GENOCEA BIOSCIENCES, INC.
Form 10-Q
November 01, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-36289

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

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	¨	Accelerated filer x
Non-accelerated filer	¨	Smaller reporting company ¨
		Emerging growth company x

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

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

As of October 31, 2018, there were 86,625,975 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. The words “anticipate”, “believe”, “contemplate”, “continue”, “could”, “estimate”, “expect”, “forecast”, “goal”, “intend”, “may”, “plan”, “potential”, “predict”, “project”, “should”, “target”, negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

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

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

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

Genocea Biosciences, Inc.
Form 10-Q
For the Quarter Ended September 30, 2018

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 34,494	$ 12,273
Prepaid expenses and other current assets	1,884	808
Total current assets	36,378	13,081
Property and equipment, net	2,836	3,460
Restricted cash	316	316
Other non-current assets	171	631
Total assets	$ 39,701	$ 17,488
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,276	$ 3,516
Accrued expenses and other current liabilities	4,233	5,604
Current portion of long-term debt	3,574	6,659
Total current liabilities	9,083	15,779
Non-current liabilities:		
Warrant liability	13,021	—
Long-term debt, net of current portion and discount	11,064	7,652
Other non-current liabilities	35	107
Total liabilities	33,203	23,538
Commitments and contingencies (Note 6)		
Stockholders' equity (deficit):		
Preferred stock	702	—
Common stock	87	29
Additional paid-in-capital	298,063	258,114
Accumulated deficit	(292,354)	(264,193)
Total stockholders' equity (deficit)	6,498	(6,050)
Total liabilities and stockholders' equity (deficit)	$ 39,701	$ 17,488

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$6,359	$10,155	$18,950	$31,324
General and administrative	4,101	3,750	11,682	10,955
Restructuring costs	—	2,591	—	2,591
Total operating expenses	10,460	16,496	30,632	44,870
Loss from operations	(10,460)	(16,496)	(30,632)	(44,870)
Other income (expense):				
Change in fair value of warrants	2,894	—	3,093	—
Interest expense, net	(266)	(366)	(708)	(1,094)
Other income (expense)	(1)	(6)	86	(14)
Total other income (expense)	2,627	(372)	2,471	(1,108)
Net loss	$(7,833)	$(16,868)	$(28,161)	$(45,978)
Other comprehensive loss:				
Comprehensive loss	$(7,833)	$(16,868)	$(28,161)	$(45,978)
Net loss per share - basic and diluted	$(0.09)	$(0.59)	$(0.35)	$(1.61)
Weighted-average number of common shares used in computing net loss per share	86,626	28,666	81,191	28,568

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2018	2017
Operating activities		
Net loss	$(28,161)	$(45,978)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	815	1,234
Stock-based compensation	1,702	3,268
Allocation of proceeds to transaction expenses	2,115	—
Change in fair value of warrant liability	(5,208)	—
Gain on sale of equipment	(50)	—
Write-off of deferred financing fees	355	—
Non-cash interest expense	460	383
Asset impairment	—	1,001
Changes in operating assets and liabilities	(5,085)	667
Net cash used in operating activities	(33,057)	(39,425)
Investing activities		
Purchases of property and equipment	(213)	(1,248)
Proceeds from sale of equipment	72	—
Proceeds from maturities of investments	—	36,089
Purchases of investments	—	(153)
Net cash (used in) provided by investing activities	(141)	34,688
Financing activities		
Proceeds from equity offerings, net of issuance costs	2,920	246
Proceeds from underwritten public offering, net of issuance costs	52,538	—
Payment of deferred financing costs	(127)	—
Proceeds from long-term debt	592	—
Repayment of long-term debt	(535)	(1,559)
Proceeds from exercise of stock options	—	459
Proceeds from the issuance of common stock under ESPP	31	150
Net cash provided by (used in) financing activities	55,419	(704)
Net increase (decrease) in cash and cash equivalents	$22,221	$(5,441)
Cash, cash equivalents and restricted cash at beginning of period	12,589	27,424
Cash, cash equivalents and restricted cash at end of period	$34,810	$21,983
Supplemental cash flow information		
Cash paid for interest	$786	$922
Property and equipment included in accounts payable and accrued expenses	$—	$33
Reclassification of warrants to additional paid-in capital	$190	$—

See accompanying notes to unaudited condensed consolidated financial statements.

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

1. Organization and operations

The Company

Genocea Biosciences, Inc. (the “Company”) is a biopharmaceutical company that was incorporated in Delaware on August 16, 2006 and has a principal place of business in Cambridge, Massachusetts. The Company seeks to discover and develop novel cancer vaccines and immunotherapies through its AnTigen Lead Acquisition System ("ATLAS"™) proprietary discovery platform. The ATLAS platform is designed to identify tumor antigens of CD4+ and CD8+ T cell immune responses for inclusion in vaccines and immunotherapies that are designed to act through T cell (or cellular) immune responses. The Company believes that using ATLAS to identify neoantigens and antigens could lead to more immunogenic and efficacious cancer vaccines and immunotherapies.

The Company's most advanced program in active development is its immuno-oncology program, GEN-009, a neoantigen cancer vaccine, for which Genocea is conducting a Phase 1/2a clinical trial. The GEN-009 program uses ATLAS to identify patient neoantigens, or newly formed antigens unique to each patient, that are associated with that individual's tumor. The Company is also exploring GEN-010, a next-generation neoantigen vaccine program, and GEN-011, a neoantigen adoptive T cell therapy program, and has identified candidate T cell antigens for cancer vaccines targeting tumor-associated antigens and cancers caused by Epstein-Barr Virus ("EBV").

The Company has one non-active Phase 3-ready product candidate, GEN-003, an investigational immunotherapy for the treatment of genital herpes, for which it is continuing to explore strategic opportunities.

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

Operating Capital Requirements

Under ASU, 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40) (“ASC 205-40”), the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the date that the financial statements are issued. As required by ASC 205-40, this evaluation shall initially not take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued. Management has assessed the Company’s ability to continue as a going concern in accordance with the requirement of ASC 205-40.

As reflected in the condensed consolidated financial statements, the Company had available cash and cash equivalents of $34.5 million at September 30, 2018. In addition, the Company had a loss from operations of approximately $30.6

million and cash used in operating activities of $33.1 million for the nine months ended September 30, 2018. As determined under ASC 205-40, these factors, combined with expected cash required to fund future operations, raise substantial doubt about the Company's ability to continue as a going concern for twelve months from the date this report is issued.

The Company plans to continue to fund its operations through strategic transactions, proceeds from sales of its common stock under its at-the-market equity offering program, public or private equity offerings, its loan and security agreement with Hercules Capital, Inc. ("Hercules"), or by other means. However, adequate additional financing may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise capital when needed, or on attractive terms, it may be forced to implement further cost reduction strategies, including ceasing development of GEN-009 and corporate activities.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. Summary of significant accounting policies

Basis of presentation and use of estimates

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and the instructions of Form 10-Q and Article 10 of Regulation S-X. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”). Certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted. These interim condensed financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company’s financial position as of September 30, 2018 and results of operations for the three and nine months ended September 30, 2018 and 2017, respectively.

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, 2017 and the notes thereto which are included in the Company’s Annual Report on Form 10-K, as filed with the SEC on February 16, 2018.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company’s management evaluates its estimates, which include, but are not limited to, estimates related to prepaid and accrued research and development expenses, stock-based compensation expense, contingencies, tax valuation reserves, fair value measurements, and reported amounts of expenses during the reporting periods. 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.

There were no changes to significant accounting policies during the nine months ended September 30, 2018, as compared to the those identified in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

Fair value of financial instruments

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

categories:

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

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

Financial instruments measured at fair value on a recurring basis include cash equivalents (Note 3) and liability-classified common stock warrants (Note 7). The Company is also required to disclose the fair value of financial instruments not carried at fair value. The fair value of the Company's debt (Note 5) is determined using current applicable rates for similar instruments as of the balance sheet dates and an assessment of the credit rating of the Company. The carrying value of the Company's debt approximates fair value because the Company's interest rate yield is near current market rates for comparable debt instruments. The Company's debt is considered a Level 3 liability within the fair value hierarchy.

For the nine months ended September 30, 2018, there were no transfers among Level 1, Level 2, or Level 3 categories. Additionally, there were no changes to the valuation methods utilized by the Company during the nine months ended September 30, 2018, other than those related to the liability-classified common stock warrants described in Note 7.

Recently adopted accounting standards

Standard	Description	Effect on the financial statements
ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606)	In May 2014, the FASB issued new revenue guidance under ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard replaces existing revenue recognition standards and significantly expand the disclosure requirements for revenue arrangements. It may be adopted either retrospectively or on a modified retrospective basis to new contracts and existing contracts with remaining performance obligations as of the effective date. ASU No. 2014-09 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017.	The Company adopted ASU No. 2014-09 as of January 1, 2018. The adoption of ASU No. 2014-09 did not impact the Company's financial statements as the Company does not currently have any contracts with customers.
ASU No. 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments	In August 2016 the FASB issued ASU No. 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments (“ASU No. 2016-15”). This guidance addresses the presentation and classification of certain cash receipts and cash payments in the statement of cash flows. The standard is effective for annual periods beginning after December 15, 2017 and for interim periods within those fiscal years. Early adoption is permitted.	The Company adopted ASU No. 2016-15 effective January 1, 2018. The adoption of ASU No. 2016-15 did not have a material impact on the Company’s financial statements.
ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash	In November 2016, the FASB issued ASU 2016-18, which requires additional disclosures related to restricted cash. The new standard requires that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU No. 2016-18 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017.	The Company adopted the standard on January 1, 2018 and reclassified $0.3 million of restricted cash to be included with cash and cash equivalents on the statement of cash flows.
ASU No. 2017-09, Compensation-Stock Compensation (Topic 718)	In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting (“ASU No. 2017-09”). This update clarifies the changes to terms or conditions of a share-based payment award that require an entity to apply modification accounting.	The Company adopted ASU No. 2017-09 effective January 1, 2018. The adoption of ASU No. 2017-09 did not have a material impact on the Company’s financial statements.

ASU No. 2017-09 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. Early application is permitted, and prospective application is required.

Recently issued accounting standards

Standard	Description	Effect on the financial statements
ASU No. 2016-02, Leases (Topic 842)	In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which replaces the existing lease accounting standards. The new standard requires a dual approach for lessee accounting under which a lessee would account for leases as finance (also referred to as capital) leases or operating leases. Both finance leases and operating leases will result in the lessee recognizing a right-of-use asset and corresponding lease liability. For finance leases the lessee would recognize interest expense and amortization of the right-of-use asset and for operating leases the lessee would recognize straight-line total lease expense. ASU No. 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018.	The Company generally does not finance purchases of equipment but it does lease office and lab facilities. The Company is in the process of evaluating the effect that this ASU will have on its consolidated financial statements and related disclosures, but expects the adoption will result in an increase in assets and liabilities on its consolidated balance sheets.
ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting	In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The new standard largely aligns the accounting for share-based payment awards issued to employees and nonemployees by expanding the scope of ASC 718 to apply to nonemployee share-based transactions, as long as the transaction is not effectively a form of financing. The new guidance will be effective for the Company on January 1, 2019.	The Company is currently evaluating the potential impact that this guidance may have on its consolidated financial statements.
ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement	In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement which requires public entities to disclose certain new information and modifies some disclosure requirements.	The Company is currently evaluating the potential impact that this guidance may have on its consolidated financial statements.

	The new guidance will be effective for fiscal years beginning after 15 December 2019 and for interim periods within those fiscal years.	
ASU 2018-15, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.	In August 2018, the FASB issued ASU 2018-15, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in Accounting Standards Codification 350-40 to determine which implementation costs to defer and recognize as an asset. The new guidance will be effective for annual periods, and interim periods within those annual periods, beginning after 15 December 2019.	The Company is currently evaluating the potential impact that this guidance may have on its consolidated financial statements.

3. Fair value of financial instruments

The following table presents the Company's financial instruments that were measured at fair value on a recurring basis by level in accordance with the hierarchy defined in Note 2 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2018				
Assets:				
Money market funds, included in cash equivalents	$34,262	$34,262	$—	$—
Total assets	$34,262	$34,262	$—	$—
Liabilities:				
Common stock warrant liabilities	$13,021	$—	$—	$13,021
Total liabilities	$13,021	$—	$—	$13,021
December 31, 2017				
Assets:				
Money market funds, included in cash equivalents	$11,528	$11,528	$—	$—
Total assets	$11,528	$11,528	$—	$—

Cash equivalents were initially valued at the transaction price, and subsequently revalued 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 any fair value measurements provided by the pricing services as of September 30, 2018 and December 31, 2017.

As of September 30, 2018 and December 31, 2017, cash and cash equivalents were comprised of funds in depository and money market accounts.

In connection with an underwritten public offering of common and preferred stock in January 2018 (see Note 7), the Company issued Class A warrants (the “Warrants”) to purchase shares of the Company’s common stock, classified as liabilities in the condensed consolidated balance sheets. The Warrants were recorded at their fair value on the date of issuance and are remeasured as of any Warrant exercise date and at the end of each reporting period, with changes in fair value recognized as income (decrease in fair value) or expense (increase in fair value) in change in fair value of warrant liability in the statements of operations.

As of the issuance dates of the Warrants, as well as at September 30, 2018, the Company utilized an option-based methodology to value the Warrants combined with a multi-scenario model, specifically a Monte Carlo simulation, to model the future movement of the stock price throughout the term of the Warrants. In addition, the valuation model considers the probability of the Company being acquired during each annual period within the Warrant term, as an acquisition event can potentially impact the settlement of the Warrants.

The assumptions used in calculating the estimated fair value of the Warrants represent the Company’s best estimates and include probabilities of settlement scenarios, future changes in the Company’s stock price, risk-free interest rates and volatility. The estimates are based, in part, on subjective assumptions and could differ materially in the future. The following table details the assumptions used in the Monte Carlo simulation models used to estimate the fair value of the Warrants at issuance and as of September 30, 2018:

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	Issuance Date	September 30, 2018
Stock price	$0.89	$ 0.78
Volatility	111.5 %	105.7 %
Remaining term (years)	5	4.3
Expected dividend yield	— %	— %
Risk-free rate	2.4% - 2.5%	2.9 %
Range of annual acquisition event probability	0.0% - 30.0%	0.0% - 30.0%

The following table reflects the change in the Company’s Level 3 Warrants from issuance through September 30, 2018

	Common Stock Warrant Liabilities
Issuance of Warrants	$ 18,231
Change in fair value	(5,208)
Warrants exercised	(2)
Balance at September 30, 2018	$ 13,021

In connection with the underwritten public offering, the Company also granted the underwriters a 30-day option to purchase additional shares of common stock and/or additional Warrants (the "Overallotment Option"). The Company’s Overallotment Option is also a Level 3 liability. The assumptions used to determine the fair value are described in Note 7.

The following table reflects the change in the fair value of the Overallotment Option liability from issuance through the date of expiration:

	Overallotment Option Liability
Issuance of Overallotment Option	$ 2,441
Change in fair value	194
Exercise of Overallotment Option	(877)
Expiration of Overallotment Option in March 2018	(1,758)
Balance at September 30, 2018	$ —

4. Accrued expenses and other current liabilities

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

	September 30, 2018	December 31, 2017
Research and development costs	$ 764	$ 2,886

Payroll and employee-related costs	1,791	1,830
Other current liabilities	1,678	844
Restructuring costs	—	44
Total	$ 4,233	$ 5,604

5. Long-term debt

On April 24, 2018 (the “Closing Date”), the Company entered into an amended and restated loan and security agreement (the “2018 Loan Agreement”) with Hercules Capital, Inc. (f/k/a Hercules Technology Growth Capital, Inc.) (“Hercules”), which provided up to $14.0 million in debt financing in the form of a term loan funded on the Closing Date (the “2018 Term Loan”). The 2018 Loan Agreement amended and restated the Company’s loan and security agreement (as amended, the “2014 Loan Agreement”) with Hercules, which had provided up to $27.0 million in debt financing (the “2014 Term Loan”). The Company accounted for the amendment as a modification to the loan.

The 2018 Term Loan will mature on May 1, 2021 and accrues interest at a floating rate per annum equal to the greater of (i) 7.75% or (ii) the sum of 7.75% plus the prime rate minus 5.0%. The 2018 Loan Agreement provides for interest-only payments until June 1, 2019, which may be extended to December 1, 2019 if certain performance milestones are met before May 31, 2019 and no event of default has occurred or is continuing. Interest-only payments may be further extended to June 1, 2020 if certain additional performance milestones are met before November 30, 2019. Thereafter, amortization payments will be payable monthly in equal installments of principal and interest (subject to recalculation upon a change in prime rates) upon expiration of the interest only period through maturity.

The 2018 Term Loan may be prepaid in whole or in part upon seven business days' prior written notice to Hercules, subject to a prepayment charge of 3.0%, if such advance is prepaid in any of the first twelve months following the Closing Date, 2.0%, if such advance is prepaid after twelve months following the Closing Date but on or prior to 24 months following the Closing Date, and 1.0% thereafter. The Company is also obligated to pay an end-of-term charge in connection with the 2014 Loan Agreement of 4.95% of the term loan advances under the 2014 Loan Agreement on January 1, 2019 and an additional end of term charge of 6.70% of the Term Loan when the Term Loan is repaid (the "End of Term Charges").

The 2018 Term Loan is secured by a lien on substantially all assets of the Company, other than intellectual property, provided that such lien on substantially all assets includes any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. The Loan Agreement contains non-financial covenants and representations, including a financial reporting covenant, and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries. There are no financial covenants.

Under the provisions of the 2014 Loan Agreement and the 2018 Loan Agreement, the Company has also entered into account control agreements ("ACAs") with Hercules and certain of the Company's financial institutions in which cash, cash equivalents, and investments are held. These ACAs grant Hercules a perfected first-priority security interest in the subject accounts. The ACAs do not restrict the Company's ability to utilize cash, cash equivalents, or investments to fund operations and capital expenditures unless there is an event of default and Hercules activates its rights under the ACAs.

The 2018 Loan Agreement contains a material adverse effect ("Material Adverse Effect") provision that requires all material adverse effects to be reported under the financial reporting covenant. Loan advances are subject to a representation that no event that has had, or could reasonably be expected to have, a Material Adverse Effect has occurred and is continuing. Under the Loan Agreement, a Material Adverse Effect means a material adverse effect upon: (i) the business, operations, properties, assets or condition (financial or otherwise) of the Company; or (ii) the ability of the Company to perform the secured obligations in accordance with the terms of the loan documents, or the ability of agent or lender to enforce any of its rights or remedies with respect to the secured obligations; or (iii) the collateral or agent's liens on the collateral or the priority of such liens. Any event that has a Material Adverse Effect or would reasonably be expected to have a Material Adverse Effect is an event of default under the Loan Agreement and repayment of amounts due under the Loan Agreement may be accelerated by Hercules under the same terms as an event of default.

Events of default under the Loan Agreement include failure to make any payments of principal or interest as due on any outstanding indebtedness, breach of any covenant, any false or misleading representations or warranties, insolvency or bankruptcy, any attachment or judgment on the Company's assets of at least $100 thousand, or the occurrence of any material default of the Company involving indebtedness in excess of $100 thousand. If an event of default occurs, repayment of all amounts due under the Loan Agreement may be accelerated by Hercules, including the applicable prepayment charge.

The 2018 Term Loan is automatically redeemable upon a change in control. The Company must prepay the outstanding principal and any accrued and unpaid interest through the prepayment date and the applicable prepayment charge. If a change in control occurs, repayment of amounts due under the Loan Agreement may be accelerated by Hercules. The Company believes acceleration of the repayment of amounts outstanding under the loan is remote, and therefore the debt balance is classified according to the contractual payment terms at September 30, 2018.

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

In connection with the 2018 Loan Agreement, the Company issued a common stock warrant to Hercules on April 24, 2018 (the "Second Warrant" and together with the First Warrant, the “Warrants”). The Second Warrant is exercisable for 329,411 shares of the Company’s common stock at an initial excise price of $0.85 per share. The exercise price and the number of shares are subject to adjustment upon a merger event, reclassification of the shares of common stock, subdivision or combination of the shares of common stock or certain dividends payments. The Second Warrant is exercisable until April 24, 2023 and will be exercised automatically on a net issuance basis if not exercised prior to the expiration date and if the then-current fair market value of one share of common stock is greater than the exercise price then in effect.

In connection with the 2018 Loan Agreement, on April 24, 2018, the Company also entered into an amendment to the equity rights letter agreement, dated November 20, 2014 (the “Amended Equity Rights Letter Agreement”). Pursuant to the Amended Equity Rights Letter Agreement, the Company had already issued to Hercules 223,463 shares (the “Shares”) of the Company’s Common Stock for an aggregate purchase price of approximately $2.0 million on November 20, 2014 at a price per share equal to the closing price of the Company’s Common Stock as reported on The Nasdaq Global Market on November 19, 2014. The Shares were issued pursuant to an exemption provided by Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). Accordingly, the Shares will be subject to resale limitations and may be resold only pursuant to an effective registration statement or an exemption from registration.

Additionally, under the Amended Equity Rights Letter Agreement, Hercules has the right to participate in any one or more subsequent private placement equity financings of up to $2.0 million on the same terms and conditions as purchases by the other investors in each subsequent equity financing. The Amended Equity Rights Letter Agreement, and all rights and obligations thereunder, will terminate upon the earlier of (1) such time when Hercules has purchased $2.0 million of subsequent equity financing securities in the aggregate, and (2) the later of (a) the repayment of all indebtedness under the Loan Agreement, or (b) the expiration or termination of the exercise period for the warrant issued in connection with the Loan Agreement. The Company allocated $36 thousand of financing costs to additional paid-in capital for issuance fees that were reimbursed to Hercules.

The Company accounted for the April 2018 amendment to the Term Loan as a modification pursuant to ASC 470-50. The remaining balance of unamortized debt financing costs of $0.3 million and $0.1 million of fees associated with the 2018 Term Loan that met the criteria to be capitalized are being amortized through the maturity date of the 2018 Term Loan, accordingly. The End of Term Charges from the 2014 Term Loan and the 2018 Term Loan are being amortized to interest expense over the life of the 2018 Term Loan using the effective interest method. At September 30, 2018 the 2018 Term Loan bears an effective interest rate of 12.0%.

As of September 30, 2018, the Company had outstanding borrowings under the 2018 Loan Agreement of $14.6 million. At December 31, 2017, the Company had outstanding borrowings under the 2014 Term Loan of $14.3 million. Interest expense was $0.4 million and $0.4 million for the three months ended September 30, 2018 and 2017, respectively, and $1.2 million and $1.3 million for the nine months ended September 30, 2018 and 2017, respectively.

Future principal payments, including the End of Term Charges, are as follows (in thousands):

	September 30, 2018
2019	$ 4,693
2020	7,030
2021	4,057
Total	$ 15,780

6. Commitments and contingencies

Lease commitments

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

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

	September 30, 2018
2018	$ 403
2019	1,637
2020	274
Total	$ 2,314

At September 30, 2018 and December 31, 2017, the Company has an outstanding letter of credit of $0.3 million with a financial institution related to a security deposit for the 2016 Lease, which is secured by cash on deposit and expires on February 29, 2020. An additional unsecured deposit was required for the 2015 Lease.

Litigation

From time-to-time the Company may be subject to legal proceedings and claims which arise in the ordinary course of its business. The Company records a liability in its consolidated financial statements for these matters when a loss is known or considered probable and the amount can be reasonably estimated to the extent necessary to make the consolidated financial statements not misleading. If a loss is not probable or cannot be reasonably estimated, a liability is not recorded in its consolidated financial statements.

Beginning on October 31, 2017, three putative class action complaints were filed in the U.S. District Court for the District of Massachusetts, naming the Company, Chief Executive Officer William D. Clark, and former Chief Financial Officer Jonathan Poole as defendants. Each complaint alleged violations of the Securities Exchange Act of 1934 and Rule 10b-5 in connection with disclosures from March 31, 2016 to September 25, 2017 concerning Genocea's development of GEN-003, the Company's proprietary HSV-2 vaccine. The court consolidated the three actions into one case, captioned Emerson et al. v. Genocea Biosciences, Inc., et al., Civil Action No. 17-cv-12137-PBS (D. Mass.), and appointed the Genocea Investor Group (a group of five purported shareholders) as lead plaintiff. On March 29, 2018, counsel for the lead plaintiff filed an amended complaint in the District of Massachusetts that alleges the same causes of action and seeks the same relief as the original complaints. The amended complaint adds Seth V. Hetherington, former Chief Medical Officer, to the original named defendants. The defendants filed a motion to dismiss on May 14, 2018. Plaintiffs filed an opposition to defendants' motion to dismiss on June 28, 2018, as well as a motion to strike exhibits referenced in defendants' motion to dismiss, on June 29, 2018. The Company and the other named defendants filed a reply brief to plaintiffs' opposition to defendants' motion to dismiss, and an opposition brief to plaintiffs' motion to strike, on July 30, 2018. The court held oral argument on the motion to dismiss and motion to strike on September 25, 2018, and took each motion under advisement.

On January 31, 2018, a putative shareholder derivative action was filed in the U.S. District Court for the District of Delaware, naming certain of the Company's directors and officers as defendants (including certain former directors and officers), and naming the Company as a nominal defendant. On June 20, 2018, a second putative shareholder derivative action was filed in the U.S. District Court for the District of Delaware, naming certain of the Company's officers and directors (including a former officer), and naming the Company as a nominal defendant. On August 24, 2018, the court consolidated the two actions into one case, captioned In re Genocea Biosciences, Inc. Derivative Litigation, Civil Action No. 18-cv-00186-MN (D. Del.). The operative complaint in the now-consolidated action alleges violations of the Securities Exchange Act of 1934 and Rule 14a-9 in connection with disclosures made in the Company's Schedule 14A Proxy Statement, filed with the SEC on April 21, 2017. The complaint also alleges claims for breach of fiduciary duty, unjust enrichment, and waste of corporate assets. On August 10, 2018, the parties filed a joint stipulation and proposed order agreeing to stay the consolidated action until, inter alia, the entry of an order granting or denying any motion to dismiss the action in the District of Massachusetts, and on August 24, 2018, the court entered the joint stipulation agreeing to stay the consolidated action.

The Company is unable at this time to determine whether the outcome of any of the litigation would have a material impact on its results of operations, financial condition or cash flows. The Company does not have contingency reserves established for any litigation liabilities.

7. Stockholders' equity

As of September 30, 2018, the Company has authorized 250,000,000 shares of common stock at $0.001 par value per share and 25,000,000 shares of preferred stock at $0.001 par value per share. As of September 30, 2018, 86,625,975 shares of common stock and 1,635 shares of preferred stock were issued and outstanding. As of December 31, 2017, 28,734,898 shares of common stock were issued and outstanding and no shares of preferred stock were issued and outstanding.

Underwritten public offering

On January 17, 2018, the Company entered into two underwriting agreements, the first relating to the underwritten public offering of 53,365,000 shares of the Company's common stock, par value $0.001 per share, and accompanying Warrants to purchase up to 26,682,500 shares of common stock, at a combined price to the public of $1.00 per share, for gross proceeds of approximately $53.4 million (the "Common Stock Offering") and the second relating to the underwritten public offering of 1,635 shares of the Company's Series A convertible preferred stock, par value $0.001 per share, which are convertible into 1,635,000 shares of common stock, and accompanying warrants to purchase up to 817,500 shares of common stock for gross proceeds of approximately $1.6 million (the "Preferred Stock Offering," and together with the Common Stock Offering, the "January 2018 Financing").

Under the terms of the underwriting agreement for the Common Stock Offering, the Company also granted the underwriters the Overallotment Option to purchase up to an additional 8,004,750 shares of common stock and/or additional warrants to purchase up to 4,002,375 shares of common stock. On January 19, 2018, the underwriters exercised their Overallotment Option to acquire additional warrants to purchase up to 1,438,050 shares of common stock. On February 21, 2018, the underwriters exercised their Overallotment Option to acquire an additional 957,745 shares of common stock. The Company received approximately $1.0 million in gross proceeds from the underwriter's exercise of the Overallotment Option. The remainder of the Overallotment Options expired unexercised.

Preferred Stock

Each share of preferred stock is convertible at any time at the option of the holder, provided that the holder will be prohibited from converting the preferred stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of common stock then issued and outstanding. Each share of preferred stock is initially convertible into 1,000 shares of common stock, subject to certain adjustments upon stock dividends and stock splits.

The preferred stock ranks pari passu on an as-converted to common stock basis with the common stock as to distributions of assets upon the Company's liquidation, dissolution or winding up, whether voluntarily or involuntarily, or a "Fundamental Transaction," as defined in the Certificate of Designation.

Shares of preferred stock have no voting rights, except as required by law and except that the consent of the holders of a majority of the outstanding preferred stock is required to amend the terms of the preferred stock.

The holders of preferred stock shall be entitled to receive dividends in the same form as dividends actually paid on shares of common stock when, as and if such dividends are declared and paid on shares of the common stock, on an as-if-converted-to-common stock basis.

Warrants

The Warrants are exercisable at any time, or from time-to-time during the period beginning on the date of issuance and expiring on the five-year anniversary of such issuance date, at an exercise price of $1.20 per share.

In the event of an "Acquisition," defined generally to include a merger or consolidation resulting in the sale of 50% or more of the voting securities of the Company, the sale of all, or substantially all, of the assets or voting securities of the Company, or other change of control transaction, as defined in the Warrants, the Company will be obligated to use its best efforts to ensure that the holders of the Warrants receive new warrants from the surviving or acquiring entity (the "Acquirer"). The new warrants to purchase shares in the Acquirer shall have the same expiration date as the Warrants and a strike price that is based on the proportion of the value of the Acquirer's stock to the Company's

common stock. If the Company is unable, despite its best efforts, to cause the Acquirer to issue new warrants in the Acquisition as described above, then, if the Company's stockholders are to receive cash in the Acquisition, the Company will settle the Warrants in cash and if the Company's stockholders are to receive stock in the Acquisition, the Company will issue shares of its common stock to each Warrant holder.

Accounting for the January 2018 Financing Transaction

In assessing the accounting for the January 2018 Financing, the Company first determined that the common and preferred stock and the Warrants represented separable freestanding financial instruments.

Next, the Company determined that the Warrants should be liability classified in accordance with ASC 480, Distinguishing Liabilities from Equity (“ASC 480”), given the ability for the holders of the Warrants to redeem the Warrants for cash in certain Acquisition scenarios, as described above. As such, the Company allocated proceeds from the Common Stock Offering and Preferred Stock Offering in order to record the related Warrants at their fair value as of the date of issuance. In addition, the Company recorded the Warrants issued to the underwriters as part of the exercise of their Overallotment Option at their fair value as of the date of issuance. As the Warrants are liability-classified, the Company remeasures the fair value of the Warrants at each reporting date. The Company recorded the Warrants issued in the January 2018 Financing at their estimated fair value of approximately $18.2 million as of the issuance date. The Company recorded expense of approximately $3.2 million in the quarter ended March 31, 2018, income of approximately $5.5 million in the quarter ended June 30, 2018, and income of approximately $2.9 million in the quarter ended September 30, 2018, in the condensed consolidated statement of operations associated with the remeasurement of the Warrants to fair value. The fair value of the warrant liability is approximately $13.0 million as of September 30, 2018 (see Note 3).

In assessing the preferred stock, the Company determined that it was more equity-like in nature, which served as the basis for evaluating the other embedded features within the preferred stock. The Company determined that the conversion feature, redemption feature and other embedded features of the preferred stock did not meet the definition of derivatives and did not require separate accounting. The Company determined that the preferred stock should be classified as permanent equity as its redemption, dividends, covenants, liquidation and conversion features are more equity-like than debt-like. The Company further assessed the conversion feature of the preferred stock to determine if it was beneficial to the holder at issuance. Given the value allocated from the preferred stock to the Warrants issued in the Preferred Stock Offering, the Company determined that the effective conversion price was in the money at issuance and calculated the intrinsic value of the beneficial conversion of approximately $0.3 million. The Company recorded this amount to additional paid-in capital upon the issuance of the preferred stock.

The Company determined that the Overallotment Option should be classified as a liability in accordance with ASC 480 on the basis that the Overallotment Option was exercisable for Warrants that are classified as liabilities under ASC 480. As the Overallotment Option is a traditional overallotment option that remained with the underwriters, no proceeds from the January 2018 Financing were allocated. Given the short-term duration of the Overallotment Option, the Company estimated its fair value was representative of the intrinsic value of the related Warrants, based on the estimated fair value of the Warrants at issuance and the exercise price of the Overallotment Option. The Company estimated the fair value of the Overallotment Option at the issuance to be approximately $2.4 million. Upon the partial exercise of the Overallotment Option by the underwriters, the Company reclassified a proportional amount of the Overallotment Option liability of $0.9 million to the Warrant liability, to reflect the fair value of the Warrants issued to the underwriters. Upon expiration of the Overallotment Option, the Company recognized the $1.8 million liability balance as expense.

In connection with the January 2018 Financing, the Company incurred approximately $4.0 million of issuance costs. The Company allocated approximately $2.6 million of the issuance costs to the common and preferred stock, and recorded these amounts against the proceeds received, and approximately $1.4 million of the issuance costs to the Warrants, based on the relative values assigned. As the Warrants were classified as liabilities, the Company immediately expensed the issuance costs allocated to the Warrants.

At-the-market equity offering program

On March 2, 2015, the Company entered into a Sales Agreement with Cowen and Company, LLC (the "Sales Agreement") to establish an at-the-market equity offering program (“ATM”) pursuant to which it was able to offer and sell up to $40 million of its common stock at prevailing market prices from time to time. On May 8, 2015, the Sales Agreement was amended to increase the offering amount under the ATM to $50 million of its common stock.

Through November 1, 2018, the Company sold an aggregate of approximately 3.7 million shares under the ATM and received approximately $4.0 million in net proceeds after deducting commissions.

Warrants

As of September 30, 2018 and December 31, 2017, the Company had warrants outstanding that represent the right to acquire 29,342,564 and 77,603 shares of common stock, respectively. As of September 30, 2018, the common stock underlying the warrants consist of 28,935,550 shares of common stock reserved for issuance upon the exercise of the Warrants, 403,136 shares of common stock reserved for issuance upon the exercise of warrants issued to Hercules and 3,878 shares of common stock reserved for issuance upon the exercise of warrants issued in periods prior to the Company's initial public offering ("IPO").

8. Stock and employee benefit plans

Stock-based compensation expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$156	$322	$456	$1,060
General and administrative	310	771	1,246	2,208
Total	$466	$1,093	$1,702	$3,268

Stock options

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

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	4,129	$ 5.48	7.07	$ —
Granted	3,805	$ 0.95		
Exercised	—	$ —		
Canceled	(2,242)	$ 4.64		
Outstanding at September 30, 2018	5,692	$ 2.78	7.51	$ 75,535
Exercisable at September, 2018	2,378	$ 4.40	5.26	$ —

Restricted stock

In May 2017, the Company granted one of its officer's 47,620 units of restricted stock ("RSUs") in accordance with the 2014 Equity Incentive Plan and subject to a Restricted Stock Unit Award Agreement with the Company. On the date of grant, 7,937 RSUs vested immediately and another 23,810 RSUs were to vest on the eighteen-month anniversary of the grant date, subject to the continued employment of the officer. The remaining 15,873 RSUs, which contained a performance condition of completing a material financing event on or before September 30, 2017, were canceled as the performance criterion was not achieved. Upon the resignation of the officer in March 2018, the remaining 23,810 RSUs were forfeited.

Performance-based awards

The Company granted stock awards to certain employees, executive officers and consultants, which contain performance-based vesting criteria. Milestone events are specific to the Company’s corporate goals, which include, but are not limited to, certain clinical development milestones, business development agreements, and capital fundraising events. Stock-based compensation expense associated with these performance-based stock options is recognized if the performance conditions are considered probable of being achieved, using management’s best estimates. The Company

determined that none of the performance-based milestones were probable of achievement during the three and nine months ended September 30, 2018, respectively, and did not recognize stock-based compensation expense for these periods. As of September 30, 2018, there were 56,336 performance-based common stock awards outstanding for which the probability of achievement was not deemed probable.

Employee stock purchase plan

On February 10, 2014, the Company's board of directors adopted the 2014 Employee Stock Purchase Plan (the "2014 ESPP"). The 2014 ESPP authorizes the initial issuance of up to 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.

In June of 2018, 2,500,000 additional shares were authorized under the 2014 ESPP and 42,132 shares were issued. As of September 30, 2018, 2,457,875 shares remain available for future issuance. The Company incurred stock-based compensation expense related to the 2014 ESPP of $10 thousand and $32 thousand the three and nine months ended September 30, 2018, respectively, and $23 thousand and $99 thousand for the three and nine months ended September 30, 2017, respectively.

9. Net loss per share

The Company computes basic and diluted earnings (loss) per share using a methodology that gives effect to the impact of outstanding participating securities (the “two-class method”). For both the three and nine-month periods ended September 30, 2018 and 2017, respectively, there is no income allocation required under the two-class method or dilution attributed to weighted average shares outstanding in the calculation of diluted loss per share.

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

	Nine Months Ended September 30,	
	2018	2017
Stock options	5,692	4,400
Restricted stock units	—	24
Warrants	29,343	78
Outstanding ESPP	82	31
Total	35,117	4,533

10. Restructuring costs

On September 25, 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. The Company also announced that it is exploring strategic alternatives for GEN-003, its Phase 3-ready investigational immunotherapy for the treatment of genital herpes. Consequently, substantially all GEN-003 spending and activities were ceased, and the Company reduced its workforce by approximately 40 percent as of the quarter ended September 30, 2017. Pursuant to ASC 420, Exit or Disposal Cost Obligations, charges for employee severance, employee benefits, and contract terminations were recorded in the year ended December 31, 2017. Asset impairment charges, pursuant to ASC 360, Property, Plant, and Equipment, were also recorded in the year ended December 31, 2017 and primarily related to fixed assets specific to GEN-003 research and development activities.

The following table summarizes the impact of the September 2017 restructuring activities for the year ended December 31, 2017 and three months ended March 31, 2018, along with the current liability recorded in the balance sheet as of December 31, 2017 and September 30, 2018 (in thousands):

(in thousands)	Charges incurred during the year ended December 31, 2017	Amount paid through December 31, 2017	Less non-cash charges during the year ended December	Remaining liability at December 31, 2017	Amount paid during Q1 2018	Remaining liability at September 30, 2018

			31, 2017			
Employee severance, benefits and related costs	$ 1,064	$ (1,050)	$ —	$ 14	$ (14)	$ —
Contract terminations	526	—	—	526	(526)	—
Asset impairments	1,028	—	(1,028)	—	—	—
Total	$ 2,618	$ (1,050)	$ (1,028)	$ 540	$ (540)	$ —

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

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

Overview

We are a biopharmaceutical company that seeks to discover and develop novel cancer vaccines and immunotherapies. We use our proprietary discovery platform, ATLAS, to identify tumor antigens of CD4+ and CD8+ T cell immune responses for inclusion in vaccines and immunotherapies that are designed to act through T cell (or cellular) immune responses. We believe that using ATLAS to identify neoantigens and antigens could lead to more immunogenic and efficacious cancer vaccines and immunotherapies.

In September 2017, we announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines. Our most advanced program in active development is our clinical immuno-oncology program, GEN-009, a neoantigen cancer vaccine, for which we are conducting a Phase 1/2a clinical trial. The GEN-009 program uses ATLAS to identify patient neoantigens, or newly formed antigens unique to each patient, that are associated with that individual's tumor. We are also exploring GEN-010, a next-generation neoantigen vaccine program, and GEN-011, a neoantigen adoptive T cell therapy program, and has identified candidate T cell antigens for cancer vaccines targeting tumor-associated antigens and cancers caused by EBV.

We have one non-active Phase 3-ready product candidate, GEN-003, an investigational immunotherapy for the treatment of genital herpes. In September 2017, we announced that we are exploring strategic alternatives for GEN-003 and are continuing to do so.

ATLAS Platform

The T cell arm of the immune system is increasingly understood to be critical in the treatment of certain cancers. However, the discovery of effective T cell targets, or antigens, has been particularly challenging for two reasons. First, the diversity of human T cell responses means that an effective T cell target for one person may be different from an effective T cell target for another person. Second, the number of candidate targets for T cell responses can be very large with up to thousands of candidate antigens per patient in some cancers. These complexities represent fundamental barriers that traditional cancer vaccine target discovery tools, which rely largely on computer modeling - so-called predictive algorithms - have, as yet, only been poorly addressed.

We have designed the ATLAS platform to overcome these T cell target discovery challenges by identifying true neoantigens in an individual rather than using traditional predictive methods. We believe ATLAS represents the most comprehensive and accurate high throughput system for T cell vaccine and immunotherapy discovery in the biopharmaceutical industry. ATLAS is designed to mimic the T cell arm of the human immune system of each patient that it profiles in a laboratory setting. Using ATLAS, we are able to measure T cell responses to the entire set of potential T cell targets for an individual’s cancer, allowing us to identify vaccine and immunotherapy targets associated with T cell responses which may kill an individual’s cancer.

We believe that we are a leader in the field of T cell vaccine and immunotherapy discovery and development. Our management and scientific teams possess considerable experience in vaccine, immunotherapy and anti-infective research, manufacturing, clinical development and regulatory matters.

Our Immuno-Oncology Programs

We are focused on combining our antigen selection and vaccine development expertise to create new immuno-oncology treatments. Our potential cancer vaccines and immunotherapies will be designed to educate T cells to recognize and attack specific targets and thereby kill cancer cells. We are first working to develop personalized cancer vaccines by applying ATLAS to identify patient neoantigens that are associated with that individual's

pre-existing immune responses to a tumor.

Neoantigens are personalized tumor mutations that are seen as “foreign” by an individual’s immune system. Data published in recent years have indicated that an individual’s response to neoantigens drives checkpoint inhibitor efficacy and that it is possible to vaccinate an individual against their own neoantigens. If approved, neoantigen vaccines could be used in combination with existing treatment approaches for cancer, including immune checkpoint inhibitors, to potentially direct and enhance an individual’s T cell response to the individual’s cancer, thereby potentially affording better clinical outcomes.

Our lead immuno-oncology program, GEN-009, is an adjuvanted neoantigen peptide vaccine candidate designed to direct a patient’s immune system to attack their tumor. GEN-009’s neoantigens are identified by our proprietary ATLAS platform, which is designed to identify tumor antigens of CD4+ and CD8+ cell immune responses to their tumor. Following ATLAS neoantigen identification, we will manufacture a personal vaccine for each patient.

In May 2018 we announced that the FDA accepted our investigational new drug ("IND") application for GEN-009. In June 2018, we initiated a Phase 1/2a clinical trial for GEN-009 in a range of tumor types in subjects with no evidence of disease but a high risk of relapse. We expect to report initial immunogenicity data from this trial in the first half of 2019.

Behind GEN-009, we continue to explore GEN-010, our vaccine candidate employing next-generation antigen delivery technology, which could provide an opportunity for even better immunogenicity and/or efficiency of production. We have also initiated early work on GEN-011, an adoptive T cell therapy to neoantigens identified by ATLAS.

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

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

The following table describes our active programs in development:

Vaccine Candidate	Program	Stage of Development	Next Milestone	Anticipated Timeline
GEN-009	First generation neoantigen cancer vaccine	Clinical	Immunogenicity data from the first patient cohort	First half of 2019
GEN-010	Second generation neoantigen cancer vaccine	Pre-clinical	Select delivery technology platform	Ongoing
GEN-011	Adoptive T cell therapy	Research	Initiate preclinical program	Ongoing
GEN-006	Immuno-oncology -tumor associated antigen vaccine	Research	Select antigen candidates	Exploring partnering opportunities
GEN-007	Epstein-Barr Virus	Research	Select antigen candidates	Exploring partnering opportunities

GEN-003 — Phase 2 immunotherapy for genital herpes, currently exploring strategic alternatives

Prior to our September 2017 strategic shift announcement, our lead program was GEN-003, a Phase 3-ready investigational immunotherapy for the treatment of genital herpes that had completed three positive clinical trials. We have ceased substantially all activities under the GEN-003 program and are currently exploring alternatives to maximize shareholder value from GEN-003.

Financing and business operations

We commenced business operations in August 2006. To date, our operations have been limited to organizing and staffing our company, acquiring and developing our proprietary ATLAS technology, identifying potential product candidates, and undertaking preclinical studies and clinical trials for our product candidates. All 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 financed our operations primarily through the issuance of our equity securities, debt financings, and amounts received through grants. As of September 30, 2018, we had received an aggregate of $339.5 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At September 30, 2018, our cash and cash equivalents were $34.5 million.

Since inception, we have incurred significant operating losses. Our net losses were $7.8 million and $28.2 million for the three and nine months ended September 30, 2018, and our accumulated deficit was $292.4 million as of September 30, 2018. We expect to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year. We will need to generate significant revenue to achieve profitability, and we may never do so.

In March 2015, we completed an underwritten public offering of 6.3 million shares of our common stock at a public offering price of $8.25 per share for an aggregate offering price of $51.7 million. In August 2015, we completed another underwritten public offering of 3.9 million shares of our common stock at a public offering price of $13.00 per share for an aggregate offering price of $50.1 million. We received net proceeds from these offerings of approximately $95.7 million, after deducting approximately $6.1 million in underwriting discounts and commissions, excluding offering costs payable by us.

In January 2018, we completed concurrent registered offerings in which we sold (i) 53.4 million shares of our common stock and accompanying 53.4 million Class A warrants to purchase up to 26.7 million shares of our common stock, at a combined price of $1.00 per share, for aggregate gross proceeds of approximately $53.4 million and (ii) 1,635 shares of our Series A convertible preferred stock, which are convertible into 1.6 million shares of our common stock, and accompanying Class A warrants to purchase up to 0.8 million shares of our common stock for aggregate gross proceeds of approximately $1.6 million. Each Class A warrant has an exercise price of $1.20 per share and will expire five years from the date of issuance. We received net proceeds from these offerings of approximately $51.7 million, after deducting approximately $3.3 million in underwriting discounts and commissions, excluding offering costs payable by us.

In April 2018, we sold 3.5 million shares under our ATM program and received net proceeds of $2.9 million, after deducting commissions. Other than the shares sold in April 2018, we did not sell any additional shares during the nine months ended September 30, 2018. For the nine months ended September 30, 2017, we sold 52 thousand shares under the ATM program and received $0.2 million in net proceeds after deducting commissions. For the three months ended September 30, 2017 there were no additional ATM sales.

Costs related to clinical trials can be unpredictable and therefore there can be no guarantee that our current balances of cash, cash equivalents and investments, and any proceeds received from other sources, will be sufficient to fund our studies or operations through this period. These funds will not be sufficient to enable us to conduct pivotal clinical trials for, seek marketing approval for, or commercially launch GEN-009 or any other product candidate. Accordingly, to obtain marketing approval for and to commercialize these or any other product candidates, we will be required to obtain further funding through public or private equity offerings, debt financings, collaboration and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital when needed would have a negative effect on our financial condition and our ability to pursue our business strategy.

Financial Overview

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 ("CROs"), contract manufacturing organizations ("CMOs"), consultants, and other vendors that conduct our clinical trials and preclinical activities;
- costs of acquiring, developing, and manufacturing clinical trial materials and lab supplies; and
- facility costs, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies.

We expense internal research and development costs to operations as incurred. We expense certain third-party costs for research and development activities based on an evaluation of the progress to completion of specific performance or tasks.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Immuno-oncology programs (1)	$5,474	$2,456	$15,870	$7,568
Other research and development (2)	879	1,321	2,524	4,032
Genital herpes (GEN-003)(3)	6	6,378	556	19,724
Total research and development	$6,359	$10,155	$18,950	$31,324

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

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

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

General and administrative expenses

General and administrative expenses consist principally of salaries and related costs for executive, finance, and other administrative personnel, professional fees, business insurance, rent, general legal activities, including the cost of maintaining our intellectual property portfolio, and other corporate expenses.

Our results also include stock-based compensation expense resulting from the issuance of stock option grants to our employees, directors, and consultants. The stock-based compensation expense is included in the respective categories of expense in our condensed consolidated statements of operations and comprehensive loss (i.e., research and development or general and administrative expenses).

Other income (expense)

Other income and expense consists of the change in warranty liability, interest expense, net of interest income, and other income (expense) for miscellaneous items.

Critical Accounting Policies and Significant Judgments and Estimates

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate estimates, which include, but are not limited to, estimates related to clinical trial accruals, prepaid and accrued research and development expenses, stock-based compensation expense, and reported amounts of revenues and expenses, including other expense as it includes fair value adjustments with respect to our warrant liability and offering costs allocated to the warrants that were expensed immediately, 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, 2017 related to prepaid and accrued research and development expenses and stock-based compensation. There have been no material changes to our accounting policies from those described in our Annual Report on Form 10-K. It is important that the discussion of our operating results that follow be read in conjunction with the critical accounting policies disclosed in our Annual Report on Form 10-K, as filed with the SEC on February 16, 2018.

Results of Operations

Comparison of the three months ended September 30, 2018 and September 30, 2017

(in thousands)	Three Months Ended September 30, 2018	2017	Increase (Decrease)
Operating expenses:			
Research and development	$6,359	$10,155	$ (3,796)
General and administrative	4,101	3,750	351
Restructuring costs	—	2,591	(2,591)
Total operating expenses	10,460	16,496	(6,036)
Loss from operations	(10,460)	(16,496)	(6,036)
Other income (expense):			
Change in fair value of warrants	2,894	—	2,894
Interest expense, net	(266)	(366)	(100)
Other income (expense)	(1)	(6)	(5)
Total other income (expense)	2,627	(372)	2,999
Net loss	$(7,833)	$(16,868)	$ (9,035)

Research and development expenses

Research and development ("R&D") expenses decreased $3.8 million in the three months ended September 30, 2018, as compared to the three months ended September 30, 2017. The decrease was due largely to reduced headcount-related costs of $1.1 million and decreased external development costs of $1.6 million. The remaining decrease in quarter-over-quarter expenses was comprised of decreased clinical costs of approximately $0.5 million, consulting costs of approximately $0.3 million, and other R&D costs of approximately $0.3 million.

Spending increases on GEN-009 and immuno-oncology programs of $3.0 million were driven primarily by increased headcount-related and consulting costs of approximately $1.5 million and increased manufacturing, clinical and lab related costs of approximately $1.5 million to support the Phase 1/2a clinical trial for GEN-009. Increased spending on this program was offset by lower costs on deprioritized infectious disease programs. On a program basis, GEN-003 costs decreased $6.4 million for the three months ended September 30, 2018, driven by decreased compensation and external manufacturing-related expenses of approximately $4.4 million, decreased consulting and professional service related costs of approximately $0.5 million, decreased clinical costs of approximately $1.1 million, and decreased lab related costs of approximately $0.2 million following the September 2017 strategic pivot.

General and administrative expenses

General and administrative expenses were $4.1 million for the three months ended September 30, 2018, a $0.4 million increase as compared to the three months ended September 30, 2017. The increase was primarily due to increased consulting and professional services costs of approximately $0.3 million and increased office and facility-related costs of approximately $0.1 million, as compared to the same period in the prior year.

Restructuring costs

On September 25, 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. As a result, the Company incurred a charge of approximately $1.1 million for employee severance and related costs, approximately $0.5 million of expense related to contract termination clauses, and approximately $1.0 million in non-cash asset impairment charges.

Change in fair value of warrants

Change in fair value of warrants reflects non-cash change in fair value of Class A warrants issued in connection the underwritten public offering of common and preferred stock in January 2018. The Warrants were recorded at their fair value on the date of issuance and are remeasured as of any Warrant exercise date and at the end of each reporting period.

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, offset by interest earned on our cash, cash equivalent and investment portfolio. The decrease of $0.1 million for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, reflects the lower outstanding principal in the three months ended September 30, 2018, as compared to the same period in the prior year, combined with increased interest income earned on our cash and cash equivalents in the current year.

Other income (expense)

Other income (expense) for thee three months ended September 30, 2018 was consistent, as compared to the three months ended September 30, 2017. The decrease in other income (expense) for the three months ended September 30, 2018 was due to foreign currency exchange adjustments recorded.

Comparison of the nine months ended September 30, 2018 and September 30, 2017

	Nine Months Ended September 30,		Increase
(in thousands)	2018	2017	(Decrease)
Operating expenses:			
Research and development	$18,950	$31,324	$(12,374)
General and administrative	11,682	10,955	727
Restructuring costs	—	2,591	(2,591)
Total operating expenses	30,632	44,870	(14,238)
Loss from operations	(30,632)	(44,870)	(14,238)
Other income (expense):			
Change in fair value of warrants	3,093	—	3,093
Interest expense, net	(708)	(1,094)	(386)
Other income (expense)	86	(14)	100
Total Other income (expense)	2,471	(1,108)	3,579
Net loss	$(28,161)	$(45,978)	$(17,817)

Research and development expenses

Research and development expenses decreased by $12.4 million in the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017. The decrease was due largely to reduced headcount costs of approximately $4.7 million, decreased external development costs of approximately $3.9 million, and decreased clinical costs of approximately $1.8 million. The remaining decrease was comprised of lab related costs of approximately $0.4 million, consulting and professional services costs of approximately $0.6 million, and other R&D costs of approximately $1.0 million.

Spending increases on GEN-009 and immuno-oncology programs of $8.3 million were driven primarily by increased headcount, clinical, and consulting costs of approximately $5.5 million and increased external manufacturing and lab

related costs of approximately $2.6 million to support the Phase 1/2a clinical trial for GEN-009. Increased spending on these programs was offset by lower costs on deprioritized infectious disease programs. On a program basis, GEN-003 costs decreased by $19.2 million for the nine months ended September 30, 2018 driven by decreased compensation cost and external manufacturing-related expenses of approximately $13.2 million, consulting and professional service costs of approximately $1.8 million, clinical and lab related costs of approximately $3.7 million, and other GEN-003 specific costs of approximately $0.5 million following the September 2017 strategic shift.

General and administrative expenses

General and administrative expenses were $11.7 million for the nine months ended September 30, 2018, a $0.7 million increase from the nine months ended September 30, 2017. The increase was primarily due to increased consulting and professional services costs of approximately $2.1 million, offset by reduced compensation and benefits costs of approximately $1.2 million and depreciation costs of approximately $0.2 million, as compared to the same period in the prior year.

Restructuring costs

On September 25, 2017, the Company announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009. As a result, the Company incurred a charge of approximately $1.1 million for employee severance and related costs, approximately $0.5 million of expense related to contract termination clauses, and approximately $1.0 million in non-cash asset impairment charges.

Change in fair value of warrants

Change in fair value of warrants reflects non-cash change in fair value of Class A warrants issued in connection with the underwritten public offering of common and preferred stock in January 2018. The Warrants were recorded at their fair value on the date of issuance and are remeasured as of any Warrant exercise date and at the end of each reporting period.

Interest expense, net

Interest expense decreased by $0.4 million for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017. The decrease in interest expense reflects the lower outstanding principal balance on our debt facility in the nine months ended September 30, 2018 in addition to increased interest income driven by higher average cash balances in the first nine months of 2018, as compared to 2017.

Other income (expense)

Other income (expense) increased by $0.1 million for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017. The increase in other income (expense) for the nine months ended September 30, 2018 was due to foreign currency exchange adjustments recorded during the nine months ended September 30, 2018, as compared to the same period in the prior year.

Liquidity and Capital Resources

Overview

Since our inception through September 30, 2018, we have received an aggregate of $339.5 million in gross proceeds from the issuance of equity securities and gross proceeds from debt facilities and an aggregate of $7.9 million from grants. At September 30, 2018, our cash and cash equivalents were $34.5 million.

For the nine months ended September 30, 2017, we sold 52 thousand shares under our ATM program and received $0.2 million in net proceeds after deducting commissions. For the nine months ended September 30, 2018 we sold an additional 3.5 million shares under the ATM program and received $2.9 million in net proceeds after deducting commissions.

Debt Financings

On April 24, 2018 (the "Closing Date"), we entered into an amended and restated loan and security agreement (the "2018 Loan Agreement") with Hercules (renamed to Hercules Capital, Inc.), which provided up to $14.0 million in debt financing in the form of a term loan funded on the Closing Date (the "2018 Term Loan"). The 2018 Loan Agreement amended and restated the 2014 Loan Agreement.

The 2018 Term Loan will mature on May 1, 2021 and accrues interest at a floating rate per annum equal to the greater of (i) 7.75% or (ii) the sum of 7.75% plus the prime rate minus 5.0%. The 2018 Loan Agreement provides for interest-only payments until June 1, 2019, which may be extended to December 1, 2019 if certain performance milestones are met before May 31, 2019 and no event of default has occurred or is continuing. Interest-only payments may be further extended to June 1, 2020 if certain additional performance milestones are met before November 30, 2019. Thereafter, amortization payments will be payable monthly in equal installments of principal and interest (subject to recalculation upon a change in prime rates) upon expiration of the interest only period through maturity.

The 2018 Term Loan may be prepaid in whole or in part upon seven business days' prior written notice to Hercules, subject to a prepayment charge of 3.0%, if such advance is prepaid in any of the first twelve months following the Closing Date, 2.0%, if such advance is prepaid after twelve months following the Closing Date but on or prior to 24 months following the Closing Date, and 1.0% thereafter. We are also obligated to pay an end of term charge in connection with the 2014 Loan Agreement of 4.95% of the term loan advances under the 2014 Loan Agreement on January 1, 2019 and an additional end of term charge of 6.70% of the Term Loan when the Term Loan is repaid (the "End of Term Charges").

The 2018 Term Loan is secured by a lien on substantially all of our assets, other than intellectual property, provided that such lien on substantially all assets includes any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. The Loan Agreement contains non-financial covenants and representations, including a financial reporting covenant, and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries. There are no financial covenants.

Contemporaneously with the 2018 Loan Agreement, we also entered into an amendment to the equity rights letter agreement, dated November 20, 2014 (the "Amended Equity Rights Letter Agreement"). Pursuant to the Amended Equity Rights Letter Agreement, we had already issued to Hercules 223,463 shares of the Company's Common Stock for an aggregate purchase price of approximately $2.0 million at a price per share equal to the closing price of our common stock as reported on The Nasdaq Global Market on November 19, 2014. The shares will be subject to resale limitations and may be resold only pursuant to an effective registration statement or an exemption from registration.

Additionally, under the Amended Equity Rights Letter Agreement, Hercules has the right to participate in any one or more subsequent private placement equity financings of up to $2.0 million on the same terms and conditions as purchases by the other investors in each subsequent equity financing. The Amended Equity Rights Letter Agreement, and all rights and obligations thereunder, will terminate upon the earlier of (1) such time when Hercules has purchased $2.0 million of subsequent equity financing securities in the aggregate and (2) the later of (a) the repayment of all indebtedness under the Loan Agreement and (b) the expiration or termination of the exercise period for the warrant issued in connection with the Loan Agreement.

In connection with the 2014 Term Loan, we issued a common stock warrant to Hercules on November 20, 2014 (the "First Warrant"). The First Warrant is exercisable for 73,725 shares of the Company's Common Stock (equal to $607,500 divided by the exercise price of $8.24). The exercise price and the number of shares are subject to adjustment upon a merger event, reclassification of the shares of Common Stock, subdivision or combination of the shares of Common Stock or certain dividends payments. The First Warrant is exercisable until November 20, 2019 and will be exercised automatically on a net issuance basis if

not exercised prior to the expiration date and if the then-current fair market value of one share of Common Stock is greater than the exercise price then in effect. The First Warrant has been classified as equity for all periods it has been outstanding.

In connection with the 2018 Loan Agreement, we issued a common stock warrant to Hercules on April 24, 2018, (the "Second Warrant" and together with the First Warrant, the “Warrants”). The Second Warrant is exercisable for 329,411 shares of the Company’s common stock. The exercise price and the number of shares are subject to adjustment upon a merger event, reclassification of the shares of common stock, subdivision or combination of the shares of common stock or certain dividends payments. The Second Warrant is exercisable until April 24, 2023 and will be exercised automatically on a net issuance basis if not exercised prior to the expiration date and if the then-current fair market value of one share of common stock is greater than the exercise price then in effect.

Operating Capital Requirements

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

We expect that our existing cash and cash equivalents, as of September 30, 2018, are sufficient to support our operating expenses and capital expenditure requirements into the fourth quarter of 2019. We are currently exploring various avenues to secure capital to advance GEN-009 through our existing Phase 1/2a clinical trial. In the event that we are unsuccessful in securing capital on acceptable terms we will review our remaining strategic alternatives to maximize shareholder value including, but not limited to, exploring a potential sale of the company or our assets and/or a shut-down of company activities. These factors raise substantial doubt about our ability to continue as a going concern.

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

- the timing and costs of current and planned clinical trials for GEN-009;
- the progress, timing, and costs of manufacturing GEN-009 for planned clinical trials;
- the initiation, progress, timing, costs, and results of preclinical studies and clinical trials for our other product candidates and potential product candidates;
- the outcome, timing, and costs of seeking regulatory approvals;
- the costs of commercialization activities for GEN-009 and other product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution, and manufacturing capabilities;
- the receipt of marketing approval;
- revenue received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, grants, licensing, consulting, or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments, and patent prosecution fees that we are obligated to pay pursuant to our license agreements;

- the costs of preparing, filing, and prosecuting patent applications, maintaining and protecting our intellectual property rights, and defending against intellectual property related claims; and
- the extent to which we in-license or acquire other products and technologies.

We will need to obtain substantial additional funding in order to commence and complete clinical trials for GEN-009 and our other product candidates in order to receive regulatory approval. To the extent that we raise additional capital through the sale of our common stock, convertible securities, or other equity securities, the ownership interests of our existing stockholders may be

materially diluted and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. In addition, debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends, that could adversely affect our ability to conduct our business.

If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back or discontinue the development of GEN-009 or our other product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to GEN-003, GEN-009 or our other product candidates that we otherwise would seek to develop or commercialize ourselves.

Cash Flows

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

	Nine Months Ended September 30,	
	2018	2017
Net cash used in operating activities	$(33,057)	$(39,425)
Net cash provided by investing activities	(141)	34,688
Net cash provided by (used in) financing activities	55,419	(704)
Net increase (decrease) in cash and cash equivalents	$22,221	$(5,441)

Operating Activities

Net cash used in operations decreased by approximately $6.4 million to $33.1 million for the nine months ended September 30, 2018 from $39.4 million for the nine months ended September 30, 2017. The decrease in net cash used was due primarily to an increase in non-cash cash items attributable to the change in fair value of the warrants of $5.2 million, offset by transaction costs associated with the January 2018 financing of $2.1 million. Other non-cash items decreases included depreciation and stock based compensation.

Investing Activities

Net cash used by investing activities was $0.1 million for the nine months ended September 30, 2018 as compared to net cash provided by investing activities of $34.7 million for the nine months ended September 30, 2017. The decrease in cash provided was due to the receipt of proceeds from maturities of investments, net of investments made, of approximately $35.9 million in the nine months ended September 30, 2017, as compared to the same period in 2018, partially offset by a decrease in cash used to purchase capital equipment in the nine months ended September 30, 2018, as compared to the same period in the prior year.

Financing Activities

Net cash provided by financing activities increased $56.1 million for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 as a result of the proceeds from the January 2018 underwritten public offering and the shares of common stock issued pursuant to our ATM facility.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K, as filed with the SEC on February 16, 2018 other than the impact of the 2018 Loan Agreement that increased our outstanding obligations up to $14.0 million and deferred payment of principal and interest to June 1, 2019.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risk related to changes in interest rates. As of September 30, 2018, we had cash and cash equivalents of $34.5 million compared to cash and cash equivalents of $12.3 million at December 31, 2017, consisting of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short term duration most of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We are also exposed to market risk related to change in foreign currency exchange rates. We contract with certain vendors that are located in Europe which have contracts denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign exchange rate risk. As of September 30, 2018 and December 31, 2017, we had minimal liabilities denominated in foreign currencies.

Item 4. Controls and Procedures

Management’s Evaluation of our Disclosure Controls and Procedures

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

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018 (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the nine months ended September 30, 2018, 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. Except as discussed below, we do not believe we are currently party to any pending legal action, arbitration proceeding or governmental proceeding, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business or operating results. 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.

Beginning on October 31, 2017, three putative class action complaints were filed in the U.S. District Court for the District of Massachusetts, naming the Company, Chief Executive Officer William D. Clark, and former Chief Financial Officer Jonathan Poole as defendants. Each complaint alleged violations of the Securities Exchange Act of 1934 and Rule 10b-5 in connection with disclosures from March 31, 2016 to September 25, 2017 concerning Genocea's development of GEN-003, the Company's proprietary HSV-2 vaccine. The court consolidated the three actions into one case, captioned Emerson et al. v. Genocea Biosciences, Inc., et al., Civil Action No. 17-cv-12137-PBS (D. Mass.), and appointed the Genocea Investor Group (a group of five purported shareholders) as lead plaintiff. On March 29, 2018, counsel for the lead plaintiff filed an amended complaint in the District of Massachusetts that alleges the same causes of action and seeks the same relief as the original complaints. The amended complaint adds Seth V. Hetherington, former Chief Medical Officer, to the original named defendants. The defendants filed a motion to dismiss on May 14, 2018. Plaintiffs filed an opposition to defendants' motion to dismiss on June 28, 2018, as well as a motion to strike exhibits referenced in defendants' motion to dismiss, on June 29, 2018. The Company and the other named defendants filed a reply brief to plaintiffs' opposition to defendants' motion to dismiss, and an opposition brief to plaintiffs' motion to strike, on July 30, 2018. The court held oral argument on the motion to dismiss and motion to strike on September 25, 2018, and took each motion under advisement. We are unable at this time to determine whether the outcome of the litigation would have a material impact on our results of operations, financial condition or cash flows.

On January 31, 2018, a putative shareholder derivative action was filed in the U.S. District Court for the District of Delaware, naming certain of the Company's directors and officers as defendants (including certain former directors and officers), and naming the Company as a nominal defendant. On June 20, 2018, a second putative shareholder derivative action was filed in the U.S. District Court for the District of Delaware, naming certain of the Company's officers and directors (including a former officer), and naming the Company as a nominal defendant. On August 24, 2018, the court consolidated the two actions into one case, captioned In re Genocea Biosciences, Inc. Derivative Litigation, Civil Action No. 18-cv-00186-MN (D. Del.). The operative complaint in the now-consolidated action alleges violations of the Securities Exchange Act of 1934 and Rule 14a-9 in connection with disclosures made in the Company's Schedule 14A Proxy Statement, filed with the SEC on April 21, 2017. The complaint also alleges claims for breach of fiduciary duty, unjust enrichment, and waste of corporate assets. On August 10, 2018, the parties filed a joint stipulation and proposed order agreeing to stay the consolidated action until, inter alia, the entry of an order granting or denying any motion to dismiss the action in the District of Massachusetts, and on August 24, 2018, the court entered the joint stipulation agreeing to stay the consolidated action. We intend to vigorously defend ourselves against this action. We are unable at this time to determine whether the outcome of the litigation would have a material impact on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors

There have been no material changes from the risk factors set forth in the Company's Annual Report Form 10-K for the year ended December 31, 2017, other than as set forth below.

Risks Related to Our Financial Position and Need for Additional Capital

We require additional financing to execute our operating plan and continue to operate as a going concern.

Our unaudited condensed consolidated financial statements for the quarter ended September 30, 2018 have been prepared assuming we will continue to operate as a going concern, but we believe that our continuing operating losses raise substantial doubt about our ability to continue as such. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to obtain necessary capital from outside sources, including obtaining additional capital from the sale of our securities or assets, obtaining loans and grant awards from financial institutions and/or government agencies where possible or entering into partnership arrangements. Our continued net operating losses increase the difficulty in obtaining such capital, and there can be no assurances that we will be able to obtain such capital on favorable terms or at all. If we are unable to obtain sufficient capital from the sale of our securities or from alternative sources, we may be required to reduce, defer, or

discontinue certain or all of our research and development activities, including discontinuing development of GEN-009, or we may not be able to continue as a going concern. For example, in September 2017, we ceased substantially all spending and activities related to GEN-003, pending our exploration of strategic alternatives for advancing that product candidate.

Item 6. Exhibits

Exhibit Number	Exhibit
3.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Genocea Biosciences, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on June 25, 2018)
4.1	Warrant Agreement between Genocea Biosciences, Inc. and Hercules Capital, Inc., dated April 24, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on April 30, 2018)
10.1	Amendment to Equity Rights Letter Agreement between Genocea Biosciences, Inc. and Hercules Capital, Inc., dated April 24, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on April 30, 2018)
10.2†	Genocea Biosciences, Inc. Amended and Restated 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on June 25, 2018)
10.3†	Genocea Biosciences, Inc. 2014 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on June 25, 2018)
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 Principal 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 Principal Financial Officer
101	The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2018 and 2017, (iii) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2017 and (iv) Notes to Unaudited Condensed Consolidated Financial Statements

†Indicates a compensatory plan.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Genocea Biosciences, Inc.

Date: November 1, 2018 By: /s/ WILLIAM D. CLARK
William D. Clark
President and Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 1, 2018 By: /s/ MICHAEL ALFIERI
Michael Alfieri
Vice President, Finance (Principal Financial and Accounting Officer)