition from other companies, the need and related uncertainty associated with the development of commercially viable products, and the need to obtain adequate additional financing to fund the development of its product candidates. The Company is also subject to a number of risks similar to other companies in the life sciences industry, including the uncertainty of success of its preclinical and clinical trials, regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability, and dependence on key individuals. The Company anticipates that it will continue to incur significant operating losses for the next several years as it continues to develop its product candidates.

Liquidity

As of September 30, 2017, the Company had an accumulated deficit of approximately $253.5 million. The Company had cash and cash equivalents of $22.0 million at September 30, 2017, which it believes is not sufficient to fund the Company’s current operating plan for at least the next twelve months from the date of filing this Quarterly Report on Form 10-Q. The Company expects to seek additional funds through equity or debt financings or proceeds from business development. It may be unable to obtain funds from equity or debt financings or proceeds from business development and, if necessary, the Company will be required to implement further cost reduction strategies, including ceasing development of GEN-009 and all corporate activities. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

At-the-market equity offering program

On March 2, 2015, the Company entered into a Sales Agreement with Cowen and Company, LLC (the "Sales Agreement") to establish an at-the-market equity offering program (“ATM”) pursuant to which it was able to offer and sell up to

$40 million of its Common Stock at prevailing market prices from time to time. On May 8, 2015, the Sales Agreement was amended to increase the offering amount under the ATM to $50 million of its Common Stock. In January 2017, the Company sold 52 thousand shares and received $0.2 million in net proceeds after deducting commissions. In April 2016, the Company sold 136 thousand shares and received $0.8 million in net proceeds after deducting commissions.

2. Summary of significant accounting policies

Basis of presentation and use of estimates

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and the instructions of Form 10-Q and Article 10 of Regulation S-X. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These interim condensed financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position as of September 30, 2017 and results of operations for the three and nine months ended September 30, 2017 and 2016.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full fiscal year. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2016 and the notes thereto which are included in the Company's Annual Report on Form 10-K, as filed with the SEC on February 17, 2017.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, estimates related to prepaid and accrued research and development expenses, stock-based compensation expense and reported amounts of revenues and expenses during the reported period. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Cash, cash equivalents and investments

The Company determines the appropriate classification of its investments at the time of purchase. All liquid investments with original maturities of three months or less from the purchase date are considered to be cash equivalents. The Company's current and non-current investments are comprised of certificates of deposit and government agency securities that are classified as available-for-sale in accordance with ASC 320, Investments—Debt and Equity Securities. The Company classifies investments available to fund current operations as current assets on its balance sheets. Investments are classified as non-current assets on the balance sheets if (i) the Company has the intent and ability to hold the investments for a period of at least one year and (ii) the contractual maturity date of the investments is greater than one year.

Available-for-sale investments are recorded at fair value, with unrealized gains or losses included in Accumulated other comprehensive income (loss) on the Company's balance sheets. Realized gains and losses are determined using the specific identification method and are included as a component of Interest income or Interest expense, respectively. There were no realized gains or losses recognized for the nine months ended September 30, 2017 and 2016.

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment’s carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than-temporary, the Company considers its intent to sell, or whether it is more likely than not that the Company will be required to sell the investment before recovery of the investment’s amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, the severity and the duration of the impairment and changes in value subsequent to period end. As of September 30, 2017, there were no investments with a fair value that was significantly lower than the amortized cost basis or any investments that had been in an unrealized loss position for a significant period.

Fair value of financial instruments

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

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

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

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

For the nine months ended September 30, 2017, there were no transfers among Level 1, Level 2, or Level 3 categories. Additionally, there were no changes to the valuation methods utilized by the Company during the nine months ended September 30, 2017.

Recently issued accounting standards

Standard	Description	Effect on the financial statements
ASU 2014-09, Revenue from Contracts with Customers (Topic 606)	The standard will replace existing revenue recognition standards and significantly expand the disclosure requirements for revenue arrangements. It may be adopted either retrospectively or on a modified retrospective basis to new contracts and existing contracts with remaining performance obligations as of the effective date. In July 2015, the FASB affirmed its proposal to defer the effective date of the new revenue standard for all entities by one year. As a result, public business entities will be required to apply the new revenue standard to annual reporting periods beginning after December 15, 2017. The standard will become effective for us on January 1, 2018 (the first quarter of our 2018 fiscal year).	The Company does not currently have and has never had any contracts that are within the scope of ASC 606 or its predecessor guidance, ASC 605 Revenue Recognition. The Company will evaluate the ASC 606 accounting considerations when it has a contract that is within its scope.
ASU 2016-02, Leases (Topic 842)	In February 2016, the FASB issued ASU 2016-02, which replaces the existing lease accounting standards. The new standard requires a dual approach for lessee accounting under which a lessee would account for leases as finance (also referred to as capital) leases or operating leases. Both finance leases and operating leases will result in the lessee recognizing a right-of-use asset and corresponding lease liability. For finance leases the lessee would recognize interest expense and amortization of the right-of-use asset and for operating leases the lessee would recognize straight-line total lease expense. ASU 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018.	The Company generally does not finance purchases of equipment but it does lease office and lab facilities. The Company is in the process of evaluating the effect that this ASU will have on its consolidated financial statements and related disclosures.
ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash	In November 2016, the FASB issued ASU 2016-18, which requires additional disclosures related to restricted cash. The new standard requires that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total	The Company does not expect the adoption of this standard to have a material effect on its consolidated financial statements.

amounts shown on the statement of cash flows.

ASU 2016-18 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017.

3. Cash, cash equivalents and investments

As of September 30, 2017, cash and cash equivalents comprised of funds in depository and money market accounts. As of December 31, 2016, cash, cash equivalents and investments comprised of funds in depository, money market accounts, U.S. treasury securities, and FDIC-insured certificates of deposit.

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

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2017				
Money market funds, included in cash equivalents	$21,282	$21,282	$ —	$ —
Total	$21,282	$21,282	$ —	$ —
December 31, 2016				
Money market funds, included in cash equivalents	$25,602	$25,602	$ —	$ —
Certificates of deposit, included in cash equivalents	992	—	992	—
Investments - U.S. treasuries	16,508	16,508	—	—
Investments - certificates of deposit	19,429	—	19,429	—
Total	$62,531	$42,110	$ 20,421	$ —

Cash equivalents and investments have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. The Company validates the prices provided by its third party pricing services by reviewing their methods and obtaining market values from other pricing sources. After completing its validation procedures, the Company did not adjust any fair value measurements provided by the pricing services as of September 30, 2017 and December 31, 2016.

Cash equivalents and investments at December 31, 2016 consisted of the following (in thousands):

	Contractual Maturity	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasuries	31-181 days	$ 16,508	$ —	$ —	$ 16,508
Certificates of deposit	4-180 days	20,421	—	—	20,421
Total		$ 36,929	$ —	$ —	$ 36,929

4. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Research and development costs	$ 2,670	$ 1,239
Payroll and employee-related costs	2,626	2,090
Other current liabilities	1,025	849
Total	$ 6,321	$ 4,178

5. Long-term debt

2014 Term Loan, First Amendment

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

In December 2015, the Company amended the Loan Agreement (the "First Amendment") with Hercules. The First Amendment required the Company to draw an additional $5.0 million and permits it to draw two additional $5.0 million tranches. One $5.0 million tranche was immediately available to draw through December 15, 2016 and a second $5.0 million tranche could have become available through December 15, 2016, subject to the Company demonstrating sufficient evidence of continued clinical progression of its GEN-003 product candidate and making favorable progress in applying its proprietary technology platform toward the development of novel immunotherapies with application in oncology. Both tranches expired unused at December 31, 2016, and $15.4 million was outstanding under the amended 2014 Term Loan at September 30, 2017.

2014 Term Loan

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

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

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

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

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

The Loan Agreement contains a material adverse effect ("Material Adverse Effect") provision that requires all material adverse effects to be reported under the financial reporting covenant. Loan advances are subject to a representation that no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing. Under the Loan Agreement, a Material Adverse Effect means a material adverse effect upon: (i) the business, operations, properties, assets or condition (financial or otherwise) of the Company; or (ii) the ability of the Company to perform the secured obligations in accordance with the terms of the Loan Agreements, or the ability of agent or lender to enforce any of its rights or remedies with respect to the secured obligations; or (iii) the collateral or agent’s liens on the collateral or the priority of such liens. Any event that has a Material Adverse Effect or would reasonably be expected to have a Material Adverse Effect is an event of default under the Loan Agreement and repayment of amounts due under the Loan Agreement may be accelerated by Hercules under the same terms as an event of default.

Events of default under the Loan Agreement include failure to make any payments of principal or interest as due on any outstanding indebtedness, breach of any covenant, any false or misleading representations or warranties, insolvency or bankruptcy, any attachment or judgment on the Company’s assets of at least $100 thousand, or the occurrence of any material default of the

Company involving indebtedness in excess of $100 thousand. If an event of default occurs, repayment of all amounts due under the Loan Agreement may be accelerated by Hercules, including the applicable prepayment charge.

The 2014 Term Loan is automatically redeemable upon a change in control. The Company must prepay the outstanding principal and any accrued and unpaid interest through the prepayment date including any unpaid agent's and lender's fees and expenses accrued to the date of the repayment including the End of Term Charge and the applicable Prepayment Charge. If a change in control occurs, repayment of amounts due under the Loan Agreement may be accelerated by Hercules. The Company believes acceleration of the repayment of amounts outstanding under the loan is remote, and therefore the debt balance is classified according to the contractual payment terms at September 30, 2017.

In connection with the 2014 Term Loan, the Company issued a common stock warrant to Hercules on November 20, 2014. The warrant is exercisable for 73,725 shares of the Company's Common Stock (equal to $607,500 divided by the exercise price of $8.24). The exercise price and the number of shares are subject to adjustment upon a merger event, reclassification of the shares of Common Stock, subdivision or combination of the shares of Common Stock or certain dividends payments. The warrant is exercisable until November 20, 2019 and will be exercised automatically on a net issuance basis if not exercised prior to the expiration date and if the then-current fair market value of one share of Common Stock is greater than the exercise price then in effect. The warrant has been classified as equity for all periods it has been outstanding.

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

Additionally, under the Equity Rights Letter Agreement, Hercules has the right to participate in any one or more subsequent private placement equity financings of up to $2.0 million on the same terms and conditions as purchases by the other investors in each subsequent equity financing. The Equity Rights Letter Agreement, and all rights and obligations thereunder, will terminate upon the earlier of (1) such time when Hercules has purchased $2.0 million of subsequent equity financing securities in the aggregate and (2) the later of (a) the repayment of all indebtedness under the Loan Agreement and (b) the expiration or termination of the exercise period for the warrant issued in connection with the Loan Agreement. The Company allocated $36 thousand of financing costs to additional paid-in capital for issuance fees that were reimbursed to Hercules.
The Company incurred $0.3 million in debt financing costs related to the First Amendment, which was recorded as a debt discount and will be amortized over the remaining loan term. In connection with the issuance of the 2014 Term Loan, the Company incurred $0.1 million of financing costs and also reimbursed Hercules $0.2 million for debt financing costs, which has been recorded as a debt discount and will be amortized over the remaining loan term. The End of Term Charge is amortized ratably over the term loan period based upon the outstanding debt and the increase in the amount of End of Term Charge due to the additional borrowing from the First Amendment is being amortized from the First Amendment date through maturity. The debt discount is being amortized to interest expense over the life of the 2014 Term Loan using the effective interest method. At September 30, 2017, the 2014 Term Loan bears an effective interest rate of 10.2%.

As of September 30, 2017 and December 31, 2016, the Company had outstanding borrowings under the 2014 Term Loan of $15.4 million and $17.0 million, respectively. Interest expense related to the 2014 Term Loan was $0.4 million and $1.3 million for the three and nine months ended September 30, 2017 and 2016, respectively.

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

	September 30, 2017
2017	$ 1,590
2018	6,659
2019	8,034
Total	$ 16,283

6. Commitments and contingencies

Lease commitments

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

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

	September 30, 2017
2017	$ 396
2018	1,607
2019	1,637
2020	274
Total	$ 3,914

At September 30, 2017 and December 31, 2016, the Company has an outstanding letter of credit of $316 thousand with a financial institution related to a security deposit for the 2016 Lease, which is secured by cash on deposit and expires on February 29, 2020. An additional unsecured deposit was required for the 2015 Lease.

Significant Contracts and Agreements

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

In September 2014, the Company received $1.2 million in the form of a grant entered into with the Bill & Melinda Gates Foundation for the identification of protective T-cell antigens for malaria vaccines. This grant provided for the continued expansion of the Company’s malaria antigen library to aid in the identification of novel protein antigens to facilitate the development of highly efficacious anti-infection malarial vaccines. Activities, and the related grant revenue, were completed under this grant by March 2016.

The Company relies on research institutions, contract research organizations ("CROs"), clinical investigators as well as clinical and commercial material manufacturers of our product candidates. Under the terms of these agreements, the Company is obligated to make milestone payments upon the achievement of manufacturing or clinical milestones defined in the contracts. In some cases, monthly service fees for project management services are charged over the duration of the arrangement. In addition, clinical and manufacturing contracts generally require reimbursement to suppliers for certain set-up, production, travel, and other related costs as they are incurred. In some manufacturing contracts, the Company also may be responsible for the payment of a reservation fee, which will equal a percentage of the expected production fees, to reserve manufacturing slots in the production timeframe. Generally, the Company is liable for actual effort expended by these organizations at any point in time during the contract through the notice period. To the extent amounts paid to a supplier exceed the actual efforts expended, the Company records a prepaid asset, and to the extent actual efforts expended exceed amounts billed or billable under a contract, an accrual for the estimate of services rendered is recorded.

In February 2014, the Company entered into a supply agreement with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. (“Fujifilm”) for the manufacture and supply of antigens for future GEN-003 clinical trials. Under the agreement,
the Company is obligated to pay Fujifilm manufacturing milestones, in addition to reimbursement of certain material production related costs. Additionally, the Company is responsible for the partial prepayment of manufacturing fees to reserve manufacturing slots in the production timeframe. In June and September 2016, the Company entered into new statements of work

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under the agreement with Fujifilm for the manufacture and supply of antigens for the Company's Phase 3 clinical trials for GEN-003. In September 2017, the Company notified Fujifilm to cease all manufacturing activities of antigens for GEN-003. Amounts recorded as of September 30, 2017 represent all liabilities for services completed or in process prior to the cancellation date, charges for terminating the contract within a certain timeframe of expected manufacture activities, and materials purchased which cannot be re-used or re-purposed by Fujifilm.

The Company incurred expenses under the agreement of $1.2 million and $3.4 million for the three and nine months ended September 30, 2017, respectively. The Company incurred expenses under the agreement of $0.5 million and $0.8 million for the three and nine months ended September 30, 2016, respectively.

Litigation

On October 31, 2017, a putative class action complaint was filed in the U.S. District Court for the District of Massachusetts, naming Genocea Biosciences, Inc., Chief Executive Officer William D. Clark, and Chief Financial Officer Jonathan Poole as defendants. The complaint alleges violations of the Securities Exchange Act of 1934 and Rule 10b-5 in connection with disclosures made in and subsequent to the Company’s Quarterly Report on Form 10-Q for the period ending March 31, 2017, filed with the SEC on May 5, 2017 and the Company’s announcement of a strategic shift to immuno-oncology on September 25, 2017. The plaintiff seeks to represent a class of shareholders who purchased or otherwise acquired the Company’s securities between May 5, 2017 and September 25, 2017. The complaint seeks unspecified damages and costs. The Company intends to vigorously defend itself against this action. The Company is unable at this time to determine whether the outcome of the litigation would have a material impact on its results of operations, financial condition or cash flows. The Company does not have contingency reserves established for any litigation liabilities.

Refund of research and development expense

In August 2009, the Company entered into an exclusive license and collaboration agreement (the “Novavax Agreement”) with Isconova AB, a Swedish company which subsequently was acquired by Novavax, Inc. ("Novavax"). Pursuant to the agreement, Novavax granted the Company a worldwide, sublicensable, exclusive license to two patent families, to import, make, have made, use, sell, offer for sale and otherwise exploit licensed vaccine products containing an adjuvant which incorporates or is developed from Matrix-A, Matrix-C and/or Matrix-M technology, in the fields of HSV and chlamydia. Matrix-M is the adjuvant used in GEN-003.

The Novavax Agreement includes a research funding clause for which the Company made monthly payments to Novavax between August 2009 and March 2012 of approximately $1.6 million. All amounts of research funding provided were to be refunded by Novavax. After December 31, 2015, any amounts remaining due from Novavax, including accrued interest, could be received in cash upon 30-day written notice provided by the Company. The Company provided this notice in January 2016.

The Company provided the research funding solely to benefit the supply plan for the Matrix-M adjuvant to the point that a Phase 1 clinical trial could be initiated. Because of the benefit received from the research funding payments, an assessment of Novavax's financial ability to repay the research funding at the time of the payments, along with the duration of which amounts could be outstanding, the Company concluded the initial research funding should be recorded as research and development expense at the time of payment. In February 2016, upon receipt of the $1.6 million refund including accrued interest, the Company recorded a gain within operating expenses on the Condensed Consolidated Statements of Operations and Comprehensive Loss.

7. Equity and net loss per share

At September 30, 2017, the Company authorized 175,000,000 shares of common stock at $0.001 par value per share. As of September 30, 2017, 28,704,164 shares of common stock were issued and outstanding. At December 31, 2016, 28,446,461 shares of common stock were issued and 28,444,520 shares of common stock were outstanding.

The Company computes basic and diluted earnings (loss) per share using a methodology that gives effect to the impact of outstanding participating securities (the “two-class method”). For both the three and nine-month periods ended September 30, 2017 and 2016, there is no income allocation required under the two-class method or dilution attributed to weighted average shares outstanding in the calculation of diluted loss per share.

As of September 30, 2017 and December 31, 2016, the Company had warrants outstanding that represent the right to acquire 77,603 shares of Common Stock, of which 73,725 represented warrants issued to Hercules and 3,878 represented warrants to purchase Common Stock issued in periods prior to the Company's initial public offering ("IPO").

The following common stock equivalents, presented on an as converted basis, were excluded from the calculation of net loss per share for the periods presented, due to their anti-dilutive effect (in thousands):

	Nine Months Ended September 30,	
	2017	2016
Stock options	4,400	3,794
Restricted stock units	24	—
Warrants	78	78
Outstanding ESPP	31	21
Total	4,533	3,893

Restricted stock

During 2013, a Company director exercised stock options and received 31,092 shares of common stock that were subject to a Stock Restriction and Repurchase Agreement with the Company. Under the terms of the agreement, shares of common stock issued were subject to a vesting schedule and unvested shares were subject to repurchase by the Company. Vesting occurred periodically at specified time intervals and specified percentages. As of September 30, 2017, all shares of common stock were fully vested.

In May 2017, the Company granted an officer 47,620 units of Restricted Stock ("RSUs") in accordance with the 2014 Equity Incentive Plan and subject to a Restricted Stock Unit Award Agreement with the Company. On the date of grant, 7,937 units of RSUs vested immediately, and another 23,810 units of RSUs will vest on the eighteen month anniversary of the grant date, subject to the continued employment of the officer. The remaining 15,873 units of RSUs, which contained a performance condition of completing a material financing event on or before September 30, 2017, were canceled as the performance criterion was not achieved. As of September 30, 2017, 23,810 units of RSUs remain unvested.

8. Stock and employee benefit plans

Stock-based compensation expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	$322	$428	$1,060	$1,234
General and administrative	771	691	2,208	1,879
Total	$1,093	$1,119	$3,268	$3,113

Stock options

The following table summarizes stock option activity for employees and nonemployees (shares in thousands):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2016	3,807	$ 5.94	5.94	$ 2,441
Granted	1,455	$ 4.78		
Exercised	(155)	$ 2.95		
Canceled	(707)	$ 5.80		
Outstanding at September 30, 2017	4,400	$ 5.68	7.06	$ —
Exercisable at September 30, 2017	2,357	$ 6.26	5.88	$ —
Vested or expected to vest at September 30, 2017	4,400	$ 5.68	7.06	$ —

Performance-based awards

The Company granted stock awards to certain employees, executive officers and consultants, which contain performance-based vesting criteria. Milestone events are specific to the Company's corporate goals, which include, but are not limited to, certain clinical development milestones, business development agreements and capital fundraising events. Stock-based compensation expense associated with these performance-based stock options is recognized if the performance conditions are considered probable of being achieved, using management's best estimates. The Company determined that none of the performance-based milestones were probable of achievement during the three and nine months ended September 30, 2017, and accordingly did not recognize stock-based compensation expense for these periods. As of September 30, 2017, there are 56,336 performance-based common stock awards outstanding for which the probability of achievement was not deemed probable.

Employee stock purchase plan

On February 10, 2014, the Company's board of directors adopted the 2014 Employee Stock Purchase Plan (the "2014 ESPP"). The 2014 ESPP authorizes the initial issuance of up to a total of 200,776 shares of common stock to participating eligible employees. The 2014 ESPP provides for six-month option periods commencing on January 1 and ending June 30 and commencing July 1 and ending December 31 of each calendar year. As of September 30, 2017, 30,741 shares remain for future issuance under the plan. The Company incurred stock-based compensation expense related to the 2014 ESPP of $23 thousand and $99 thousand for the three and nine months ended September 30, 2017, respectively, and $45 thousand and $110 thousand for the three and nine months ended September 30, 2016, respectively.

9. Restructuring costs

On September 25, 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. The Company also announced that it is exploring strategic alternatives for GEN-003, its Phase 3-ready investigational immunotherapy for the treatment of genital herpes. Consequently, substantially all GEN-003 spending and activities were ceased and the Company reduced its workforce by approximately 40 percent as of the quarter ended September 30, 2017. Pursuant to ASC 420, Exit or Disposal Cost Obligations, charges for employee severance, employee benefits, and contract terminations were recorded for the three months ended September 30, 2017. Asset impairment charges, pursuant to ASC 360, Property, Plant, and Equipment, were also recorded for the three months ended September 30, 2017 and primarily related to fixed assets specific to GEN-003 research and development activities.

The following table summarizes the impact of the September 2017 restructuring activities for the three and nine months ended September 30, 2017, along with the current liability recorded in the balance sheet as of September 30, 2017 (in thousands):

	Charges incurred during the nine months ended September 30, 2017	Amount paid through September 30, 2017	Less non-cash charges during the nine months ended September 30, 2017	Amount accrued at September 30, 2017
Employee severance, benefits and related costs	$ 1,064	$ —	$ —	$ 1,064
Contract terminations	526	—	—	526
Asset impairments	1,001	—	1,001	—
Total	$ 2,591	$ —	$ 1,001	$ 1,590

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

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

Overview

We are a biopharmaceutical company that seeks to discover and develop novel cancer vaccines through our AnTigen Lead Acquisition System ATLAS proprietary discovery platform. The ATLAS platform is designed to recall a patient's pre-existing CD4+ and CD8+ T cell immune responses to their tumor to identify neoantigens and antigens for inclusion in vaccines that are designed to act through T cell (or cellular) immune responses. We believe that using ATLAS to identify neoantigens and antigens for inclusion in cancer vaccines could lead to more immunogenic and efficacious cancer vaccines.

In September 2017, we announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. Currently, all of our research programs and product candidates in active development are at the preclinical stage. Our most advanced program in active development is our preclinical immuno-oncology program, GEN-009, a neoantigen cancer vaccine. The GEN-009 program leverages ATLAS to identify patient neoantigens, or newly formed antigens unique to each patient, that are associated with that individual's tumor. We are also exploring partnering opportunities in the development of cancer vaccines targeting tumor-associated antigens and a vaccine targeting cancers caused by EBV.

We have one Phase 3-ready product candidate, GEN-003, an investigational immunotherapy for the treatment of genital herpes. In September 2017, we announced that we are exploring strategic alternatives for GEN-003. Consequently, substantially all GEN-003 spending and activities were ceased and we reduced our workforce by approximately 40 percent.

Our Immuno-Oncology Program

We are focused on combining our antigen selection and vaccine development expertise with that of leading cancer innovators to unlock new targets in immuno-oncology. Our potential cancer vaccines will be designed to educate T cells to recognize and attack specific targets and thereby kill cancer cells. We are working to develop personalized cancer vaccines by leveraging ATLAS to identify patient neoantigens that are associated with that individual’s tumor. Neoantigens are personalized tumor mutations that are seen as "foreign" by an individual's immune system. Data published in recent years have indicated that an individual's response to neoantigens drives checkpoint inhibitor efficacy and that it is possible to vaccinate an individual against their own neoantigens. Genocea’s lead immuno-oncology program, GEN-009, is an adjuvanted neoantigen peptide vaccine candidate designed to direct a patient's immune system to attack their tumor. GEN-009's neoantigen peptides are identified by Genocea's proprietary ATLAS platform, which recalls a patient's pre-existing CD4+ and CD8+ T cell immune responses to their tumor. Following ATLAS neoantigen identification, Genocea will manufacture a personal vaccine for each patient.

We anticipate filing a personalized cancer vaccine investigational new drug ("IND") application with the FDA in early 2018 for GEN-009. We plan to initiate a Phase 1 clinical trial for GEN-009 in a range of tumor types in the first half of 2018 and expect to report initial immunogenicity data in the first half of 2019.

We are also using ATLAS to develop general cancer vaccines targeting tumor-associated, or shared, antigens and vaccines against cancers of viral origin. Our strategy in immuno-oncology combines our own internal neoantigen vaccine development programs with a focus on partnering ATLAS for these other immuno-oncology applications.

Refer to Part I in our Annual Report on Form 10-K, as filed with the SEC on February 17, 2017, under the heading "Business - Our Immuno-Oncology Program" for additional details on this program, including our current collaborations.

In November 2015, we commenced a new program focused on EBV. EBV infection has been linked to cancers with high unmet needs such as non-Hodgkin’s lymphoma, nasopharyngeal carcinoma and gastric carcinoma. We believe that ATLAS is highly suited to the creation of a new immunotherapy for EBV, given that T cell responses are understood to be crucial for protection against EBV. Furthermore, EBV is part of the herpes virus family, in which we have deep experience through our prior development of GEN-003. We are currently seeking a partner to advance the development of this vaccine.

GEN-003 — Phase 2 immunotherapy for genital herpes

Prior to our September 2017 strategic shift announcement, our lead program was GEN-003, a Phase 3-ready investigational immunotherapy for the treatment of genital herpes. We completed three positive clinical trials for which key data from those clinical trials is described below. We are currently exploring strategic alternatives to maximize shareholder value from GEN-003, during which time we have ceased substantially all activities under the GEN-003 program.

Phase 1/2 Trial

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

Phase 2 Dose Optimization Trial

A 310-subject Phase 2 dose optimization trial was completed in March 2016. The objective of this trial was to confirm the results of the Phase 1/2a trial and to test six combinations of proteins and adjuvant to determine the optimal dose for future trials and potentially improve on the profile of GEN-003. Subjects were randomized to one of six dosing groups of either 30µg or 60µg per protein paired with one of three adjuvant doses (25 µg, 50 µg, or 75 µg). A seventh group received placebo. Subjects received three doses of GEN-003 or placebo at 21-day intervals. Baseline viral shedding and genital lesion rates were established for each subject in a 28-day observation period prior to the commencement of dosing by collecting 56 genital swab samples (two per day), which were analyzed for the presence of HSV-2 DNA, and by recording the days on which genital lesions were present. This 28-day observation period was repeated immediately after the completion of dosing, and at six and twelve months following dosing. No maintenance doses were given. After the 28-day observation period immediately after dosing, patients in the placebo arm were rolled over across the six active dose combinations under a separate protocol. Subsequent to March 2016, we extended this clinical trial to include a separate protocol for an extension study which includes a 28-day observation period at 24 months post-dosing to evaluate the reduction versus baseline in both the viral shedding rate and the genital lesion rate.

The primary endpoint of the trial was the reduction in viral shedding rate versus baseline, a measure of anti-viral activity. A number of exploratory secondary endpoints were also studied, including, the reduction in genital lesion rates, the percent of patients who were recurrence free from lesions up to six and 12 months after dosing, and the time to first recurrence of lesions after dosing. We advanced the two most promising doses from this dose optimization study, the 60 µg per protein combined with either 50 or 75 µg of Matrix-M2 adjuvant ("60/50 Dose" and "60/75 Dose" respectively), into a Phase 2b efficacy trial for which positive twelve-month, placebo-controlled clinical efficacy data was announced in July 2017 (see Phase 2b trial below).

Phase 2b Trial

In December 2015, a Phase 2b clinical trial was initiated as our first study testing potential Phase 3 endpoints with a Phase 3-ready formulation of GEN-003, manufactured with commercially-scalable processes. The trial enrolled 131 subjects that were randomized to one of three dose groups - placebo, 60/50 Dose, and 60/75 Dose. All subjects received three injections at 21-day intervals.

In September 2016, we announced positive viral shedding rate reductions from the ongoing Phase 2b study. The study achieved its primary endpoint, with GEN-003 demonstrating a statistically significant (versus placebo and baseline) 40% reduction in the viral shedding rate compared to baseline immediately after dosing in the 60/50 Dose group, using a new Phase 3-ready formulation. This result was consistent with a statistically significant (versus placebo and baseline) viral shedding rate reduction of 41% at this same dose and time point in a prior Phase 2 clinical trial. In addition, the reactogenicity profile of this dose, an indication of the strength of the immune response to GEN-003, was consistent between the trials. This same dose in the prior Phase 2 clinical trial subsequently demonstrated virologic and clinical efficacy that was durable for at least one year after dosing.

The 60/75 Dose group reduced the viral shedding rate by 27%, which is lower than the rate observed in the prior trial, and also showed a less acceptable reactogenicity profile than the prior trial. We believe that the increase in reactogenicity of this dose indicates an overstimulation of the T cell immune system leading to the reduced efficacy with this dose in this trial, as would be expected with the known bell-shaped T cell dose response curve. The likely driver of this effect is a more potent adjuvant formulation following customary manufacturing process changes to prepare for Phase 3 clinical trials and commercialization of GEN-003.

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

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

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

In July 2017, we announced positive clinical results from the Phase 2b trial. At twelve months after dosing, GEN-003 demonstrated statistically significant improvements versus placebo in both the median genital lesion rate and across multiple clinical endpoints. The 60/50 Dose significantly reduced the median rate of genital lesions during the twelve months following dosing compared to placebo (49% reduction versus placebo). The median genital lesion rate is an important overall measure of disease that captures both the frequency and duration of recurrences, both of which are important to both patients and their caregivers. Importantly, these results were achieved at the Phase 3 dose and expected Phase 3 primary endpoint. GEN-003 also consistently demonstrated significant benefits versus placebo across several other clinical endpoints across the dose groups as summarized in the following table:

Endpoint	60/50 (n=43)	60/75 (n=44)	Placebo (n=44)
Number of subjects contributing clinical data	43	44	44
Median genital lesion rate at baseline*	5.2%	4.4%	10.1%
Mean genital lesion rate at baseline*	10.7%	10.4%	12.0%
Median genital lesion rate (percent of days with lesions over 12 months)	2.3%	2.8%	4.5%
Percent reduction versus placebo	(49)%	(37)%	NA
p-value versus placebo[1]	0.01	0.08	NA
Mean genital lesion rate	3.6%	4.7%	7.3%
Median number of recurrences over 12 months	1.5	2.0	4.0
Percent reduction versus placebo	(63)%	(50)%	NA
p-value versus placebo[1]	0.01	0.07	NA
Mean number of recurrences over 12 months	2.7	3.2	4.4
Median duration of recurrences (days)	2.7	4.0	3.6
Percent reduction versus placebo	-25%	11%	NA
p-value versus placebo[1]	0.02	0.92	NA
Mean duration of recurrences (days)	3.2	4.4	4.8
	20%	16%	7%

Kaplan-Meier estimate of percent recurrence free 12 months after first dose			
p-value versus placebo(2)	0.04	0.07	NA
Kaplan-Meier estimate of percent recurrence free 12 months after last dose	20%	17%	8%
p-value versus placebo(2)	0.12	0.05	NA
Number of subjects contributing shedding data	30	32	31
Viral Shedding Rate Reduction from Baseline at 12 months	(42)%	(39)%	(52)%
p-value versus baseline(3)	0.02	0.07	0.03
p-value versus placebo(3)	0.67	0.61	NA

* Baseline measurements reflect percent of days with genital lesions captured over a period of only 59-68 days prior to the commencement of dosing. Baseline rates will not be captured or used in the calculation of any of the endpoints in Phase 3 trials where post-treatment comparisons are the approvable standard.

Statistical tests pre-specified in Phase 2b trial protocol as follows:

(1) Wilcoxon Rank Sum test

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(2) Log rank test
(3) Poisson mixed effect model with empirical variance
NS = $p>0.05$
We believe the variability in the shedding data observed at the 28-day observation period twelve months after dosing in this Phase 2b trial is a consequence of the sporadic nature of shedding and the small number of subjects who provided data in this Phase 2b trial.
GEN-003 also continues to demonstrate a safety profile appropriate for its therapeutic setting in the judgment of the trial's independent Drug Monitoring Committee. There was no grade 4 reactogenicity or related serious adverse events ("AEs") and discontinuations due to AEs were low and similarly distributed across active dose groups and placebo. Around the end of the first quarter of 2017, we had a successful end-of-Phase 2 meeting with the U.S Food and Drug Administration ("FDA"). We believe that progress made and data generated to date in the GEN-003 preclinical and clinical trials remains valuable to the Company for the future.

Other infectious disease programs
Our other infectious disease programs include GEN-004, a potential universal Streptococcus pneumoniae, or pneumococcus, vaccine to protect against a leading cause of infectious disease mortality worldwide and early stage programs focused on genital herpes prophylaxis, chlamydia, and malaria. In October 2015, we announced that top-line results from the Phase 2a clinical trial for GEN-004 showed consistent reductions versus placebo in the pre-specified endpoints of the rate and density of upper airway colonization in a human challenge model, but that neither of the endpoints achieved statistical significance. GEN-004 was safe and well tolerated by subjects. Although we did not achieve statistical significance in this study and have suspended the development of the GEN-004 program, the consistent apparent effect gives us confidence in the vaccine concept and in future potential for GEN-004. In November 2016, we paused activities on our other early stage programs focused on genital herpes prophylaxis, chlamydia, and malaria in order to focus all of our internal research and pre-clinical resources on our immuno-oncology investments. We believe that progress made and data generated to date in these infectious disease clinical and research programs remains valuable to the Company for the future.
Financing and business operations

We commenced business operations in August 2006. To date, our operations have been limited to organizing and staffing our company, acquiring and developing our proprietary ATLAS technology, identifying potential product candidates and undertaking preclinical studies and clinical trials for our product candidates. All of our revenue to date has been grant revenue. We have not generated any product revenue and do not expect to do so for the foreseeable future. We have primarily financed our operations through the issuance of our equity securities, debt financings and amounts received through grants. As of September 30, 2017, we had received an aggregate of $279.8 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At September 30, 2017, our cash and cash equivalents were $22.0 million.

Since inception, we have incurred significant operating losses. Our net losses were $16.9 million and $46.0 million for the three and nine months ended September 30, 2017, respectively, and our accumulated deficit was $253.5 million as of September 30, 2017. We expect to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We will need to generate significant revenue to achieve profitability, and we may never do so.

For the nine months ended September 30, 2017, we sold 52 thousand shares under our ATM program and received $0.2 million in net proceeds after deducting commissions. For the nine months ended September 30, 2016, we sold 136 thousand shares under our ATM program and received $0.8 million in net proceeds after deducting commissions.

We expect that our existing cash and cash equivalents are sufficient to support our operating expenses and capital expenditure requirements into the middle of 2018. We are currently exploring various avenues to secure capital to advance GEN-009 through our planned IND filing in early 2018 and to initiate a Phase 1 clinical trial for GEN-009 in a range of tumor types in the first half of 2018. If we are able to secure such funding, then we would expect to be able to report initial immunogenicity data in the first half of 2019. In the event that we are unsuccessful in securing capital on acceptable terms for some or all of our programs, then we will review our remaining strategic alternatives to maximize shareholder value including, but not limited to, exploring a potential sale of the company or our assets.

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 any proceeds received from other sources, will be sufficient to fund our studies or operations through this period. These funds will not be sufficient to enable us to conduct any preclinical or clinical trials for, seek marketing approval for or commercially launch GEN-009 or any other product candidate. Accordingly, to perform preclinical or clinical trials, obtain marketing approval for and to commercialize these or any other product candidates, we will be required to obtain further funding through public or private equity offerings, debt financings, collaboration and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital when needed would have a negative effect on our financial condition and our ability to pursue our business strategy.

Financial Overview

Grant revenue

Grant revenue consists of revenue earned to conduct vaccine development research. We have received grants from private not-for-profit organizations and federal agencies. These grants have related to the discovery and development of several of our product candidates, including product candidates for the prevention of pneumococcus, chlamydia, malaria, and immunotherapy of cancer. Revenue under these grants is recognized as research services are performed. Funds received in advance of research services being performed are recorded as deferred revenue.

We have no products approved for sale and none of our active product candidates are near the point of commercialization. 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 CROs, contract manufacturing organizations ("CMOs"), consultants and other vendors that conduct our clinical trials and preclinical activities;
- costs of acquiring, developing and manufacturing clinical trial materials and lab supplies; and
- facility costs, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Genital herpes (GEN-003)(1)	$6,378	$4,979	$19,724	$11,339
Immuno-oncology program (2)	2,655	1,269	8,136	2,437
Other research and development (3)	1,122	2,563	3,464	9,045
Total research and development	$10,155	$8,811	$31,324	$22,821

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

(2) Includes direct and indirect internal costs and external costs for our immuno-oncology research and development activities.

(3) Includes costs that are not specifically allocated by project, including facilities costs, depreciation expense, and other costs. In addition, costs for programs that were paused in 2016 or earlier are included in this line item.

We expect our overall research and development expenses will decrease given the strategic shift and restructuring announced in September 2017 that resulted in our ceasing clinical trials for GEN-003. However, we do expect our research and development costs incurred on our immuno-oncology programs to increase as we continue to develop our supply chain and manufacturing capabilities for our GEN-009 program, prepare an IND, prepare for the initiation of clinical trials for GEN-009, and advance our next generation neoantigen vaccine program, GEN-010, in preclinical development.

General and administrative expenses

General and administrative expenses consist principally of salaries and related costs for personnel, including stock-based compensation and travel expenses, in executive, business development and other administrative functions. Other general and administrative expenses include facility-related costs, communication expenses and professional fees associated with corporate and intellectual property legal expenses, consulting and accounting services.

We anticipate that our general and administrative expenses will decrease in the foreseeable future given the strategic shift and restructuring announced in September 2017, that resulted in our ceasing clinical trials for GEN-003, notwithstanding our requirements to operate as a public company. We expect that costs for insurance, hiring activities, and professional services, such as outside consultants, lawyers and accountants, among other expenses, to remain flat or decrease as we refocus on preclinical and early clinical research and development activities. 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.

Restructuring costs

On September 25, 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. Consequently, substantially all GEN-003 spending and activities were ceased and the Company reduced its workforce by approximately 40 percent as of the quarter ended September 30, 2017. Charges for employee severance and benefits costs, contract terminations, and impaired assets were recognized and recorded in the three months ended September 30, 2017. Asset impairment charges primarily relate to fixed assets specific to GEN-003 research and development activities.

Refund of research and development expenses

The refund of research and development expenses recorded in the nine months ended September 30, 2016 related to a one-time payment received in February 2016 from Novavax pursuant to contractual obligations under the Novavax Agreement that existed to refund research and development expenses paid to Novavax between 2009 and 2012.

Interest income

Interest income consists of interest earned on our cash, cash equivalent and investment portfolio.

Interest expense

Interest expense consists of interest expense on our long-term debt facilities and non-cash interest related to the amortization of debt discount and issuance costs.

Critical Accounting Policies and Significant Judgments and Estimates

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate estimates, which include, but are not limited to, estimates related to clinical trial accruals, prepaid and accrued research and development expenses, stock-based compensation expense and reported amounts of revenues and expenses during the reported period. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances. Actual results may differ materially from those estimates or assumptions.

The critical accounting policies we identified in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2016 related to prepaid and accrued research and development expenses and stock-based compensation. There have been no material changes to our accounting policies from those described in our Annual Report on Form 10-K. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies disclosed in our Annual Report on Form 10-K, as filed with the SEC on February 17, 2017.

Results of Operations

Comparison of the Three Months Ended September 30, 2017 and September 30, 2016

	Three Months Ended September 30,		Increase
(in thousands)	2017	2016	(Decrease)
Grant revenue	$—	$—	$ —
Operating expenses:			
Research and development	10,155	8,811	1,344
General and administrative	3,750	3,619	131
Restructuring costs	2,591	—	2,591
Total operating expenses	16,496	12,430	4,066
Loss from operations	(16,496)	(12,430)	4,066
Other income and expenses:			
Interest income	63	103	(40)
Interest expense	(435)	(438)	(3)
Total other income and expense	(372)	(335)	37
Net loss	$(16,868)	$(12,765)	$ 4,103

Research and development expenses

Research and development ("R&D") expenses increased $1.3 million in the three months ended September 30, 2017 as compared to the three months ended September 30, 2016. The increase was due largely to increases in external manufacturing and research related costs (approximately $1.7 million), offset by decreased clinical costs (approximately $0.3 million).

On a program basis, GEN-003 costs increased by $1.4 million for the three months ended September 30, 2017 driven by increased compensation and external manufacturing related expenses (approximately $2.2 million) to support both the Phase 3 clinical drug supply and clinical planning activities in advance of the previously planned Phase 3 trials, partially offset by reduced clinical costs, due to timing of activities in support of our clinical trials. Spending increases on GEN-009 and immuno-oncology programs (approximately $1.4 million) were driven primarily by increased manufacturing and compensation, consulting and professional services in anticipation of an IND filing in early 2018. Increased spending on these programs was offset by lower costs on deprioritized infectious disease programs.

General and administrative expenses

General and administrative expenses were $3.8 million for the three months ended September 30, 2017, a $0.1 million increase from the same three month period in 2016. Increases in consulting and professional services of $0.3 million were offset by a $0.2 million reduction in depreciation expense with all other expenditures across various activities remaining consistent with the same quarter in the prior year.

Restructuring costs

On September 25, 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. Consequently, substantially all GEN-003 spending and activities were ceased and the Company reduced its workforce by approximately 40 percent as of the quarter ended September 30, 2017. We incurred a charge of approximately $1.1 million for employee severance, benefits and related costs in the third quarter of 2017 which will be paid in the fourth quarter of 2017. In addition, we incurred approximately $0.5 million of expense due to contract termination clauses that we anticipate will result in future cash payments and approximately $1.0 million in non-cash asset impairment charges.

Interest Income

Interest income of approximately $0.1 million for the three months ended September 30, 2017 was generally consistent with the same quarter in the prior year due to rising investment yields offset by lower invested balances.

Interest Expense

Interest expense was unchanged from the same three month period in 2016. Interest expense consists of interest expense on our long-term debt facilities and non-cash interest related to the amortization of debt discount and issuance costs.

Comparison of the Nine Months Ended September 30, 2017 and September 30, 2016

	Nine Months Ended September 30,		Increase
(in thousands)	2017	2016	(Decrease)
Grant revenue	$—	$235	$(235)
Operating expenses:			
Research and development	31,324	22,821	8,503
General and administrative	10,955	11,569	(614)
Restructuring costs	2,591	—	2,591
Refund of research and development expense	—	(1,592)	(1,592)
Total operating expenses	44,870	32,798	12,072
Loss from operations	(44,870)	(32,563)	12,307
Other income and expenses:			
Interest income	211	323	(112)
Interest expense	(1,319)	(1,299)	20

Total other income and expense	(1,108)	(976)	132
Net loss	$(45,978)	$(33,539)	$ 12,439

Grant revenue

We did not record any grant revenue in the nine months ended September 30, 2017 as compared to $0.2 million in the nine months ended September 30, 2016. The $0.2 million decrease was due to the completion of work, as of March 31, 2016, related to a $1.2 million grant entered into with the Bill & Melinda Gates Foundation in September 2014.

Research and development expenses

Research and development expenses increased $8.5 million in the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016. Higher research and development spending was due largely to increases in external manufacturing and research related costs (approximately $5.3 million), compensation, consulting and professional services (approximately $2.8 million), depreciation and facility costs (approximately $0.4 million), offset by decreased clinical costs (approximately $0.3 million). The remaining increases, all insignificant by spending category, are attributable to the overall growth of the research and development function.

On a program basis, GEN-003 costs increased by $8.4 million for the nine months ended September 30, 2017 driven by increased external manufacturing related expenses (approximately $4.9 million) to support the Phase 3 clinical drug supply and increases in headcount and consulting and professional service costs (approximately $4.4 million) in advance of the previously planned Phase 3 trials. Spending increases on GEN-009 and immuno-oncology programs (approximately $5.7 million) were driven primarily by increased manufacturing (approximately $1.7 million) and compensation, consulting and professional services (approximately $2.5 million) in anticipation of an IND filing in early 2018. Increased spending on these programs was offset by lower costs on deprioritized infectious disease programs.

General and administrative expenses

General and administrative expenses decreased $0.6 million in the nine months ended September 30, 2017 reflecting lower office and facility costs and depreciation costs partially offset by higher compensation, consulting and professional services costs.

Restructuring costs

On September 25, 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. Consequently, substantially all GEN-003 spending and activities were ceased and the Company reduced its workforce by approximately 40 percent as of the quarter ended September 30, 2017. We incurred a charge of approximately $1.1 million for employee severance, benefits and related costs in the third quarter of 2017 which will be paid in the fourth quarter of 2017. In addition, we incurred approximately $0.5 million of expense due to contract termination clauses that we anticipate will result in future cash payments and approximately $1.0 million in non-cash asset impairment charges.

Refund of research and development costs

In February 2016, we recorded a gain upon receipt of $1.6 million, including accrued interest, pursuant to contractual obligations under the Novavax Agreement to refund research and development expenses paid to Novavax between 2009 and 2012.

Interest Income

Interest income decreased approximately $0.1 million for the nine months ended September 30, 2017 due to lower invested balances due to working capital needs to fund operations.

Interest Expense

Interest expense was unchanged from the same nine month period in 2016. Interest expense consists of interest expense on our long-term debt facilities and non-cash interest related to the amortization of debt discount and issuance costs.

Liquidity and Capital Resources

Overview

Since our inception through September 30, 2017, we have received an aggregate of $279.8 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At September 30, 2017, our cash and cash equivalents were $22.0 million.

For the nine months ended September 30, 2017, we sold 52 thousand shares under our ATM program and received $239 thousand in net proceeds after deducting commissions.

Debt Financings

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

In December 2015, we entered into an amendment to the Loan Agreement (the "First Amendment") with Hercules. The First Amendment required us to draw an additional $5.0 million and permitted us to draw two additional $5.0 million tranches. One $5.0 million tranche was immediately available to draw through December 15, 2016 and a second $5.0 million tranche could have become available through December 15, 2016, subject to the Company demonstrating sufficient evidence of continued clinical progression of its GEN-003 product candidate and making favorable progress in applying its proprietary technology platform toward the development of novel immunotherapies with application in oncology. Both tranches expired unused at December 31, 2016, and $15.4 million was outstanding under the amended 2014 Term Loan at September 30, 2017.

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

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

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

Contemporaneously with the 2014 Term Loan, we issued a common stock warrant to Hercules on November 20, 2014. The warrant is exercisable for 73,725 shares of our Common Stock (equal to $607,500 divided by the exercise price of $8.24 per share).

Operating Capital Requirements

Our primary uses of capital are for compensation and related expenses, manufacturing costs for pre-clinical and clinical materials, third party clinical trial R&D services, laboratory and related supplies, clinical costs, legal and other regulatory expenses, and general overhead costs. We expect these costs will continue to be the primary operating capital
requirements for the near future.

We expect that our existing cash and cash equivalents are sufficient to support our operating expenses and capital expenditure requirements into the middle of 2018. We are currently exploring various avenues to secure capital to advance GEN-009 through our Phase 1 clinical trial, which we expect to initiate in the first half of 2018. If we are able to secure such funding, then we would expect to be able to report initial immunogenicity data in the first half of 2019. In the event that we are unsuccessful in securing capital on acceptable terms we will review our remaining strategic alternatives to maximize shareholder

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value including, but not limited to, exploring a potential sale of the company or our assets and/or a shut-down of company activities. These factors raise substantial doubt about our ability to continue as a going concern.

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 planned clinical trials for GEN-009;
- the progress, timing and costs of manufacturing GEN-009 for 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-009 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 will need to obtain substantial additional funding in order to commence and complete clinical trials for GEN-009 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 of GEN-009 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-009 or our other product candidates that we otherwise would seek to develop or commercialize ourselves. We are currently exploring various avenues to secure capital to advance GEN-009 through its Phase 1 clinical trial, which we expect to initiate in the first half of 2018. If we are able to secure such funding, then we would expect to be able to report initial immunogenicity data in the first half of 2019. We do not intend to commence Phase 1 clinical trials for GEN-009 unless we are able to secure such capital.

Cash Flows

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

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	Nine Months Ended September 30,	
	2017	2016
Net cash used in operating activities	$(39,425)	$(30,103)
Net cash provided by investing activities	34,688	38,168
Net cash provided by financing activities	(704)	1,093
Net (decrease) increase in cash and cash equivalents	$(5,441)	$9,158

Operating Activities

Net cash used in operations increased by approximately $9.3 million to $39.4 million for the nine months ended September 30, 2017 from $30.1 million for the nine months ended September 30, 2016. The increase in net cash used was due primarily to a higher net loss of approximately $11.8 million offset by $1.0 million of non-cash asset impairment charges and $1.4 million of changes in our working capital accounts

Investing Activities

Net cash provided by investing activities was $34.7 million for the nine months ended September 30, 2017 compared to $38.2 million for the nine months ended September 30, 2016 as proceeds from maturities of investments, net of investments made, used to fund operations decreased approximately $4.2 million. The decrease in net investment proceeds was offset by a decrease in capital expenditures of $0.7 million.

Financing Activities

Net cash provided by financing activities decreased $1.8 million for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016. Debt principal repayments of $1.6 million combined with $0.2 million in lower net proceeds from other equity transactions resulted in a net cash usage from financing activities at September 30, 2017.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K, as filed with the SEC on February 17, 2017.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risk related to changes in interest rates. As of September 30, 2017, we had cash and cash equivalents of $22.0 million compared to cash, cash equivalents and investments of $63.4 million at December 31, 2016, consisting primarily of money market funds, U.S Treasury securities, and FDIC insured certificates of deposits. The investments in these financial instruments are made in accordance with an investment policy approved by our Board of Directors, which specifies the categories, allocations and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments in which we invest could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio that may include cash, cash equivalents and investment securities available-for-sale in a variety of securities, which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations or our financial position would be materially affected by an immediate change of 10% in interest rates.

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

We are also exposed to market risk related to change in foreign currency exchange rates. We contract with certain vendors that are located in Europ