

GENOCEA BIOSCIENCES, INC.

Form 10-Q

November 06, 2014

[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

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

(State or Other Jurisdiction of
Incorporation or Organization)

51-0596811

(IRS Employer
Identification No.)

100 Acorn Park Drive

Cambridge, Massachusetts

(Address of Principal Executive Offices)

02140

(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** o

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** o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o

Accelerated filer o

Non-accelerated filer x (Do not check if a smaller reporting company)

Smaller reporting company o

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

As of November 3, 2014, there were 17,610,154 shares of the registrant's Common Stock, par value \$0.001 per share, outstanding.

Table of Contents

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve 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, and other similar expressions or negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed in our Annual Report on Form 10-K and other filings with the Securities Exchange Commission (the SEC), including the following:

- the timing of results of our ongoing and planned clinical trials for GEN-003 and GEN-004;
- our estimates regarding the amount of funds we require to complete our current and future Phase 2 clinical trials for GEN-003 and our current Phase 2a trial for GEN-004;
- our estimate for when we will require additional funding;
- our plans to commercialize GEN-003 and our other vaccine candidates;
- the timing of, and our ability to, obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- the potential benefits of strategic partnership agreements and our ability to enter into selective strategic partnership arrangements;

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

- 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.

Table of Contents

Genocea Biosciences, Inc.

Form 10-Q

For the Quarter Ended September 30, 2014

TABLE OF CONTENTS

	Page
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	
<u>Financial Statements (unaudited)</u>	4
<u>Condensed Balance Sheets as of September 30, 2014 and December 31, 2013</u>	4
<u>Condensed Statements of Operations for the three and nine months ended September 30, 2014 and 2013</u>	5
<u>Condensed Statement of Comprehensive Loss for the three and nine months ended September 30, 2014 and 2013</u>	6
<u>Condensed Statements of Cash Flows for the nine months ended September 30, 2014 and 2013</u>	7
<u>Notes to Unaudited Condensed Financial Statements</u>	8
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	28
<u>Item 4.</u>	
<u>Controls and Procedures</u>	28
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1</u>	
<u>Legal Proceedings</u>	30
<u>Item 1A.</u>	
<u>Risk Factors</u>	30
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	30
<u>Item 6.</u>	
<u>Exhibits</u>	31

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****Genocea Biosciences, Inc.****Condensed Balance Sheets****(unaudited)****(in thousands, except per share data)**

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,145	\$ 12,208
Marketable securities	27,048	
Restricted cash		157
Prepaid expenses and other current assets	1,328	510
Total current assets	53,521	12,875
Property and equipment, net	1,874	865
Restricted cash	316	158
Other assets	88	1,863
Total assets	\$ 55,799	\$ 15,761
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,522	\$ 2,176
Accrued expenses and other current liabilities	2,087	1,418
Deferred revenue	766	12
Current portion of long-term debt	3,376	861
Current portion of deferred rent	99	26
Total current liabilities	7,850	4,493
Non-current liabilities:		
Long-term debt, net of current portion	6,254	8,933
Accrued interest payable	70	11
Deferred rent, net of current portion	196	237
Warrant to purchase redeemable securities		656
Deferred revenue, net of current portion	448	
Other non-current liabilities	17	
Total liabilities	14,835	14,330
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock:		
Seed convertible preferred stock, \$0.001 par value;		
Authorized	0 and 4,615 shares at September 30, 2014 and December 31, 2013, respectively;	
Issued and outstanding	0 and 4,615 shares at September 30, 2014 and December 31, 2013, respectively; aggregate liquidation preference of \$0 and \$3,000 at September 30, 2014 and December 31, 2013, respectively	3,000
Series A redeemable convertible preferred stock, \$0.001 par value;		

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

Authorized 0 and 36,662 shares at September 30, 2014 and December 31, 2013, respectively; Issued and outstanding 0 and 35,577 shares at September 30, 2014 and December 31, 2013, respectively; aggregate liquidation preference of \$0 and \$23,125 at September 30, 2014 and December 31, 2013, respectively			23,125
Series B redeemable convertible preferred stock, \$0.001 par value;			
Authorized 0 and 35,099 shares at September 30, 2014 and December 31, 2013, respectively; Issued and outstanding 0 and 34,581 shares at September 30, 2014 and December 31, 2013, respectively; aggregate liquidation preference of \$0 and \$24,937 at September 30, 2014 and December 31, 2013, respectively			24,937
Series C redeemable convertible preferred stock, \$0.001 par value;			
Authorized 0 and 53,276 shares at September 30, 2014 and December 31, 2013, respectively; Issued and outstanding 0 and 53,276 shares at September 30, 2014 and December 31, 2013, respectively; aggregate liquidation preference of \$0 and \$30,500 at September 30, 2014 and December 31, 2013, respectively			30,500
Stockholders' equity (deficit):			
Common stock, \$0.001 par value;			
Authorized 175,000 and 191,690 shares at September 30, 2014 and December 31, 2013, respectively; Issued 17,610 and 327 shares at September 30, 2014 and December 31, 2013, respectively; outstanding 17,591 and 303 at September 30, 2014 and December 31, 2013, respectively			18
Additional paid-in-capital		144,713	
Accumulated other comprehensive loss		10	
Accumulated deficit		(103,777)	(80,131)
Total stockholders' equity (deficit)		40,964	(80,131)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$	55,799	\$ 15,761

See accompanying notes to unaudited financial statements.

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

	Three Months Ended, September 30,		Nine Months Ended, September 30,			
	2014	2013	2014	2013		
Grant revenue	\$	\$	224	\$	711	
Operating expenses:						
Research and development		6,115	3,275	15,073	11,354	
General and administrative		2,843	1,424	7,167	3,113	
Total operating expenses		8,958	4,699	22,240	14,467	
Loss from operations		(8,958)	(4,475)	(22,240)	(13,756)	
Other expense:						
Change in fair value of warrant			(60)	(725)	(166)	
Loss on debt extinguishment			(200)		(200)	
Interest expense, net		(213)	(104)	(681)	(338)	
Other expense		(213)	(364)	(1,406)	(704)	
Net loss	\$	(9,171)	\$	(4,839)	\$	(23,646)
Comprehensive loss	\$	(9,160)	\$	(4,839)	\$	(23,636)
Reconciliation of net loss to net loss applicable to common stockholders						
Net loss	\$	(9,171)	\$	(4,839)	\$	(23,646)
Accretion of redeemable convertible preferred stock to redemption value			(405)	(180)	(1,200)	
Net loss attributable to common stockholders	\$	(9,171)	\$	(5,244)	\$	(23,826)
Net loss per share attributable to common stockholders-basic and diluted	\$	(0.53)	\$	(17.72)	\$	(1.60)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted		17,465		296		14,918
						296

See accompanying notes to unaudited financial statements.

Table of Contents

Genocea Biosciences, Inc.

Condensed Statements of Comprehensive Loss

(unaudited)

(in thousands)

	Three Months Ended, September 30,		Nine Months Ended, September 30,	
	2014	2013	2014	2013
Net loss	\$ (9,171)	\$ (4,839)	\$ (23,646)	\$ (14,460)
Other comprehensive income (loss):				
Unrealized gain on available-for-sale securities	11		10	
Comprehensive loss	\$ (9,160)	\$ (4,839)	\$ (23,636)	\$ (14,460)

See accompanying notes to unaudited financial statements.

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

	Nine Months Ended, September 30,	
	2014	2013
Operating activities		
Net loss	\$ (23,646)	\$ (14,460)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	298	231
Stock-based compensation	2,146	447
Net amortization of premium on investments	14	
Change in fair value of warrants liability	725	166
Gain on sale of equipment	(18)	
Non-cash interest expense	60	2
Loss on debt extinguishment		200
Changes in operating assets and liabilities:		
Restricted cash		97
Prepaid expenses and other current assets	(819)	(251)
Other long-term assets	766	(170)
Accounts payable	(671)	145
Deferred revenue	1,202	32
Accrued expenses	659	354
Deferred rent	32	(116)
Accrued interest payable	60	(146)
Net cash used in operating activities	(19,192)	(13,469)
Investing activities		
Purchases of property and equipment	(1,237)	(386)
Purchase of marketable securities	(27,053)	
Net cash used in investing activities	(28,290)	(386)
Financing activities		
Proceeds from IPO, net of issuance costs	59,974	
Proceeds from issuance of preferred stock, net		15,250
Proceeds from issuance of long-term debt		3,466
Repayment of long-term debt	(212)	(4,246)
Proceeds from the exercise of warrants	33	
Payments for debt issuance costs		(58)
Net cash provided by financing activities	60,419	14,414
Net increase in cash and cash equivalents	\$ 12,937	\$ 559
Cash and cash equivalents at beginning of period	12,208	11,516
Cash and cash equivalents at end of period	\$ 25,145	\$ 12,075
Supplemental cash flow information		
Cash paid for interest	\$ 582	\$ 264
Supplemental disclosure of non-cash financing activities		
Conversion of preferred stock to common stock upon closing of IPO	\$ 81,742	\$
Reclassification of prepaid IPO closing costs from non-current assets to additional paid-in capital	\$ 998	\$

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

Reclassification of warrants to additional paid-in capital	\$	1,381	\$	
Accretion of redeemable convertible preferred stock to redemption value	\$	180	\$	1,200
Vesting of restricted stock	\$	8	\$	

See accompanying notes to unaudited financial statements.

Table of Contents

Genocea Biosciences, Inc.

Notes to Condensed Financial Statements

(unaudited)

1. Organization and operations

The Company

Genocea Biosciences, Inc. (the Company) is a clinical stage biopharmaceutical company that was incorporated in Delaware on August 16, 2006 and has a principal place of business in Cambridge, Massachusetts. The Company has two products in clinical development:

- GEN-003, which has completed a Phase 1/2a clinical trial and is currently in a Phase 2 dose optimization clinical trial, to treat patients with genital herpes, and
- GEN-004, which is being developed to prevent infections caused by pneumococcus. The Company has completed a Phase 1 clinical trial and is currently conducting a Phase 2a clinical trial.

The Company also has other product candidates that are currently in preclinical development. The Company developed GEN-003, GEN-004 and its preclinical product candidates using its proprietary platform technology called the AnTigen Lead Acquisition System (ATLAS). The ATLAS proprietary technology platform mimics the human immune response in the laboratory, potentially improving the effectiveness of vaccine discovery and reducing the time needed to create promising vaccines.

2. Summary of significant accounting policies

Initial Public Offering

On February 10, 2014, the Company completed its initial public offering (IPO) of its common stock, \$0.001 par value per share (Common Stock), pursuant to a registration statement on Form S-1, as amended. An aggregate of 5,500,000 shares of Common Stock registered under the registration statement were sold at a price of \$12.00 per share. Net proceeds of the IPO were \$61.4 million, excluding offering expenses of \$2.4 million payable by the Company. In conjunction with this transaction, all shares of the Company's redeemable convertible preferred stock were converted into 11,435,593 shares of common stock, and 96,988 employee and nonemployee performance-based options vested.

Basis of presentation and use of estimates

The accompanying condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP). 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 and results of operations for the interim periods ended September 30, 2014 and 2013.

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, 2013 and the notes thereto which are included in the Company s Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 21, 2014.

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 clinical trial accruals, stock-based compensation expense, warrants to purchase redeemable securities, and reported amounts of revenues and expenses during the reported period. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

The Company utilized significant estimates and assumptions in determining the fair value of its common stock (Common Stock) prior to completion of the IPO. The Company utilized various valuation methodologies in accordance with the framework of the 2004 and 2013 American Institute of Certified Public Accountants Technical Practice Aids, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its Common Stock. Each valuation methodology includes estimates and assumptions that require the Company s judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company s Common Stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or a sale of the Company. Significant changes to the key

Table of Contents

assumptions used in the valuations could result in different fair values of Common Stock at each valuation date and materially affect the financial statements.

Cash, cash equivalents and marketable securities

The Company considers all highly liquid investments with maturities of 90 days or less from the purchase date to be cash equivalents. Cash and cash equivalents are held in depository and money market accounts and are reported at fair value.

Marketable securities consist of U.S. treasury securities with maturities of more than 90 days. The Company has determined the appropriate balance sheet classification of the securities as current since they are available for use in current operating activities, regardless of actual maturity dates. Investments are classified as available-for-sale pursuant to ASC 320, *Investments - Debt and Equity Securities*, and are recorded on the balance sheet at fair value with unrealized gains and losses (excluding other-than-temporary impairments) reported as a separate component of accumulated other comprehensive income (loss). Realized gains and losses, as well as other-than-temporary impairments, are recognized in the statement of operations based on the specific identification method.

The Company reviews its marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairment of marketable securities are recognized in the condensed interim statements of operations if the Company has experienced a credit loss, has the intent to sell the marketable securities, or if it is more likely than not that the Company will be required to sell the marketable securities before recovery of the amortized cost basis.

Concentrations of credit risk and off-balance sheet risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and marketable securities. The Company's cash, cash equivalents and marketable securities are held in accounts with financial institutions that management believes are creditworthy. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no financial instruments with off-balance sheet risk of loss.

Deferred initial public offering costs

Deferred public offering costs, which primarily consist of direct, incremental legal and accounting fees related to the IPO, were capitalized within other assets as of December 31, 2013. The Company incurred \$2.4 million in IPO costs and in February 2014, these public offering costs were offset against the proceeds upon completion of the IPO.

Fair value of financial instruments

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

- Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2 Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Table of Contents

- Level 3 Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

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

Financial instruments measured at fair value on a recurring basis include cash equivalents and marketable securities (Note 3) and warrants to purchase redeemable securities (Note 5).

An entity may elect to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in net loss. The Company did not elect to measure any additional financial instruments or other items at fair value. The Company is also required to disclose the fair value of financial instruments not carried at fair value. The fair value of the Company's long-term debt is determined using current applicable rates for similar instruments as of the balance sheet dates and assessment of the credit rating of the Company. The carrying value of the Company's long-term debt approximates fair value because the Company's interest rate yield is near current market rates. The Company's long-term debt is considered a Level 3 liability within the fair value hierarchy.

Except for the valuation methodology utilized to value the warrants to purchase redeemable securities (Note 5), there have been no changes to the valuation methods utilized by the Company during the three and nine months ended September 30, 2014 and 2013. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the three and nine months ended September 30, 2014 and 2013.

Reverse stock split

On January 20, 2014, our board of directors and stockholders approved a 1-for-11.9 reverse stock split of the Company's Common Stock, which was effected on January 21, 2014. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares upon the completion of our IPO. The Company's historical share and per share information were retroactively adjusted to give effect to this reverse stock split. Shares of Common Stock underlying outstanding stock options were proportionately reduced and the respective exercise prices proportionately increased. Shares of Common Stock reserved for future issuance were presented on an as converted basis and the financial statements disclose the adjusted conversion ratios.

Recently adopted accounting pronouncements

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09). ASU 2014-09 will replace existing revenue guidelines with a new model, in which revenue is recognized upon

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

transfer of control over goods or services to a customer. ASU 2014-09 allows companies to adopt the new standard using either a full retrospective (with certain practical expedients) or a modified retrospective method of transition. Under the modified retrospective approach, financial statements will be prepared for the year of adoption using the new standard, but prior periods will not be adjusted. Instead, companies will recognize a cumulative catch-up adjustment to the opening balance of retained earnings at the effective date for contracts that still require performance by the company, and disclose all line items in the year of adoption as if they were prepared under current revenue requirements. ASU 2014-09 is effective retrospectively for annual reporting periods beginning after December 15, 2016, and interim periods therein. At this time, the Company has not decided on which method it will use to adopt the new standard, nor has it determined the effects of the new guidelines on its results of operations and financial position. For the foreseeable future, the Company's revenues will be limited to grants received from government agencies or nonprofit organizations, and the Company is evaluating the effects of the new standard on this type of revenue stream.

In June 2014, the Financial Accounting Standards Board issued ASU No. 2014-10, *Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation* (ASU 2014-10). ASU 2014-10 eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. ASU 2014-10 is effective prospectively for annual reporting periods beginning after December 15, 2014, and interim periods therein. Early application of the amendments is permitted for any annual reporting period or interim period in which the Company's financial statements have not yet been issued. The Company adopted ASU 2014-10 on June 30, 2014, and the adoption did not have a material impact on our condensed financial statements.

Table of Contents

In August 2014, the Financial Accounting Standards Board issued ASU No. 2014-15, *Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern* (ASU 2014-15). ASU 2014-15 requires a company to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company is evaluating the effects of the new standard, but doesn't expect it will have a material effect on its financial conditions, results of operations, or cash flows.

3. Cash, cash equivalents and marketable securities

As of September 30, 2014 and December 31, 2013, cash, cash equivalents and, in the case of September 30, 2014, marketable securities comprised funds in depository, money market accounts and U.S treasury securities.

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

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2014				
Cash	\$ 671	\$ 671	\$	\$
Money Market funds, included in cash equivalents	24,474	24,474		
Marketable securities - U.S. treasuries	27,048	27,048		
Total	\$ 52,193	\$ 52,193	\$	\$
December 31, 2013				
Cash	\$ 249	\$ 249	\$	\$
Money Market funds, included in cash equivalents	11,959	11,959		
Total	\$ 12,208	\$ 12,208	\$	\$

Cash equivalents and marketable securities 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 pricing methods and obtaining market values from other pricing sources. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by the pricing services as of September 30, 2014 and December 31, 2013.

Marketable securities at September 30, 2014 consist of the following (in thousands):

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

	Contracted Maturity	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current					
U.S. Treasuries	258-365 days	\$ 16,029	\$ 7	\$	\$ 16,036
U.S. Treasuries	380-457 days	11,009	3		11,012
Total		\$ 27,038	\$ 10	\$	\$ 27,048

At September 30, 2014, the aggregate fair value of marketable securities in an unrealized gain position was \$27 million with unrealized gains of \$9,500. The Company evaluated its securities for other-than-temporary impairment and considered the decline in market value for the securities to be primarily attributable to current economic and market conditions. It is not more likely than not that the Company will be required to sell the securities, and the Company does not intend to do so prior to the recovery of the amortized cost basis. Based on this analysis, these marketable securities were not considered to be other-than-temporarily impaired as of September 30, 2014.

The Company did not hold any marketable securities as of December 31, 2013.

Table of Contents**4. Long-Term Debt**

In October 2011, the Company entered into a Loan and Security Agreement with a financial institution, which provided for up to \$5.0 million in debt financing (Term Loan). The Term Loan provided for a draw-down period on the facility through March 1, 2012. On March 1, 2012, the Company drew down the full \$5.0 million available under the terms of this arrangement.

From March 1, 2012 through May 1, 2012, the Company was obligated to make interest-only payments at the greater of the financial institution's prime rate plus 5.00% or 8.00%. The Company began making 36 equal monthly payments of principal and accrued interest thereafter. During the 36-month period, the Term Loan bears interest at the greater of the financial institution's prime rate plus 4.75% or 8.00%. The Company was also obligated to pay 6.50% of the advance on the final repayment date of the draw, which was April 1, 2015. This final payment was accrued over the term of the debt and was recorded in accrued interest payable.

In connection with the Term Loan, the Company issued a fully-exercisable warrant to purchase 517,242 shares of Series B preferred stock. Upon completion of our IPO, these Series B preferred stock warrants automatically converted into warrants exercisable for 43,465 shares of Common Stock at an exercise price of \$6.90 per share (Note 5). The Term Loan is collateralized by all the assets of the Company, except for those assets collateralized by an equipment term loan that was repaid as of December 31, 2013.

On September 30, 2013, the Company entered into a new loan agreement which provided up to \$10.0 million in debt financing (New Term Loan). Upon the closing of the New Term Loan, the Company drew down \$3.5 million and paid off the remaining balance under the Term Loan. As part of the early repayment, the Company incurred a loss on debt extinguishment of \$0.2 million. The New Term Loan provides for a draw-down period on the remaining facility of \$6.5 million, which the Company drew down on December 19, 2013. The Company is obligated to make interest-only payments for the first nine months and 33 equal payments of principal, together with accrued interest thereafter for each advance. The New Term Loan bears interest at a rate of 8.0% per annum. The Company is also obligated to pay 2.0% of the advance on the final repayment date of each draw. The final payment is being accrued over the term of the debt and recorded in accrued interest payable on the balance sheets. Should an event of default occur, including the occurrence of a material adverse change, the Company would be liable for immediate repayment of all amounts outstanding, including the 2.0% final payment associated with each draw. The New Term Loan is collateralized by all the assets of the Company.

In connection with the New Term Loan, the Company issued a warrant to purchase 689,655 shares of Series C preferred stock at \$0.58 per share. Upon the completion of our IPO, these Series C preferred stock warrants automatically converted into warrants exercisable for 57,954 shares of Common Stock at an exercise price of \$6.90 per share (Note 5).

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

	September 30,	
	2014	
2014	\$	713
2015		3,636
2016		3,636

2017		1,803
Total	\$	9,788

5. Warrants

As of December 31, 2013, the Company had outstanding warrants to purchase 2,291,512 shares of redeemable convertible preferred stock. On January 29, 2014, 21,695 warrants to purchase Series A preferred stock were exercised for cash. On February 4, 2014, an additional 28,926 warrants to purchase Series A preferred stock were exercised for cash. Prior to the completion of our IPO on February 10, 2014, warrants to purchase 987,840 shares of Series A preferred stock were exercised in a cashless exercise for 316,932 shares of Series A preferred stock, which automatically converted into 26,633 shares of Common Stock upon the completion of our IPO. Also upon the completion of our IPO, warrants exercisable for 1,253,051 shares of redeemable convertible preferred stock were automatically converted into warrants exercisable for 105,297 shares of Common Stock. On February 12, 2014, 43,465 warrants were exercised in a cashless exercise for 16,593 shares of Common Stock. On April 23, 2014, 57,954 warrants were exercised in a cashless exercise for 37,250 shares of Common Stock.

The warrants outstanding consist of the following (in thousands):

Table of Contents

	September 30, 2014	December 31, 2013
Warrants to purchase Series A Preferred Stock		1,085
Warrants to purchase Series B Preferred Stock		517
Warrants to purchase Series C Preferred Stock		690
Warrants to purchase Common Stock	4	
Total	4	2,292

In connection with the completion of our IPO, all the warrants exercisable for redeemable convertible preferred stock were automatically converted into warrants exercisable for Common Stock, resulting in the reclassification of the related warrant to purchase redeemable securities liability to additional paid-in capital as the warrants to purchase shares of Common Stock are accounted for as equity instruments. The warrant to purchase redeemable securities liability was re-measured to fair value prior to reclassification to additional paid-in capital. As of September 30, 2014, the Company had no outstanding warrants to purchase redeemable securities liability.

The warrant to purchase redeemable securities liability measured at fair value as of December 31, 2013 is as follows (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2013				
Warrants to purchase redeemable securities	\$ 656	\$	\$	\$ 656
Total	\$ 656	\$	\$	\$ 656

The following table sets forth a summary of changes in the fair value of the Company's warrants to purchase redeemable securities, which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs (in thousands):

	Nine months ended September 30, 2014
Beginning balance	\$ 656
Change in fair value	725
Warrants exercised	(323)
Reclassification to equity	(1,058)
Ending balance	\$

These warrants are considered Level 3 liabilities because their fair value measurements are based, in part, on significant inputs not observed in the market and reflect the Company's assumptions as to the expected volatility of the Company's preferred stock. At December 31, 2013, the Company determined the fair value of the warrants to purchase redeemable securities based on input from management and the board of directors, which utilized an independent valuation of the Company's enterprise value, determined utilizing an analytical valuation model. Any reasonable changes in the assumptions used in the valuation could materially affect the financial results of the Company. At December 31, 2013,

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

the analytical valuation model used to calculate the fair value of warrants to purchase redeemable securities was a hybrid approach based on an Option-Pricing Model (OPM) backsolve method and the Probability-Weighted Expected Return Model (PWERM). Thirty-five percent of the value was attributed to the OPM backsolve method and 65% was attributed to the PWERM. After the enterprise value was determined, the total enterprise value was then allocated to the various outstanding equity instruments, including the warrants to purchase redeemable securities, utilizing the OPM.

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

Table of Contents

The fair value of warrants to purchase 21,695 shares of Series A preferred stock prior to exercise on January 29, 2014 was estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	January 29, 2014	
Fair value of underlying instrument	\$	0.65
Expected Volatility		55.57%
Expected term (in years)		0.04
Risk-free interest rate		1.52%
Expected dividend yield		0.0%

These warrants were re-measured to a fair value of \$7,783, which resulted in an increase in fair value of \$2,142. The fair value of the warrants was reclassified to additional paid-in capital upon exercise on January 29, 2014.

The fair value of warrants to purchase 28,926 shares of Series A preferred stock prior to exercise on February 4, 2014 was estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	February 4, 2014	
Fair value of underlying instrument	\$	0.65
Expected Volatility		55.03%
Expected term (in years)		0.02
Risk-free interest rate		1.46%
Expected dividend yield		0.0%

These warrants were re-measured to a fair value of \$10,357, which resulted in an increase in fair value of \$2,839. The fair value of the warrants was reclassified to additional paid-in capital upon exercise on February 4, 2014.

The fair value of warrants to purchase 987,840 shares of Series A preferred stock prior to a cashless exercise for 316,932 shares of Series A preferred stock on February 10, 2014, which automatically converted into 26,633 shares of Common Stock upon the completion of our IPO, was estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	February 10, 2014	
Fair value of underlying instrument	\$	7.74
Expected Volatility		50.81%
Expected term (in years)		0.003
Risk-free interest rate		1.48%
Expected dividend yield		0.0%

These warrants were re-measured to a fair value of \$304,423, which resulted in an increase in fair value of \$46,581. The fair value of the warrants was reclassified to additional paid-in capital upon exercise on February 10, 2014.

The fair value of warrants exercisable for 1,253,051 shares of redeemable convertible preferred stock, which were automatically converted into warrants exercisable for 105,297 shares of Common Stock, was estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

Table of ContentsFebruary 10,
2014

Fair value of underlying instrument	\$	6.69
Expected Volatility		92.9%
Expected term (in years)		8.66
Risk-free interest rate		2.43%
Expected dividend yield		0.0%

The fair value of the remaining 105,297 warrants to purchase Common Stock were re-measured to a fair value of \$1,058,269, which resulted in an increase in fair value of \$673,040. The fair value of the warrants was reclassified to additional paid-in capital upon conversion on February 10, 2014.

6. Commitments and contingencies*Significant Contracts and Agreements*

In August 2006, the Company entered into an agreement to license certain intellectual property from The Regents of the University of California. The agreement required the Company to pay a non-refundable license fee of \$25 thousand and to issue 12,605 shares of Common Stock to the University. Such consideration was recorded in research and development expenses in 2006. The agreement also calls for payments to be made by the Company upon the occurrence of a certain development milestone and a certain commercialization milestone for each distinct product covered by the licensed patents, in addition to certain royalties to be paid on marketed products or sublicense income. The Company incurred expenses of \$10 thousand for the three and nine months ended September 30, 2014 and none for the three and nine months ended September 30, 2013.

In November 2007, the Company entered into an agreement to license certain intellectual property from Harvard University. The agreement required the Company to pay a non-refundable license fee of \$75 thousand, and to issue 10,773 shares of Common Stock to the University. Such consideration, which totaled \$93 thousand, was recorded in research and development expenses in 2007. The agreement also calls for payments to be made by the Company upon the occurrence of certain development and regulatory milestones, in addition to certain royalties to be paid on marketed products or sub-license income. In addition, the Company must make annual maintenance fee payments, which vary depending on the type of products under development. The Company incurred \$132 thousand for the three and nine months ended September 30, 2014 and none for the three and nine months ended September 30, 2013.

In August 2009, the Company entered into an agreement to license certain intellectual property from Isconova AB, now Novavax. The agreement required the Company to pay a non-refundable license fee of \$750 thousand. The Company was also required to pay \$200 thousand on the one-year anniversary in 2010. Such consideration was recorded in research and development expenses. The agreement also calls for payments to be made by the Company upon the occurrence of certain development and commercial milestones, in addition to certain royalties to be paid on marketed products or sublicense income. In addition, the Company entered into a committed funding agreement whereby the Company is obligated to purchase a total of \$1.6 million of services on a full-time equivalent basis. These services are expensed as incurred. The Company incurred expenses of \$390 thousand for the three and nine months ended September 30, 2014 and none for the three and nine months ended September 30, 2013.

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

In January 2010, the Company entered into an agreement to license certain intellectual property from the University of Washington. The agreement required the Company to pay a non-refundable license fee of \$20 thousand, and to issue 2,100 shares of Common Stock to the University. Such consideration was recorded in research and development expenses in 2010. The agreement also calls for payments to be made by the Company upon the occurrence of certain development and commercial milestones, in addition to certain royalties to be paid on marketed products or sublicense income. In addition, the Company must make annual maintenance fee payments, which vary depending on the number of years from the effective date. The Company incurred expenses of none and \$20 thousand for the three and nine months ended September 30, 2014, respectively, and none and \$45 thousand for the three and nine months ended September 30, 2013, respectively. Effective October 27, 2014, the agreement between the Company and the University of Washington was terminated.

In March 2014, the Company announced a joint research collaboration with Dana-Farber Cancer Institute and Harvard Medical School to characterize anti-tumor T cell responses in melanoma patients. This collaboration extends the use of our proprietary ATLAS platform for the rapid discovery of T cell antigens to cancer immunotherapy approaches.

Table of Contents

In September 2014, the Company received \$1.2 million in the form of a grant entered into with the Bill & Melinda Gates Foundation for the identification of protective T cell antigens for malaria vaccines. The grant will allow for the continued expansion of the Company's malaria antigen library and aid in the identification of novel protein antigens to facilitate the development of highly efficacious anti-infection malarial vaccines. The Company will begin to incur costs and recognize revenue under the agreement in the fourth quarter of 2014.

Supply agreements

In August 2009, the Company entered into a supply agreement with a third party for the manufacture and supply of antigens used in the Company's product candidates. The agreement calls for payments to be made by the Company upon the occurrence of certain manufacturing milestones, in addition to reimbursement of certain consumables. In June 2013, the Company entered into another supply agreement with the same vendor for the manufacture and supply of antigens to be used in the Company's next clinical trials. The Company incurred expenses of \$18 thousand and \$754 thousand related to these agreements for the three and nine months ended September 30, 2014, respectively, and \$206 thousand and \$409 thousand for the three and nine months ended September 30, 2013, respectively.

In February 2014, the Company entered into a supply agreement with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. (Fujifilm) for the manufacture and supply of antigens for future GEN-003 clinical trials. Under the agreement, the Company is obligated to pay Fujifilm manufacturing milestones, in addition to reimbursement of certain material production related costs. Additionally, the Company is responsible for the payment of a reservation fee, which will equal a percentage of the expected production fees, to reserve manufacturing slots in the production timeframe. The Company incurred \$769 thousand and \$1.1 million in milestones under this agreement for the three and nine months ended September 30, 2014, respectively.

Restricted cash related to facilities leases

Restricted cash related to facilities leases consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
2012 Facilities Sublease	\$	\$ 157
2012 Master Facilities Lease	316	158
Total	\$ 316	\$ 315

At September 30, 2014, the Company has an outstanding letter of credit with a financial institution related to a security deposit for the 2012 Master Facilities Lease, which is secured by cash on deposit. The letter of credit related to the 2012 Facilities Sublease expired on April 30, 2014.

Litigation

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

7. Redeemable convertible preferred stock

Upon the completion of our IPO on February 10, 2014, all of the outstanding shares of the Company's redeemable convertible preferred stock were converted into 11,435,593 shares of its Common Stock. As of September 30, 2014, the Company does not have any redeemable convertible preferred stock issued or outstanding.

8. Common stock

At September 30, 2014, the Company had authorized 175,000,000 shares of Common Stock, \$0.001 par value per share, of which 17,609,822 shares were issued and 17,591,032 were outstanding.

Table of Contents***Restricted stock***

During 2006 and 2007, the Company's founders and certain employees were issued shares and entered into Stock Restriction and Repurchase Agreements with the Company. During 2013, a director of the Company early 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 agreements, shares of Common Stock issued are subject to a vesting schedule. Vesting occurs periodically at specified time intervals and specified percentages. All shares of Common Stock become fully vested within four years of the date of grant. As of September 30, 2014, the Company has issued 35,964 shares of restricted Common Stock of which 17,180 shares have vested and 18,784 shares are subject to repurchase by the Company.

Reserve for future issuance

The Company has reserved for future issuances the following number of shares of Common Stock (in thousands):

	September 2014	December 31, 2013
Conversion of Seed Preferred Stock		388
Conversion of Series A Preferred Stock		2,990
Conversion of Series B Preferred Stock		3,613
Conversion of Series C Preferred Stock		4,419
Options to purchase common stock	2,394	1,823
Warrants to purchase Series A Preferred Stock	4	91
Warrants to purchase Series B Preferred Stock		43
Warrants to purchase Series C Preferred Stock		58
	2,398	13,425

9. Stock-based compensation

The Company's board of directors adopted the 2014 Equity Incentive Plan (the "2014 Equity Plan"), which was approved by its stockholders and became effective upon the completion of our IPO on February 10, 2014. The 2014 Equity Plan replaced the 2007 Equity Incentive Plan (the "2007 Equity Plan").

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

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

Outstanding options awards granted from the 2007 Equity Plan, at the time of the adoption of the 2014 Equity Plan, remain outstanding and effective. The shares of Common Stock underlying awards that are cancelled, forfeited, repurchased, expire or are otherwise terminated under the 2007 Equity Plan are added to the shares of Common Stock available for issuance under the 2014 Equity Plan. As of September 30, 2014, the number of common shares that may be issued under both equity plans is 2,393,676 and 316,579 remain available for future grants.

Stock Based Compensation Expense

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

Table of Contents

	Three months ended September 30, 2014		2013		Nine months ended September 30, 2014		2013	
Research and development	\$	291	\$	100	\$	1,139	\$	210
General and administrative		306		125		1,007		237
Total	\$	597	\$	225	\$	2,146	\$	447

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, 2013	1,576	\$ 2.66	7.64	\$ 6,682
Granted	817	\$ 14.26		
Exercised	(262)	\$ 2.38		
Canceled	(54)	\$ 4.27		
Outstanding at September 30, 2014	2,077	\$ 7.22	8.09	\$ 8,022
Exercisable at September 30, 2014	957	\$ 3.13	6.99	\$ 5,855
Vested or expected to vest at September 30, 2014	1,811	\$ 6.83	7.99	\$ 7,392

Performance-Based Stock Options

The Company granted stock options to certain employees, executive officers and consultants, which contain performance-based vesting criteria. Milestone events are specific to the Company's corporate goals, which include, but are not limited to, certain clinical development milestones, business development agreements and capital fundraising events. Stock-based compensation expense associated with these performance-based stock options is recognized if the performance conditions are considered probable of being achieved, using management's best estimates. During the three and nine months ended September 30, 2014, the Company determined that zero and 96,988 performance-based milestones, respectively, were probable of achievement and, accordingly, recorded \$435 thousand in related stock-based compensation expense during the nine months ended September 30, 2014. As of September 30, 2014, there are 56,336 performance-based common stock options outstanding for which the probability of achievement was not deemed probable.

Employee Stock Purchase Plan

In connection with the completion of the Company's IPO on February 10, 2014, the Company's board of directors adopted the 2014 Employee Stock Purchase Plan (the "2014 ESPP"). The 2014 ESPP authorizes the initial issuance of up to a total of 200,776 shares of Common Stock to participating eligible employees. The 2014 ESPP provides for six-month option periods commencing on January 1 and ending June 30 and commencing July 1 and ending December 31 of each calendar year. The first offering under the 2014 ESPP began on July 1, 2014. The Company incurred \$21 thousand in stock-based compensation expense related to the 2014 ESPP for the three and nine months ended September 30, 2014.

10. Income taxes

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. There were no significant income tax provisions or benefits for the three and nine months ended September 30, 2014 and 2013. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has provided a full valuation allowance against its deferred tax assets.

Table of Contents**11. Net loss per share attributable to common stockholders**

The Company computes basic and diluted earnings (loss) per share using a methodology that gives effect to the impact of outstanding participating securities (the two-class method). As the three and nine month periods ended September 30, 2014 and 2013 resulted in net losses, there is no income allocation required under the two-class method or dilution attributed to weighted average shares outstanding in the calculation of diluted loss per share.

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

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Preferred stock		10,703		10,703
Warrants	4	193	4	193
Outstanding options	2,077	1,574	2,077	1,574
Outstanding ESPP	7,043		7,043	
Total	9,124	12,470	9,124	12,470

12. Subsequent events

The Company has evaluated all events or transactions that occurred after September 30, 2014. In the judgment of management, there were no material events that impacted the unaudited condensed financial statements or disclosures.

Table of Contents

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

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

Overview

We are a clinical stage biotechnology company that discovers and develops novel vaccines and immunotherapies to address diseases with significant unmet clinical needs. We use our proprietary discovery platform, ATLAS, to rapidly design first-in-class products that act through T cell (or cellular) immune responses, which are increasingly recognized as having potential value to treat or protect against many infectious diseases, cancer, and autoimmune disorders.

In September 2013, we announced human proof of concept data for GEN-003, a candidate therapeutic vaccine, or immunotherapy, that we are developing to treat genital herpes infections. It is estimated that the prevalence of genital herpes in the United States is 53 million, with approximately 11 million patients diagnosed and seven million being treated. It is estimated that, by 2020, the prevalence of genital herpes in the United States will have risen to 57 million, with 13 million patients diagnosed and eight million being treated. Oral antiviral therapy is insufficient for many patients and approximately three million treated patients continue to suffer from three or more outbreaks per year.

Data from our Phase 1/2a trial represented the first reported instance of an immunotherapy working against an infectious disease. We have now completed the follow-up review of patients for 12 months after their last dose of vaccine. Final analysis of the data 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 dose group, the viral shedding rate fell by 52% versus baseline and, at six months after the final dose, the shedding rate remained at 40% below baseline. At 12 months, the viral shedding rate returned to baseline for this dose group. The reduction in the genital lesion rate after completion of the third dose was greatest for the 30µg dose group, at 48%. After six months, the reduction from baseline in genital lesion rate for this dose group was 65% and, after 12 months, the genital lesion rate was 42% lower than baseline. GEN-003 was safe and well tolerated over the 12 months of this trial. We believe the six-month duration of reduced viral shedding and genital lesion rates may be clinically meaningful. We initiated a Phase 2 dose optimization clinical trial in July 2014 which will compare the best dose of GEN-003 from our Phase 1/2a trial to other combinations of protein and adjuvant to determine the optimal dose for future trials and potentially improve on the current profile of GEN-003. If GEN-003 successfully completes clinical development and is approved, we believe it would represent an important new treatment option for patients with genital herpes.

We are also developing a second T cell-stimulating vaccine candidate, GEN-004, a potential universal vaccine against pneumococcus, a leading cause of infectious disease mortality worldwide. GEN-004 is designed to stimulate T helper 17 (TH17) cells in the nasopharynx to prevent colonization by pneumococcus. There is strong evidence that TH17 cells play an important role in protecting against pneumococcal infections, including that: Job syndrome patients lack CD4+/TH17 cells and are highly susceptible to pneumococcus; children with mutations of the IL-17A gene are more likely to be colonized with pneumococcus; HIV patients are predisposed to pneumococcal disease due to a CD4+ deficiency; and, a low CD4+T cell count is linked to reactivity to pneumococcal proteins and the likelihood of colonization.

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

In June 2014, we announced top line data from a Phase 1 clinical trial for GEN-004. This trial met its safety, tolerability and immunogenicity goals including measurable increases in the blood of T helper 17 (TH17) cells, a rare cell type that provides immunity at epithelial and mucosal surfaces. We initiated a Phase 2 trial in September 2014 to demonstrate that GEN-004 can reduce the frequency, magnitude or duration of colonization of pneumococcus in the nasopharynx in healthy adults.

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, 2014, we had received an aggregate of \$158.0 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, 2014, our cash and cash equivalents and marketable securities were \$52.2 million.

Since inception, we have incurred significant operating losses. Our net losses were \$9.2 million and \$23.6 million for the three and nine months ended September 30, 2014, respectively, and our accumulated deficit was \$103.8 million as of September 30, 2014. 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.

On January 20, 2014, the board of directors and stockholders approved a 1-for-11.9 reverse stock split of the Company's Common Stock, which was effected on January 21, 2014. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares. The Company's historical share and per share information has been retroactively adjusted to give effect to this reverse stock split. Shares of Common Stock underlying outstanding stock options were proportionately reduced and the respective exercise prices proportionately increased. Shares of Common Stock reserved for future issuance were presented on an as converted basis and the financial statements disclose the adjusted conversion ratios.

We believe that our cash and cash equivalents at September 30, 2014 will enable us to fund our operating expenses and capital expenditure requirements through at least the end of 2015, by which time we expect to have completed our ongoing Phase 2 dose optimization clinical trial and commenced our Phase 2 dose regimen clinical trial for GEN-003 for genital herpes and completed our

Table of Contents

current Phase 2a clinical trial for GEN-004 for pneumococcus. However, costs related to clinical trials can be unpredictable and therefore there can be no guarantee that our current balances of cash, and cash equivalents and marketable securities and any proceeds received from other sources will be sufficient to fund these studies or our operations through this period. These funds will not be sufficient to enable us to conduct pivotal clinical trials for, seek marketing approval for or commercially launch GEN-003, GEN-004 or any other product candidate. Accordingly, to obtain marketing approval for and to commercialize these or any other product candidates, we will be required to obtain further funding through public or private equity offerings, debt financings, collaboration and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital when needed would have a negative effect on our financial condition and our ability to pursue our business strategy.

Status of products in development as of September 30, 2014

GEN-003 for the treatment of genital herpes infections

GEN-003 is in Phase 2 clinical development for the treatment of genital herpes. We initiated a Phase 2 dose-optimization clinical trial in July 2014, which will compare the best dose of GEN-003 from our Phase 1/2a trial to other combinations of protein and adjuvant to determine the optimal dose for future trials and potentially improve on the current profile of GEN-003. Top line data from this trial is expected in mid 2015.

GEN-004 for the prevention of pneumococcal infections

GEN-004 has completed is in Phase 1 clinical development. The Company initiated a Phase 2a clinical trial in September 2014 to demonstrate that GEN-004 can reduce colonization of pneumococcus in the nasopharynx in healthy adults. Topline data from this trial is expected in mid 2015.

Products in research and pre-clinical development

We have ongoing pre-clinical development programs in chlamydia and HSV-2 prophylaxis and a research program in malaria. Additionally, we have an ongoing immuno-oncology collaboration with the Dana Farber Cancer Institute and Harvard Medical School.

Financial Overview

Revenue

Grant revenue consists of revenue earned to conduct vaccine development research. We have received grants from a private not-for-profit organization and federal agencies. These grants have related to the discovery and development of several of our product candidates, including product candidates for the prevention of pneumococcus, chlamydia, and malaria. Revenue under these grants is recognized as research services are performed. Funds received in advance of research services being performed are recorded as deferred revenue. We plan to continue to pursue grant funding, but there can be no assurance we will be successful in obtaining such grants in the future.

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

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

Research and Development Expenses

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

- personnel-related expenses, including salaries, benefits, stock-based compensation expense and travel;
- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, consultants and other vendors that conduct our clinical trials and preclinical activities;
- costs of acquiring, developing and manufacturing clinical trial materials and lab supplies; and

Table of Contents

- 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 for the three and nine months ended September 30, 2014 and 2013:

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
HSV-2 (GEN-003)(1)	\$ 4,020	\$ 1,634	\$ 8,622	\$ 4,809
Pneumococcus (GEN-004)(1)	1,210	1,027	3,600	5,026
Other research and development (2)	885	614	2,851	1,519
Total research and development	\$ 6,115	\$ 3,275	\$ 15,073	\$ 11,354

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

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

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

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in the future to support the continued research and development of our product candidates and to operate as a public company. These increases will likely include increased costs for insurance, costs related to the

hiring of additional personnel and payments to outside consultants, lawyers and accountants, among other expenses. Additionally, if and when we believe a regulatory approval of our first product candidate appears likely, we anticipate that we will increase our salary and personnel costs and other expenses as a result of our preparation for commercial operations.

Interest Expense, Net

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

Other Expense

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

Accretion of Preferred Stock

Certain classes of our preferred stock were redeemable beginning in 2017 at the original issuance price plus any declared or accrued but unpaid dividends upon written election of the preferred stockholders in accordance with the terms of our articles of incorporation. Accretion of preferred stock reflects the accretion of issuance costs and, for Series B preferred stock, cumulative dividends based on their respective redemption values. On February 10, 2014, we completed our IPO and all shares of preferred stock

Table of Contents

were converted into 11,435,593 shares of our Common Stock. No accretion of preferred stock is recorded after this date as no shares of preferred stock are outstanding.

Critical Accounting Policies and Significant Judgments and Estimates

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

The critical accounting policies we identified in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2013 related to 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 March 21, 2014.

Results of Operations*Comparison of the Three Months Ended September 30, 2014 and September 30, 2013*

(in thousands)	Three Months Ended, September 30,		Increase (Decrease)	
	2014	2013		
Grant revenue	\$	\$ 224	\$ (224)	
Operating expenses:				
Research and development		6,115	3,275	2,840
General and administrative		2,843	1,424	1,419
Total operating expenses		8,958	4,699	4,259
Loss from operations		(8,958)	(4,475)	(4,483)
Other (expense) income:				
Other (expense) income			(260)	260
Interest expense, net		(213)	(104)	(109)
Other (expense) income		(213)	(364)	151
Net loss	\$	(9,171)	\$ (4,839)	\$ (4,332)

Grant Revenue

Grant revenue decreased \$0.2 million to zero for the three months ended September 30, 2014 from \$0.2 million for the three months ended September 30, 2013. The decrease was due to the completion of a grant to fund research for our pneumococcus program during 2013. In September 2014, we received \$1.2 million from a grant entered into with the Bill & Melinda Gates Foundation. We will begin to incur costs and recognize revenue under the agreement in the fourth quarter of 2014.

Research and Development Expenses

Research and development expense increased \$2.8 million to \$6.1 million for the three months ended September 30, 2014 from \$3.3 million for the three months ended September 30, 2013. The increase was attributable to: an increase of \$0.7 million in R&D personnel costs due to an increase in headcount, including \$0.2 million in increased stock-based compensation; an increase of \$1.6 million in GEN-003 external costs related to manufacturing and the recently initiated Phase 2 dose optimization trial; an increase of \$0.3 million in GEN-004 clinical trial costs related to the recently initiated Phase 2a study; an increase of \$0.4 million in licensing milestone payments related to the start of GEN-003 and GEN-004 clinical studies; offset by a \$0.2 million reduction in external consulting costs.

Table of Contents*General and Administrative Expenses*

General and administrative expense increased \$1.4 million to \$2.8 million for the three months ended September 30, 2014 from \$1.4 million for the three months ended September 30, 2013. The increase was due largely to additional personnel costs due to an increase in headcount of \$0.5 million, including \$0.2 million in increased stock-based compensation; \$0.6 million in increased audit, legal and consulting expenses and \$0.3 million in public company overhead costs.

Other Expense

Other expense decreased \$0.3 million to zero for the three months ended September 30, 2014 from \$0.3 million for the three months ended September 30, 2013. The decrease was due largely to a \$0.2 million loss on debt extinguishment related to the re-finance of a term note in September 2013.

Interest Expense, Net

Interest expense, net increased \$0.1 million to \$0.2 million for the three months ended September 30, 2014 from \$0.1 million for the three months ended September 30, 2013. The increase was due primarily to higher average principal balances for the third quarter of 2014 as compared to the same period in 2013.

Comparison of the Nine Months Ended September 30, 2014 and September 30, 2013

(in thousands)	Nine Months Ended, September 30,		Increase (Decrease)
	2014	2013	
Grant revenue	\$	\$	711 \$ (711)
Operating expenses:			
Research and development	15,073	11,354	3,719
General and administrative	7,167	3,113	4,054
Total operating expenses	22,240	14,467	7,773
Loss from operations	(22,240)	(13,756)	(8,484)
Other expense:			
Other expense	(725)	(366)	(359)
Interest expense, net	(681)	(338)	(343)
Other expense	(1,406)	(704)	(702)
Net loss	\$ (23,646)	\$ (14,460)	\$ (9,186)

Grant Revenue

Grant revenue decreased \$0.7 million to zero for the nine months ended September 30, 2014 from \$0.7 million for the nine months ended September 30, 2013. The decrease was due to the completion of a grant to fund research for our pneumococcus program during 2013. In September 2014, we received \$1.2 million from a grant entered into with the Bill & Melinda Gates Foundation. We will begin to incur costs and recognize revenue under the agreement in the fourth quarter of 2014.

Research and Development Expenses

Research and development expense increased \$3.7 million to \$15.1 million for the nine months ended September 30, 2014 from \$11.4 million for the nine months ended September 30, 2013. The increase was attributable to: an increase of \$2.1 million in R&D personnel costs, including \$0.9 million in stock-based compensation; an increase of \$0.4 million in licensing milestones related to the start of GEN-003 and GEN-004 Phase 2 clinical studies; an increase of \$0.1 million in GEN-003 external costs, reflecting increased manufacturing costs offset by lower clinical trial costs; an increase of \$1.1 million in GEN-004 clinical trials costs partially offset by lower manufacturing costs.

Table of Contents

General and Administrative Expenses

General and administrative expense increased \$4.1 million to \$7.2 million for the nine months ended September 30, 2014 from \$3.1 million for the nine months ended September 30, 2013. The increase of \$4.1 million was primarily due to additional personnel costs in 2014 of \$1.6 million, including \$0.7 million in increased stock-based compensation due to the vesting of certain performance-based common stock options; \$1.3 million in increased audit, legal and consulting expenses, and \$1.2 million in public company overhead costs.

Other Expense

Other expense increased \$0.4 million to \$0.7 million for the nine months ended September 30, 2014 from \$0.4 million for the nine months ended September 30, 2013. The increase was due to an increase in the fair value of warrants to purchase preferred stock as a result of an increase in the fair value of the underlying stock both before and on the date of the completion of our IPO on February 10, 2014. Additionally, a decrease of \$0.2 million related to the loss on debt extinguishment of a term note.

Interest Expense, Net

Interest expense, net increased \$0.3 million to \$0.7 million for the nine months ended September 30, 2014 from \$0.3 million for the nine months ended September 30, 2013. The increase was due primarily to higher average principal balances related to our term loan for the nine months of 2014 as compared to the same period in 2013.

Liquidity and Capital Resources

Overview

Since our inception through September 30, 2014, we have received an aggregate of \$158.0 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, 2014, our cash and cash equivalents and marketable securities were \$52.2 million, comprising cash and cash equivalents of \$25.1 million and marketable securities of \$27.1 million. In February 2014, we completed an IPO of 5.5 million shares of our Common Stock at a price of \$12.00 per share for an aggregate offering price of \$66.0 million. We received net proceeds from the offering of approximately \$61.4 million, after deducting approximately \$4.6 million in underwriting discounts and commission, excluding offering costs payable by us.

Debt Financings

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

In October 2011, we entered into a Loan and Security Agreement, or the Term Loan, which provided for up to \$5.0 million in debt financing. The Term Loan provided for a draw-down period on the loan through March 1, 2012. In March 2012, we drew down the full \$5.0 million available through the facility.

From March 1, 2012 through May 1, 2012 we were obligated to make interest-only payments at the greater of (1) the lender's prime rate plus 5.0%, or (2) 8.0%. Thereafter, we were required to make 36 equal monthly payments of principal and accrued interest. During this 36-month period the Term Loan bore interest at the greater of (i) the lender's prime rate plus 4.75% or (ii) 8.0%. We were also obligated to pay 6.5% of the advance on the final repayment date, which was scheduled to be April 1, 2015. In connection with the Term Loan, we issued warrants to purchase 517,242 shares of Series B preferred stock at an exercise price of \$0.58 per share. Upon execution of the Term Loan, the warrant to purchase 258,621 shares was immediately exercisable and the remaining warrant to purchase 258,621 shares became exercisable when we drew down the full amount of the loan on March 1, 2012. The \$5.0 million term loan was collateralized by all of our corporate assets, excluding our intellectual property, and by a negative pledge on our intellectual property.

On September 30, 2013, we entered into a new loan agreement, or the New Term Loan, which provided up to \$10.0 million in debt financing. Upon the closing, we drew down \$3.5 million and paid off the outstanding principal and interest on the Term Loan. Under the terms of the New Term Loan, we could draw additional advances of up to the remaining \$6.5 million through December 31, 2013. On December 19, 2013, we drew down the remaining \$6.5 million on the New Term Loan. Each advance shall be repaid in 42 monthly installments. For the first nine months following each advance, we are obligated to make interest-only payments. Thereafter, we are required to make 33 equal monthly payments of principal together with interest. On the first business day of the 42nd month, we are also obligated to make a payment equal to 2.0% of the original principal amount of the advance. We may prepay the outstanding principal amount of the New Term Loan at any time. The New Term Loan was collateralized by a blanket lien on all our corporate assets, excluding our intellectual property, and by a negative pledge on our intellectual property. In connection with the New Term Loan, we issued a warrant to purchase 689,655 shares of Series C preferred stock at an exercise price of \$0.58 per share. Upon execution of the New Term Loan, the warrant was immediately exercisable to purchase 689,655 shares. Upon completion of our

Table of Contents

IPO, the warrants became exercisable for an aggregate of 57,954 shares of our Common Stock at an exercise price of \$6.90 per share. In April 2014, the 57,954 warrants were exercised in a cashless exercise for 37,250 shares of Common Stock.

Operating Capital Requirements

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

We believe that our existing cash and cash equivalents at September 30, 2014 will be sufficient to fund our operations through at least the end of 2015, by which time we expect to have completed our ongoing Phase 2 dose optimization clinical trial and commenced our Phase 2 dose regimen clinical trial for GEN-003 for genital herpes and completed our planned Phase 2a clinical trial for GEN-004 for pneumococcus. We expect that these funds will not be sufficient to enable us to seek marketing approval or commercialize any of our product candidates.

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

- the timing and costs of our ongoing Phase 2 dose optimization clinical trial and planned Phase 2 dose regimen trial for GEN-003 and our ongoing Phase 2a clinical trial for GEN-004;
- the progress, timing and costs of manufacturing GEN-003 and GEN-004 for current and planned clinical trials;
- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our other product candidates and potential product candidates;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for GEN-003, GEN-004 and other product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

- the receipt of marketing approval, revenue received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, grants, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the extent to which we in-license or acquire other products and technologies.

We expect that we will need to obtain substantial additional funding in order to commercialize GEN-003, GEN-004 and our other product candidates in order to receive regulatory approval. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interests of our existing stockholders may be materially diluted and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. In addition, debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely affect our ability to conduct our business. If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back or discontinue the development or commercialization of GEN-003, GEN-004 or our other product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to GEN-003, GEN-004 or our other product candidates that we otherwise would seek to develop or commercialize ourselves.

Table of Contents**Cash Flows**

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

	Nine Months Ended September 30,	
	2014	2013
Net cash used in operating activities	\$ (19,192)	\$ (13,469)
Net cash used in investing activities	(28,290)	(386)
Net cash provided by financing activities	60,419	14,414
Net increase in cash and cash equivalents	\$ 12,937	\$ 559

Operating Activities

The increase in net cash used in operations increased \$5.7 million to \$19.2 million for the nine months ended September 30, 2014 from \$13.5 million for the nine months ended September 30, 2013. The increase was due primarily to an increase in the net loss of approximately \$9.2 million, a decrease of \$0.2 million on loss on debt extinguishment, which was partially offset by an increase in stock based compensation of \$1.7 million, an increase in change in fair value of warrant liability of \$0.6 thousand and an increase of \$1.3 million in our working capital accounts.

Investing Activities

Net cash used in investing activities increased \$27.9 million to \$28.3 million for the nine months ended September 30, 2014 from \$0.4 million for the nine months ended September 30, 2013. The increase was due largely to the purchase of marketable securities of \$27.1 million and an increase in cash used to purchase property and equipment of \$1.2 million.

Financing Activities

Net cash provided by financing activities increased \$46.0 million to \$60.4 million for the nine months ended September 30, 2014 from \$14.4 million for the nine months ended September 30, 2013. The increase was due largely to the net proceeds from our IPO in 2014 of \$60.0 million, an increase in proceeds from the exercise of stock options and warrants of \$0.6 million, which was partially offset by the issuance of preferred stock of \$15.3 million in 2013, the issuance of long-term debt of \$3.5 million in 2013 and a reduction of repayments of long-term debt of \$4.0 million, which was due to the debt refinancing in September 2013.

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 March 21, 2014, except as noted below:

In February 2014, the Company entered into a supply agreement with Fujifilm for the manufacture and supply of certain antigens of the Company for its GEN-003 clinical program. Under the agreement, the Company is obligated to pay Fujifilm manufacturing milestones, in addition to reimbursement of certain production related costs. Additionally, the Company is responsible for the payment of a reservation fee, which will equal a percentage of the expected production fees, to reserve manufacturing slots in the production timeframe. The Company has incurred \$769 thousand and \$1.1 million under this agreement for the three and nine months ended September 30, 2014, respectively.

Table of Contents

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, 2014 and December 31, 2013, we had cash and cash equivalents and marketable securities of \$52.2 million and \$12.2 million, respectively, consisting primarily of money market funds and U.S Treasury securities. The investments in these financial instruments are made in accordance with an investment policy approved by our board of directors, which specifies the categories, allocations and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments in which we invest could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio that may include cash, cash equivalents and investment securities available-for-sale in a variety of securities, which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations or our financial position would be materially affected by an immediate change of 10% in interest rates.

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

We are also exposed to market risk related to change in foreign currency exchange rates. We contract with certain vendors that are located in Europe which have contracts denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign exchange rate risk. As of September 30, 2014 and December 31, 2013, we had minimal liabilities denominated in foreign currencies.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2014 (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2014, our disclosure controls and procedures were effective at the reasonable assurance level, having implemented the remediation measures relating to the material weakness described below.

A material weakness is defined under SEC rules as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls. As of March 31, 2014, as a result of management's evaluation of our disclosure controls and procedures, and other internal reviews and evaluations that were completed after the quarter ended March 31, 2014, management concluded that we had a material weakness in our control environment and financial reporting process regarding our disclosure controls and procedures related to accounting for a milestone-based stock option award. Specifically, non-cash stock compensation expense relating to a milestone-based option granted to our Chief Executive Officer on July 25, 2013 was incorrectly calculated at mark-to-market on the vesting date rather than the grant date fair value.

This error was corrected prior to the filing of our Quarterly Report on Form 10-Q for the period ended March 31, 2014 as filed with the SEC on May 9, 2014, and has no impact on the financial results disclosed in prior periods. We do not believe the material weakness described above caused any meaningful or significant misreporting of our financial condition and results of operations for the three and nine months ended September 30, 2014.

Table of Contents

Management's Remediation Initiatives

Management has implemented corrective measures to address the material weakness described above. In an effort to remediate the identified material weakness and enhance our internal controls, we have completed the following series of measures:

- Improved the technical capabilities of the accounting group through training and the retention of expert consultants to assist in the analysis and recording of complex accounting transactions;

- Replaced the accounting software used to calculate stock compensation expense and completed testing of stock compensation expense calculations in the new system through parallel operation and reconciliation of new and old systems;

- Improved segregation of duties related to data entry and review of information in stock compensation systems; and

- Improved the process for the review and monitoring of complex accounting matters.

We believe the measures described above have remediated the material weakness we identified and strengthened our internal control over financial reporting. We are committed to continuing to improve our internal control processes and will continue to diligently and vigorously review our financial reporting controls and procedures.

Changes in Internal Control Over Financial Reporting

During the three months ended September 30, 2014, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of September 30, 2014, we were not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on our financial position or profitability. No governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

Item 1A. Risk Factors

There have been no material changes from the risk factors set forth in the Company's Annual Report on Form 10-K, as filed with the SEC on March 21, 2014, and in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, as filed with the SEC on May 9, 2014.

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

Use of Proceeds from Registered Equity Securities

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

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

Edgar Filing: GENOCEA BIOSCIENCES, INC. - Form 10-Q

We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10% or more of our Common Stock or to any affiliate of ours. We have invested the balance of the net proceeds from the offering in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities. There has been no material change in our planned use of the balance of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

Table of Contents

Item 6. Exhibits

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

Table of Contents

Exhibit Number	Exhibit
31.1	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Chief Executive Officer
31.2	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Chief Financial Officer
32.1	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Executive Officer
32.2	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Financial Officer
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Balance Sheets as of September 30, 2014 and December 31, 2013, (ii) Condensed Statements of Operations for the three and nine months ended September 30, 2014 and 2013, (iii) Condensed Statement of Comprehensive Loss for the three and nine months ended September 30, 2014 and 2013, (iv) Condensed Statements of Cash Flows for the nine months ended September 30, 2014 and 2013 and (v) Notes to Unaudited Condensed Financial Statements

Table of Contents

SIGNATURES

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

Genocea Biosciences, Inc.

Date: November 6, 2014

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

Date: November 6, 2014

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