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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 March 31, 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	**51-0596811**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
100 Acorn Park Drive **Cambridge, Massachusetts**	**02140**
(Address of Principal Executive Offices)	(Zip Code)

(617) 876-8191

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

As of May 5, 2014, there were 17,324,429 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. The words "anticipate", "believe", "contemplate", "continue", "could", "estimate", "expect", "forecast", "goal", "intend", "may", "plan", "potential", "predict", "project", "should", "target", "will", "would", or the 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 two planned Phase 2 clinical trials for GEN-003 and our initiated Phase 1 trial and planned 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;
- 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 industry, business, market or other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

Genocea Biosciences, Inc.
Form 10-Q
For the Three Months Ended March 31, 2014

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Genocea Biosciences, Inc.
(A Development Stage Company)
Condensed Balance Sheets

(unaudited)

(in thousands, except per share data)

	March 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 65,839	$ 12,208
Restricted cash	157	157
Prepaid expenses and other current assets	944	510
Total current assets	66,940	12,875
Property and equipment, net	814	865
Restricted cash	316	158
Other assets	143	1,863
Total assets	$ 68,213	$ 15,761
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,263	$ 2,176
Accrued expenses and other current liabilities	1,483	1,418
Deferred revenue	12	12
Current portion of long-term debt	1,770	861
Current portion of deferred rent	17	26
Total current liabilities	4,545	4,493
Non-current liabilities:		
Long-term debt, net of current portion	8,040	8,933
Accrued interest payable	25	11
Deferred rent, net of current portion	230	237
Warrant to purchase redeemable securities	—	656
Total liabilities	12,840	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; Issued and outstanding — 0 and 4,615 shares at March 31, 2014 and December 31, 2013, respectively; aggregate liquidation preference of $0 and $3,000 at March 31, 2014 and December 31, 2013, respectively	—	3,000
Series A redeemable convertible preferred stock, $0.001 par value;		
Authorized — 0 and 36,662 shares; Issued and outstanding — 0 and 35,577 shares at March 31, 2014 and December 31, 2013, respectively; aggregate liquidation preference of $0 and $23,125 at March 31, 2014 December 31, 2013, respectively	—	23,125
Series B redeemable convertible preferred stock, $0.001 par value;		
Authorized — 0 and 35,099 shares; Issued and outstanding — 0 and 34,581 shares at March 31, 2014 and December 31, 2013, respectively; aggregate liquidation preference of $0 and $24,937 at March 31, 2014 and December 31, 2013, respectively	—	24,937
Series C redeemable convertible preferred stock, $0.001 par value;		
Authorized — 0 and 53,276 shares; Issued and outstanding — 0 and 52,586 shares at March 31, 2014 and December 31, 2013, respectively; aggregate liquidation preference of $0 and $30,500 at March 31, 2014 and December 31, 2013, respectively	—	30,500
Stockholders' equity (deficit):		
Common stock, $0.001 par value;		
Authorized — 191,690 shares; Issued — 17,322 and 327 shares at March 31, 2014 and December 31, 2013, respectively; outstanding — 17,299 and 303 at March 31, 2014 and December 31, 2013, respectively	17	—
Additional paid-in-capital	142,816	—
Deficit accumulated during the development stage	(87,460)	(80,131)
Total stockholders' equity (deficit)	55,373	(80,131)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 68,213	$ 15,761

See accompanying notes to unaudited financial statements.

Genocea Biosciences, Inc.
(A Development Stage Company)
Condensed Statements of Operations and Comprehensive Loss

(unaudited)

(in thousands, except per share data)

	Three Months Ended, March 31,		The Period from August 16, 2006 (Inception) to March 31,
	2014	2013	2014
Grant revenue	$ —	$ 259	$ 6,694
Operating expenses:			
Research and development	4,407	3,980	64,529
General and administrative	1,966	810	22,918
Total operating expenses	6,373	4,790	87,447
Loss from operations	(6,373)	(4,531)	(80,753)
Other (expense) income:			
Change in fair value of warrant	(725)	(6)	(557)
Loss on debt extinguishment	—	—	(200)
Interest expense, net	(231)	(127)	(1,922)
Other (expense) income	(956)	(133)	(2,679)
Net loss	$ (7,329)	$ (4,664)	$ (83,432)
Comprehensive loss	$ (7,329)	$ (4,664)	$ (83,432)
Reconciliation of net loss to net loss attributable to common stockholders			
Net loss	$ (7,329)	$ (4,664)	$ (83,432)
Accretion of redeemable convertible preferred stock to redemption value	(180)	(395)	(6,094)
Net loss attributable to common stockholders	$ (7,509)	$ (5,059)	$ (89,526)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.76)	$ (17.09)	$ (153.56)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	9,859	296	583

See accompanying notes to unaudited financial statements.

Genocea Biosciences, Inc.
(A Development Stage Company)
Condensed Statements of Cash Flows

(unaudited)

(in thousands)

	Three Months Ended, March 31,		The Period from August 16, 2006 (Inception) to March 31,
	2014	2013	2014
Operating activities			
Net loss	$ (7,329)	$ (4,664)	$ (83,432)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	78	86	1,686
Stock-based compensation	881	63	2,717
Stock issued for services	—	—	21
Stock issued for interest	—	—	2
Stock issued for license agreement	—	—	6
Non-cash interest expense for warrant issuance	—	—	509
Change in fair value of warrants liability	725	6	557
Non-cash interest expense	16	10	326
Loss on debt extinguishment	—	—	200
Changes in operating assets and liabilities:			
Restricted cash	(158)	—	(473)
Prepaid expenses and other current assets	(435)	88	(886)
Other long-term assets	723	—	(1,053)
Accounts payable	(1,095)	(306)	1,049
Deferred revenue	—	—	12
Accrued expenses	60	(338)	1,447
Deferred rent	(15)	(39)	248
Accrued interest payable	15	36	25
Net cash used in operating activities	(6,534)	(5,058)	(77,039)
Investing activities			
Purchases of property and equipment	(27)	(335)	(2,501)
Net cash used in investing activities	(27)	(335)	(2,501)
Financing activities			
Proceeds from IPO, net of issuance costs	60,133	—	60,133
Proceeds from issuance of notes payable and warrants to purchase redeemable preferred stock	—	—	4,075
Proceeds from issuance of preferred stock, net	—	—	71,348
Proceeds from issuance of long-term debt	—	—	15,547
Repayment of long-term debt	—	(417)	(5,780)
Proceeds from sale of restricted and unrestricted common stock	—	—	3
Proceeds from exercise of stock options	26	2	78
Proceeds form the exercise of warrants	33	—	33
Payments for debt issuance costs	—	—	(58)
Net cash provided by (used in) financing activities	60,192	(415)	145,379
Net increase (decrease) in cash and cash equivalents	$ 53,631	$ (5,808)	$ 65,839
Cash and cash equivalents at beginning of period	12,208	11,516	—
Cash and cash equivalents at end of period	$ 65,839	$ 5,708	$ 65,839
Supplemental cash flow information			
Cash paid for interest	$ 174	$ 81	$ 1,039
Supplemental disclosure of non-cash financing activities			
Conversion of preferred stock to common stock upon closing of IPO	$ 81,742	$ —	$ 81,742
IPO closing costs included in accounts payable and accrued expenses	$ 187	$ —	$ 187
Reclassification of prepaid IPO closing costs from non-current assets to additional paid-in capital	$ 998	$ —	$ 998
Reclassification of warrants to additional paid-in capital	$ 1,381	$ —	$ 1,381
Accretion of redeemable convertible preferred stock to redemption value	$ 180	$ —	$ 6,094
Vesting of restricted stock	$ 3	$ —	$ 3
Leasehold improvements financed by landlord	$ —	$ —	$ 237
Conversion of convertible debt and accrued interest to preferred stock	$ —	$ —	$ 4,298

See accompanying notes to unaudited financial statements.

Genocea Biosciences, Inc.
(A Development Stage Company)

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 is in a Phase 1/2a clinical trial to treat patients with herpes simplex virus type-2 ("HSV-2"), and GEN-004, which is being developed to prevent infections caused by pneumococcus and is in a Phase 1 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 drastically reducing the time needed to create promising vaccines.

The Company is in the development stage and is devoting substantially all of its efforts to product research and development, initial market development, and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other development stage companies, including dependence on key individuals, competition from other companies, the need for development of commercially viable products, and the need to obtain adequate additional financing to fund the development of its product candidates. The Company is also subject to a number of risks similar to other companies in the life sciences industry, including regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability, and dependence on key individuals.

As of March 31, 2014, the Company had a deficit accumulated during the development stage of approximately $87.5 million. The Company had cash and cash equivalents of $65.8 million as of March 31, 2014. The Company believes that its existing cash and cash equivalents will be sufficient to fund operations and capital expenditures for at least the next twelve months.

2. Summary of significant accounting policies

Initial Public Offering

On February 10, 2014, the Company closed 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 March 31, 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 assumptions used in the valuations could result in different fair values of Common Stock at each valuation date and materially affect the financial statements.

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.

- 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 (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 months ended March 31, 2014 and 2013 or the period from August 16, 2006 (inception) through March 31, 2014. 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 months ended March 31, 2014 and 2013 or the period from August 16, 2006 (inception) through March 31, 2014.

Reverse stock split

On January 20, 2014, the Board of Directors and stockholders approved a 1-for-11.9 reverse stock split of the Company's Common Stock, which was effected on January 21, 2014. Stockholders entitled to fractional shares as a result of the reverse stock split

received a cash payment in lieu of receiving fractional shares upon the closing of the 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.

3. Cash and cash equivalents

As of March 31, 2014 and December 31, 2013, cash and cash equivalents comprise funds in depository and money market accounts.

The following table presents the cash and cash equivalents 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)
March 31, 2014				
Cash	$ 1,327	$ 1,327	$ —	$ —
Money Market funds, included in cash equivalents	64,512	64,512	—	—
Total	$ 65,839	$ 65,839	$ —	$ —
December 31, 2013				
Cash	$ 249	$ 249	$ —	$ —
Money Market funds, included in cash equivalents	11,959	11,959	—	—
Total	$ 12,208	$ 12,208	$ —	$ —

Cash equivalents 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 March 31, 2014 and December 31, 2013.

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 closing of the 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 9 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% per annum. The Company is also obligated to pay 2% 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% 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 closing of the 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):

	March 31, 2014
2014	$ 924
2015	3,636
2016	3,636
2017	1,804
Total	$ 10,000

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 closing of the 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 closing of the IPO. Also upon the closing of the 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.

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

	March 31, 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	62	—
Total	62	2,292

In connection with the closing of the 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 March 31, 2014, the Company had no outstanding warrant 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):

	Three months ended March 31, 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, the analytical valuation model used to calculate the fair value of warrants to purchase redeemable securities was a hybrid approach based on an OPM backsolve method and the PWERM. 35% 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.

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 closing of the 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:

	February 10, 2014
Fair value of underlying instrument	$ 6.96
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.

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 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. There were no other research and development expenses associated with this agreement in any of the other financial periods presented.

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 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 none, none and $266 thousand in annual maintenance fees and clinical milestones to Harvard University for the three months ended March 31, 2014 and 2013 and the period from August 16, 2006 (inception) to March 31, 2014, respectively.

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. The agreement 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 has 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 has expensed none, none and $1.7 million related to these services for the three months ended March 31, 2014 and 2013 and the period from August 16, 2006 (inception) to March 31, 2014, respectively.

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. These amounts were 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 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 has expensed $20 thousand, $45 thousand and $110 thousand related to this agreement for the three months ended March 31, 2014 and 2013 and the period from August 16, 2006 (inception) to March 31, 2014, respectively.

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 has expensed $613 thousand, $70 thousand and $8.1 million related to these agreements for the three months ended March 31, 2014, 2013 and the period from August 16, 2006 (inception) to March 31, 2014, 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 the GEN-003 Phase 2 dose optimization clinical trial. 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. As of March 31, 2014, the Company has incurred $25 thousand in costs under this agreement.

Restricted cash related to facilities leases

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

	March 31, 2014	December 31, 2013
2012 Facilities Sublease	$ 157	$ 157
2012 Master Facilities Lease	316	158
Total	$ 473	$ 315

At March 31, 2014, the Company has two outstanding letters of credit with a financial institution related to security deposits for the 2012 Facilities Sublease and the 2012 Master Facilities Lease, for a total of $473 thousand, which are secured by cash on deposit. The letter of credit related to the 2012 Facilities Sublease will expire on April 30, 2014.

Litigation

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

7. Redeemable convertible preferred stock

Upon the closing of the 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 March 31, 2014, the Company does not have any redeemable convertible preferred stock issued or outstanding.

8. Common stock

At March 31, 2014, the Company had authorized 191,689,655 shares of Common Stock, $0.001 par value per share, of which 17,322,144 shares were issued and 17,299,472 were outstanding.

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

25,262 shares of common stock which 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 distribution. As of March 31, 2014, the Company has issued 31,135 shares of restricted common stock of which 7,463 shares have vested and 22,672 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):

	March 31, 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	2,647	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	58
	2,709	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 closing of the 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 1st, from January 1st, 2015 through January 1, 2024, in amount equal to the lesser of 4% of the outstanding shares of the Company's outstanding common stock as of the close of business on the immediately preceding December 31st or the number of shares determined the Company's board of directors.

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 March 31, 2014, the number of common shares that may be issued under both equity plans is 2,646,788 and 643,982 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):

	Three months ended March 31,	
	2014	2013
Research and development	$ 477	$ 18
General and administrative	404	45
Total	$ 881	$ 63

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	479	$ 12.09		
Exercised	(12)	$ 2.22		
Canceled	(40)	$ 2.27		
Outstanding at March 31, 2014	2,003	$ 4.93	8.00	$ 26,556
Exercisable at March 31, 2014	1,036	$ 2.54	6.92	$ 16,219
Vested or expected to vest at March 31, 2014	1,871	$ 5.07	7.99	$ 24,538

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 months ended March 31, 2014, the Company determined that 96,988 performance-based milestones were probable of achievement and accordingly, recorded $435 thousand in related stock-based compensation expense. There

were no such milestones that were considered probable of achievement during the three months ended March 31, 2013, and accordingly, no stock-based compensation related to these milestones was recorded for this period. As of March 31, 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 closing 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. Unless otherwise determined by the administrator of the 2014 ESPP, the first offering will begin on July 1, 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 months ended March 31, 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.

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 month period ended March 31, 2014 and 2013 and the period from August 16, 2006 (inception) to March 31, 2014 resulted in net losses, there is no income allocation required under the two-class method or dilution attributed to weighted average shares outstanding in the calculation of diluted loss per share.

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

	March 31, 2014	March 31, 2013	The period from August 16, 2006 (inception) March 31, 2014
Preferred stock	—	8,493	—
Warrants	62	135	62
Outstanding options	2,003	1,099	2,003
Total	2,065	9,727	2,065

12. Subsequent events

The Company has evaluated all events or transactions that occurred after March 31, 2014. In the judgment of management, there were no material events that impacted the unaudited condensed financial statements or disclosures.

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 many autoimmune disorders. In September 2013, we announced human proof-of-concept data for GEN-003, a candidate immunotherapy to treat patients infected with herpes simplex virus-2, or HSV-2. This data represents the first reported instance of a vaccine significantly reducing viral shedding, an indicator of disease activity in HSV-2. We have subsequently demonstrated that response to GEN-003 lasts for six-months and offers a highly significant reduction in clinical symptoms as measured by lesion days. If GEN-003 successfully completes clinical development and is approved, we believe it would represent an important new treatment option for patients with HSV-2. We are also developing a second T cell-enabled product candidate, GEN-004, to prevent infections caused by *Streptococcus pneumoniae* or pneumococcus, a leading cause of infectious disease mortality worldwide.

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 of 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. At March 31, 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 $6.7 million from grants. At March 31, 2014, our cash and cash equivalents were $65.8 million.

Since inception, we have incurred significant operating losses. Our net losses were $7.3 million for the three months ended March 31, 2014, and our accumulated deficit was $87.5 million as of March 31, 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 March 31, 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 1/2a clinical trial and the first of our planned Phase 2 clinical trials for GEN-003 for HSV-2 and our Phase 1 clinical trial and our planned 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 balance of cash and cash equivalents 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.

Significant events in the three months ended March 31, 2014:

Completed IPO

- In February 2014, we completed our IPO, issuing 5.5 million shares of Common Stock and raising net proceeds of $61.4 million excluding offering expenses of $2.4 million.

Entered into supply agreement with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. ("Fujifilm")

- In February 2014, we entered into a supply agreement with Fujifilm for the manufacture and supply of antigens for our upcoming GEN-003 Phase 2 dose-optimization clinical trial.

Appointment of Jonathan Poole as chief financial officer

- Mr. Poole's deep finance and strategic planning expertise in the biopharmaceutical industry will further strengthen our leadership team as GEN-003 and GEN-004 advance in clinical development.

Status of products in development as of March 31, 2014

GEN-003 for the treatment of HSV-2 infections

GEN-003 is in Phase 1/2a clinical development for the treatment of HSV-2. 12-month data from this trial is expected in mid-2014 and we are currently actively preparing for the initiation of a Phase 2 dose-optimization clinical trial, also in the second quarter of 2014.

GEN-004 for the prevention of pneumococcal infections

GEN-004 is in Phase 1 clinical development to demonstrate the T cell response associated with natural protection against pneumococcus and the trial is fully enrolled. Data from this trial is expected in the second quarter of 2014 and we are currently planning to initiate a Phase 2 clinical trial in the third quarter of 2014 to seek to demonstrate that GEN-004 can reduce pneumococcus colonization in humans.

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.

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
- 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 months ended March 31, 2014 and 2013 (in thousands):

	Three Months Ended March 31,	
	2014	2013
HSV-2 (GEN-003)(1)	$ 1,923	$ 1,630
Pneumococcus (GEN-004)(1)	1,411	1,832
Other research and development (2)	1,073	518
Total research and development	$ 4,407	$ 3,980

(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.

At March 31, 2014, we had incurred an aggregate of $43.8 million in research and development expenses related to GEN-003 and GEN-004 since inception. 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) Income

Other (expense) income consists of fair value adjustments on warrants to purchase preferred stock.

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 closed our IPO and all shares of preferred stock were converted into 11,435,593 shares of our Common Stock. No accretion of preferred stock will be recorded after this date as no shares of preferred stock will be 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 March 31, 2014 and March 31, 2013

(in thousands)	Three Months Ended, March 31, 2014	2013	Increase (Decrease)
Grant revenue	$ —	$ 259	$ (259)
Operating expenses:			
Research and development	4,407	3,980	427
General and administrative	1,966	810	1,156
Total operating expenses	6,373	4,790	1,583
Loss from operations	(6,373)	(4,531)	(1,842)
Other income (expense):			
Other income (expense)	(725)	(6)	(719)
Interest expense, net	(231)	(127)	(104)
Other income (expense)	(956)	(133)	(823)
Net loss	$ (7,329)	$ (4,664)	$ (2,665)

Grant Revenue

Grant revenue was $0 and $259 thousand for the three months ended March 31, 2014 and 2013, respectively. The decrease of $0.3 million was due to the completion of a grant to fund research for our pneumococcus program during 2013.

Research and Development Expenses

Research and development expenses were $4.4 million and $4.0 million for the three months ended March 31, 2014 and 2013, respectively. The increase of $0.4 million was primarily due to increased spending on GEN-003 of $0.3 million as a result of increased costs related to the manufacturing of clinical trials materials, which was partially offset by a reduction in costs related to the Phase 1/2a clinical trial; increased spending on other research and development of $0.6 million as a result of increased employee compensation costs; partially offset by a decrease in spending on GEN-004 of $0.4 million due to a decrease in costs related to the manufacturing of clinical trials materials, which was partially offset by an increase in costs related to the Phase 1 clinical trial.

General and Administrative Expenses

General and administrative expenses were $2.0 million and $0.8 million for the three months ended March 31, 2014 and 2013, respectively. The increase of $1.2 million was primarily due to additional personnel costs in 2014 of $0.2 million, an increase in non-cash stock based compensation of $0.4 million due to the vesting of certain performance-based common stock options, $0.3 million in increased audit and legal expenses and $0.3 million in public company overhead costs.

Other (Expense) Income

Other (expense) income was $0.7 million million for the three months ended March 31, 2014 and de minimis for the same period of 2013, respectively. The increase of $0.7 million was due to an increase in the fair value of our 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 closing of the IPO.

Interest Expense, Net

Interest expense was $0.2 million and $0.1 million for the three months ended March 31, 2014 and 2013, respectively. The increase of $0.1 million was due primarily to higher average principal balances for the first three months of 2014 as compared to the same period in 2013.

Liquidity and Capital Resources

Overview

Since our inception through March 31, 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 $6.7 million from grants. At March 31, 2014, our cash and cash equivalents were $65.8 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

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 the 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.

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 March 31, 2014 will be sufficient to fund our operations through at least the end of 2015. We believe that these funds will be sufficient to enable us to obtain clinical data from our ongoing Phase 1/2a clinical trial and planned GEN-003 Phase 2 clinical trials and our Phase 1 clinical trial and planned Phase 2a clinical trial for GEN-004. 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 1/2a clinical trial and the first of our planned Phase 2 clinical trials for GEN-003 and our Phase 1 clinical trial and planned 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;
- subject to receipt of marketing approval, revenue received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, grants, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements;

- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and

- the extent to which we in-license or acquire other products and technologies.

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

Cash Flows

The following table summarizes our sources and uses of cash for the three months ended March 31, 2014 and 2013 (in thousands):

	Three Months Ended March 31,	
	2014	2013
Net cash used in operating activities	$ (6,534)	$ (5,058)
Net cash used in investing activities	(27)	(335)
Net cash provided by (used in) financing activities	60,192	(415)
Net increase (decrease) in cash and cash equivalents	$ 53,631	$ (5,808)

Operating Activities

The increase in net cash used in operations for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was due primarily to an increase in the net loss of approximately $2.7 million along with changes in our working capital accounts.

Net cash used in operating activities was $6.5 million for the three months ended March 31, 2014 and consisted primarily of net loss of $7.3 million adjusted for non-cash items including depreciation expense of $0.1 million, stock-based compensation expense of $0.9 million, an increase in the fair value of warrants of $0.7 million and a net decrease in operating assets and liabilities of $0.3 million.

Net cash used in operating activities was $5.1 million for the three months ended March 31, 2013 and consisted primarily of a net loss of $4.7 million adjusted for non-cash items including depreciation expense of $0.1 million, stock-based compensation expense of $0.1 million and a net decrease in operating assets and liabilities of $0.6 million.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2014 and 2013 were de minimis and $0.3 million, respectively. The use of net cash in all periods primarily resulted from purchases of property and equipment to facilitate our increased research and development activities and headcount.

Financing Activities

Net cash provided by (used in) financing activities for the three months ended March 31, 2014 and 2013 was $60.2 million and ($0.4) million respectively. Cash provided by financing activities for the year ended March 31, 2014 primarily consisted of $60.1 million in net proceeds from our IPO and $0.1 million in proceeds from the exercise of stock options and warrants. Net cash provided by financing activities for the year ended March 31, 2013 consisted primarily of $0.4 million from repayment of long-term debt.

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 Phase II clinical study. 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. As of March 31, 2014, the Company incurred $25 thousand in costs under this agreement.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risk related to changes in interest rates. As of March 31, 2014 and December 31, 2013, we had cash and cash equivalents of $65.8 million and $12.2 million, respectively, consisting of money market funds. 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 which 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. While 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 March 31, 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 March 31, 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 of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of March 31, 2014, our disclosure controls and procedures were not effective at the reasonable assurance level due 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 a result of management's review of the evaluation and results, and other internal reviews and evaluations that were completed after the end of quarter, 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 this Form 10-Q 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 quarter ended March 31, 2014.

Management's Remediation Initiatives

Management is pursuing the implementation of 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 initiated, or plan to initiate, the following series of measures:

- Improve 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;

- Replace the accounting software used to calculate stock compensation expense and ensure robust testing of stock compensation expense

calculations in the new system;

- Improve segregation of duties related to data entry and review of information in stock compensation systems; and
- Improve the process for the review and monitoring of complex accounting matters.

We believe the measures described above will remediate the material weakness we have identified and strengthen 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. As we continue to evaluate and work to improve our internal control over financial reporting, we may determine to take additional measures to address control deficiencies or determine to modify, or in appropriate circumstances not to complete, certain of the remediation measures described above.

Changes in Internal Control Over Financial Reporting

During the three months ended March 31, 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.

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 March 31, 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

Other than described below, 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.

We have had a material weakness in internal control over financial reporting in the past and cannot assure you that additional material weaknesses will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in material misstatements in our financial statements which could require us to restate financial statements, cause investors to lose confidence in our reported financial information and have a negative effect on our stock price.

During the quarter ended March 31, 2014, management and our independent registered public accounting firm have identified a material weakness in our internal control over financial reporting (as defined in the Public Company Accounting Oversight Board's Auditing Standard No. 5) related to the accounting for non-cash stock compensation expense for a milestone based stock option award. See "Part I. Financial Information – Item 4. Controls and Procedures" of this Quarterly Report on Form 10-Q for more details on the material weakness.

We cannot assure you that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional significant deficiencies or material weaknesses, cause us to fail to meet our periodic reporting obligations or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting. The existence of a material weakness could result in errors in our financial statements that could result in a restatement of financial statements, cause us to fail to meet our reporting obligations and cause investors to lose confidence in our reported financial information, leading to a decline in our stock price.

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 and filed pursuant to Rule 462(b) of the Securities Act. 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.

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 percent 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 Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act.

Stock options and other equity awards

During the three months ended March 31, 2014, we granted options to purchase a total of 479,277 shares of our common stock to employees, at a weighted average price of $12.09 per share. During the same period, we issued 11,693 shares of common stock upon the exercise of options to purchase such shares of common stock at a weighted average price of $2.22 per share.

Option grants and the issuance of common stock upon exercise of such options were exempt pursuant to Rule 701 and Section 4(a)(2) of the Securities Act.

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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.

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Exhibit Number	Exhibit
10.1+	Bioprocessing Services Agreement between Genocea Biosciences, Inc. and FUJIFILM Diosynth Biotechnologies U.S.A., Inc. dated February 26, 2014
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 March 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Balance Sheets as of March 31, 2014 and December 31, 2013, (ii) Condensed Statements of Operations and Comprehensive Loss for the three months ended March 31, 2014 and 2013 and for the period from August 16, 2006 (inception) to March 31, 2014, (iii) Condensed Statements of Cash Flows for the three months ended March 31, 2014 and 2013 and for the period from August 16, 2006 (inception) to March 31, 2014 and (iv) Notes to Unaudited Condensed Financial Statements

* As provided in Rule 406T of Regulation S-T, this information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.

\+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been submitted separately to the SEC.

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: May 9, 2014

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

Date: May 9, 2014

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

Exhibit 10.1

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [* * *] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

BIOPROCESSING SERVICES AGREEMENT

This Bioprocessing Services Agreement dated **26 February 2014** (this "Agreement") between Genocea Biosciences, Inc. ("Sponsor"), a Delaware corporation, with offices at Cambridge Discovery Park, 100 Acorn Park Drive, Cambridge, MA 02140 and FUJIFILM Diosynth Biotechnologies U.S.A., Inc., a Delaware corporation ("Fujifilm"), having its principal place of business at 101 J. Morris Commons Lane, Morrisville, NC 27560, (each a "Party", collectively, the "Parties").

Sponsor desires Fujifilm to perform services in accordance with the terms of this Agreement and the Scope (as hereinafter defined) related to the production of the Drug Substance (as defined below) for research and development and/or clinical trial uses; and Fujifilm desires to perform such services and supply Substance to Sponsor;

In consideration of the above statements, which form part of this Agreement, and other good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto agree as follows:

Definitions:

"**Agreement**" shall have the meaning set forth in the preamble.

"**Alliance Manager**" shall have the meaning set forth in Section 22(b).

"**Batch**" means a specific quantity of Drug Substance produced from a single Run.

"**Batch Packet**" shall mean [* * *].

"**Batch Record**" shall mean the Batch record instruction issued from the Master Manufacturing Record for completion in production and/or completed Batch record production instruction as the context dictates.

"**Cell Line**" shall mean the cell line for expression of the Drug Substance.

"**Certificate of Analysis**" shall mean a document prepared by Fujifilm in a Fujifilm standard format certifying the Batch of the Drug Substance release tests performed by Fujifilm, or Qualified Subcontractors, the specifications and test results for each Batch, as further specified in the Quality Agreement.

"**cGMP"** shall mean the regulatory requirements for current good manufacturing practices promulgated by the FDA under 21 C.F.R. Parts 210, 211, 600 and 610 and ICH, Guidance for Industry Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, as the same may be amended from time to time.

"**cGMP Batch**" shall mean a Batch intended to be manufactured in accordance with cGMP.

"**cGMP Run**" shall mean a Run intended to be manufactured in accordance with cGMP.

"**Change Order**" shall have the meaning set forth in Section 7(a).

"**Claim**" shall have the meaning set forth in Section 16(a).

"**Completion**", "**Completed**" and correlatives shall mean the completion by Sponsor of Technology Transfer or the completion by Fujifilm of a Milestone, all as defined in [* * *], Program or Scope.

"**Completion Date**" shall mean the date of Completion of a Milestone.

"**Confidential Information**" shall have the meaning set forth in Section 8(d).

"**Conforming Product**" means Drug Substance that conforms to all of the warranties set forth in Section 17(g).

"**Demonstration Batch**" shall mean a Batch designated by Sponsor to demonstrate scalability of the process in the Fujifilm non-cGMP process development laboratory.

"**Demonstration Run**" shall mean a Run used to demonstrate scalability of the process in the Fujifilm [* * *].

"**Designated Equipment**" shall mean equipment owned by Sponsor and located at the Fujifilm Facility.

"**Drug Substance**" shall mean the active bulk component that is identified in the applicable Scope to be manufactured by Fujifilm.

"**Drug Product**" shall mean the final dosage form which contains Drug Substance in association with other active or inactive ingredients.

"**Effective Date**" shall mean the date of last signature.

"**Engineering Batch**" means a Batch produced from an Engineering Run, and which may be used by Sponsor for Sponsor's toxicology studies or otherwise in accordance with this Agreement.

"**Engineering Run**" means a Run used for process demonstration and engineering of some or all of the Manufacturing Process steps.

"**Fujifilm Confidential Information**" shall have the meaning set forth in Section 8(b).

"**Fujifilm Factor**" shall mean [* * *].

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [* * *] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

"**Fujifilm Facility**" shall mean either the Fujifilm Diosynth facility in RTP, North Carolina, USA or Billingham, UK, or both, as the context requires.

"**Indemnified Party**" shall have the meaning set forth in Section 16(c).

"**Indemnity Claim**" shall have the meaning set forth in Section 16(c).

"**Initiation**" shall mean the start of activities associated with a Milestone.

"**Joint Steering Committee**" shall have the meaning set forth in Section 22(a).

[* * *] means any [* * *] of a Drug Substance or Drug Product with [* * *] that is attributed to Fujifilm's Drug Substance(s) manufacturing activity and/or release testing of Drug Product and [* * *] of the Batch Packet by Sponsor.

"**Loss**" shall have the meaning set forth in Section 16(a).

"**Manufacturing Process**" shall mean the process, or applicable portion(s) thereof, for manufacturing the Drug Substances, including the manufacture, analysis, documentation, quality evaluation, and storage of components, intermediates and Drug Substances pursuant to this Agreement, as mutually agreed and described in the Master Manufacturing Record, as such process may be developed and/or changed from time to time in accordance with this Agreement.

"**Master Cell Bank**" shall mean the [* * *] previously generated and to be provided by Genocea.

"**Master** [* * *] **Bank**" shall mean the initial cGMP [* * *] stocks ([* * *]) being generated for Genocea by a third party and to be provided to Fujifilm by Genocea.

"**Master Manufacturing Record**" shall mean for each Program the mutually agreed document which sets out in detail the master production instructions for the Manufacturing Process, as such instructions are defined in sections 6.4 and 6.5 of the Rules and Guidance for Pharmaceutical Manufacturers and Distributors Part II: Basic Requirements for Active Substances Used as Starting Materials.

"**Milestone(s)**" means any or all of the milestones set forth in the [* * *] for a Scope.

"**New IP**" shall have the meaning set forth in section 10(a).

"**Non-Conforming Batch**" shall mean: [* * *].

"**Non-Conforming Product**" shall mean a Drug Substance which: (i) has not been produced in accordance with cGMP; and/or (ii) does not meet the Product Specification agreed jointly in

writing by Sponsor and Fujifilm in quality control documentation, and (iii) is not in compliance with Fujifilm's warranty in Section 17(g).

"**Non-Manufacturing**" shall mean activities that are not cGMP activities, including Process Development Runs and Demonstration Batches.

"**Party**" or "**Parties**" shall have the meaning set forth in the preamble.

"**Process Consumables**" shall have the meaning set forth in the Scope and shall include raw materials, resins and consumables.

"**Process Development Batch**" means a Batch produced from a Process Development Run, including a Demonstration Batch.

"**Process Development Run**" means a Run used to demonstrate the transfer of Sponsor's then current production process to Fujifilm and/or development at Fujifilm of the process, including a Demonstration Run.

"**Product**" shall mean any, some or all of the products listed in a Scope to be manufactured by Fujifilm, including Drug Substances from [* * *].

"**Product Specification**" means the specifications for the Drug Product or Drug Substance as applicable, each as set forth in quality control documentation.

"**Production Batch**" means a Batch produced from a Production Run, including an Engineering Batch and/or cGMP Batch.

"**Production Fee(s)**" shall mean the following fees associated with a particular Production Batch as set out in the applicable [* * *].

"**Production Run**" means a Run conducted in accordance with the Master Manufacturing Record that is used to create Product for research and development or for clinical use, including an Engineering Run and/or cGMP Run.

"**Program**" shall mean the services to be performed under this Agreement and the supply of Product as more fully described in each Scope.

"**Program Price and Payment Schedule**" shall mean the schedule attached as Appendix 3-A to this Agreement for the Scope, and additional schedules identified as Appendix 3-B, Appendix 3-C and so on for any additional Scope.

"**Qualified Subcontractor**" shall mean a subcontractor that is a contract testing laboratory or a cell bank manufacturer with whom Fujifilm has a signed agreement, with provisions that protect Sponsor Confidential Information at least as stringent as the provisions of this Agreement, and

that has been audited and approved as a supplier by Fujifilm's quality assurance department to provide the services to be subcontracted.

"**Quality Agreement**" shall mean the quality agreement attached as Appendix 2 to this Agreement.

"**Reservation Fee**" shall mean [* * *] of the associated Production Fee(s) set forth in the Program Price and Payment Schedule [* * *], as applicable in accordance with Section 5(b) and/or Section 21(b)(7).

"**Run**" shall mean the activity for single complete operation of all, or a discreet portion of (if appropriate from the context), the process (including, if applicable, [* * *].

"**Scope**" shall mean the scope of work attached as Appendix 1-A to this Agreement for the initial Scope, and additional schedules identified as Appendix 1-B, Appendix 1-C and so on for any additional Scopes, each to be signed by each Party and including the Sponsor Deliverables, Milestones, the final schedule of stages [* * *], and timelines for the activities, as may be amended from time to time through Change Orders.

"**Sponsor**" shall have the meaning set forth in the preamble.

"**Sponsor Deliverables**" shall have the meaning set forth in the Scope.

"**Sponsor's Confidential Information**" shall have the meaning set forth in Section 8(a).

"**Start Date**" shall mean the start date for a particular Milestone or Run set forth in the [* * *] for a Scope (as may be amended by mutual agreement from time to time as set forth in this Agreement).

"**Technology Transfer**" means, for each Scope, the transfer from Sponsor to Fujifilm of information, data and technology as set forth in Section 2(c).

"**Work Output**" shall have the meaning set forth in Section 9(a).

"**Working Cell Bank**" shall mean the [* * *] to be generated directly from the Master Cell Bank by Fujifilm.

"**Working [* * *] Bank**" shall mean the cGMP [* * *] stocks ([* * *]) being generated for Genocea by a third party and to be provided to Fujifilm by Genocea.

Section 1.

Scope of Work/Performance of Program/Acceptance of Milestones

a) Fujifilm will perform the Program for Sponsor in accordance with the terms and conditions of this Agreement, the Scope (attached as **Appendix 1-A**) and the Quality

Agreement (attached as **Appendix 2**). Fujifilm shall not engage in any negligent act or omission, which may reasonably be expected to prevent or delay the successful execution of the Program.

b) Terms defined in the terms and conditions of this Agreement shall have same meaning when used in the Scope or Quality Agreement. In the event of any conflict among the components of this Agreement, the following order of precedence shall apply:

1. the terms and conditions;
2. the Quality Agreement; and
3. the Scope.

c) As further set forth in the Scope, Fujifilm will timely provide Sponsor with Milestones, Drug Substances and other deliverables, including Drug Product testing, without a delay within the time periods specified in the Program Price and Payment Schedule. Fujifilm will not deliver Product that does not meet the applicable Product Specifications. Delays in providing Drug Substance solely attributable to Fujifilm will result in liquidated damages as specified in Section 5(d) and are subject to the provisions of Section 14(a).

d) Sponsor shall perform its obligations as set forth in the Scope and Quality Agreement, shall support and cooperate with the execution of the Program and shall not engage in any negligent act or omission, which may reasonably be expected to prevent or delay the successful execution of the Program.

(1) All Non-Manufacturing deliverables listed in the Scope and other documents that, according to Fujifilm quality systems, require Sponsor's approval either in a form of a signature on a document (qualification protocols, reports, etc.) or in another format shall be reviewed and approved [* * *] by Sponsor without a delay within the time periods specified in Scope or Quality Agreement. Such approval shall constitute Sponsor's acceptance [* * *]. If Sponsor's review is [* * *], unless Fujifilm shall notify Sponsor within [* * *].

(2) All documentation related to manufacturing activities and cGMP testing that, according to Fujifilm quality systems, require Sponsor's approval either in a form of a signature on a document or in another format shall be set forth in the Quality Agreement or otherwise communicated in advance to Sponsor by [* * *] of the quality control documentation and shall be reviewed by Sponsor for approval by [* * *]. If Sponsor's review is [* * *] or they shall constitute Sponsor delay subject to provisions of Sections 19 and 14(b).

e) Following Completion of Technology Transfer, Fujifilm shall perform the Process Development services as set forth in the applicable Scope, and develop, confirm and/or refine processes to produce the Product and/or to develop and/or scale-up a Manufacturing Process suitable for cGMP manufacture of the Product. One or more Process Development Runs and one or more Engineering Runs shall be conducted if and as mutually agreed in writing by the Parties in Scope.

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f) Fujifilm shall provide Sponsor with [* * *] as requested by Sponsor. Sponsor's representative may be present on the floor during execution of the Engineering Run. After Completion of the Process Development Run(s), the Parties shall mutually agree on [* * *] for [* * *] for Completion [* * *] of the results of Engineering Batches, which shall be documented in a [* * *] Change Order and/or manufacturing documentation. If the empirical results from the Engineering Batches point to the need for additional work prior to initiation of cGMP manufacturing, Fujifilm shall propose a Change Order in accordance with Section 7(c), including a reasonable timeline for such work and the Start Dates and Completion Dates for all subsequent Milestones. Sponsor shall have the right to make whatever lawful use of such [* * *] as it shall determine, providing that Product from such Batches must not be used in human trials.

g) For each Non-Manufacturing Milestone, Fujifilm shall provide Sponsor with [* * *] at the times and as otherwise specified in the Scope and Program timelines jointly agreed by Sponsor and Fujifilm's Program teams in the [* * *] and [* * *] at the Completion of each Milestone or as mutually agreed in a Change Order.

(1) All Non-Manufacturing deliverables that are provided by Fujifilm require [* * *] provided to Fujifilm Alliance Manager. If within the [* * *] period after Sponsor's receipt of each deliverable, or [* * *], such deliverable will be deemed accepted by Sponsor; provided that Fujifilm provides timely answers to information requests and resolution of issues arising from Sponsor's review of such deliverables so that Sponsor is able to reasonably respond within the applicable time frame. If Fujifilm answers are not timely, the time for Sponsor review and approval shall be extended for a reasonable period. If Sponsor requests, [* * *] and Sponsor shall have the right to make whatever lawful use of such [* * *] as it shall determine, providing that [* * *] must not be used in human trials. Fujifilm shall have the right to [* * *] and shall notify Sponsor of this [* * *] as soon as practicable but no later than [* * *] from Sponsor notification. Such written notice shall explain why [* * *] with Sponsor's findings. Any disagreement whether [* * *] or not shall be resolved in good faith according to the mechanism described in Section 15.

(2) For each [* * *], Fujifilm shall use commercially reasonable efforts to reform the deliverable and shall re-submit the deliverable to Sponsor within [* * *], or if not reasonably possible to complete the deliverable within [* * *], Fujifilm shall initiate the reforming procedures within such [* * *] period and notify Sponsor of the procedures Fujifilm has taken and will take and [* * *] and [* * *] to Sponsor as soon as reasonable possible using commercially reasonable efforts to resubmit within [* * *].

(3) In case of breach of warranties (including for Non-Conforming Deliverable), under this Agreement, Sponsor may terminate in accordance with Section 14 and

[* * *] shall follow the procedure in [* * *]. The terms of this Section 1(g) are subject to Section 14.

h) Fujifilm shall not subcontract, sublicense, or otherwise delegate all or any portion of its obligation under this Agreement related directly to handling or manipulation of Drug Substance, Drug Product or Working Cell Bank, Master Cell Bank, Working [* * *] Bank or Master [* * *] Bank, without prior written approval from Sponsor. For clarity, the limitation does not apply to subcontracting by Fujifilm any activities related to upkeep of its facilities, testing of raw materials, or testing of Product to the extent agreed in writing in Scope or a Change Order. Any subcontractor that would perform contract work must be a "Qualified Subcontractor." Fujifilm shall remain responsible and liable for all activities of all subcontractors as if performed by Fujifilm under this Agreement.

i) All Process Consumables used in the Manufacturing Process shall comply with any applicable materials specifications.

j) Fujifilm shall generate and/or maintain all portions of each Master Cell Bank, Working Cell Bank, Master [* * *] Bank and/or Working [* * *] Bank in safe and secure storage under its control in the Fujifilm Facility in accordance with the mutually agreed storage guidelines. Fujifilm shall not use any Master Cell Bank, Working Cell Bank, Master [* * *] Bank and/or Working [* * *] Bank for any purpose except as authorized by this Agreement. On Sponsor's request from time to time, all or any specified portion of the Cell Banks and/or [* * *] Banks shall be returned to the Sponsor or a designee as directed by Sponsor, at Sponsor expense. At the conclusion of the Scope, any retained portion of the Cell Banks and [* * *] Banks shall be returned to the Sponsor or a designee as directed by Sponsor, at Sponsor expense.

Section 2.

Sponsor Deliverables

a) As further set forth in the Scope, Sponsor will use commercially reasonable efforts to timely provide Fujifilm with Sponsor Deliverables (as defined in the Scope). Failure by Sponsor to provide Sponsor Deliverables within the timeframe set forth in the Scope may result in additional charges to Sponsor pursuant to a Change Order or a delay in meeting Program objectives as further described in Section 19.

b) Title to Sponsor Deliverables shall remain with Sponsor. Fujifilm shall not sell, pledge, hypothecate, dispose of, or otherwise transfer any interest in Sponsor Deliverables except as otherwise provided in this Agreement, and shall use Sponsor Deliverables solely for purposes of performing the Program in accordance with the particular Scope. Fujifilm shall provide safe and secure storage conditions for Sponsor Deliverables while they are at Fujifilm's location.

c) For each Scope, Sponsor shall use commercially reasonable efforts to transfer to Fujifilm all material information and technology reasonably necessary for Fujifilm to

perform process development related to and subsequently to manufacture Product for Sponsor ("**Technology Transfer**"). Specifically, Sponsor shall use commercially reasonable efforts to (i) provide reasonable access to Sponsor's scientists who developed and/or are familiar with the Product and the Sponsor's processes, and (ii) supply Fujifilm with all Product-specific controls, specifications, raw materials, assays, SOPs and standards. Fujifilm shall assign a project team of appropriately trained and experienced technical staff, and shall use commercially reasonable efforts to accept and implement the transferred information and materials provided by Sponsor.

Section 3.

Compliance with Government Regulations

a) Fujifilm shall operate a compliant current cGMP facility located at RTP, NC and Billingham, UK (each a "**Fujifilm Facility**") pursuant to (a) the U.S. Federal Food, Drug and Cosmetics Act as amended (21 USC 301 et seq.), (b) U.S. regulations in Title 21 of the U.S. Code of Federal Regulations Parts 210, 211, 600 and 610, and (c) the EC Guide to Good Manufacturing Practice for Medicinal Products, v.4, including relevant sections of DIR 2003/94/EC International Conference on Harmonization (ICH) , in each case including successor laws, regulations or guides. All Product requested by Sponsor under this Agreement shall be manufactured solely by Fujifilm at the Fujifilm Facility in RTP, NC. [* * *] In addition, Fujifilm shall perform each Program in compliance in all respects with statutory and regulatory guidelines applicable to the Product's clinical phase. Fujifilm shall not permit debarred persons to participate in any Program. Fujifilm shall undertake reasonable steps to prevent such participation.

b) Sponsor and Fujifilm each acknowledges that it has consulted with the other Party in designing the Program in a manner consistent with current US and EU regulatory guidelines. Notwithstanding the foregoing, neither Party warrants that the Program and/or the Program results will satisfy the requirements of any regulatory agencies at the time of submission of Program results to such agencies. Sponsor shall have the right and responsibility for determining regulatory strategy, decision and actions to the extent relating to the Product and Fujifilm shall have the right and responsibility for determining regulatory strategy, decision and actions to the extent relating to (i) the Fujifilm Facility; (ii) Fujifilm's quality systems; (iii) any requirement imposed on Fujifilm by a Regulatory Authority or (iv) any other commitments made by Fujifilm prior to, on or after the Effective Date of this Agreement. Fujifilm shall monitor and maintain reasonable records respecting its compliance with cGMPs, including the process of establishing and implementing the operating procedures, equipment files, and the training of personnel as are reasonably necessary to assure such compliance. Fujifilm hereby represents that, to Fujifilm's knowledge, no requirement imposed on Fujifilm by a Regulatory Authority as of the Effective Date or any other commitments made by Fujifilm prior to the Effective Date of this Agreement shall delay or prevent Fujifilm from performing the Program or otherwise complying with its obligations hereunder, and Fujifilm shall immediately notify Sponsor during the term of this Agreement if that representation is no longer accurate on

an ongoing basis, in reasonable detail with a plan to immediately correct such delay or non-compliance.

c) Should such U.S. government or European Medicines Agency ("EMA") regulatory requirements change, Fujifilm will use reasonable efforts to satisfy the new requirements. In the event that compliance with such new U.S. or EMA regulatory requirements necessitates a change in the Scope, Fujifilm will submit to Sponsor a Change Order, as herein after defined, in accordance with Section 7 of this Agreement.

d) Sponsor shall provide Fujifilm with information in Sponsor's possession concerning any health hazards or potential health hazards associated with exposure to or the handling, storage, use or disposal of raw materials and/or Product, including, without limitation, a Material Safety Data Sheet for Product, if one exists. In the event that any such information is updated or corrected, Sponsor shall promptly notify Fujifilm thereof and provide Fujifilm with the updated or corrected information.

e) Subject to this Section 3, in the event of a conflict in government regulations, the Party primarily responsible for compliance shall determine in good faith which regulations shall be followed by Fujifilm in its performance of the Program to comply with regulatory requirements and advance the Program.

Section 4.

Facility Visits

The terms and conditions of Sponsor audits and other visits are provided in the Quality Agreement.

Section 5.

Compensation

a) Sponsor shall make the payments set forth in the [* * *] as follows for all activities, which duration is not expected to exceed [* * *] months: (i) on [* * *] Fujifilm will invoice Sponsor for [* * *] of the Milestone payment applicable to such Milestone, and (ii) on [* * *], Fujifilm will invoice Sponsor for the remaining [* * *] of the Milestone payment applicable to such Milestone. Unless otherwise agreed in Scope or a Change Order, for activities expected to last longer than six months, Fujifilm shall issue interim invoices as follows: (1) on [* * *] Fujifilm will invoice Sponsor for [* * *] of the Milestone payment applicable to such Milestone, (2i) on [* * *], Fujifilm will invoice Sponsor for [* * *] for each Milestone payment applicable to such Milestone, and (3) on [* * *], Fujifilm will invoice Sponsor for the remaining [* * *] of the Milestone payment applicable to such Milestone.

b) (1) Fujifilm shall [* * *] for Production Batch(es) in the [* * *] in the Scope or [* * *].

(2) For clarification, Fujifilm shall [* * *] for Non-Manufacturing Batch(es) in the timeframe agreed in the Scope or Program Price and Payment Schedule, [* * *].

c) In addition to the Milestone amounts set forth in the Program Price and Payment Schedule, Process Consumables purchased for the Program will be invoiced separately as such costs are incurred by Fujifilm. For Process Consumables, the bill of materials for manufacturing and estimated procurement budget shall be prepared by the Program team as specified in Scope and shall be approved by Sponsor in writing. Sponsor agrees to pay [* * *]. Fujifilm shall use commercially reasonable efforts to procure materials at the lowest available price and only in the quantity necessary for program performance, unless otherwise agreed by Sponsor. These amounts will be invoiced as they are incurred by Fujifilm. Within thirty (30) days of completion of all Manufacturing under this Agreement under a Scope or early termination, Sponsor will provide Fujifilm with written notice specifying its preferred method of disposition for any remaining, unused raw materials and other Program Consumables, the reasonable third party costs for which shall be borne solely by Sponsor. In specifying its preferred method for such disposition, Sponsor may choose from the following three options:

1. Having Fujifilm deliver remaining raw materials to Sponsor or a designated storage site.
2. Having Fujifilm deliver remaining raw materials to a destruction site; or
3. Assign ownership of remaining materials to Fujifilm at no cost, which request Fujifilm, in its sole discretion can choose to accept or reject

In the event that Sponsor fails to provide written notice of its preferred method of disposition to Fujifilm within the above thirty (30) day period, Fujifilm will select the method of disposition, the reasonable third party costs for which shall be borne solely by Sponsor.

d) Fujifilm recognizes the importance of [* * *]. Fujifilm shall [* * *] of the timeframe specified in the [* * *] as updated as described in Section 5(a). In the event that the [* * *] is not completed [* * *], in addition to all other remedies of Sponsor under this Agreement, in equity and at law, at Sponsor's discretion, Sponsor may cancel all or a portion of the affected manufacturing campaign without incurring manufacturing termination fees under Section 21 and shall be entitled to initiate the dispute resolution mechanism under Section 15 or terminate the Agreement in accordance with Section 14, provided, however, that [* * *].

e) All raw materials, resins and other Process Consumables used in the Manufacturing Process shall comply with any applicable materials specifications.

f) Payments or notice that Sponsor may dispute the invoice are due thirty (30) days from the date of receipt of invoice issued by Fujifilm consistent with the Program Price and Payment Schedule. Unless disputed as provided below, late payments are subject to an interest charge of [* * *] per annum above the prime rate on the due date as posted by the Bank of America (or its successor). Unless within sixty (60) days of the receipt of invoice, Sponsor has advised the Alliance Manager at Fujifilm in good faith and in writing

the specific basis for disputing an invoice, failure to pay an invoice within ninety (90) days from the date of invoice may, at Fujifilm's election, constitute a material breach of this Agreement. Invoices will include a summary of activities completed during the invoice period, including activities completed and an indication of Process Consumables purchased. For purposes of this Section 5(f), "notice" and "in writing" includes email notification sent to Alliance Manager at Fujifilm.

g) If Sponsor is more than ninety (90) days late in paying any undisputed amount due greater than $[* * *] ("Late Payment"), Sponsor hereby grants a purchase money security interest to Fujifilm in an amount equivalent to the Late Payment in material produced hereunder, Process Consumables and/or proceeds thereof to secure payment of the Late Payment by Sponsor in favor of Fujifilm.

Section 6.

Quality Review; Batch Packet; Acceptance; Non-Conforming Batch

a) Fujifilm shall disposition cGMP Batches following internal standard operating procedures and procedures that are set forth in the Quality Agreement. Upon disposition of a cGMP Batch determined by Fujifilm to conform to cGMP and Product Specifications, Fujifilm shall provide Sponsor's quality assurance department with a Batch Packet and a recommendation for such Batch to be released. Within [* * *] after Sponsor's receipt of such documentation, Sponsor shall review the Batch Packet to determine, to the extent ascertainable from such documentation, whether or not Sponsor agrees that the Product covered by such Batch Packet is Conforming Product. Upon Sponsor's written acceptance of the Batch Packet, the Product shall be delivered as provided in Section 13. Product [* * *] shall also be treated as [* * *] for purposes of this Agreement, provided that the Sponsor's notice shall specify both the basis for its assertion of a [* * *] and also reasonable information to indicate that the asserted [* * *] was attributed to Fujifilm's manufacturing activity and/or release testing and was not or could not reasonably have been expected to have been revealed by the Sponsor Approval process above or by reasonable delivery inspection by Sponsor. Sponsor shall report any [* * *] following Fujifilm's complaint procedure no later than [* * *] following the manufacturing date.

b) In the event Sponsor's review of Batch Packet indicates that the Batch may be a Non-Conforming Batch, Sponsor shall immediately notify Fujifilm's quality assurance department in writing and Fujifilm shall initiate an investigation. The Parties shall cooperate in good faith in analyzing and investigating the Batch. The Parties shall use good faith efforts to mutually determine if the Batch is a [* * *] or if [* * *] shall be investigated and if it is ascertained that it has [* * *], it will be treated as [* * *] for purposes of this Agreement. If the Parties cannot come to mutual agreement within [* * *] after Sponsor's notice, or longer if reasonably required to complete the investigation, then the Parties shall revert to the dispute resolution procedure set forth in Section 6(f).

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c) The following provisions shall apply if during disposition of the cGMP Batch or as a result of Sponsor's review of the applicable Batch Packet and followed investigation or through dispute resolution set forth in Section 6(f) and [* * *], it is ascertained that such cGMP Batch is a Non-Conforming Batch:

(i) The Non-Conforming Batch shall not be delivered to Sponsor, except as provided in Section 6(e).

(ii) The following provisions shall apply if the Non-Conforming Batch arose other than as a result of a Fujifilm Factor:

(1) Sponsor shall be obliged to make payment for activities under the Manufacturing heading in respect of such **[* * *]** in the applicable **[* * *]**.

(2) If Sponsor wishes Fujifilm to carry out additional work under the Program, such additional work, including further manufacture, shall be carried out at a time to be agreed and subject to agreement of the price payable in respect of such further manufacture, such agreement to be recorded in a Change Order.

(iii) If the Non-Conforming Batch arose as a result of a Fujifilm Factor, manufacture of a further cGMP Batch that is a Conforming Batch shall be undertaken at [* * *], and Fujifilm shall promptly (a) acquire all raw materials and other Process Consumables necessary for conducting the required Production Run(s) to produce the replacement product, (b) prepare the documentation for such Production Run(s), (c) conduct appropriate quality investigation of the non-conformity and resolve and/or correct as appropriate, in consultation with Sponsor and with appropriate sign-off by Fujifilm and Sponsor for any changes deemed necessary for such Production Run(s), and (d) within [* * *] following completion of item "(c)" schedule the Production Run(s) in a cGMP manufacturing suite at the very next available time period.

d) Notwithstanding anything to the contrary in this Agreement, the remedies set out in Section 6(c)(iii) shall be Sponsor's sole remedies in relation to a Non-Conforming Batch; provided that Sponsor shall also have the right to exercise its termination rights under Section 14.

e) For the avoidance of doubt, the Parties will follow the mutually agreed quality procedures set forth in the Quality Agreement while accepting or rejecting the disputed Batch; provided that in the event of a conflict, the applicable provisions of this Agreement shall control. [* * *] Fujifilm shall dispose of any Non-Conforming Batch [* * *] with all Applicable Laws with respect to such disposal, at [* * *]. Shipment of the Non-Conforming batch through interstate or international commerce may be subject to limitation by law or cGMP and must be approved by Fujifilm Quality Assurance.

f) The Parties shall resolve any dispute between them under this Section 6 as follows:

(i) regarding decision whether or not a Batch is a Non-Conforming Batch and whether or not a Batch shall be rejected or accepted for human use, a dispute shall be resolved jointly by heads of Sponsor's and Fujifilm's Quality Assurance organizations and if not so resolved, through the dispute procedures according to Section 15;

g) (ii) regarding allocation of financial responsibility for a Non-Conforming batch, dispute shall be resolved through the Joint Steering Committee, but if the Parties are unable to resolve a dispute within [* * *] business days, despite their good faith efforts, either Party may refer the dispute to the Chief Executive Officer (or other designee) of each Party. In the event that no agreement is reached by the Chief Executive Officers (or other designees) with respect to such dispute within [* * *] days after its referral to them, the actions outlined in Section 15 will come into effect.

Section 7.

Change Orders

a) "Change Order" means a document to support a meaningful deviation from a Scope mutually approved in writing by both Parties that (i) describes in reasonable detail an amendment and/or modification to the Program and/or the Scope, and (ii) that is required: (a) to meet new or unforeseen applicable regulatory or quality assurance requirements; (b) to address unforeseen issues which arise from the empirical results related to the biology of the molecule; and/or (c) as a result of a change in the written assumptions for the Scope agreed upon by the Parties in relation to the Program design and objectives, manpower requirements, timing, and capital expenditure requirements, if any; (d) to perform activities that meaningfully deviate from the Scope but requested by Sponsor. After duly executed by both Parties, a Change Order is hereby deemed to be incorporated into the applicable Scope.

b) Sponsor shall have the right to request reasonable modifications to the Program and/or the Scope by providing notice thereof to Fujifilm. Upon receipt of such notice, Fujifilm shall generate a Change Order, and submit such Change Order to Sponsor for Sponsor's review and approval. If Sponsor approves the Change Order notwithstanding Fujifilm's notice of any resulting cost increase, Sponsor shall reimburse Fujifilm for the cost of such changes as detailed in the Change Order, provided that pricing shall be based upon similar underlying assumptions as used in the Scope Pricing. Upon Sponsor's approval of such Change Order, the Change Order will be implemented as soon as it is commercially practical to do so in a commercially reasonable effort to meet the development and manufacturing timelines as set forth in the Scope or as described in the Change Order. For the avoidance of doubt, if Sponsor requests a reduction in the Scope, for example, fewer batches in a manufacturing campaign or removal of other Program elements, cancellation charges shall be applicable equivalent to the charges set out in Section 21(c) below [* * *].

c) Fujifilm may only initiate a Change Order if it reasonably determines that a meaningful deviation from the Scope is required in order to successfully and timely complete any Milestone in the Scope that could not reasonably have been anticipated at the time when the Scope and/or [* * *] was prepared and mutually agreed by the Parties. Before Fujifilm may amend the Scope, Fujifilm shall prepare a Change Order describing in reasonable detail the nature of such change(s), and propose such Change Order to Sponsor for Sponsor's review and written approval. All approved Change Orders shall be signed by the Alliance Manager of each Party or by such other authorized representatives of Fujifilm and Sponsor that the Party may designate. If any changes contemplated by a Change Order will have a financial, timing and/or other impact on the Scope, Fujifilm shall provide Sponsor with a written description of such impacts in the Change Order. If Sponsor approves the Change Order notwithstanding Fujifilm's notice of any resulting cost increase, Sponsor shall reimburse Fujifilm for the cost of such changes as detailed in the Change Order, provided that pricing shall be based upon similar underlying assumptions as used in the Scope Pricing. Upon Fujifilm and Sponsor's approval of the Change Order, the Change Order will be implemented as soon as it is commercially practical to do so in a commercially reasonable effort to meet the development and manufacturing timelines as set forth in the Scope. Fujifilm shall continue work on the Program during any such negotiations, but shall not commence work with respect to the Change Order unless authorized in writing by Sponsor. [* * *]. If lack of timely review by Sponsor is the principal cause of delay of Fujifilm's manufacturing activities, it shall constitute Sponsor delay subject to provisions of Sections 15, 19 and 21. If Sponsor rejects a Change Order, the dispute resolution procedures set out in Section 15 shall apply.

d) If a Change Order is not agreeable to both Parties, the Parties shall resolve the dispute in accordance with Section 22 and Section 15. If reasonably possible, the Parties shall continue to perform the Scope as modified by previously executed Change Orders, if any, without regard to the unresolved Change Order until resolution of the dispute.

Section 8.

Confidential Information/Legal Proceedings

a) For the duration of this Agreement and any successor agreement and for three (3) years thereafter, Fujifilm will not disclose, without Sponsor's written permission, any Sponsor's Confidential Information unless such disclosure: (i) is necessary to disclose for purposes of this Agreement to an affiliate of Fujifilm that is under a similar obligation to keep such information confidential; (ii) is or becomes publicly available through no fault of Fujifilm; (iii) is disclosed by a third party entitled to disclose it; (iv) is already known to Fujifilm as shown by its prior written records. Fujifilm shall furnish only that portion of Confidential Information that is legally required by any law, rule, regulation, order decision, decree, subpoena or other legal process to be disclosed. If such disclosure is requested by legal process, Fujifilm will make all reasonable efforts to notify Sponsor of this request promptly prior to any disclosure to permit Sponsor to oppose such disclosure by appropriate legal action. Fujifilm shall use reasonable precautions to

protect the confidentiality of Sponsor's Confidential Information comparable to precautions taken to protect its own proprietary information.

b) For the duration of this Agreement and any successor agreement and for three (3) years thereafter, Sponsor will not disclose, without Fujifilm's written permission, any Fujifilm Confidential Information unless such disclosure: (i) is necessary to disclose for purposes of this Agreement to an affiliate of Sponsor that is under a similar obligation to keep such information confidential, (ii) is to a regulatory authority in connection with making regulatory filings and maintaining regulatory approvals for the Product(s), or potential or actual partners, sublicensees, acquirers, investors or otherwise in connection with obtaining financing; (ii) is or becomes publicly available through no fault of Sponsor; or (iii) is disclosed by a third party entitled to disclose it; (iv) is already known to Sponsor as shown by its prior written records. Sponsor shall furnish only that portion of Confidential Information that is legally required by any law, rule, regulation, order decision, decree, subpoena or other legal process to be disclosed. If such disclosure is requested by legal process, Sponsor will make all reasonable efforts to notify Fujifilm of this request promptly prior to any disclosure to permit Fujifilm to oppose such disclosure by appropriate legal action. Sponsor shall use reasonable precautions to protect the confidentiality of Fujifilm Confidential Information comparable to precautions taken to protect its own proprietary information.

c) If either Party shall be obliged to provide testimony or records Confidential Information of the other in any legal or administrative proceeding, then Party to whom the Confidential Information belongs shall reimburse the other Party for its out-of-pocket costs therefore plus an hourly fee for its employees or representatives equal to the internal fully burdened costs of such employee or representative.

d) For both Parties, "Confidential Information" shall mean and include without limitation the existence and terms and conditions of this Agreement, inventions, methods, plans, processes, specifications, characteristics, raw data, analyses, equipment design, trade secrets, costs, marketing, sales, and performance information, including patents and patent applications, grant applications, notes, and memoranda, whether in writing or presented, stored or maintained electronically, magnetically or by other means, which are disclosed by the disclosing Party to the recipient Party in writing or in other tangible form and marked "confidential" or, if [* * *] of such disclosure, or that is reasonably recognizable as confidential or proprietary either by the nature of the information or in the form or circumstances transmitted. Sponsor Confidential Information shall include without limitation the Drug Substances, Master Cell Bank, Working Cell Bank, Master [* * *]Banks, Working [* * *] Banks, any Manufacturing Process documentation provided by Sponsor to Fujifilm, and all elements of the Manufacturing Process (other than Fujifilm intellectual property pre-existing on the Effective Date). Each Manufacturing Process developed by Fujifilm for Sponsor and specific portions of documents and records describing or relating to the Manufacturing Process shall be deemed to be Sponsor Confidential Information, including the Master Manufacturing Record and all Batch Packet and Batch Records and Work Product.

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e) Each recipient Party shall use the Confidential Information only for purposes of this Agreement, and shall disclose Confidential Information only to employees, consultants, subcontractors or agents who are bound in written agreements by similar obligations of confidentiality and nonuse and who have a need to know such information in order to perform their duties or services in connection with recipient Party's obligations under this Agreement.

f) The Mutual Non-Disclosure Agreement between the Parties dated August 23, 2011 (as amended) ("CDA"), is superseded by this Agreement effective as of the date of this Agreement, and the Parties agree that all Confidential Information provided on or after the date of this Agreement will be subject to this Agreement and not the CDA.

g) All Confidential Information shall remain the property of the disclosing Party and shall be returned to the disclosing Party on termination or expiration of this Agreement. However, each Party may retain one copy of the disclosing Party's Confidential Information, as defined on section 8(d) for record keeping and legal purposes in a secure environment, provided such copy is maintained as Confidential Information.

Section 9.

Work Output

a) All reports specified in the Scope and other cGMP documentation, including the Batch Record, Certificate of Analysis, and the Batch Packet ("Work Output") will be prepared using Fujifilm's standard format(s) unless otherwise specified in the Scope.

b) Sponsor will be supplied with copies of Work Output generated as a result of the Program as set forth in the Scope or Quality Agreement. All Work Output and Product samples will be archived by Fujifilm for a period of [* * *] years following completion of the Program unless otherwise defined by the Program or required by applicable U.S. laws or regulations. [* * *] after completion of the Program, Work Output and Product samples will be sent to Sponsor and a return fee will be charged. Sponsor may elect to have the materials retained in the Fujifilm archives for an additional period of time at additional cost to Sponsor. If Sponsor chooses to have Fujifilm dispose of Work Output and Product samples, a disposal fee will be charged. Notwithstanding the foregoing, Fujifilm will continue to retain such written materials and Product samples as required by regulations and as may be required by law, pertaining to such activities as well as for archival purposes.

Section 10.

Inventions and Patents

a) "New IP" means any and all intellectual property that is made, created, conceived and/or reduced to practice (1) in the course of performing under this Agreement; and/or (2) which utilizes Sponsor Confidential Information and/or is specifically related thereto;

and/or (3) which utilizes Drug Substance and/or Drug Product, and/or is specifically related thereto; and/or (4) is specifically related to the manufacture or uses of the Drug Substance and/or Drug Product, in any of cases (1), (2), (3) or (4) whether made, created, conceived and/or reduced to practice solely by Fujifilm or jointly by Fujifilm and Sponsor or others, and excluding Fujifilm Project IP. Fujifilm shall promptly disclose to Sponsor any and all New IP reported to Fujifilm by its employees, Subcontractors and agents or which Fujifilm otherwise becomes aware of. New IP is deemed to be Sponsor Confidential Information. Sponsor shall solely own all right, title and interest in any and all New IP. Fujifilm hereby assigns all right, title and interest in the New IP to Sponsor free and clear of all liens, claims and encumbrances. If Sponsor requests and at Sponsor's expense, Fujifilm will execute any and all applications, assignments or other instruments and give testimony which shall be necessary to apply for and obtain Letters of Patent of the US or of any foreign country with respect to the New IP and Sponsor shall compensate Fujifilm for the time devoted to such activities and reimburse it for expenses incurred. For New IP assigned pursuant to this section, Sponsor shall provide Fujifilm a royalty-free license necessary to perform each Program for the term of this Agreement. Subject to the terms and conditions of this Agreement, Sponsor hereby grants to Fujifilm an irrevocable, fully paid, non-exclusive license, under any New IP that is related to and/or capable of being applied to products and/or processes other than the Manufacturing Process, Drug Substance, Drug Product and/or the manufacture thereof, to practice such New IP: (i) for Fujifilm's internal research purposes, and (ii) with the prior written consent of Sponsor, which may be granted or withheld in its sole discretion, on request from time to time by Fujifilm, in connection with third party products and/or processes; provided that for clarification, in no case may Fujifilm use New IP in connection with products and processes that are competitive with, and/or for the same indication as, Manufacturing Process, Drug Substances, Drug Products and/or the manufacture thereof.

b) With respect to any Manufacturing Process or portion thereof that is developed by Fujifilm hereunder, whether made, created, conceived and/or reduced to practice solely by Fujifilm or jointly by Fujifilm and Sponsor or others, Sponsor shall own such Manufacturing Process in accordance with Section 10(a); provided that Fujifilm retains the right to use any pre-existing Fujifilm intellectual property in any underlying process, protocol, technology, know-how or the like in conducting its laboratory and manufacturing operations and activities, and all rights, title and interest in and to any Fujifilm intellectual property rights therein. Fujifilm hereby grants to Sponsor an irrevocable, fully paid, non-exclusive license, with the right to grant and authorize sublicenses, under any and all Fujifilm intellectual property that Fujifilm incorporates into any Manufacturing Process, and/or that is necessary to the practice of the Manufacturing Process, and/or to the generation of the Working Cell Bank, to practise such Fujifilm intellectual property for the sole and limited purpose of using Product produced hereunder for research and development and/or clinical trial purposes, and/or the practise of the Manufacturing Process by or on behalf of Sponsor or a Sponsor sublicensee for the manufacture of Drug Substance and Drug Product for use and/or sale by or on behalf of Sponsor or its sublicensee.

c) "Fujifilm Project IP" means any and all intellectual property that is made and/or created in the course of performing under this Agreement, whether made and/or created solely by Fujifilm or jointly by Fujifilm and Sponsor or others, which utilizes, relates generally to or is based on Existing Fujifilm IP (and not utilizing or specifically related to Sponsor Confidential Information, Drug Substance, Drug Product, and/or the Manufacturing Process and/or not otherwise specifically related to the manufacture or uses of the Drug Substance and/or Drug Product). "**Existing Fujifilm IP**" means Fujifilm's current and/or future business and operating intellectual property for conducting laboratory and/or GMP or non-GMP manufacturing services (but such Fujifilm Project IP and Existing Fujifilm IP is included in Fujifilm intellectual property and so shall be subject to the license granted in Section 10(b). Fujifilm shall solely own all right, title and interest in any and all Fujifilm Project IP.

d) Fujifilm will advise Sponsor in writing in reasonable detail of the technical processes it will use in the Manufacturing Process, including any Third Party rights and/or in-licenses that, to Fujifilm's knowledge, are required.

e) In the event Fujifilm must purchase any Designated Equipment required specifically for Sponsor's Program and Sponsor reimburses Fujifilm for the cost of such Designated Equipment, Sponsor shall own all right, title and interest in and to any and all such Designated Equipment. All Designated Equipment shall be maintained by Fujifilm per Fujifilm's maintenance program.

f) Sponsor reserves the right to use data during the course of a Program or Scope to support applications necessary to apply for and obtain Letters of Patent of the U.S. or any foreign country with respect to New IP so long as no information which Sponsor is required to keep confidential under this Agreement is disclosed in any such application.

Section 11.

Independent Contractor

Fujifilm shall perform the Program as an independent contractor of Sponsor and shall have complete and exclusive control over its facilities, equipment, employees and agents. The provisions of this Agreement shall not be construed to establish any form of partnership, agency or other joint venture of any kind between Fujifilm and Sponsor, nor to constitute either Party as the agent, employee or legal representative of the other. All persons furnished by either Party to accomplish the intent of this Agreement shall be considered solely as the furnishing Party's employees or agents and the furnishing Party shall be solely responsible for compliance with all laws, rules and regulations involving, but not limited to, employment of labor, hours of labor, working conditions, workers' compensation, payment of wages, and withholding and payment of applicable taxes, including, but not limited to income taxes, unemployment taxes, and social security taxes.

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Section 12.

Insurance

a) Fujifilm shall secure and maintain in full force and effect throughout the term of the Agreement and for a reasonable period thereafter policies of insurance for (a) workmen's compensation in statutory amounts, and (b) general liability, automobile liability, and product liability having policy limits, deductibles and other terms appropriate to the conduct of Fujifilm's business in Fujifilm's reasonable judgment.

b) Sponsor shall secure and maintain in full force and effect throughout the term of the Agreement and for a reasonable period thereafter policies of insurance for general liability and product liability, having policy limits, deductibles and other terms appropriate to the conduct of Sponsor's business in Sponsor's reasonable judgment.

Section 13.

Delivery

Within [* * *] following Sponsor approval (pursuant to Section 6(a) of the Batch Packet for each Production Batch, Fujifilm shall notify Sponsor and make each Batch available to Sponsor at Fujifilm's Facility. Fujifilm shall package for shipment and deliver Drug Substances, samples or other materials at Sponsor's expense and in accordance with Sponsor's full written and reasonable instructions with Sponsor bearing all packaging, shipping and insurance charges. Freight terms shall be Ex Works (Incoterms 2010). Fujifilm shall retain representative samples of Drug Substances and raw materials for record keeping, testing and regulatory purposes as mutually agreed in the Scope or Quality Agreement. Sponsor shall provide for shipping within sixty (60) calendar days of completion of manufacturing. In the event of any delay by Sponsor in shipping one or more shipments of Drug Substances in accordance with this Section 13, the Parties acknowledge and agree that liability and risk of loss for each such shipment of Drug Substances shall automatically transfer to (and be assumed by) Sponsor effective upon expiration of the applicable sixty (60) day period. If Sponsor requires a longer period for shipping, Sponsor must make arrangements with Fujifilm or a third party for storage on Sponsor's behalf and at Sponsor's expense.

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Section 14.

Default/Limitation of Warranty

a) If Fujifilm is in default of its material obligations under this Agreement and/or a Program and/or a Scope, then Sponsor shall promptly notify Fujifilm in writing of any such default. Fujifilm shall have a period of **[* * *]** from the date of receipt of such notice within which to cure such default; provided that if such default is not capable of being cured within such **[* * *]** period, on written request received within the **[* * *]** period with a detailed explanation of efforts that have been made and will be made to cure, the cure period shall be extended for such amount of time as may be reasonably necessary to cure such breach **[* * *]**, so long as Fujifilm is making diligent efforts to cure. If Fujifilm fails to cure such breach [* * *], then this Agreement shall, at Sponsor's option, immediately terminate. Termination does not relieve Sponsor from its payment obligation for work already performed or costs already committed as described in Section 21(b)(i) and (ii).

b) If Sponsor is in default of its material obligations under this Agreement and/or a Program and/or a Scope, then, Fujifilm shall promptly notify Sponsor in writing of any such default. Sponsor shall have a period of **[* * *]** from the date of receipt of such notice within which to cure such default; provided that if such default is not capable of being cured within such **[* * *]** period, on written request received within the **[* * *]** period with a detailed explanation of efforts that have been made and will be made to cure, **[* * *]**, so long as Sponsor is making diligent efforts to cure. If Sponsor fails to cure such breach [* * *], this Agreement may, at Fujifilm's option, immediately terminate.

c) Notwithstanding anything herein to the contrary, except for damages included in a third party claim covered by the indemnification obligations in this Agreement or arising out of, resulting from or relating to breach of Section 8 *Confidentiality* or Article 10 *IP* or other unauthorized use of the other Party's intellectual property or Confidential information: (i) **UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE ENTITLED TO INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES ARISING IN CONNECTION WITH THE DEFAULT OR BREACH OF ANY OBLIGATION OF THE OTHER PARTY UNDER THIS AGREEMENT, THE SCOPE OR ANY DOCUMENTS OR APPENDICES RELATED THERETO, and (ii) EACH OF FUJIFILM'S AND SPONSOR'S MAXIMUM LIABILITY FOR DAMAGES IN CONNECTION WITH A CLAIM RELATED TO THIS AGREEMENT, REGARDLESS OF THE CAUSE OF ACTION, WILL NOT EXCEED AN AMOUNT EQUAL TO [* * *].**

d) **EXCEPT AS EXPRESSLY STATED HEREIN, NEITHER PARTY PROVIDES TO THE OTHER PARTY HERETO ANY WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE CONFIDENTIAL INFORMATION, MATERIALS AND SERVICES PROVIDED HEREUNDER, AND ALL SUCH WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE ARE WAIVED. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT INCLUDING ANY SCOPE, PROGRAM PRICE AND PAYMENT SCHEDULE OR**

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QUALITY AGREEMENT, INCLUDING THE WARRANTIES AND OTHER OBLIGATIONS OF FUJIFILM, FUJIFILM MAKES NO OTHER WARRANTIES THAT THE EXECUTION OF THE SCOPE WILL RESULT IN ANY SPECIFIC QUANTITY OR QUALITY OF DRUG SUBSTANCE OR DRUG PRODUCT.

Section 15.

Dispute Resolution

a) In the event any dispute shall arise between Sponsor and Fujifilm with respect to any of the terms and conditions of this Agreement or the Program (whether or not cross-referencing or identifying this Section 15 as the dispute procedure); then senior executives of Sponsor and Fujifilm shall meet as promptly as practicable after notice of such dispute to resolve in good faith such dispute.

b) If Sponsor and Fujifilm are unable to satisfactorily resolve the dispute within thirty (30) days following referral to the senior executives, then such dispute shall be referred to mediation in accordance with the rules of the American Arbitration Association. The Parties shall participate in the mediation in a good faith attempt to settle the dispute. The mediation shall be held in the location determined by the mediator.

c) If mediation fails to resolve the dispute within forty-five (45) days of the initial meeting pursuant to Section 15 a) above, then such dispute shall be finally settled by an arbitrator in accordance with this Section 15; provided that if the dispute relates to the scope, inventorship, validity and/or infringement of any intellectual property rights, the Parties shall litigate the dispute unless otherwise agreed in writing. The arbitration will be held in the location determined by the arbitrator, and except as noted below, shall be conducted in accordance with the rules of the American Arbitration Association, applying the applicable substantive laws in accordance with Section 25, by a neutral arbitrator agreeable to both Parties if the dispute involves less than $1,000,000, and by a panel of three (3) neutral arbitrators if greater than that amount. If the Parties do not agree on an arbitrator within thirty (30) days of the end of the mediation period, the American Arbitration Association shall appoint an arbitrator to hear the case in accordance with its rules. The arbitrator shall have no authority to award consequential, punitive or exemplary damages or to vary from or ignore the terms of this Agreement and shall be bound by controlling law. Finally, notwithstanding anything to the contrary in this Agreement, at any time each of the Parties may seek judicial intervention for emergency relief, such as restraining orders and injunctions where appropriate.

d) Subject to Section 15(e), any decision by the arbitrator shall be binding upon the Parties and may be entered as final judgment in any court having jurisdiction. The cost of any arbitration proceeding shall be borne by the Parties, as the arbitrator shall determine if the Parties have not otherwise agreed. The arbitrator shall render their final decision in writing to the Parties.

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e) Each Party agrees to the American Arbitration Association's Optional Appellate Arbitration Rules, and either Party may appeal an arbitration award that has been rendered pursuant to the applicable Arbitration Rules and has become final. Such appeal must be filed with notice given to the other side within ninety (90) days after the date of receipt by such Party of the Arbitrator's decision. The cost of any appellate arbitration proceeding shall be borne by the Parties, as the arbitrator shall determine if the Parties have not otherwise agreed. The appellate arbitrators shall render their final decision in writing to the Parties.

Section 16.

Indemnification

a) Fujifilm shall indemnify Sponsor and its affiliates and their respective officers, directors and employees from any loss, cost, damage or expense ("Loss") from any lawsuit, action, claim, demand, assessment or proceeding ("Claim") arising from, related to or as a result of: (i) Fujifilm's violation of any applicable law, rule, regulation or ordinance in Fujifilm's performance of this Agreement; (ii) Fujifilm's negligence, gross negligence or intentional misconduct or inaction in Fujifilm's performance of this Agreement; (iii) Fujifilm's violation, non-compliance or non-performance of any of the terms of this Agreement, (iv) the infringement or alleged infringement in the United States arising from Fujifilm's performance of the services to Sponsor under this Agreement on the intellectual property rights of a third party [* * *]; and/or (v) third party personal injury or property damage to [* * *]; provided that if such Loss or Claim arises in whole or in part from Sponsor's negligence, gross negligence or intentional misconduct or inaction, then the amount of the Loss that Fujifilm shall indemnify Sponsor for pursuant to this Section 16 shall be reduced by an amount in proportion to the percentage of Sponsor's responsibilities for such Loss determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties.

b) Sponsor shall indemnify Fujifilm and its affiliates and their respective officers, directors and employees from any Claim and/or Loss arising from or related to: (i) Fujifilm's proper involvement with the Sponsor Deliverables; (ii) Sponsor's violation of any applicable law, rule, regulation or ordinance in Sponsor's performance of this Agreement; (iii) the negligence, gross negligence or intentional misconduct or inaction of Sponsor in Sponsor's performance of this Agreement; (iv) the infringement or alleged infringement in the United States arising from [* * *] use of Sponsor Deliverables including the Manufacturing Process provided by Sponsor to Fujifilm in accordance with this Agreement, or the use, import, export or sale of the Drug Product in the United States, on the intellectual property rights of a third party, except to the extent falling within Section 16(a); or, (v) Sponsor's violation, non-compliance or non-performance of any of the terms of this Agreement; or (vi) third party personal injury or property damage arising from Conforming Product or for [* * *]; provided that if such Loss or Claim arises in whole or in part from Fujifilm's negligence, gross negligence or intentional misconduct or inaction, then the amount of such Loss that Sponsor shall indemnify Fujifilm for pursuant to this Section 16 shall be reduced by an amount in proportion to the

percentage of Fujifilm's responsibilities for such Loss as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties.

c) Upon receipt of notice of any Claim which may give rise to a right of indemnity from the other Party hereto, the Party seeking indemnification (the "Indemnified Party") shall give written notice thereof to the other Party, (the "Indemnifying Party") with a Claim for indemnity ("Indemnity Claim"). Any delay or failure to give notice shall not discharge the duty of the Indemnifying Party to indemnify except to the extent it is prejudiced by such delay or failure. Such Claim for indemnity shall indicate the nature of the Claim and the basis therefore. Promptly after a Claim is made for which the Indemnified Party seeks indemnity, the Indemnified Party shall permit the Indemnifying Party, at its option and expense, to assume the complete defense of such Claim, provided that (i) the Indemnified Party will have the right to participate in the defense of any such Claim at its own cost and expense, and (ii) the Indemnifying Party will, prior to making any settlement, consult with the Indemnified Party as to the terms of such settlement and receive approval thereof, not to be unreasonably withheld. The Indemnified Party shall have the right, at its election, to release and hold harmless the Indemnifying Party from its obligations hereunder with respect to such Claim and assume the complete defense of the same in return for payment by the Indemnifying Party to the Indemnified Party of the amount of the Indemnifying Party's settlement offer. The Indemnifying Party will not, in defense of any such Claim, except with the consent of the Indemnified Party, consent to the entry of any judgment or enter into any settlement which does not include as an unconditional term thereof, the giving by the claimant or plaintiff to the Indemnified Party of a release from all liability in respect thereof. After notice to the Indemnified Party of the Indemnifying Party's election to assume the defense of such Claim, the Indemnified Party shall reasonably cooperate with the Indemnifying Party, who shall be liable to the Indemnified Party for such legal or other expenses subsequently incurred by the Indemnified Party in connection with the defense thereof at the request of the Indemnifying Party. As to those Claims with respect to which the Indemnifying Party does not elect to assume control of the defense, the Indemnified Party will afford the Indemnifying Party an opportunity to participate in such defense at the Indemnifying Party's own cost and expense, and will not settle or otherwise dispose of any of the same without the consent of the Indemnifying Party.

Section 17.

Representations and Warranties

a) Each Party represents and warrants to the other that it has the full right and authority to enter into this Agreement and to perform in accordance with the terms and conditions set forth herein.

b) Each Party represents and warrants to the other that neither it nor any of its officers, directors, or its employees performing services under this Agreement has been debarred, or convicted of a crime which could lead to debarment, under the Generic

Drug Enforcement Act of 1992, 21 United States Code §§335(a) and (b) or Section 306(b)(1)(b) of the FDC Act.

c) Each Party represents and warrants to the other Party that it has obtained and will at all times during the term of this Agreement, hold and comply with all licenses, permits and authorizations necessary to perform this Agreement as now or hereafter required under any applicable statutes, laws, ordinances, rules and regulations of the United States and any applicable foreign, state, and local governments and governmental entities.

d) Sponsor hereby represents and warrants to Fujifilm that to the best of its knowledge, it has legal title and/or a valid license to the Cell Line, Sponsor Confidential Information and the Drug Substance necessary to conduct the Program and that to the best of its knowledge, the Sponsor Deliverables and Drug Substance when used by Fujifilm in the United States in the Manufacturing Process in accordance with this Agreement will not infringe on the intellectual property rights of a third party.

e) Sponsor hereby represents and warrants to Fujifilm that it has the full right and authority to grant the purchase money security interest indicated in Section 5 hereof.

f) Fujifilm represents and warrants to Sponsor that to the best of its knowledge, Fujifilm has legal title and/or a valid license to Existing Fujifilm IP necessary to conduct the Program and that to the best of its knowledge, the Existing Fujifilm IP when used in the United States will not infringe on the intellectual property rights of a third party.

g) Fujifilm represents and warrants to Sponsor that each Production Batch of Drug Substance delivered to Sponsor hereunder: (i) was manufactured and analyzed in conformance with the [* * *], the Product Specifications and Quality Agreement; (ii) was manufactured in compliance with the requirements of cGMP and all applicable laws and regulations; (iii) was [* * *]; (iv) is not subject to [* * *]; and (v) was transferred free and clear of any liens or encumbrances of any kind to the extent arising through or as a result of the acts or omissions of Fujifilm, its Subcontractors, consultants or agents.

h) Fujifilm represents and warrants that it lawfully controls operations in the Fujifilm Facility, and will maintain the Fujifilm Facility and ensure that any Subcontractor facility will be maintained, in accordance with cGMP and in such condition as will allow Fujifilm to manufacture the Drug Substance(s) in compliance with cGMP and in conformance with the applicable Master Manufacturing Record, Quality Agreement and all applicable statutes, laws, ordinances, rules and regulations of the United States and any applicable foreign, state, and local governments and governmental entities.

i) Sponsor represents and warrants to Fujifilm that the Master Cell Bank supplied to Fujifilm will, at the time of delivery, meet the sterility, mycoplasma and [* * *] specifications in the quality control documentation for such Master Cell Bank. Provided that the foregoing representation and warranty is satisfied, Fujifilm represents and warrants to Sponsor that the Working Cell Bank generated by Fujifilm from the Master

Cell Bank will, at the time of production and release, meet the sterility, mycoplasma and [* * *] specifications included in the quality control documentation for the Working Cell Bank. Fujifilm represents and warrants that it will store and handle the Working Cell Bank in accordance with mutually agreed conditions to ensure that the sterility, mycoplasma and [* * *] specifications continue to be met whilst the Working Cell Bank is in Fujifilm's possession.

Section 18.

Force Majeure

Either Party shall be excused from performing its respective obligations under this Agreement if its performance is delayed or prevented by any event beyond such Party's reasonable control, including, but not limited to, acts of God, fire, explosion, weather, disease, war, insurrection, civil strife, riots, government action, acts of terrorism or power failure, provided that such performance shall be excused only to the extent of and during such disability. The Party subject to such event shall promptly notify the other Party of the occurrence thereof and, if known, the expected duration. Any time specified or estimated for completion of performance in the Scope falling due during or subsequent to the occurrence of any or such events shall be automatically extended for a reasonable period of time to recover from such disability. Fujifilm will promptly notify Sponsor if, by reason of any of the events referred to herein, Fujifilm is unable to meet any such time for performance specified or estimated in the Scope, and Fujifilm will use commercially reasonable efforts to overcome the event and [* * *].

Section 19.

Allocation of Resources

If delays in the agreed commencement or performance of the Program occur or are anticipated because of Sponsor's request or inability to supply Fujifilm with agreed Sponsor Deliverables set forth in the applicable Program Scope required to begin or perform the Program within twenty (20) days after such agreed time, Fujifilm shall immediately notify Sponsor, and the Joint Steering Committee shall convene to determine the reasonable course of action. If the delay shall continue for more than ten (10) business days after the Joint Steering Committee meeting without resolution, the dispute shall be escalated as provided in Section 15 and Fujifilm may reallocate resources being held for performance of the Program without incurring liability to Sponsor for the period of any anticipated delay. In addition, upon such delay being removed or remedied, Fujifilm will use commercially reasonable efforts to promptly allocate resources to performance of the Program as set forth in the Scope. The parties acknowledge that Fujifilm has allocated resources to the Program that may be difficult or impractical to reallocate to other programs in the event of a delay solely attributable to Sponsor's activities. In recognition of this, Sponsor and Fujifilm shall discuss a Change Order to compensate Fujifilm for any idled personnel or capacity not reallocated despite Fujifilm's diligent efforts to reallocate personnel and capacity and to mitigate any loss.

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Section 20.

Use of Names

The Parties anticipate opportunities for joint or independent press releases or other announcements relating to the activities contemplated hereby. Notwithstanding the foregoing, neither Party shall use the name of the other Party or the names of the employees of the other Party in any advertising or sales promotional material or in any publication without prior written permission of such Party. Such consent may not be unreasonably withheld.

Section 21.

Term/Termination

a) This Agreement shall take effect on the date first written above and continue in effect for a period of ten (10) years. Each Program and Scope shall remain in effect from the date of its execution by both Parties until Completion of the Program or Scope or termination of the Program or Scope as provided in this Section 21.

b) In addition to the termination rights set forth in Section 14, Sponsor may at any time terminate this Agreement, or any Program, Scope or Run prior to Completion by giving thirty (30) days written notice to Fujifilm. In the event Sponsor elects to terminate for convenience under this Section 21(b) or in the event that Fujifilm rightfully terminates this Agreement pursuant to Section 14, Sponsor shall pay Fujifilm upon receipt of Fujifilm's invoice and Fujifilm's compliance with Section 21(h), the following amounts:

(i) All amounts owed for work Completed but not yet invoiced; plus

(ii) All unpaid third party costs incurred, or committed and non-cancelable, for Process Consumables, provided that Fujifilm shall use its commercially reasonable efforts to cancel open orders or return any unused Process Consumables; plus if applicable

(iii) A termination fee calculated as follows, which shall be [* * *] for any particular [* * *] based on the duration between the date of Sponsor's notice to Fujifilm and the Start Date of such Run, as follows:

(1) For cancellation more than **[* * *]** in advance of **[* * *]**;

(2) For cancellation during the **[* * *]** period but more than **[* * *]** in advance of [* * *]; and

(3) For cancellation during the **[* * *]** period but more than **[* * *]** in advance of **[* * *]**; and

(4) For cancellation during the **[* * *]** period but more than **[* * *]** in advance of or during **[* * *]**.

(5) For cancellation during the **[* * *]** period in advance of or during **[* * *]**.

(6) **[* * *]** are due for cancellation of [* * *] or other [* * *] prior to commencement of Demonstration Batch. Following commencement of [* * *], the cancellation fee for the [* * *] shall be **[* * *]**. Upon cancellation of all other Non-Manufacturing activities, other than process characterization, scheduled post [* * *], Sponsor shall pay **[* * *]** as set forth in the Scope or [* * *], less in each case any prepaid fees and expenses for such activities, unless otherwise specified in applicable Scope.

(7) [* * *], and the remaining after offset against payments as provided in [* * *] shall be applied by Fujifilm against any [* * *] under Section 21(b)(iii).

c) No cancellation fees are due in the event of any of the following:

(i) [* * *].
(ii) if Sponsor cancels for material breach by Fujifilm under Section 14 or as the non-affected Party in Section 21(d) or under Section 21(e); or
(iii) [* * *]; or
(iv) [* * *] for this reason.

d) The non-affected Party shall have the right to terminate a Program, Scope, Run or this Agreement without penalty, including without payment of any termination fee, by providing written notice thereof to the affected Party, such termination to be effective [* * *] from the date of such notice, if, as a result of a force majeure event (as described in Section 18), an affected Party is unable fully to perform its obligations under the Program, Scope, Run or this Agreement for any consecutive period of [* * *].

e) Further, if any change in circumstance occurs during the term to make the warranty in [* * *] inaccurate, Fujifilm shall notify Sponsor in writing immediately, including a reasonably detailed explanation, and Sponsor shall have the right to immediately terminate this Agreement or the affected Run, Scope or Program, without penalty.

f) The expiration or termination of a Scope or this Agreement for any reason shall relieve neither Party of its obligation to the other for obligations in respect of: (i) confidentiality of information; (ii) consents for advertising purposes and publications; (iii) indemnification; (iv) inventions and patents; (v) compensation for services performed (vi) dispute resolution, and (vii) the following provisions shall survive the termination or expiration of this Agreement: Sections 1(h), 1(j), 3, 8, 9, 10 (except "New IP" for the provision of Section 10(a) with respect to the cases set out in section 10(a)(3) and 10(a)(4) will not survive after the termination or expiration of this Agreement so long as Fujifilm does not practice, infringe or misappropriate Sponsor intellectual property rights; provided that Section 10 shall survive as to all New IP arising under Section 10(a)(3)

and/or 10(a)(4) during the term of this Agreement), 11, 12, 15, 16, 17, 20, 21(f), and 25 through 28 (inclusive) and the Definitions. In addition:

(i) On expiration or termination of this Agreement any advanced payments made by Sponsor shall be applied to the total amounts then earned and due under the [* * *] (as amended to include any executed Change Orders) and as listed in Section 21(b) and any prior unpaid, undisputed invoice amounts. Fujifilm shall provide a complete final accounting within [* * *] after expiration or termination of this Agreement. Any remaining balance will be returned to Sponsor along with such accounting, and any balance due shall be paid to Fujifilm within [* * *] after receipt of invoice, in each case following Completion of the initiated or scheduled activities (if Sponsor elects to continue such activities under the terms of this Agreement after expiration or termination) and written reconciliation of Program activities and wind-down plan subject to agreement in a Change Order that shall be prepared by Alliance Managers upon termination or expiration.

(ii) Unless otherwise agreed by the Parties in writing, within [* * *] following expiration or termination of a Scope, Fujifilm shall promptly (except as may be needed to complete any Runs that are in process, if Sponsor elects to continue such activities under this Agreement after expiration or termination of a Scope) at Sponsor's sole cost and expense (i) return (or, at Sponsor's written election, destroy) all quantities of the all quantities of the Master Cell Bank, Working Cell Bank, Master [* * *] Bank and Working [* * *] Bank received or generated by Fujifilm under this Agreement, and (ii) deliver to Sponsor all reference materials being held by Fujifilm or its Subcontractors, (iii) deliver all remaining Process Consumables and works-in-process to Sponsor, and (iv) deliver all Completed Product and other deliverables.

(iii) Upon expiration or termination of a Scope or at any time upon written request of Sponsor, within [* * *], Fujifilm shall return to Sponsor any or all Sponsor Confidential Information received in tangible form in connection with the Scope, except for a single copy and/or sample which may be retained in a secure environment solely for purposes of determining Fujifilm's obligations hereunder and which shall remain subject to the obligations of nonuse and confidentiality set forth in this Agreement.

(iv) Upon expiration or termination of a Scope or at any time upon written request of Fujifilm, within [* * *], Sponsor shall return to Fujifilm any or all Fujifilm Confidential Information, (for clarity, Work Output is Sponsor Confidential Information), received in tangible form in connection with the Scope, except for a single copy and/or sample which may be retained in a secure environment solely for purposes of determining Sponsor's obligations hereunder and which shall remain subject to the obligations of nonuse and confidentiality set forth in this Agreement.

(v) Fujifilm shall make all Designated Equipment associated with the Scope available for transfer to Sponsor, at Sponsor's sole cost and expense, within [* * *] following expiration or termination of this Agreement. Sponsor shall be responsible for making all arrangements to recover the Designated Equipment.

(vi) Within [* * *] after termination or expiration of a Scope or this Agreement as applicable, an officer of Fujifilm and an officer of Sponsor shall certify compliance with this Section 21(f).

Section 22.

Program Management.

a) Joint Steering Committee. Effective on the Effective Date, Sponsor and Fujifilm shall establish a Joint Steering Committee (the "Joint Steering Committee") comprised of three (3) representatives designated by Sponsor and three (3) representatives designated by Fujifilm, each of whom shall have experience and seniority sufficient to enable him or her to make decisions on behalf of the party he or she represents.

b) Alliance Managers. Each party shall appoint one person to serve as an Alliance Manager (each, an "Alliance Manager") with responsibility for overseeing the day-to-day activities of the parties with respect to the Program and for being the primary point of contact between the parties with respect to the Program. The Fujifilm customer Project Leader will serve as the Fujifilm Alliance Manager. The Alliance Managers shall report to the Joint Steering Committee.

c) Replacement of Joint Steering Committee Representatives and Alliance Managers. Each party shall be free to replace its representative members on the Joint Steering Committee or its Alliance Manager with new appointees who have authority to act on behalf of such party, on notice to the other party.

(d) Responsibilities of Joint Steering Committee. The Joint Steering Committee shall be responsible for overseeing and directing the parties' interaction and performance of their respective obligations under this Agreement. Without limiting the generality of the foregoing, its duties shall include:

(i) Monitoring the performance of the Program;
(ii) Resolving disagreements that arise under the Agreement; and
(iii) Determining the need for and terms of any Change Orders.

e) Meetings. The Joint Steering Committee shall meet at such times as the Joint Steering Committee determines to resolve issues arising hereunder and to perform its responsibilities under this Agreement, provided that the Joint Steering Committee shall meet not less than four (4) times per calendar year unless otherwise mutually agreed. Such meetings may be in person or by telephone as agreed by the Joint Steering Committee. To the extent that meetings are held in person, they shall alternate between

the offices of the parties unless the parties agree otherwise. The Alliance Managers shall attend all meetings of the Joint Steering Committee. The objective of the Joint Steering Committee is that all decisions shall be unanimous. In addition, the Vice President of Development for Sponsor and the Vice President of Business Development of Fujifilm, or designated Fujifilm Program sponsor, shall convene on a monthly basis in person or by teleconference to discuss any issues, problems or other matters that cannot be resolved by the Parties' Alliance Managers as well as to monitor the general progress of the Program.

f) Administration. The chairperson of the Joint Steering Committee shall be designated every six months on an alternating basis between the parties. The initial chairperson will be selected by Fujifilm. The chairperson shall be responsible for calling meetings, sending notices of meetings and for leading such meetings.

g) Minutes. Within [* * *] after each Joint Steering Committee meeting, the Alliance Manager for the party whose representative chaired the Joint Steering Committee meeting shall prepare and distribute minutes of the meeting, which shall provide a description in reasonable detail of the discussions had at the meeting and a list of any actions, decisions or determinations approved by the Joint Steering Committee. Minutes shall be approved or disapproved and revised, as necessary, at the next meeting. Final minutes shall be distributed to the members of the Joint Steering Committee.

h) Dispute Resolution. In the event that the Joint Steering Committee cannot reach agreement with respect to any material issue, then the issue shall be resolved in accordance with the dispute resolution provisions in Section 15.

i) Limitations. The Joint Steering Committee is not empowered to amend the terms of this Agreement.

Section 23.

Assignment

This Agreement shall not be assigned in whole or in part by either Party without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed. Any attempt to assign this Agreement without such consent shall be void and of no effect. Notwithstanding the foregoing, either Party shall be entitled, without the prior written consent of the other Party, to assign all or a part of its rights under this Agreement to an affiliate, or to assign all of its rights under this Agreement to a purchaser of all or substantially all of its assets, or an entity with which it may merge where it is not the surviving company, provided that in each case within [* * *] after the closing, the affiliate, purchaser or the assignee agrees in writing to assume all obligations undertaken by its assignor in this Agreement. No assignment shall relieve the assigning Party of responsibility for the performance of any of its obligations hereunder. The terms of this Agreement shall inure to the benefit of successors and assigns.

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [* * *] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Section 24.

Notice

All notices to be given as required in this Agreement shall be in writing and shall be delivered personally, sent by telecopies, or mailed either by a reputable overnight carrier or first class mail, postage prepaid to the Parties at the addresses set forth below or such other addresses as the Parties may designate in writing. Such notice shall be effective on the date sent, if delivered personally or sent by telecopier, the date after delivery if sent by overnight carrier and on the date received if mailed first class.

If to Sponsor:

President
Genocea Biosciences, Inc.
Cambridge Discovery Park
100 Acorn Park Drive, 5th floor
Cambridge, MA 02140
Tel: 617-876-8191
Fax: 617-876-8192

If to Fujifilm:

President
Fujifilm Diosynth Biotechnologies
101 J. Morris Commons Lane
Morrisville, NC 27560
P: 919-337-4404
F: 919-337-0899

With copies to:

General Counsel
Fujifilm Diosynth Biotechnologies
Belasis Avenue, Billingham, TS23 1LH, United Kingdom
F: +44 1642 364463

Assistant General Counsel
FUJIFILM Holdings America Corporation
200 Summit Lake Drive
Valhalla, New York 10595-1356
F: 914-789-8514

Section 25.

Choice of Law

a) This Agreement shall be construed and enforced in accordance with the laws of and in the venue of the State of Delaware except for its rules regarding conflict of laws. Subject to

Section 15, all actions related to or arising out of this Agreement shall be brought in the state or federal courts located in Delaware, and each Party submits to the exclusive jurisdiction of such courts, except that the U.S. Court of Appeals for the Federal Circuit, or similar non-U.S. tribunal for patent matters outside the United States, shall have exclusive jurisdiction with regard to the inventorship, scope or validity of any patent rights.

b) Each recipient Party agrees that the disclosing Party might be irreparably injured by an actual or threatened material breach of Section 8 and/or Section 10 of this Agreement by the recipient Party, and without prejudice to any other rights and remedies otherwise available to the other Party, the recipient Party agrees, upon proof of any such actual or threatened material breach, to the granting of equitable relief, including injunctive relief and specific performance, in the other Party's favor without proof of actual damages or posting of bond or other security, subject to the court's discretion.

Section 26.

Waiver/Severability

No waiver of any provision of this Agreement, whether by conduct or otherwise, in any one or more instances shall be deemed to be or be construed as a further or continuing waiver of any such provision, or of any other provision or condition of this Agreement. If any provisions hereof shall be determined to be invalid or unenforceable, the validity and effect of the other provisions of this Agreement shall not be affected thereby.

Section 27.

Nonsolicitation

For the term of this Agreement, and for [* * *] following termination of this Agreement, for any reason, neither Sponsor nor Fujifilm nor any of their employees or agents shall, directly or indirectly, solicit, hire, or attempt to solicit or hire, any employees of the other who were involved in the Program, unless otherwise approved by the other Party; provided that nothing herein shall restrict either Party from indirectly soliciting any such employees or agents by general employment advertising or third party employment agencies.

Section 28.

Entire Agreement; No implied Rights; Interpretation; Modification/Counterparts

a) This instrument including the attached Appendices sets forth the entire agreement between the Parties hereto with respect to the performance of the Program by Fujifilm for Sponsor and the other subject matter hereof and as such, supersedes all prior and contemporaneous negotiations, agreements, representations, understandings, and commitments with respect thereto , including the CDA as to Confidential Information exchanged after the Effective Date of this Agreement; and shall take precedence over all terms, conditions and provisions on any purchase order form or form of order acknowledgment or other document purporting to address the same subject matter. Except as expressly provided in Section 10 hereof, no right or license, either express or implied, is granted under any intellectual property right or by virtue of the disclosure of

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [* * *] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Confidential Information under this Agreement, or otherwise. Nothing in this Agreement shall be construed to limit a Party's remedies for use of its intellectual property or materials by the other Party outside of the use expressly permitted herein. The terms of this Agreement Sections 1 through 28 shall prevail in the event of a conflict between this Agreement Sections 1 through 28 and any of its Appendices. All headings in this Agreement are for convenience of reference only and shall not affect the interpretation of this Agreement. The term "includ(ing)(e/es)" and correlatives means "includ(ing)(e/es) without limitation." This Agreement shall not be waived, released, discharged, changed or modified in any manner except by an instrument signed by the duly authorized officers of each of the Parties hereto, which instrument shall make specific reference to this Agreement and shall express the plan or intention to modify same.

b) This Agreement may be executed in one or more counterparts each of which shall be deemed an original but all of which together shall constitute one and the same instrument. A PDF signature document shall be deemed to be and shall be as effective as an original signature document.

c) This Agreement becomes effective and binding on both Parties on and as of the last date that the Parties hereto have executed this Agreement. Should terms contained herein be at variance with the terms and conditions specified in Sponsor's written acceptance, then the terms and conditions contained herein take precedence.

Genocea Biosciences, Inc.

By: /s/ William D. Clark

Name: William D. Clark

Title: President and CEO

Date: 2/28/14

FUJIFILM Diosynth Biotechnologies U.S.A., Inc.

By: /s/ M.E. Meeson

Name: M.E. Meeson

Title: Senior Vice President of Finance

Date: 2/26/14

FUJIFILM Diosynth Biotechnologies U.S.A., Inc.

By: /s/ Stephen Spearman

Name: Stephen Spearman

Title: President

Date: 2/26/14

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APPENDICES:

Appendix 1-A: Scope of Work
Appendix 2: Quality Agreement
Appendix 3-A: Price and Payment Schedule

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APPENDIX 1-A

Scope of Work for Phase 2 Manufacturing of
[* * *]

Genocea Biosciences, Inc.
Cambridge Discovery Park, 100 Acorn Park Drive, 5th Floor, Cambridge, MA 02140

FUJIFILM Diosynth Biotechnologies U.S.A., Inc.
101 J. Morris Commons Lane Morrisville, North Carolina 27560

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[†]

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Appendix 2

FUJIFILM Diosynth Biotechnologies — Genocea Biosciences, Inc.
Clinical Material Manufacturing Quality Agreement

Table of Contents

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FUJIFILM Diosynth Biotechnologies — Genocea Biosciences, Inc.
Clinical Material Manufacturing Quality Agreement

General Information

This Quality Agreement outlines the roles, responsibilities and time requirements with respect to the Quality Assurance of the Intermediate and/or Drug Substance produced by FUJIFILM Diosynth Biotechnologies U.S.A., Inc. (referred to in this Quality Agreement as "Fujifilm") or FUJIFILM Diosynth Biotechnologies UK Limited (FDBK) (collectively referred to as FFDB) for Genocea Biosciences, Inc. (here within known as "Sponsor") and fulfils the requirements as outlined in ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients. In addition, Fujifilm may perform [* * *] as outlined within the Agreement. The product(s) covered by this Quality Agreement are listed in Attachment C.

The Quality Agreement is an appendix to the Bioprocessing Services Agreement (Agreement) executed by Sponsor and Fujifilm.

Unless otherwise defined specifically in this Quality Agreement, all general terms used herein will be interpreted in accordance with the definitions provided in the Agreement. Any terms not so defined will be interpreted with the definitions so stated in ICH Q7 or 21 CFR Parts 210, 211, 600, & 610.

The Authorized Quality Representatives will resolve any disputes or conflicts relating to this Quality Agreement in a timely and equitable manner and in compliance with all applicable quality and regulatory requirements. Such resolutions shall be [* * *] by the Authorized Quality Representatives of each company. If any issue remains unresolved for more than twenty (20) business days, the senior corporate Quality officials from each company should be contacted to resolve this issue. In the event the parties fail to reach agreement on such issue within thirty (30) calendar days after notice is provided to the senior corporate Quality officials, then such dispute shall be resolved according to the provisions as detailed in the Agreement.

All communication affecting the contents of this Quality Agreement will be between the Authorized Quality Representatives, as set forth below:

For Sponsor: Matthew Curtis, Director of Regulatory Affairs

For FFDB: David Patterson, Sr. Vice President, Quality Operations

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Signatures

Sponsor Authorized Quality Assurance Representative

By: /s/ Matthew Curtis Date: 2/28/14
(Signature)

Name: Matthew Curtis
Tel.: [* * *]
Cell: [* * *]
Email: [* * *]

Address: Genocea Biosciences
Cambridge Discovery Park
100 Acorn Park Drive, 5th Floor
Cambridge, MA 02140

FFDB Authorized Quality Assurance Representative

By: /s/ David Patterson Date: 2/26/14
(Signature)

Name: David Patterson
Tel.: [* * *]
Email: [* * *]

Address: FUJIFILM Diosynth Biotechnologies U.S.A., Inc.
101 J. Morris Commons Lane
Morrisville, North Carolina, USA, 27560

Confidential

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [* * *] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. WHERE TWENTY-ONE PAGES OF MATERIAL HAVE BEEN OMITTED, THE REDACTED MATERIAL IS MARKED WITH [●].

Quality Responsibilities Table

The responsible party is denoted by ✔

Description	FFDB (time frame)	Sponsor (time frame)
[●]		

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Attachments

Attachment A — Batch Packet Documentation

[* * *]

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Attachment B — Master Documents

Master Documents include:

[* * *]

Master Documents requiring Sponsor review and approval:

[* * *]

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Attachment C — Product List

Product	Site
[* * *]	

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Attachment D — Definitions

API	Active Pharmaceutical Ingredient, may be used interchangeably with Drug Substance.
Approved Supplier	A supplier who has met minimum approval standards and who has been approved to provide required items or services that may impact product quality.
Authorized Quality Representatives	An individual named within the Quality Agreement with the authority to resolve any disputes or conflicts relating to this Quality Agreement in a timely and equitable manner and in compliance with all applicable quality and regulatory requirements.
Batch	A specific quantity of material produced in a process or fraction of a process. Batches are defined as the material represented at the end of the intermediate processing steps or the material represented at the end of the processing step for API.
cGMP	Current Good Manufacturing Practices pursuant to (a) the U.S. Federal Food, Drug and Cosmetics Act as amended (21 USC 301 et seq.), (b) U.S. regulations in Title 21 of the U.S. Code of Federal Regulations Parts 210, 211, 600 and 610 (c) the EC Guide to Good Manufacturing Practice for Medicinal Products, v.4, including relevant sections of DIR 2003/94/EC, and (d) International Conference on Harmonization (ICH) Guidance for Industry Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.
Complaint	Any written, electronic, or oral communication by the Customer, Sponsor, or other source (e.g. fill finish manufacturing site) outside of the FFDB which expresses dissatisfaction related to the identity, strength, quality, purity, safety or effectiveness of a product manufactured by FFDB after it is dispositioned or released. This includes suspected tampering, counterfeiting or diversion.
Critical Raw Materials	Raw materials that comprise final formulation components and / or that combine structurally or chemically with the product (i.e. excipient), which has the potential to influence the properties (safety, immunogenicity) of the product.

Deviation	An unplanned event requiring investigation which 1) may affect the quality or compliance status of the product, process materials, equipment or facility involved or 2) may not be in alignment with regulatory submissions.
Disposition	A recommendation given by FFDB Quality on the suitability of the Intermediate or Drug Substance for further processing.
Drug Product	The dosage form in the final immediate packaging intended for clinical use.
Drug Substance or **DS**	Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the Drug Product. Such substances are intended to furnish pharmacological activity or other direct effect on the diagnosis, cure mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
Process Consumables	Process Consumables include any disposable equipment or equipment parts or Raw Material used in the manufacture of an intermediate or Drug Substance that do not themselves participate in a chemical or biological reaction. Such other materials include: [* * *].
Product	Any (a) API/Drug Substance, or (b) Drug Product comprised of API/Drug Substance, or (c) intermediate(s) of (a) or (b) , in each case as specified in the applicable Scope.
Raw Material	Any ingredient intended for use in the manufacture of an intermediate or API, including those that may not appear in the final formulation. These include chemicals used directly and/or indirectly in the manufacturing process.
Statement of Compliance	A FFDB QA Disposition of Product Statement stating that a specific Batch of Drug Substance complies with all Product, GMP and regulatory requirements and is signed by an authorized representative of FFDB.
Test Methods	Methods used for QC testing, including Standard Test Methods and Compendial Methods.

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APPENDIX 3-A: PROGRAM PRICE AND PAYMENT SCHEDULE

PHASE II PROGRAM PRICE

Activities	Estimated Budget
[☼]	

Pricing Assumptions:

- **[* * *]**

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ADDITIONAL SERVICES - ESTIMATES

Other Program Services - Activities	Estimated Budget 1st Antigen	Estimated Budget 2nd Antigen
[* * *]	[* * *]	

Estimate for Raw Materials/Consumables (for budgetary purpose only)

- **[* * *]**
- **[* * *]**

If needed, the cost of any capital expenditures necessary to transfer the process to Fujifilm will be communicated to Sponsor. At this time no capital expenditure is anticipated for this program.

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PAYMENT SCHEDULE

Reservation Fee

Activity/Milestone	Payment	Reservation Fee Credit	Net Payment	Estimated Invoice Date

[*****]

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14 and 15d-14
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William D. Clark, Chief Executive Officer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Genocea Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ WILLIAM D. CLARK
William D. Clark
President & Chief Executive Officer

Date: May 9, 2014

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14 and 15d-14
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jonathan Poole, Chief Financial Officer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Genocea Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e))) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ JONATHAN POOLE
Jonathan Poole
Chief Financial Officer

Date: May 9, 2014

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Genocea Biosciences, Inc. (the "Company") for the period ended March 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, William D. Clark, as the President & Chief Executive Officer of the Company, does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ WILLIAM D. CLARK
William D. Clark*
President &Chief Executive Officer

Date: May 9, 2014

* A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-Q or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Genocea Biosciences, Inc. (the "Company") for the period ended March 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Jonathan Poole, as the Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ JONATHAN POOLE
Jonathan Poole*
Chief Financial Officer

Date: May 9, 2014

*A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-Q or as a separate disclosure document.