

GENOCEA BIOSCIENCES, INC.

Form 10-Q

April 30, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2019

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

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

Indicate by check mark whether the registrant has submitted electronically 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 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
Non-accelerated filer Smaller reporting company
Emerging growth company

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.

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

As of April 26, 2019, there were 112,400,736 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 conduct clinical trials for GEN-009, file an investigational new drug (“IND”) application for other product candidates, including GEN-010 and GEN-011, and to continue our investments in immuno-oncology;
- our plans to commercialize GEN-009 and our other product candidates, including GEN-010 and GEN-011;
- 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 rights; and
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing and the timing thereof.

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 March 31, 2019

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

| | March 31, 2019 | December 31, 2018 |
|---|----------------------|-------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$29,038 | \$26,361 |
| Prepaid expenses and other current assets | 1,537 | 696 |
| Restricted cash | 316 | — |
| Total current assets | 30,891 | 27,057 |
| Property and equipment, net | 2,531 | 2,582 |
| Operating lease right-of-use asset | 1,342 | — |
| Restricted cash | — | 316 |
| Other non-current assets | 1,060 | 1,160 |
| Total assets | \$35,824 | \$31,115 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$1,811 | \$1,659 |
| Accrued expenses and other current liabilities | 2,965 | 3,816 |
| Operating lease liabilities | 1,432 | — |
| Current portion of long-term debt | 6,115 | 5,257 |
| Total current liabilities | 12,323 | 10,732 |
| Non-current liabilities: | | |
| Warrant liability | 9,259 | 3,472 |
| Long-term debt, net of current portion and discount | 8,007 | 9,565 |
| Other non-current liabilities | — | 11 |
| Total liabilities | 29,589 | 23,780 |
| Commitments and contingencies (Note 9) | | |
| Stockholders' equity: | | |
| Preferred stock | 701 | 701 |
| Common stock | 112 | 87 |
| Additional paid-in capital | 312,993 | 298,551 |
| Accumulated deficit | (307,571) | (292,004) |
| Total stockholders' equity | 6,235 | 7,335 |
| Total liabilities and stockholders' equity | \$35,824 | \$31,115 |

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 March 31, | |
|---|---------------------------------|------------|
| | 2019 | 2018 |
| Operating expenses: | | |
| Research and development | \$6,460 | \$7,275 |
| General and administrative | 3,017 | 3,109 |
| Total operating expenses | 9,477 | 10,384 |
| Loss from operations | (9,477) | (10,384) |
| Other expense: | | |
| Change in fair value of warrants | (5,787) | (5,298) |
| Interest expense, net | (302) | (201) |
| Other expense | (1) | (7) |
| Total other expense | (6,090) | (5,506) |
| Net loss | \$(15,567) | \$(15,890) |
| Comprehensive loss | \$(15,567) | \$(15,890) |
| Net loss per share - basic and diluted | \$(0.15) | \$(0.22) |
| Weighted-average number of common shares used in computing net loss per share | 101,700 | 71,238 |

See accompanying notes to unaudited condensed consolidated financial statements.

Genocea Biosciences, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(unaudited)
(in thousands)

| | Common Shares | Shares | Preferred Shares | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---------------|--------|------------------|----------------------------|---------------------|----------------------------|
| | Shares | Amount | Amount | Capital | Deficit | Equity |
| Balance at December 31, 2018 | 86,771 | \$ 87 | \$ 701 | \$ 298,551 | \$(292,004) | \$ 7,335 |
| Issuance of common stock, net of issuance costs | 25,600 | 25 | — | 14,001 | — | 14,026 |
| Exercise of stock options | 22 | — | — | 12 | — | 12 |
| Stock-based compensation expense | — | — | — | 429 | — | 429 |
| Net loss | — | — | — | — | (15,567) | (15,567) |
| Balance at March 31, 2019 | 112,393 | \$ 112 | \$ 701 | \$ 312,993 | \$(307,571) | \$ 6,235 |

| | Common Shares | Shares | Preferred Shares | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---------------|--------|------------------|----------------------------|---------------------|----------------------------|
| | Shares | Amount | Amount | Capital | Deficit | (Deficit) |
| Balance at December 31, 2017 | 28,735 | \$ 29 | \$ — | \$ 258,114 | \$(264,193) | \$(6,050) |
| Issuance of common stock, net of issuance costs | 54,323 | 54 | 701 | 35,109 | — | 35,864 |
| Stock-based compensation expense | — | — | — | 644 | — | 644 |
| Net loss | — | — | — | — | (15,890) | (15,890) |
| Balance at March 31, 2018 | 83,058 | \$ 83 | \$ 701 | \$ 293,867 | \$(280,083) | \$ 14,568 |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Three Months Ended March 31, | |
|--|---------------------------------|------------|
| | 2019 | 2018 |
| Operating activities | | |
| Net loss | \$(15,567) | \$(15,890) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation and amortization | 272 | 270 |
| Stock-based compensation | 429 | 644 |
| Allocation of proceeds to transaction expenses | — | 2,115 |
| Change in fair value of warrant liability | 5,787 | 3,183 |
| Gain on sale of equipment | — | (38) |
| Non-cash interest expense | 162 | 98 |
| Changes in operating assets and liabilities | (1,382) | (3,515) |
| Net cash used in operating activities | (10,299) | (13,133) |
| Investing activities | | |
| Purchases of property and equipment | (221) | — |
| Proceeds from sale of equipment | — | 56 |
| Net cash (used in) provided by investing activities | (221) | 56 |
| Financing activities | | |
| Proceeds from issuance of common stock, net of issuance costs | 14,026 | 52,538 |
| Payment of deferred financing costs | — | (20) |
| Repayment of long-term debt | (841) | (535) |
| Proceeds from exercise of stock options | 12 | — |
| Net cash provided by financing activities | 13,197 | 51,983 |
| Net increase in cash and cash equivalents | \$2,677 | \$38,906 |
| Cash, cash equivalents and restricted cash at beginning of period | 26,677 | 12,589 |
| Cash, cash equivalents and restricted cash at end of period | \$29,354 | \$51,495 |
| Supplemental cash flow information | | |
| Cash paid for interest | \$289 | \$242 |

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 discovers and develops novel cancer immunotherapies using its ATLAS™ proprietary discovery platform. The ATLAS platform profiles each patient's CD4⁺ and CD8⁺ T cell immune responses to every potential target or "antigen." Genocea believes that this approach optimizes antigen selection for cancer vaccines and cellular therapies, because it identifies antigens to which a patient's T cells already mount anti-tumor responses. The Company believes that ATLAS could lead to more immunogenic and efficacious cancer immunotherapies.

The Company's most advanced program is GEN-009, a neoantigen (or personalized) cancer vaccine, for which it is conducting a Phase 1/2a clinical trial. The GEN-009 program uses ATLAS to identify neoantigens, or newly formed tumor mutations unique to each patient, for inclusion in each patient's GEN-009 vaccine. The Company is also advancing GEN-011, a neoantigen-specific adoptive T cell therapy program as well as GEN-010, a next-generation neoantigen vaccine program. The Company continues to consider strategic alternatives for GEN-003, its Phase 3-ready investigational immunotherapy for the treatment of genital herpes.

The Company is devoting substantially all of its efforts to product research and development, initial market development, and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other early clinical stage companies, including dependence on key individuals, competition from other companies, the need and related uncertainty associated to 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, dependence on third parties, the need to obtain additional financing, dependence on key individuals, regulatory approval of products, uncertainty of market acceptance of products, competition from companies with greater financial, technological and other resources, compliance with government regulations, protection of proprietary technology, and product liability. 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 Accounting Standards Update ("ASU"), 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40), also referred to as Accounting Standards Codification ("ASC") 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 \$29.0 million at March 31, 2019. In addition, the Company had a loss from operations of approximately \$9.5 million and cash used in operating activities of \$10.3 million for the three months ended March 31, 2019. These

factors, combined with the Company's forecast of cash required to fund operations for a period of at least one year from the date of issuance of these condensed consolidated financial statements, raise substantial doubt about the Company's ability to continue as a going concern.

The Company plans to continue to fund its operations through public or private equity offerings, strategic transactions, proceeds from sales of its common stock under its at-the-market equity offering program, 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 cost reduction strategies, including ceasing development of GEN-009 and other corporate programs and 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

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring accruals necessary for a fair presentation of the Company's financial statements for interim periods in accordance with accounting principles generally accepted in the United States (U.S. GAAP).

We operate as one operating segment, which is discovering, researching and developing novel cancer immunotherapies.

The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our audited consolidated financial statements and the accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2018 ("2018 Form 10-K"). Our accounting policies are described in the "Notes to Consolidated Financial Statements" in our 2018 Form 10-K and updated, as necessary, in our Quarterly Reports on Form 10-Q. The December 31, 2018 condensed consolidated balance sheet data presented for comparative purposes was derived from our audited financial statements, but does not include all disclosures required by U.S. GAAP. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, estimates related to clinical trial accruals, estimates related to prepaid and accrued research and development expenses, stock-based compensation expense, and warrants to purchase redeemable securities. 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.

Summary of Significant Accounting Policies

There were no changes to significant accounting policies during the three months ended March 31, 2019, as compared to the those identified in the 2018 Form 10-K, except for the Company's adoption of ASC Topic 842, Leases on January 1, 2019. The following is the Company's new accounting policy for leases.

Leases

The Company determines if an arrangement is a lease at inception if the lease term is greater than 12 months. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in our consolidated balance sheets. Finance leases are included in property and equipment and other current liabilities in our consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses an estimate of its incremental

borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. The Company uses the implicit rate when readily determinable. The operating lease ROU asset is reduced by deferred lease payments and unamortized lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company has lease agreements with lease and non-lease components, which are generally accounted for separately. The non-lease components generally consist of common area maintenance that is expensed as incurred.

Recently adopted accounting standards

| Standard | Description | Effect on the financial statements |
|--|---|--|
| ASU No. 2016-02, Leases (Topic 842) | <p>In February 2016, the FASB established ASC Topic 842, Leases, (ASC 842) by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. The new standard establishes a right-of-use model ("ROU") that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement.</p> <p>The Company adopted ASC 842 effective January 1, 2019.</p> | <p>The adoption of ASC 842 resulted in the Company recognizing ROU assets and related operating lease liabilities of \$1.3 million and \$1.4 million, respectively, in our condensed consolidated balance sheet as of March 31, 2019.</p> <p>The Company used the modified retrospective method of adoption, with January 1, 2019 as the effective date of initial application. The Company elected the short-term lease recognition exemption for all leases that qualify. The Company elected the package of practical expedients for leases that commenced prior to January 1, 2019, allowing it not to reassess (i) whether any expired or existing contracts contain leases, (ii) the lease classification for any expired or existing leases and (iii) the initial indirect costs for any existing leases.</p> |
| ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting | <p>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.</p> <p>The Company adopted ASU No. 2018-07 effective January 1, 2019.</p> | <p>The adoption of ASU No. 2018-07 did not have a material impact on the Company's condensed consolidated financial statements.</p> |

Recently issued accounting standards

| Standard | Description | Effect on the financial statements |
|---|---|---|
| ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure | <p>In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the</p> | <p>The Company is currently evaluating the potential impact that this standard may have on its consolidated financial</p> |

Framework—Changes to the Disclosure Requirements for Fair Value Measurement

Disclosure Requirements for Fair Value Measurement which requires public entities to disclose certain new information and modifies some disclosure requirements.

statements.

The new guidance will be effective for fiscal years beginning after December 15, 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 Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements.

The new guidance will be effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019.

3. Fair value of financial instruments

The Company has certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

Level 1 - Fair values are determined by utilizing quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access;

Level 2 - Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates, yield curves and foreign currency spot rates; and

Level 3 - Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The Company's financial assets consist of cash equivalents and the Company's financial liabilities consist of warrant liability.

The fair value of the Company's cash equivalents is determined using quoted prices in active markets. Our cash equivalents consist of money market funds. The Company's cash equivalents have been classified as Level 1.

The fair value of the Company's warrant liability (Note 7) is determined using a Monte Carlo simulation. 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, volatility and probability of the Company being acquired. The estimates are based, in part, on subjective assumptions and could differ materially in the future. The Company's warrant liability has been classified as Level 3.

| | Total | Quoted prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
|-------------------|----------|---|---|---|
| March 31, 2019 | | | | |
| Assets: | | | | |
| Cash equivalents | \$28,834 | \$28,834 | \$ | —\$ — |
| Total assets | \$28,834 | \$28,834 | \$ | —\$ — |
| Liabilities: | | | | |
| Warrant liability | \$9,259 | \$— | \$ | —\$ 9,259 |
| Total liabilities | \$9,259 | \$— | \$ | —\$ 9,259 |
| December 31, 2018 | | | | |
| Assets: | | | | |
| Cash equivalents | \$24,651 | \$24,651 | \$ | —\$ — |
| Total assets | \$24,651 | \$24,651 | \$ | —\$ — |
| Liabilities: | | | | |
| Warrant liability | \$3,472 | \$— | \$ | —\$ 3,472 |

Total liabilities \$3,472 \$— \$ —\$ 3,472

The following table reflects the change in the Company's Level 3 warrant liabilities from December 31, 2018 through March 31, 2019:

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| | Warrant Liability |
|------------------------------|----------------------|
| Balance at December 31, 2018 | \$ 3,472 |
| Issuance of Warrants | — |
| Change in fair value | 5,787 |
| Warrants exercised | — |
| Balance at March 31, 2019 | \$ 9,259 |

4. Accrued expenses and other current liabilities

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

| | March 31, 2019 | December 31, 2018 |
|------------------------------------|----------------------|-------------------------|
| Research and development costs | \$ 1,186 | \$ 759 |
| Payroll and employee-related costs | 1,047 | 2,147 |
| Other current liabilities | 732 | 910 |
| Total | \$ 2,965 | \$ 3,816 |

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 2.75% plus the prime rate. 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 paid an end-of-term charge of \$0.8 million in connection with the 2014 Loan Agreement on January 1, 2019, and is obligated to pay an additional end of term charge of 6.7% 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 2018 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. As of March 31, 2019, the Company was in compliance with all covenants of the 2018 Loan Agreement.

Under the provisions of 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.

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 \$100,000, or the occurrence of any material default of the Company involving indebtedness in excess of \$100,000. If an event of default occurs, repayment of all amounts due under the 2018 Loan Agreement may be accelerated by Hercules, including the applicable prepayment charge.

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 2018 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.

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 March 31, 2019.

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"). The Second Warrant is exercisable for 329,411 shares of the Company's common stock at an initial exercise 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. The Second Warrant has been classified as equity for all periods it has been outstanding.

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 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. The End of Term Charges from the 2014 Term Loan are being amortized to interest expense over the life of the 2018 Term Loan using the effective interest method. At March 31, 2019, the 2018 Term Loan bears an effective interest rate of 12.4%.

As of March 31, 2019 and December 31, 2018, the Company had outstanding borrowings of \$14.1 million and \$14.8 million, respectively. Interest expense was \$0.4 million and \$0.3 million for the three months ended March 31, 2019 and 2018, respectively.

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

| | |
|-----------|-----------|
| March 31, | |
| 2019 | |
| 2019 | \$ 3,836 |
| 2020 | 7,031 |
| 2021 | 4,071 |
| Total | \$ 14,938 |

6. Stockholders' equity

As of March 31, 2019, 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 March 31, 2019, 112,393,445 shares of common stock and 1,635 shares of preferred stock were issued and outstanding. As of December 31, 2018, 86,771,175 shares of common stock were issued and outstanding and 1,635 shares of preferred stock were issued and outstanding.

Private Placement

In February 2019, the Company completed a private placement financing transaction (the “Initial Closing”). Pursuant to a Subscription Agreement (the “Subscription Agreement”), the Company issued 25,599,979 shares (the “Shares”) of common stock, prefunded warrants (the “Pre-Funded Warrants”) to purchase 4,250,000 shares of common stock (the “Pre-Funded Warrant Shares”), and warrants (the “Private Placement Warrants”) to purchase up to 7,462,494 shares of common stock (the “Warrant Shares”). The Shares, Pre-Funded Warrants and Private Placement Warrants (collectively, the “Units”) were sold at a purchase price of \$0.5026 per Unit. The Company received net cash proceeds of approximately \$14.0 million including transactions costs for the purchase of the Shares, Pre-Funded Warrant Shares and Warrant Shares.

The Company has the option to issue up to 51,352,857 Shares in a second closing (the “Second Closing”). The optional Second Closing is conditioned upon a decision by a majority of the Company’s board of directors that, from a scientific or medical perspective, the top-line results from Part A of the Phase 1/2a clinical trial for GEN-009 warrant further clinical study (the “Data”). The Company will have fourteen (14) business days after receiving the Data to exercise its option to proceed with the Second Closing. The per share price for the Shares in the Second Closing will be equal to the greater of (i) \$0.4713 or (ii) 0.80 multiplied by the applicable volume weighted average price (which shall run from the date the Company announces the Data through the date the Company exercises its option to proceed with the Second Closing). The purchasers of the Shares, Pre-Funded Warrants and Private Placement Warrants named (the “Purchasers”) in the Initial Closing are eligible to participate in the Second Closing. If a Purchaser does not purchase at least 50% of the shares of common stock that it specified to purchase in the Second Closing (each such Purchaser, a “Non-Participating Purchaser”), it will forfeit any unexercised Private Placement Warrants purchased in the Initial Closing as the Company’s sole remedy for such failure. The other Purchasers that are not Non-Participating Purchasers will have the option, but not the obligation, to purchase the shares of common stock allocated to the Non-Participating Purchasers in the Second Closing.

The holder may exercise the Private Placement Warrants and Pre-Funded Warrants at any time or from time to time through February 14, 2024 and February 14, 2039, respectively, unless the holder becomes a Non-Participating Purchaser, in which case it will forfeit any unexercised Private Placement Warrants. Certain holders will be prohibited from exercising such warrants into shares of our common stock if, as a result of such exercise, the holder, together with its affiliates, would own more than a specific percentage of the total number of shares of our common stock then issued and outstanding. The Private Placement Warrants and Pre-Funded Warrants are exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). The exercise price upon exercise of each Private Placement Warrant is \$0.5656 per share of common stock and the exercise price of each Pre-Funded Warrants is \$0.01 per share of common stock, of which \$0.5025 per share was paid by the holder at the Initial Closing. The exercise price of the warrants is subject to appropriate adjustment in the event of stock dividends, subdivisions, stock splits, stock combinations, reclassifications or reorganizations affecting our common stock. If, at any time while the Private Placement Warrant or Pre-Funded Warrant is outstanding, there is a Change of Control, which generally includes 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, then the holder has the right thereafter to receive, upon exercise of the Private Placement Warrant or Pre-Funded Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Change of Control if it had been, immediately prior to such Change of Control, the holder of the number of Warrant Shares then issuable upon exercise in full of the Private Placement Warrant or Pre-Funded Warrant (the “Alternate Consideration”). If holders of common stock are given any choice as to the securities, cash or property to be received in a Change of Control, then the holder will be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Change of Control. Except for the right to participate in certain dividends and distributions and as otherwise provided in the Private Placement Warrants and the Pre-Funded Warrants or by virtue of a holder’s ownership of our common stock, the holders of the Warrants and Pre-Funded Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants.

The Company determined that the Second Closing requires separate accounting, but the value is insignificant, and that the Private Placement Warrants and the Pre-Funded Warrants should be equity classified in accordance with ASC 480, Distinguishing Liabilities from Equity (“ASC 480”) for the period ended March 31, 2019. The Company also determined that the Pre-Funded Warrants should be included in the determination of basic earnings per share in accordance with ASC 260, Earnings per Share.

Underwritten public offering

In January 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 ("Public Offering Warrants"), 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"). The Company also granted the underwriters an Overallotment Option ("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. The underwriters exercised their Overallotment Option and acquired additional warrants to purchase up to 2,395,795 shares of common stock.

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.

The Company determined that the preferred stock should be equity classified in accordance with ASC 480, Distinguishing Liabilities from Equity ("ASC 480") for the periods ended March 31, 2019 and December 31, 2018, respectively. For the three months ended March 31, 2018, the Company recorded \$0.3 million in additional paid in capital as a result of the preferred stock's beneficial conversion feature.

Public Offering Warrants

The Public Offering 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 Public Offering Warrants, the Company will be obligated to use its best efforts to ensure that the holders of the Public Offering 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 Public Offering 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 Public Offering 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.

The Company determined that the Public Offering Warrants should be liability classified in accordance with ASC 480. As the Public Offering Warrants are liability-classified, the Company remeasures the fair value of the Warrants at each reporting date. The Company initially recorded the Public Offering Warrants at their estimated fair value of approximately \$18.2 million. In connection with the Company's remeasurement of the Public Offering Warrants to the fair value, the Company recorded expense of approximately \$5.8 million and \$3.2 million in the quarters ended March 31, 2019 and 2018, respectively. The fair value of the warrant liability is approximately \$9.3 million and \$3.5 million as of March 31, 2019 and December 31, 2018, respectively (see Note 3).

Issuance Costs

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 within additional paid in capital, and approximately \$1.4 million of the issuance costs to the Public Offering Warrants. As the Public Offering Warrants were classified as liabilities, the Company immediately expensed the issuance costs allocated to the Public Offering Warrants in the three months ended March 31, 2018.

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 March 31, 2019, the Company has sold an aggregate of approximately 3.7 million shares under the ATM and received approximately \$4.0 million in net proceeds after deducting commissions.

7. Warrants

As of March 31, 2019, the Company had the following shares of common stock outstanding related to outstanding warrants:

| | Shares | Exercise price | Expiration date | Classification |
|--|------------|----------------|-----------------|----------------|
| First Warrants | 73,725 | \$ 8.24 | Q4 2019 | Equity |
| Second Warrants | 329,411 | \$ 0.85 | Q2 2023 | Equity |
| Public Offering Warrants | 28,935,550 | \$ 1.20 | Q1 2023 | Liability |
| Initial Closing Private Placement Warrants | 7,462,494 | \$ 0.57 | Q1 2024 | Equity |
| Initial Closing Pre-Funded Warrants | 4,250,000 | \$ 0.01 | Q1 2039 | Equity |
| | 41,051,180 | | | |

The following table details the assumptions used in the Monte Carlo simulation models used to estimate the fair value of the Warrant Liability as of March 31, 2019 and December 31, 2018, respectively:

| | March 31, 2019 | December 31, 2018 |
|---|-------------------|----------------------|
| Stock price | \$ 0.59 | \$ 0.29 |
| Volatility | 117.7 % | 111.3 % |
| Remaining term (years) | 3.8 | 4.1 |
| Expected dividend yield | — | — |
| Risk-free rate | 2.2 % | 2.4%-2.5% |
| Range of annual acquisition event probability | 15.0%-30.0% | 0.0%-30.0% |

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 condensed consolidated statements of operations as follows (in thousands):

| | Three Months Ended March 31, 2019 | 2018 |
|----------------------------|---|--------|
| Research and development | \$ 182 | \$ 141 |
| General and administrative | 247 | 503 |
| Total | \$ 429 | \$ 644 |

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 | Aggregate Intrinsic Value |
|--------|---|--|---------------------------------|
|--------|---|--|---------------------------------|

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| | | | Term (years) | |
|----------------------------------|--------|---------|--------------|-----------|
| Outstanding at December 31, 2018 | 7,139 | \$ 2.35 | 7.80 | \$— |
| Granted | 3,830 | \$ 0.58 | | |
| Exercised | (22) | \$ 0.54 | | |
| Cancelled | (556) | \$ 4.10 | | |
| Outstanding at March 31, 2019 | 10,391 | \$ 1.61 | 8.62 | \$201,625 |
| Exercisable at March 31, 2019 | 2,538 | \$ 3.73 | 6.19 | \$2,323 |

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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 months ended March 31, 2019, and did not recognize stock-based compensation expense for this period. As of March 31, 2019, 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 2018, 2,500,000 additional shares were authorized under the 2014 ESPP. As of March 31, 2019, 2,312,675 shares remain available for future issuance. The stock-based compensation expense related to the 2014 ESPP was insignificant for the three months ended March 31, 2019 and 2018, respectively.

9. 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. Both the 2015 Lease and the 2016 Lease are classified as operating leases and have remaining lease terms of 11 months at March 31, 2019. The right of use asset and lease liability were calculated using an estimated incremental borrowing rate of 10% for both the 2015 and 2016 Leases. For both the three months ended March 31, 2019 and March 31, 2018, rent expense was \$0.4 million.

In March 2019, the Company entered into an agreement to sublease a portion of the leased space under the 2015 Lease, through the end of the lease term in February 2020. Since the Company retained its obligations under the sublease, it did not adjust the lease liability and instead is accounting for the sublease payments as rental income.

Maturities of lease liabilities for both the 2016 Lease and the 2015 Lease are as follows (in thousands):

| | |
|----------------------|---------|
| | March |
| | 31, |
| | 2019 |
| 2019 | \$1,231 |
| 2020 | 274 |
| Total lease payments | 1,505 |

| | |
|-----------------------------|---------|
| Less imputed interest (73) | |
| Total | \$1,432 |

At March 31, 2019 and December 31, 2018, 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.

Litigation

Beginning on October 31, 2017, three putative class action complaints were filed in the U.S. District Court for the District of Massachusetts (the “District of Massachusetts” or the “Court”), naming the Company, Chief Executive Officer William D. Clark, and former Chief Financial Officer Jonathan Poole as defendants. The Court consolidated the three actions into one case, captioned Emerson et al. v. Genocece Biosciences, Inc., et al., Civil Action No. 17-cv-12137-PBS (D. Mass.), and appointed the Genocece 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 alleged violations of the Securities Exchange Act of 1934 and Rule 10b-5 in connection with the Company’s disclosures from March 31, 2016 to September 25, 2017 concerning the development of GEN-003. The amended complaint added Seth V. Hetherington, former Chief Medical Officer, to the original named defendants, and sought unspecified damages and costs. On December 6, 2018, the District of Massachusetts granted defendants’ motion to dismiss the amended complaint for failure to state a claim. On January 7, 2019, the lead plaintiff filed a notice of appeal in the District of Massachusetts regarding the Court order dismissing the amended complaint. The appeal has been docketed in the First Circuit under the caption Yuksel, et al. v. Genoccea Biosciences, et al., Civil Action No. 19-1036 (1st Cir.). The Company is unable at this time to determine whether the outcome of the securities action litigation would have a material impact on its results of operations, financial condition or cash flow.

Beginning on January 31, 2018, two putative shareholder derivative actions were filed in the U.S. District Court for the District of Delaware, naming certain of the Company’s officers and directors (including certain former directors and officers) as defendants, and naming the Company as a nominal defendant. On August 24, 2018, the court consolidated the two actions into one case, captioned In re Genoccea 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. In light of the December 6, 2018 order granting defendants’ motion to dismiss in the District of Massachusetts, the Company and the plaintiffs in the derivative action entered into joint stipulation on February 5, 2019 to stay the derivative action through the duration of the appeal in the securities action. The Company is unable at this time to determine whether the outcome of the derivative litigation would have a material impact on our results of operations, financial condition or cash flows.

10. Net loss per share

The Company computes basic and diluted loss per share using a methodology that gives effect to the impact of outstanding participating securities (the “two-class method”). For both the three-month periods ended March 31, 2019 and 2018, 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):

| | Three Months Ended March 31, | |
|---------------|------------------------------------|--------|
| | 2019 | 2018 |
| Stock options | 10,391 | 5,192 |
| Warrants | 36,801 | 29,016 |
| ESPP | 2,313 | — |
| Total | 49,505 | 34,208 |

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 discovers and develops novel cancer immunotherapies using ATLAS proprietary discovery platform. The ATLAS platform profiles each patient's CD4⁺ and CD8⁺ T cell immune responses to every potential target or "antigen." Genoclea believes that this approach optimizes antigen selection for cancer vaccines and cellular therapies, because it identifies antigens to which a patient's T cells already mount anti-tumor responses. The Company believes that ATLAS could lead to more immunogenic and efficacious cancer immunotherapies.

Our most advanced program is GEN-009, a neoantigen (or personalized) cancer vaccine, for which we are conducting a Phase 1/2a clinical trial. The GEN-009 program uses ATLAS to identify neoantigens, or immunogenic tumor mutations unique to each patient, for inclusion in each patient's GEN-009 vaccine. We are also advancing GEN-011, a neoantigen-specific adoptive T cell therapy program as well as GEN-010, a next-generation neoantigen vaccine program. The Company continues to consider strategic alternatives for GEN-003, its Phase 3-ready investigational immunotherapy for the treatment of genital herpes.

Key Development Highlights

GEN-009 First Patients Dosed - In January 2019, we announced that we had commenced dosing patients and completed enrollment in this first part of the trial. We expect to report immunogenicity results from the initial patient cohort in mid-2019.

ATLAS Platform

Harnessing and directing the T cell arm of the immune system to kill tumor cells is increasingly viewed as having potential in the treatment of many cancers, and this approach has clearly shown efficacy in hematologic malignancies. Vaccines or cellular therapies employing this approach must target specific differences from normal tissue present in a tumor, such as genetic mutations. However, the discovery of such targets, or "antigens," has been particularly challenging for two reasons. First, the genetic diversity of human T cell responses means that effective antigens vary from person to person. Second, the number of candidate antigens can be very large, with up to thousands of candidates per patient in some cancers.

We have designed the ATLAS platform to overcome these antigen discovery challenges. We believe that ATLAS represents the most comprehensive, accurate, and high-throughput system for T cell immune response profiling in the biopharmaceutical industry. ATLAS employs components of the T cell arm of the human immune system from each patient that it profiles in a laboratory setting. Using ATLAS, we measure that patient's T cell responses to the entire set of potential antigens for that individual's cancer. We therefore identify the antigens to which that patient has made anti-tumor responses.

We believe that we are a leader in the field of T cell-related immunotherapy discovery and development. Our management and scientific teams possess considerable experience in oncology, immunology, and vaccinology spanning research, manufacturing, clinical development and regulatory affairs.

Our Immuno-Oncology Programs

Our cancer immunotherapies are designed to educate T cells to recognize and attack specific targets (vaccines) - or to introduce T cells already educated to attack these targets (cellular therapies) - and thereby kill cancer cells. We are first developing 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 immune checkpoint inhibitor ("ICI") 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 ICIs, to potentially direct and enhance an individual's T cell response to their cancer, thereby potentially effecting better clinical outcomes. Data also support the potential of isolating and expanding T cell populations targeting specific neoantigens for therapeutic benefit.

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. Following ATLAS neoantigen identification, we manufacture a personalized vaccine for each patient using only those neoantigens determined to be stimulatory to the immune system by ATLAS.

The following table describes our active immuno-oncology programs in development:

| Vaccine Candidate | Program | Stage of Development | Next Milestone | Anticipated Timeline |
|-------------------|---|----------------------|---|----------------------|
| GEN-009 | First generation neoantigen cancer vaccine | Phase 1/2a | Immunogenicity data from the first patient cohort | Mid-2019 |
| GEN-010 | Second generation neoantigen cancer vaccine | Pre-clinical | Select delivery technology platform | Ongoing |
| GEN-011 | Adoptive T cell therapy | Pre-clinical | IND filing | First half of 2020 |

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

We are also using ATLAS to pursue discovery of novel candidate antigens for non-personalized cancer immunotherapies. Such programs would target shared neoantigens, non-mutated, shared tumor-associated antigens, and cancers of viral origin (e.g., cancers driven by Epstein-Barr Virus infection).

Financing and business operations

We commenced business operations in August 2006. We have financed our operations primarily through the issuance of our equity securities, debt financings, and amounts received through grants. As of March 31, 2019, we had received an aggregate of \$354.5 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 March 31, 2019, our cash and cash equivalents were \$29.0 million.

Since inception, we have incurred significant operating losses. Our net losses were \$15.6 million for the three months ended March 31, 2019, and our accumulated deficit was \$307.6 million as of March 31, 2019. 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 February 2019, we completed a private placement financing transaction. As detailed in Note 6, Stockholders' Equity, we issued Shares, Pre-funded Warrant Shares and Warrants for net cash proceeds of approximately \$14.0 million including transactions costs, fees and expenses. We have the option to issue up to approximately 51.4 million Shares in a Second Closing. The optional Second Closing is conditioned upon a decision by a majority of the Company's board of directors that, from a scientific or medical perspective, the top-line results from Part A of the Phase 1/2a clinical trial for GEN-009 warrant further clinical study.

Costs related to clinical trials can be unpredictable and there can be no guarantee that our current balances of cash and cash equivalents combined with proceeds received from other sources, will be sufficient to fund our trials 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, 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.

The following table identifies research and development expenses for our product candidates as follows (in thousands):

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| | Three Months Ended March 31, | |
|--------------------------------|------------------------------------|---------|
| | 2019 | 2018 |
| Discovery and Pre-IND | \$788 | \$6,059 |
| Phase 1/2a programs | 4,720 | — |
| Other research and development | 952 | 1,216 |
| Total research and development | \$6,460 | \$7,275 |

Discovery and Pre-IND includes costs incurred to support our discovery research and translational science efforts up to the initiation of Phase 1 development. Phase 1/2a programs are Phase 1 or Phase 2 development activities. Pivotal programs are in Phase 3 development or in registration stage. Other research and development includes costs that are not specifically allocated to active product candidates, including facilities costs, depreciation expense, and other costs.

We expect that our overall research and development expenses will increase due to our continued development of our clinical operations and our supply chain capabilities for our GEN-009 program, as well as our advancement of GEN-011 through preparation and submission of an IND and subsequent initiation of a clinical trial.

General and administrative expenses

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

We anticipate that our general and administrative expenses will increase in the future to support the continued research and development of our product candidates and to operate as a public company. Additionally, if and when we believe a regulatory approval of our first product candidate appears likely, we anticipate that we will increase costs in preparation for commercial operations.

Other expense

Other expense consists of the change in warranty liability, interest expense, net of interest income, and other expense for miscellaneous items, such as transaction expenses.

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 U.S. 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 prepaid and accrued research and development expenses, stock-based compensation expense, and the fair value of our warrant liability. 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.

There were no changes to our critical accounting policies during the three months ended March 31, 2019, as compared to the those identified in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018. 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 28, 2019.

Results of Operations

Comparison of the three months ended March 31, 2019 and March 31, 2018

| (in thousands) | Three Months Ended | | Increase (Decrease) |
|----------------------------------|--------------------|------------|------------------------|
| | March 31, 2019 | 2018 | |
| Operating expenses: | | | |
| Research and development | \$6,460 | \$7,275 | \$ (815) |
| General and administrative | 3,017 | 3,109 | (92) |
| Total operating expenses | 9,477 | 10,384 | (907) |
| Loss from operations | (9,477) | (10,384) | (907) |
| Other expense: | | | |
| Change in fair value of warrants | (5,787) | (5,298) | 489 |
| Interest expense, net | (302) | (201) | 101 |
| Other income (expense) | (1) | (7) | (6) |
| Total other expense | (6,090) | (5,506) | 584 |
| Net loss | \$(15,567) | \$(15,890) | \$ (323) |

Research and development expenses

Research and development ("R&D") expenses decreased \$0.8 million in the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. The decrease was primarily due to lower costs associated with manufacturing start up activities and deprioritized programs partially offset by costs associated with the GEN-009 Phase 1/2a clinical trial.

General and administrative expenses

General and administrative expenses decreased \$0.1 million in the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. The decrease was primarily due to decreased consulting and professional services fees partially offset by increased headcount.

Change in fair value of warrants

Change in fair value of warrants reflects non-cash change in fair value of Common Stock Offering Warrants. 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 equivalents. The increase of \$0.1 million for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018, reflects the increased interest expense related to our long-term debt.

Liquidity and Capital Resources

Overview

Since our inception through March 31, 2019, we have received an aggregate of \$354.5 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 March 31, 2019, our cash and cash equivalents were \$29.0 million.

There were no sales under our ATM program during the first quarter of 2019.

Operating Capital Requirements

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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 March 31, 2019, are sufficient to support our operations into the first quarter of 2020. We had available cash and cash equivalents of \$29.0 million at March 31, 2019. In addition, we had a loss from operations of \$9.5 million and cash used in operating activities of \$10.3 million for the three months ended March 31, 2019. These factors, combined with our forecast of cash required to fund operations for a period of at least one year from the date of issuance of these financial statements, raise substantial doubt about our ability to continue as a going concern.

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

- the timing and costs of our planned clinical trials for GEN-009;
- the progress, timing, and costs of manufacturing GEN-009 for planned clinical trials;
- the initiation, progress, timing, costs, and results of preclinical studies and clinical trials for our other product candidates and potential product candidates;
- the outcome, timing, and costs of seeking regulatory approvals, including an IND for GEN-011;
- 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 payments, 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 complete clinical trials and receive regulatory approval for GEN-009 and our other product candidates. 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-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):

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| | Three Months Ended | |
|---|--------------------|------------|
| | March 31, | |
| | 2019 | 2018 |
| Net cash used in operating activities | \$(10,299) | \$(13,133) |
| Net cash provided by (used in) investing activities | (221) | 56 |
| Net cash provided by financing activities | 13,197 | 51,983 |
| Net increase in cash and cash equivalents | \$2,677 | \$38,906 |

Operating Activities

Net cash used in operations decreased \$2.8 million for the three months ended March 31, 2019 compared to the three months ended March 31, 2018. The decrease in net cash used was due primarily to a decrease in accounts payable and accrued expenses partially offset by an increase in prepaid expenses.

Investing Activities

Net cash used in investing increased \$0.3 million for the three months ended March 31, 2019 compared to the three months ended March 31, 2018. The increase in net cash used was primarily due to capitalized software costs.

Financing Activities

Net cash provided by financing activities decreased \$38.8 million for the three months ended March 31, 2019 compared to the three months ended March 31, 2018. In the three months ended March 31, 2018, the Underwritten Public Offering generated gross proceeds of \$56.0 million, whereas in the three months ended March 31, 2019, the Private Placement generated gross proceeds of \$15.0 million.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risk related to changes in interest rates. As of March 31, 2019, we had cash and cash equivalents of \$29.0 million, consisting primarily 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. Since our investments are limited to money market funds, 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 March 31, 2019, we had minimal liabilities denominated in foreign currencies.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed,

summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2019 (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of March 31, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the three months ended March 31, 2019, 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.

In our Annual Report on Form 10-K for the year ending December 31, 2019, our independent registered public accounting firm may be required to provide an assessment as to the effectiveness of 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 (the “District of Massachusetts” or the “Court”), naming the Company, Chief Executive Officer William D. Clark, and former Chief Financial Officer Jonathan Poole as defendants. The Court consolidated the three actions into one case, captioned Emerson et al. v. Genoccea Biosciences, Inc., et al., Civil Action No. 17-cv-12137-PBS (D. Mass.), and appointed the Genoccea 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 alleged violations of the Securities Exchange Act of 1934 and Rule 10b-5 in connection with the Company’s disclosures from March 31, 2016 to September 25, 2017 concerning the development of GEN-003. The amended complaint added Seth V. Hetherington, former Chief Medical Officer, to the original named defendants, and sought unspecified damages and costs. On December 6, 2018, the District of Massachusetts granted defendants’ motion to dismiss the amended complaint for failure to state a claim. On January 7, 2019, the lead plaintiff filed a notice of appeal in the District of Massachusetts regarding the Court order dismissing the amended complaint. The appeal has been docketed in the First Circuit under the caption Yuksel, et al. v. Genoccea Biosciences, et al., Civil Action No. 19-1036 (1st Cir.). The Company is unable at this time to determine whether the outcome of the securities action litigation would have a material impact on its results of operations, financial condition or cash flow.

Beginning on January 31, 2018, two putative shareholder derivative actions were filed in the U.S. District Court for the District of Delaware, naming certain of the Company’s officers and directors (including certain former directors and officers) as defendants, and naming the Company as a nominal defendant. On August 24, 2018, the court consolidated the two actions into one case, captioned In re Genoccea 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. In light of the December 6, 2018 order granting defendants’ motion to dismiss in the District of Massachusetts, the Company and the plaintiffs in the derivative action entered into joint stipulation on February 5, 2019 to stay the derivative action through the duration of the appeal in the securities action. The Company is unable at this time to determine whether the outcome of the derivative litigation would have a material impact on our results of operations, financial condition or cash flows.

The Company does not have contingency reserves established for any litigation liabilities.

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, 2018.

Item 6. Exhibits

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| Exhibit Number | Exhibit |
|----------------|--|
| 10.1* | <u>Subscription Agreement, dated as of February 11, 2019, among Genoceca Biosciences, Inc. and the purchasers party thereto</u> |
| 31.1 | <u>Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Chief Executive Officer</u> |
| 31.2 | <u>Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Chief Financial Officer</u> |
| 32.1 | <u>Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Executive Officer</u> |
| 32.2 | <u>Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Financial Officer</u> |

101 The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of March 31, 2019 and December 31, 2018, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income for the three months ended March 31, 2019 and 2018, (iii) Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the three months ended March 31, 2019 and 2018, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2019 and 2018 and (v) Notes to Unaudited Condensed Consolidated Financial Statements

* Filed herewith.

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: April 30, 2019 By: /s/ WILLIAM D. CLARK

William D. Clark

President and Chief Executive Officer and Director

(Principal Executive Officer)

Date: April 30, 2019 By: /s/ DIANTHA DUVALL

Diantha Duvall

Chief Financial Officer

(Principal Financial and Accounting Officer)