

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, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-36289



GENOCEA BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

51-0596811

(I.R.S. Employer Identification No.)

100 Acorn Park Drive, Cambridge, MA 02140

(Address of principal executive offices, including zip code)

(617) 876-8191

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value	GNCA	Nasdaq Capital Market

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, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by a 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.

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

The number of shares outstanding of the registrant's common stock as of April 27, 2021 was 54,434,839.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

**Genocea Biosciences, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share data)**

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 66,035	\$ 79,769
Prepaid expenses and other current assets	2,785	2,458
Total current assets	68,820	82,227
Property and equipment, net	4,853	5,123
Right of use assets	8,831	9,308
Restricted cash	631	631
Other non-current assets	803	1,204
Total assets	\$ 83,938	\$ 98,493
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,034	\$ 534
Accrued expenses and other current liabilities	4,593	7,344
Deferred revenue	1,641	1,641
Lease liabilities	2,156	1,614
Current portion of long-term debt	2,000	13,862
Total current liabilities	11,424	24,995
Non-current liabilities:		
Warrant liabilities	55,264	56,118
Lease liabilities, net of current portion	7,839	8,398
Long-term debt, net of current portion	7,649	—
Total liabilities	82,176	89,511
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; (25,000,000 shares authorized at March 31, 2021 and December 31, 2020; — shares issued and outstanding at March 31, 2021 and December 31, 2020)	—	—
Common stock, \$0.001 par value; (170,000,000 shares authorized at March 31, 2021 and December 31, 2020, 54,368,582 shares issued and outstanding at March 31, 2021 and 53,018,813 shares issued and outstanding at December 31, 2020)	54	53
Additional paid-in capital	388,359	383,597
Accumulated deficit	(386,651)	(374,668)
Total stockholders' equity	1,762	8,982
Total liabilities and stockholders' equity	\$ 83,938	\$ 98,493

See accompanying notes to the 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	
	2021	2020
Operating expenses:		
Research and development	\$ 8,751	\$ 9,987
General and administrative	3,671	3,388
Total operating expenses	12,422	13,375
Loss from operations	(12,422)	(13,375)
Other income (expense):		
Change in fair value of warrants	854	781
Interest expense, net	(279)	(259)
Other expense	(136)	—
Total other income	439	522
Net loss	\$ (11,983)	\$ (12,853)
Comprehensive loss	\$ (11,983)	\$ (12,853)
Net loss per share:		
Basic	\$ (0.18)	\$ (0.46)
Diluted	\$ (0.17)	\$ (0.46)
Weighted-average number of shares used in computing net loss per share:		
Basic	66,158	28,141
Diluted	74,220	28,141

See accompanying notes to the condensed consolidated financial statements.

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

	Common Stock		Preferred Stock	Additional	Accumulated	Total
	Shares	Amount	Amount	Paid-In Capital	Deficit	Stockholders' Equity
Balance at December 31, 2020	53,019	\$ 53	\$ —	\$ 383,597	\$ (374,668)	\$ 8,982
Issuance of common stock, net	1,301	1	—	3,978	—	3,979
Stock-based compensation expense	—	—	—	580	—	580
Issuance of warrants	—	—	—	120	—	120
Issuance of common stock under employee benefit plans	49	—	—	84	—	84
Net loss	—	—	—	—	(11,983)	(11,983)
Balance at March 31, 2021	<u>54,369</u>	<u>\$ 54</u>	<u>\$ —</u>	<u>\$ 388,359</u>	<u>\$ (386,651)</u>	<u>\$ 1,762</u>

	Common Stock		Preferred Stock	Additional	Accumulated	Total
	Shares	Amount	Amount	Paid-In Capital	Deficit	Stockholders' Equity
Balance at December 31, 2019	27,453	\$ 27	\$ 701	\$ 355,268	\$ (330,954)	\$ 25,042
Issuance of common stock, net	187	1	—	439	—	440
Stock-based compensation expense	—	—	—	384	—	384
Issuance of common stock under employee benefit plans	4	—	—	—	—	—
Net loss	—	—	—	—	(12,853)	(12,853)
Balance at March 31, 2020	<u>27,644</u>	<u>\$ 28</u>	<u>\$ 701</u>	<u>\$ 356,091</u>	<u>\$ (343,807)</u>	<u>\$ 13,013</u>

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31	
	2021	2020
Operating activities		
Net loss	\$ (11,983)	\$ (12,853)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	381	276
Stock-based compensation	580	384
Change in fair value of warrant liability	(854)	(781)
Non-cash interest expense	117	109
Other	101	84
Changes in operating assets and liabilities	(735)	(1,015)
Net cash used in operating activities	(12,393)	(13,796)
Investing activities		
Purchases of property and equipment	(1,109)	(233)
Proceeds from sale of equipment	65	16
Net cash used in investing activities	(1,044)	(217)
Financing activities		
Proceeds from issuance of common stock, net	3,979	440
Proceeds from issuance of common stock under employee benefit plans	84	—
Payments on finance lease	(23)	(45)
Payment of deferred financing costs	(289)	—
Proceeds from long-term debt	10,000	—
Debt prepayment costs	(88)	—
Repayment of long-term debt	(13,960)	—
Net cash provided by (used in) financing activities	(297)	395
Net decrease in cash, cash equivalents and restricted cash	(13,734)	(13,618)
Cash, cash equivalents and restricted cash at beginning of period	80,400	40,758
Cash, cash equivalents and restricted cash at end of period	\$ 66,666	\$ 27,140
Non-cash financing activities and supplemental cash flow information		
Property and equipment included in accounts payable and accrued expenses	\$ 306	\$ —
Right-of-use asset obtained in exchange for lease liabilities	\$ —	\$ 5,931
Cash paid in connection with operating lease liabilities	\$ 709	\$ 394
Cash paid for interest	\$ 166	\$ 261

See accompanying notes to the condensed consolidated financial statements.

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

1. Organization and operations

Genocea Biosciences, Inc. ("Genocea" or 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 is dedicated to discovering and developing novel cancer immunotherapies using its proprietary ATLAS™ platform. The ATLAS platform can profile each patient's CD4⁺ and CD8⁺ T cell immune responses to every potential target or "antigen" identified by next generation sequencing of that patient's tumor. ATLAS zeroes in on both antigens that activate anti-tumor T cell responses and inhibitory antigens, Inhibigens™, that drive pro-tumor immune responses. Genocea believes this approach ensures that cancer immunotherapies, such as vaccines and cellular therapies, focus T cell responses on the tumor targets most vulnerable to T cell targeting. Consequently, the Company believes that ATLAS may enable more immunogenic and efficacious cancer immunotherapies. Genocea operates as one segment, which is discovering, researching, developing and commercializing novel cancer immunotherapies.

Genocea's GEN-011 program is an adoptive T cell therapy comprising neoantigen-targeted peripheral T cells ("NPTs"). NPTs are peripheral blood-derived T cells targeted to ATLAS-identified anti-tumor antigens. By employing ATLAS to optimize neoantigen selection and by using T cells derived from peripheral blood, Genocea believes GEN-011 will enable potential patient efficacy, accessibility and cost advantages over other autologous T cell therapies. The Company is conducting a first-in-human clinical trial for GEN-011. Genocea's GEN-009 program is a neoantigen vaccine delivering adjuvanted synthetic long peptides from ATLAS-identified anti-tumor neoantigens. After reporting initial clinical responses for GEN-009 delivered in combination with standard-of-care checkpoint inhibitors ("CPIs") in 2020, the Company continues to monitor patients to confirm these initial efficacy signals.

Genocea 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 and uncertainties common to companies in the biotech and pharmaceutical industry, including, but not limited to, the risks associated with the uncertainty of success of its preclinical and clinical trials; the challenges associated with gaining regulatory approval of product candidates; the risks associated with commercializing pharmaceutical products, if approved for marketing and sale; the potential for development by third parties of new technological innovations that may compete with Genocea's products; the dependence on key personnel; the challenges of protecting proprietary technology; the need to comply with government regulations; the high cost of drug development; competition from other companies; the uncertainty of being able to secure additional capital when needed to fund operations; and the challenges and uncertainty associated with the outbreak of the novel coronavirus ("COVID-19") that could adversely impact the Company's operations, supply chain, preclinical development work, clinical trials and ability to raise capital.

The Company regularly evaluates 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 financial statements are issued. As of March 31, 2021, Genocea had an accumulated deficit of \$386.7 million and anticipates that it will continue to incur significant operating losses for the foreseeable future as it continues to develop its product candidates. Until such time, if ever, as the Company can generate substantial product revenue and achieve profitability, Genocea expects to finance its cash needs through a combination of equity offerings, strategic transactions, or other sources of funding. If the Company is unable to raise additional funds when needed, it may be required to implement further cost reduction strategies, including ceasing development of GEN-011 or other corporate programs and activities.

Genocea had available cash and cash equivalents of \$66.0 million at March 31, 2021. In addition, the Company used cash of \$12.4 million in its operating activities for the three months ended March 31, 2021. Genocea's available cash and cash equivalents at March 31, 2021 are expected to fund operations for a period of at least a year from the date the financial statements are issued.

2. Summary of significant accounting policies

Basis of presentation

The condensed consolidated financial statements include the accounts of the Company and a wholly owned subsidiary. Intercompany accounts and transactions have been eliminated. In the opinion of the Company's management, the condensed consolidated financial statements reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation. The preparation of these condensed consolidated financial statements and accompanying notes in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported. Actual results could differ materially from those estimates. These condensed consolidated financial statements and accompanying notes should be read in conjunction with the Company's annual consolidated financial statements and accompanying notes included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (the "2020 10-K").

Significant accounting policies

Genocea's significant accounting policies have not changed materially from those disclosed in the 2020 10-K.

New Accounting Pronouncements

In 2019, the Financial Accounting Standards Board issued a new standard on Simplifying the Accounting for Income Taxes. The new standard simplifies the accounting for income taxes and became effective beginning after December 15, 2020. The Company adopted this standard on January 1, 2021. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

3. Revenue

In May 2020, Genoclea entered into a material transfer agreement (the "MTA") with Shionogi & Co., Ltd. ("Shionogi") pursuant to which the Company agreed to transfer certain HSV-2 antigens from its GEN-003 program to Shionogi to evaluate the potential development of a novel HSV-2 vaccine. In connection with the agreement, Genoclea provided Shionogi with an option to negotiate an exclusive development and commercialization license for the HSV-2 antigens.

Under the terms of the MTA, Shionogi paid the Company a total of \$3.0 million in non-refundable, creditable (with respect to the up-front fee pursuant to a development and commercialization agreement) fees. Prior to the expiration of the MTA, Shionogi has the option to negotiate a development and commercialization agreement. If executed, the terms of the development and commercialization agreement are expected to include an upfront payment, regulatory and sales milestones, and tiered royalties. Final terms of the development and commercialization agreement will be based on evaluation of the HSV-2 assets and overall diligence. If licensed, Shionogi will assume responsibility for global development and commercialization of an HSV-2 vaccine product.

Genoclea evaluated the promised goods and services within the MTA and determined those which represented separate performance obligations. As a result, the Company concluded there were two separate performance obligations at the inception of the MTA: (i) a combined performance obligation consisting of a limited use research license and the delivery of the initial antigen materials and (ii) the right to negotiate a license prior to expiration of the MTA, which was deemed to be a material right. The Company determined that the exclusive limited use research license and the delivery of the initial antigen materials should be combined as they are not capable of being distinct. A third party would not be able to provide the initial antigen materials as it contains Genoclea's proprietary intellectual property, and Shionogi could not benefit from the research license without the initial antigen materials. The Company determined that the option to negotiate the development and commercialization agreement prior to the expiration of the MTA is a material right. The \$3.0 million fee associated with the MTA is creditable against the upfront fee for the development and commercialization agreement and represents a discount that would otherwise not be available to the customer without entering into the MTA.

Genoclea estimated the standalone selling price of the initial antigen materials based on the expected cost plus a margin approach. The Company developed its standalone selling price for the material right by applying a probability-weighted likelihood that Shionogi will exercise its option to license the HSV-2 assets.

As of March 31, 2021, \$1.6 million allocated to the material right is considered a contract liability and is recorded as deferred revenue on the Company's condensed consolidated balance sheet. Revenue associated with the material right will be recognized upon either (i) the execution of a development and commercialization agreement or (ii) the termination of the MTA.

4. Fair value of financial instruments

Genoclea 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 and liabilities measured at fair value consist of cash equivalents and warrant liabilities, respectively.

The fair value of Genoclea's cash equivalents is determined using quoted prices in active markets. The Company's cash equivalents consist of money market funds that are classified as Level 1.

The fair value of Genoclea's warrant liabilities is determined using a Monte Carlo simulation. See **Note 9. Warrants** for assumptions used and methodologies utilized in calculating the estimated fair value. The Company's warrant liabilities are classified as Level 3.

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2021 and December 31, 2020 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2021				
Assets:				
Cash equivalents	\$ 64,144	\$ 64,144	\$ —	\$ —
Total assets	\$ 64,144	\$ 64,144	\$ —	\$ —
Liabilities:				
Warrant liabilities	\$ 55,264	\$ —	\$ —	\$ 55,264
Total liabilities	\$ 55,264	\$ —	\$ —	\$ 55,264
December 31, 2020				
Assets:				
Cash equivalents	\$ 76,866	\$ 76,866	\$ —	\$ —
Total assets	\$ 76,866	\$ 76,866	\$ —	\$ —
Liabilities:				
Warrant liabilities	\$ 56,118	\$ —	\$ —	\$ 56,118
Total liabilities	\$ 56,118	\$ —	\$ —	\$ 56,118

The following table reflects the change in Genocoe's Level 3 warrant liabilities (in thousands):

	Warrant Liabilities	
Balance at December 31, 2020	\$	56,118
Change in fair value		(854)
Balance at March 31, 2021	\$	55,264

5. Accrued expenses and other current liabilities

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

	March 31, 2021	December 31, 2020
Research and development costs	\$ 2,817	\$ 2,592
Payroll and employee-related costs	910	2,779
Other current liabilities	866	1,973
Total	\$ 4,593	\$ 7,344

6. Commitments and contingencies

Operating leases

As of March 31, 2021, Genocoe has a lease for two floors of lab and office space in a multi-tenant building in Cambridge, Massachusetts through February 2025. A portion of this leased space is an expansion of the Company's initial lease. Genocoe's right to use and control this expansion space began in March 2020. Genocoe has the option to extend the lease term for an additional five years, which is not included in the Company's ROU assets and associated lease liabilities as of March 31, 2021. In the fourth quarter of 2020, Genocoe incurred costs related to improvements made to its leased office space that were determined to be lessee assets and which were partially reimbursed by the lessor. In the first quarter of 2021, the Company recognized an increase in its lease liabilities of \$0.5 million, which reflects the cash received from the lessor during the quarter for previously approved reimbursements. The Company will amortize the reimbursement as an increase to the ROU asset and a reduction in lease expense over the remaining lease term.

In January 2021, Genocoe entered into a sublease agreement for one floor of lab and office space through June 2022, with an option for the sublessee to extend the sublease for an additional two months. After the initial option, which is at the sublessee's sole discretion, the sublease agreement contains additional options for the Company and the sublessee to mutually extend the sublease for up to an additional eighteen months. As Genocoe retained its obligations under the sublease, it will record the payments received from the sublease as a reduction of lease expense. For the three months ended March 31, 2021, the Company recorded sublease income of \$0.4 million.

For the three months ended March 31, 2021 and 2020 lease expense, net of sublease income, was \$0.3 million and \$0.5 million, respectively. The weighted average remaining lease term and weighted average discount rate of the Company's operating leases are as follows:

	March 31, 2021	December 31, 2020
Weighted average remaining lease term in years	3.91	4.17
Weighted average discount rate	8.13 %	8.12 %

The following table summarizes the presentation of leases in the Company's condensed consolidated balance sheets (in thousands):

	Classification	March 31, 2021	December 31, 2020
Assets			
Operating	Right of use assets	\$ 8,831	\$ 9,278
Finance	Right of use assets	—	30
Total lease assets		<u>\$ 8,831</u>	<u>\$ 9,308</u>
Liabilities			
Current			
Operating	Lease liabilities	\$ 2,156	\$ 1,592
Finance	Lease liabilities	—	22
Non-current			
Operating	Lease liabilities, net of current portion	7,839	8,398
Total lease liabilities		<u>\$ 9,995</u>	<u>\$ 10,012</u>

The minimum lease payments related to the Company's operating leases as of March 31, 2021 were as follows (in thousands):

Remainder of 2021	\$ 2,162
2022	2,943
2023	3,017
2024	3,092
2025	517
Total lease payments	11,731
Less imputed interest	(1,736)
Total	<u>\$ 9,995</u>

At March 31, 2021 and December 31, 2020, the Company had an outstanding letter of credit of \$0.6 million, with a financial institution related to a security deposit for the office and lab space lease, which is secured by cash on deposit and expires in February 2025.

Contractual obligations

Genocea has entered into certain agreements with various universities, contract research organizations and contract manufacturing organizations, which generally include cancellation clauses.

Harvard University license agreement

Genocea has an exclusive license agreement with Harvard University ("Harvard"), granting the Company an exclusive, worldwide, royalty-bearing, sublicensable license to three patent families, to develop, make, have made, use, market, offer for sale, sell, have sold and import licensed products and to perform licensed services related to the ATLAS discovery platform. Genocea is also obligated to pay Harvard milestone payments up to \$1.6 million in the aggregate upon the achievement of certain development and regulatory milestones. As of March 31, 2021, the Company has paid \$0.3 million in aggregate milestone payments. Genocea is obligated under this license agreement to use commercially reasonable efforts to develop, market and sell licensed products in compliance with an agreed-upon development plan. In addition, the Company is obligated to achieve specified development milestones and in the event Genocea is unable to meet its development milestones for any type of product or service, absent any reasonable proposed extension or amendment thereof, Harvard has the right, depending on the type of product or service, to terminate this agreement with respect to such products or to convert the license to a non-exclusive, non-sublicensable license with respect to such products and services.

Upon commercialization of the Company's products covered by the licensed patent rights or discovered using the licensed methods, Genocera is obligated to pay Harvard royalties on the net sales of such products and services sold by the Company, the Company's affiliates, and the Company's sublicensees. This royalty varies depending on the type of product or service but is in the low single digits. The sales-based royalty due by the Company's sublicensees is the greater of the applicable royalty rate or a percentage in the high single digits or the low double digits of the royalties Genocera receives from such sublicensee, depending on the type of product. Based on the type of commercialized product or service, royalties are payable until the expiration of the last-to-expire valid claim under the licensed patent rights or for a period of 10 years from first commercial sale of such product or service. The royalties payable to Harvard are subject to reduction, capped at a specified percentage, for any third-party payments required to be made. In addition to the royalty payments, if the Company receives any additional revenue (cash or non-cash) under any sublicense, it must pay Harvard a percentage of such revenue, excluding certain categories of payments, varying from the low single digits to up to the low double digits depending on the scope of the license that includes the sublicense.

The license agreement with Harvard will expire on a product-by-product or service-by-service and country-by-country basis until the expiration of the last-to-expire valid claim under the licensed patent rights. The Company may terminate the agreement at any time by giving Harvard advance written notice. Harvard may also terminate the agreement in the event of a material breach by the Company that remains uncured; in the event of the Company's insolvency, bankruptcy, or similar circumstances; or if Genocera challenges the validity of any patents licensed to it.

Oncovir license and supply agreement

Genocera has a license and supply agreement with Oncovir, Inc. ("Oncovir") under which Oncovir will manufacture and supply an immunomodulator and vaccine adjuvant, Hiltonol® (poly-ICLC) ("Hiltonol"), to the Company for use in connection with the research, development, use, sale, manufacture, commercialization and marketing of products combining Hiltonol with the Company's technology (the "Combination Product"). Hiltonol is the adjuvant component of GEN-009, which will consist of synthetic long peptides or neoantigens identified using the Company's proprietary ATLAS platform, formulated with Hiltonol.

Oncovir granted the Company a non-exclusive, assignable, royalty-bearing worldwide license, with the right to grant sublicenses through one tier, to certain of Oncovir's intellectual property in connection with the research, development, or commercialization of Combination Products, including the use of Hiltonol, but not the use of Hiltonol for manufacturing or the use or sale of Hiltonol alone. The license will become perpetual, fully paid-up, and royalty-free on the later of January 25, 2028 or the date on which the last valid claim of any patent licensed to the Company under the agreement expires.

Under this agreement, Genocera is obligated to pay Oncovir low to mid six figure milestone payments upon the achievement of certain clinical trial milestones for each Combination Product and the first marketing approval for each Combination Product in certain territories, as well as tiered royalties in the low-single digits on a product-by-product basis based on the net sales of Combination Products.

Genocera may terminate the agreement upon a decision to discontinue the development of the Combination Product or upon a determination by the Company or an applicable regulatory authority that Hiltonol or a Combination Product is not clinically safe or effective. The agreement may also be terminated by either party due to a material uncured breach by the other party, or due to the other party's bankruptcy, insolvency, or dissolution.

7. Debt

In April 2018, the Company entered into an amended and restated loan and security agreement, which was subsequently amended in November 2019 (as amended, the "Hercules Loan Agreement"), with Hercules Capital, Inc. ("Hercules"). The Hercules Loan Agreement provided a \$14.0 million secured term loan that was scheduled to mature on May 1, 2021 and that accrued interest at a floating rate per annum equal to the greater of (i) 8.00%, or (ii) the sum of 3.00% plus the prime rate. The Company was also obligated to pay a final payment charge of \$1.0 million at maturity.

On February 18, 2021 (the "2021 Loan Closing Date"), Genocera entered into a Loan and Security Agreement (the "2021 Loan Agreement") with Silicon Valley Bank ("SVB") for a \$10 million secured term loan (the "2021 Term Loan"). \$9.0 million of the proceeds from the 2021 Term Loan were used to repay the Company's borrowings that were outstanding at the 2021 Loan Closing Date under its previous loan and security agreement with Hercules, paying off all obligations owing under, and extinguishing, the Hercules Loan Agreement on the 2021 Loan Closing Date. The remaining proceeds from the 2021 Term Loan of \$1.0 million were received by the Company for working capital and general corporate purposes.

The 2021 Term Loan will mature on September 1, 2023, which may be extended to March 1, 2024 if certain performance milestones are achieved and no event of default has occurred or is continuing. The 2021 Term Loan accrues interest at a floating per annum rate equal to the greater of (i) 6.25% or (ii) the sum of 3.0% plus the prime rate. The 2021 Term Loan provides for interest-only payments until September 30, 2021, which may be extended to March 31, 2022 if certain performance milestones are achieved and no event of default has occurred or is continuing. 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 2021 Term Loan is subject to a final payment charge of \$0.5 million. The 2021 Term Loan may be prepaid in whole (but not in part), subject to a prepayment charge of 3.0%, if prepaid in any of the first twelve (12) months following the Closing Date, 2.0%, if prepaid after twelve (12) months following the Closing Date but on or prior to twenty four (24) months following the Closing Date, and 1.0% thereafter.

The 2021 Term Loan is secured by a lien on substantially all of the assets of the Company, other than intellectual property, provided that such lien on substantially all assets includes any rights to payments and proceeds from the sale, licensing or disposition of intellectual property.

The 2021 Loan Agreement contains customary 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, 2021, the Company was in compliance with all covenants under the 2021 Loan Agreement.

The 2021 Loan Agreement also includes customary events of default, including payment defaults, breaches of covenants, change of control and occurrence of a material adverse effect. Amounts outstanding during an event of default shall be payable on demand and shall accrue interest at an additional rate of 4.0% per annum of the past due amount outstanding. The Company has determined that the risk of subjective acceleration under the material adverse events clause was remote and therefore has classified the long-term portion of the outstanding principal in non-current liabilities.

In connection with the 2021 Loan Agreement, Genocsa issued to SVB a warrant, dated February 18, 2021 (the "SVB Warrant") to purchase 43,478 shares of the common stock of the Company. See **Note 9. Warrants**. The Company recorded the fair value of the SVB warrant as a discount on the 2021 Term Loan that will be amortized over the expected term of the loan.

As of March 31, 2021 and December 31, 2020, the Company had outstanding borrowings, net of unamortized debt issuance costs, of \$9.6 million and \$13.9 million, respectively. Interest expense was \$0.3 million and \$0.4 million for the three months ended March 31, 2021 and 2020, respectively.

Future principal payments, including final payment charges, as of March 31, 2021 are as follows:

	Principal Payments on Long-Term Debt	
Remainder of 2021	\$	1,250
2022		5,000
2023		4,250
	\$	<u>10,500</u>

8. Stockholders' equity

Agreement with Lincoln Park Capital

Genocsa has a purchase agreement with Lincoln Park Capital ("LPC") pursuant to which, for a period of 30 months beginning in October 2019, the Company has the right, at its sole discretion, to sell up to an additional \$27.5 million of the Company's common stock to LPC based on prevailing market prices of its common stock at the time of each sale. The purchase agreement limits the Company's sales of shares of common stock to LPC to approximately 5.2 million shares of common stock, representing 19.99% of the shares of common stock outstanding on the date of the purchase agreement. The purchase agreement also prohibits the Company from directing LPC to purchase any shares of common stock if those shares, when aggregated with all other shares of the Company's common stock then beneficially owned by LPC and its affiliates, would result in LPC and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of the Company's common stock. As of March 31, 2021, the Company had \$24.0 million remaining under its agreement with LPC.

At-the-market equity offering program

Genocsa has an agreement with Cowen and Company, LLC ("Cowen") to establish an at-the-market equity offering program ("ATM") pursuant to which Cowen is able to offer and sell up to \$50.0 million of the Company's common stock at prevailing market prices. In the three months ended March 31, 2021, the Company sold approximately 1.3 million shares under the ATM program and received net proceeds of \$4.0 million, after deducting commissions. Through March 31, 2021, the Company has sold an aggregate of approximately 4.2 million shares under the ATM and received \$13.8 million in net proceeds. As of March 31, 2021, the Company had \$35.8 million in gross proceeds remaining under the ATM.

9. Warrants

As of March 31, 2021, the Company had the following potentially issuable shares of common stock related to unexercised warrants outstanding (shares in thousands):

	Shares	Exercise Price	Expiration Date	Classification
Hercules Warrant	41	\$ 6.80	Q2 2023	Equity
2018 Warrants	3,617	\$ 9.60	Q1 2023	Liability
2019 Warrants	933	\$ 4.52	Q1 2024	Equity
2019 Pre-Funded Warrants	531	\$ 0.08	Q1 2039	Equity
2020 Warrants	33,613	\$ 2.25	Q3 2024	Liability
2020 Pre-Funded Warrants	12,223	\$ 0.01	N/A	Equity
SVB Warrant	43	\$ 3.45	Q1 2026	Equity
	<u>51,001</u>			

Hercules Warrant

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 dividend payments. Genoclea determined that the Hercules Warrant should be equity-classified.

2018 Warrants

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 dividend payments. 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 2018 Warrants, Genoclea will be obligated to use its best efforts to ensure that the holders of the 2018 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 2018 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, Genoclea will settle the 2018 Warrants in cash and if the Company's stockholders are to receive stock in the Acquisition, Genoclea will issue shares of its common stock to each Warrant holder.

As a result, the Company determined that the 2018 Warrants should be liability-classified. As the 2018 Warrants are liability-classified, the Company remeasures the fair value at each reporting date. Genoclea initially recorded the 2018 Warrants at their estimated fair value of \$18.2 million. In connection with the Company's remeasurement of the 2018 Warrants to fair value, it recorded income of \$0.2 million and \$0.8 million for the three months ended March 31, 2021 and 2020, respectively. The fair value of the warrant liability related to the 2018 Warrants is \$1.5 million and \$1.7 million as of March 31, 2021 and December 31, 2020, respectively.

The following table details the assumptions used in the Monte Carlo simulation models used to estimate the fair value of the 2018 Warrants as of March 31, 2021 and December 31, 2020, respectively:

	March 31, 2021	December 31, 2020
Stock price	\$ 2.71	\$ 2.42
Volatility	50.0% - 95.3%	50.0% - 101.5%
Remaining term (years)	1.8	2.0
Expected dividend yield	— %	— %
Risk-free rate	0.16 %	0.13 %
Acquisition event probability	25.0 %	25.0 %

2019 Warrants and 2019 Pre-Funded Warrants

The exercise price of the warrants is subject to appropriate adjustment in the event of stock dividends, subdivisions, stock splits, stock combinations, reclassifications, reorganizations or a change of control affecting the Company's common stock. Genoclea determined that the 2019 Warrants and the 2019 Pre-Funded Warrants should be equity-classified. The Company also determined that the 2019 Pre-Funded Warrants should be included in the determination of basic earnings per share.

2020 Warrants and 2020 Pre-Funded Warrants

The exercise price of the 2020 Pre-Funded Warrants and the 2020 Warrants is subject to adjustment in the event of stock dividends, subdivisions, stock splits, stock combinations, reclassifications, reorganizations or a change of control affecting the Company's common stock. Genoccea determined that the 2020 Pre-Funded Warrants should be equity-classified and be included in the determination of basic earnings per share.

The holders of the 2020 Warrants are entitled to down round protection until July 24, 2021. The Company is required to obtain shareholder approval for the adjustment to the exercise price as a result of any common stock issuance at a price per share less than \$2.25. As a result, Genoccea determined that the 2020 Warrants should be liability-classified for the period from issuance through July 2021. As the 2020 Warrants are liability-classified, the Company remeasures the fair value at each reporting date. Genoccea initially recorded the 2020 Warrants at their estimated fair value of \$62.5 million. In connection with the Company's remeasurement of the 2020 Warrants to fair value, the Company recorded income of \$0.7 million for the three months ended March 31, 2021. The fair value of the warrant liability related to the 2020 Warrants is \$53.8 million and \$54.5 million as of March 31, 2021 and December 31, 2020, respectively.

The following table details the assumptions used in the Monte Carlo simulation models used to estimate the fair value of the 2020 Warrants as of March 31, 2021 and December 31, 2020, respectively:

	March 31, 2021	December 31, 2020
Stock price	\$ 2.71	\$ 2.42
Volatility	93.9 %	119.1 %
Remaining term (years)	3.3	3.6
Expected dividend yield	—	—
Risk-free rate	0.44 %	0.22 %
Acquisition event probability	40.0 %	40.0 %

SVB Warrant

In connection with the 2021 Loan Agreement, Genoccea issued to SVB the SVB Warrant to purchase 43,478 shares of the common stock of the Company. See **Note 7. Debt**. 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 dividend payments. The Company determined that the SVB Warrant should be equity-classified.

10. Employee benefit plans

Genoccea grants equity awards in the form of stock options and service-based and market-based restricted stock units ("RSUs") to employees and directors of, and consultants and advisors to, the Company through its Amended and Restated 2014 Equity Incentive Plan, ("2014 Equity Incentive Plan"). As of March 31, 2021, there were approximately 0.7 million shares remaining for future issuance under the 2014 Equity Incentive Plan.

The options have a ten-year term and were issued with an exercise price equal to the closing market price of Genoccea's common stock on the grant date. For equity awards with service-based vesting conditions, the Company recognizes compensation expense over the vesting period, which is generally over a four-year period. For equity awards with a market-based vesting condition, the Company recognizes compensation expense over the requisite service period. The number of shares issuable, if any, when a market-based RSU award vests will depend on the degree of achievement of the corporate stock price metrics within the performance period of the award. The Company measures the fair value of stock options on the date of grant using the Black-Scholes option pricing model. The fair value of the service-based RSUs is the closing market price of Genoccea's common stock on the grant date.

Determining the fair value of market-based RSUs

The Company measures the fair value of market-based RSUs on the date of grant using a Monte Carlo simulation model. The Monte Carlo simulation requires the input of assumptions, including the Company's stock price, the volatility of its stock price, remaining term in years, expected dividend yield, and risk-free rate. In addition, the valuation model considers the Company's probability of being acquired within the term of the market-based RSUs, as an acquisition event can potentially impact the vesting. The Company used its own trading history to calculate the expected volatility of the market-based RSUs granted. The risk-free interest rate is determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected term assumed at the grant date.

The following table details the assumptions used in the Monte Carlo simulation model used to estimate the fair value of the market-based RSUs granted during the three months ended March 31, 2021:

	Three Months Ended March 31	
	2021	
Stock price	\$	3.01
Volatility		97.65 %
Remaining term (years)		2.8
Risk-free rate		0.29 %
Annual acquisition event probability		33.0 %

Stock-based compensation expense

Total stock-based compensation expense recognized for stock options and RSUs is as follows (in thousands):

	Three Months Ended March 31	
	2021	2020
Research and development	\$ 258	\$ 160
General and administrative	322	224
Total	\$ 580	\$ 384

Stock options

The following table summarizes stock option activity (shares and aggregate intrinsic value in thousands):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	2,329	\$ 7.05		\$ 505
Granted	1,614	\$ 3.01		
Exercised	(38)	\$ 2.22		
Forfeited/cancelled	(66)	\$ 12.82		
Outstanding at March 31, 2021	3,839	\$ 5.30	8.8	\$ 715
Exercisable at March 31, 2021	930	\$ 12.61	7.0	\$ 134

RSUs

The following table summarizes RSU activity (shares in thousands):

	Shares	Weighted-Average Grant Date Fair Value
Outstanding as of December 31, 2020	550	\$ 2.13
Granted ⁽¹⁾	1,904	\$ 2.52
Vested	(11)	\$ 1.98
Forfeited/cancelled	(9)	\$ 2.11
Outstanding as of March 31, 2021	2,434	\$ 2.44

- The number granted represents the number of shares issuable upon vesting of service-based and market-based RSUs, assuming the Company achieves its corporate stock price metrics at the target achievement level.

Employee stock purchase plan

The 2014 Employee Stock Purchase Plan, as amended (the "ESPP"), issues shares of common stock to participating eligible employees during two six-month offering periods each year. As of March 31, 2021, there were approximately 0.1 million shares remaining for future issuance under the ESPP.

11. Net loss per share

Basic and diluted net loss per share was calculated as follows for the three months ended March 31, 2021 and 2020 (in thousands, except per share amounts):

	Three Months Ended March 31	
	2021	2020
Numerator:		
Net loss	\$ (11,983)	\$ (12,853)
Less: Change in fair value of 2020 Warrants	673	—
Adjusted net loss	<u>\$ (12,656)</u>	<u>\$ (12,853)</u>
Denominator:		
Weighted average common stock outstanding – basic	66,158	28,141
Dilutive effect of common stock issuable from assumed exercise of warrants	8,062	—
Weighted average common stock outstanding – diluted	<u>74,220</u>	<u>28,141</u>
Net loss per share:		
Basic	\$ (0.18)	\$ (0.46)
Diluted	\$ (0.17)	\$ (0.46)

The following potential common shares were excluded from the calculation of net loss per share due to their anti-dilutive effect for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31	
	2021	2020
Warrants	4,634	4,591
Stock options	3,839	1,370
RSUs	2,434	45
Total	<u>10,907</u>	<u>6,006</u>

The 2020 Warrants have been included in the calculation of diluted net loss per share for the three months ended March 31, 2021 as the warrants are both liability-classified and in-the-money. The Company used the treasury stock method to determine the number of dilutive shares.

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”, “will”, “would”, or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed in our Annual Report on Form 10-K for the year ended December 31, 2020 (the “2020 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-011, to continue preclinical studies for our other product candidates and to continue our investments in immuno-oncology;
- our estimates regarding the timing and costs of manufacturing GEN-011;
- our estimates regarding the timing of GEN-011 patient enrollment and dosing;
- our estimates regarding GEN-011 third-party manufacturing capacity;
- our estimates regarding the timing and amount of funds we require to perform monitoring activities to support the GEN-009 clinical trial;
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the timing of, and our ability to, obtain and maintain regulatory approvals for our product candidates;
- the effect of the novel coronavirus (COVID-19) pandemic on the economy generally and on our business and operations specifically, including our research and development efforts, our clinical trials and our employees, and the potential disruptions in supply chains and to our third party manufacturers, including the availability of materials and equipment;
- the potential benefits of strategic partnership agreements and our ability to enter into strategic partnership arrangements;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our manufacturing methods and product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- our ability to quickly and efficiently identify and develop product candidates; and
- our commercialization, marketing and manufacturing capabilities and strategy.

These factors are discussed more fully in our 2020 10-K and elsewhere in this and other reports we file with the SEC. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and investors should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make or collaborations or strategic partnerships we may enter into. 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.

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

Management's discussion and analysis of our financial condition and results of operations should be read in conjunction with our 2020 10-K and our unaudited condensed consolidated financial statements and accompanying notes and other disclosures included in this Quarterly Report on Form 10-Q.

Overview

We are a biopharmaceutical company dedicated to discovering and developing novel cancer immunotherapies using our proprietary ATLAS™ platform. The ATLAS platform can profile each patient's CD4⁺ and CD8⁺ T cell immune responses to every potential target or "antigen" identified by next-generation sequencing of that patient's tumor. ATLAS zeroes in on both antigens that activate anti-tumor T cell responses and inhibitory antigens, Inhibigens™, that drive pro-tumor immune responses. We believe this approach ensures that cancer immunotherapies, such as vaccines and cellular therapies, focus T cell responses on the tumor targets most vulnerable to T cell targeting. Consequently, we believe that ATLAS may enable more immunogenic and efficacious cancer immunotherapies.

Our GEN-011 program is an adoptive T cell therapy comprising neoantigen-targeted peripheral cells ("NPTs"). NPTs are peripheral blood-derived T cells targeted to ATLAS-identified anti-tumor antigens. By employing ATLAS to optimize neoantigen selection and by using T cells derived from peripheral blood, we believe GEN-011 will enable potential patient efficacy, accessibility and cost advantages over other autologous T cell therapies. We are conducting a first-in-human clinical trial (the "TITAN trial") for GEN-011. Our GEN-009 program is a neoantigen vaccine delivering adjuvanted synthetic long peptides from ATLAS-identified anti-tumor neoantigens. After reporting initial clinical responses for GEN-009 delivered in combination with standard-of-care checkpoint inhibitors ("CPIs") in 2020, we continue to monitor patients to further evaluate these initial efficacy signals.

ATLAS platform

Harnessing and directing T cells to kill tumor cells is increasingly viewed as having potential to treat many cancers. Vaccines or cellular therapies employing this approach must target specific differences from normal tissue present in the patient, such as antigens arising from genetic mutations or cancer-causing viruses. However, the discovery of optimal antigens for such immunotherapies has been particularly challenging for two reasons. First, the number of candidate antigens can be very large, with up to thousands of candidates per patient in some cancers. Second, the genetic diversity of human T cell responses means that effective antigens may vary from person to person. An effective antigen selection system must therefore account both for each patient's tumor and for their T cell repertoire.

ATLAS selects antigens through an *ex vivo* assay that unveils CD4⁺ and CD8⁺ T cell immune responses each patient has made to nearly any possible tumor-specific antigen, including candidate neoantigens, tumor-associated antigens and tumor-associated viral antigens. In doing so, we believe that ATLAS provides the most comprehensive and accurate system for identifying the right and wrong antigens for cancer immunotherapies. Previously, all candidate antigens were thought either to be targets of effective anti-tumor responses (stimulatory) or irrelevant. However, using ATLAS, we have identified Inhibigens and demonstrated, in preclinical studies, that such antigens can promote rapid tumor growth, reduce or eliminate the protection of an otherwise effective vaccine, and dampen or reverse the effects of checkpoint inhibitors. We have also demonstrated that classical antigen prediction methodologies often mischaracterize Inhibigens as stimulatory. We therefore believe that both by identifying the optimal neoantigens and by excluding Inhibigens, ATLAS enables differentiated immune responses and clinical efficacy.

We believe ATLAS could have beneficial uses beyond cancer. We have previously demonstrated its effectiveness in identifying novel protective antigens for infectious disease therapies, and we believe it also could provide benefits in autoimmune and other disease therapies. While we believe Inhibigens should be avoided in cancer immunotherapies, they could prove to be beneficial in other therapies. ATLAS could be a key tool in optimizing antigen selection for therapies across a number of diseases.

Intellectual property

Our ATLAS and immuno-oncology intellectual property portfolio comprises eight patent families and two additional pending patent families, all but one of which are wholly owned by us. The first patent family, in-licensed from Harvard University, is directed to one arm of the ATLAS method for identifying antigens. This patent family is comprised of issued United States ("U.S.") patents, with patent terms ranging from 2027 to 2031, as well as granted foreign patents. The second family is directed to expanded ATLAS methods for identifying antigens, as currently practiced by us. This family is comprised of issued U.S. patents, with patent terms ranging from 2029 to 2030, as well as granted foreign patents and pending U.S. and foreign applications. The third family is directed to ATLAS-based methods for selecting or deselecting Inhibigens and stimulatory antigens, cancer diagnosis, prognosis and patient selection, as well as related compositions. This patent family is comprised of an issued U.S. patent with a patent term to 2038, pending applications in eleven foreign jurisdictions, and a pending U.S. application. Additional patents issuing from these applications are expected to have patent terms until at least 2038. The fourth, fifth and sixth families are directed to various methods using ATLAS-identified antigens. These families comprise pending U.S. and foreign applications. Patents issuing from these applications are expected to have patent terms until at least 2039. The two further families and two potential additional families currently comprise Patent Cooperation Treaty ("PCT") applications or U.S. provisional applications and are directed to further methods using ATLAS-identified antigens, to dose regimens for GEN-009, and to our cell-based therapy GEN-011.

Our immuno-oncology programs

GEN-009

GEN-009 is a neoantigen vaccine candidate delivering adjuvanted synthetic long peptides spanning ATLAS-identified anti-tumor neoantigens. We are conducting a Phase 1/2a clinical trial for GEN-009 across a range of solid tumor types. Part A of the trial is assessing the monotherapy GEN-009 for safety, immunogenicity and ability to prevent disease relapse in certain cancer patients with no detectable tumor at the time of vaccination but with a risk of relapse. Part B of the trial is assessing the safety, immunogenicity and preliminary antitumor activity of GEN-009 in combination with CPI therapy in patients with advanced or metastatic tumors.

We have observed the following from our data presented at various medical meetings throughout 2020:

In Part A of the trial, we have observed the following in the eight dosed patients:

- 100% of patients had measurable CD4⁺ and/or CD8⁺ T cell responses to their GEN-009 vaccine;
- Responses were detected against 99% of the administered vaccine neoantigens (N=88 administered antigens), a response rate in excess of that which has been reported previously by others in response to candidate neoantigen vaccines;
- GEN-009 was well tolerated, with no dose-limiting toxicities observed; and
- Only one of the eight vaccinated patients has developed a recurrence of their tumor.

In Part B of the trial, we continue to evaluate immune responses and efficacy in two cohorts of patients, those who are checkpoint-sensitive and those who are checkpoint-resistant.

- In the checkpoint-sensitive cohort, we believe we have shown compelling signals of response.
 - Of the nine checkpoint-sensitive patients, three have independent RECIST™ criteria responses that appear to be attributable to GEN-009.
 - Of those three patients, one patient achieved a complete response and two patients achieved a partial response after vaccination.
- In the checkpoint resistant cohort, we believe that GEN-009 has shown early evidence of stabilization of disease.
 - This group of seven patients initially started their CPI therapy but quickly progressed and transitioned to standard of care therapy which generally consists of radiation and/or chemotherapy. After completing the standard-of-care therapy, these patients received GEN-009 vaccination.
 - Of the seven patients, five appear to have achieved initial disease stabilization.

We believe the GEN-009 data confirm the potential antigen selection advantages of ATLAS and suggest a differentiating advantage for GEN-011.

GEN-011

We believe that GEN-011 represents a new category of solid tumor adoptive T cell therapy, neoantigen-targeted peripheral T cells ("NPTs"). The first neoantigen-targeted T cell therapy to demonstrate clinical efficacy in patients with solid tumors is tumor-infiltrating lymphocyte ("TIL") therapy. TILs consist of a subset of lymphocytes that have invaded a tumor but, importantly, are not all necessarily specific for tumor antigens. TIL therapy requires a fresh, uncontaminated, viable tumor resection from each patient, from which TILs will be obtained. These TILs are then non-specifically expanded in the presence of high dose interleukin-2 ("IL-2") *ex vivo* and infused into that same patient, who has undergone lymphodepletion preconditioning, followed by high dose IL-2 treatment. In certain patients with solid tumors resistant to CPI therapy, TIL therapy has resulted in durable clinical responses. TIL therapy has some drawbacks: it is infeasible to get sufficient tumor or TILs from some patients, the need for fresh tumor adds time and cost to the therapy, and the therapy – particularly because of the high dose IL-2 – may cause serious adverse events.

GEN-011 differs from TIL therapy in two critical ways. First, we use ATLAS to design the product to be highly specific for the neoantigens of anti-tumor T cell responses. Second, we rely on T cells extracted from peripheral blood, which is readily available. We believe these differences may result in GEN-011, if approved, offering efficacy, patient accessibility and cost advantages over other neoantigen-targeting solid tumor T cell therapies.

The potential efficacy advantages derive from the following product features:

- Targeting up to 30 tumor-specific antigens simultaneously to limit tumor escape, with minimal bystander, non-tumor-specific T cells;
- Avoiding T cells specific for Inhibitors that may be detrimental to clinical response;
- Including both CD4⁺ and CD8⁺ tumor antigen-specific T cells; and
- Using peripheral blood-derived T cells, which are believed to have potential for superior activity and persistence when compared to TILs.

The potential patient accessibility and cost advantages derive from the fact that:

- No extra surgery or viable tumor is required as starter material;
- GEN-011 can treat any patient, while some adoptive T cell therapies engineer T cells for applicability to certain human leukocyte antigen types, often limiting their clinical utility to certain subsets of western Caucasians; and
- The GEN-011 cell expansion process is comparatively straightforward, with no T cell receptor ("TCR") vector design or transduction required.

Across more than 16 development and engineering runs in blood derived from cancer patients and healthy donors, we have demonstrated that GEN-011 NPTs:

- Are 99% T cells made up of both CD4⁺ and CD8⁺ T cells with the desired T cell phenotype (>98% central and effector memory, on average);
- Highly neoantigen-specific (96% neoantigen-specific, with activity against 89% of target neoantigens on average);
- Powerfully cytolytic against their targets with no off-target cytotoxicity *in vitro*;
- Polyfunctional, secreting effector, stimulatory and chemoattractive mediators; and
- Highly active and potent.

We are conducting the TITAN trial, treating patients with GEN-011 as monotherapy for tumors that have not achieved an adequate response after CPI therapy. Our target indications include melanoma, non-small cell lung cancer, small cell lung cancer, squamous cell carcinoma of the head and neck, urothelial carcinoma, renal cell carcinoma, cutaneous squamous cell carcinoma, and anal squamous cell carcinoma.

The TITAN trial will contain two patient cohorts:

- Cohort A patients will receive GEN-011 in a repeated low dose regimen with no lymphodepletion and an intermediate dose of IL-2 after each GEN-011 dose;
- Cohort B patients will receive GEN-011 as a single high dose with both lymphodepletion and high dose IL-2.

The TITAN trial's objectives are safety, clinical activity including overall response rate and duration of response and GEN-011's proliferation and persistence as well as tumor T cell penetration. We expect to have initial data from a small subset of patients late in the fourth quarter of 2021 or the first quarter of 2022. However, patient accrual to clinical trials and subsequent dosing and compliance are dependent upon both patient choice and health, and investigator decisions. Predictions of data availability and release of results may be affected by individual patient events among other factors.

Other research activities

In addition to our two clinical programs, we are conducting research in several areas:

- Exploring the potential for novel antigens of protective T cell responses to SARS-CoV-2 ("COVID-19") to provide effectiveness against multiple virus strains, partly in collaboration with the University of Massachusetts Medical School;
- Identifying TCRs to ATLAS-identified shared neoantigens, in collaboration with the University of Minnesota;
- Exploring T cell responses to oncoviruses associated with certain cancers such as Epstein-Barr virus and human papilloma virus;
- Identifying shared antigen immunotherapies encompassing shared neoantigens and non-mutated tumor-associated antigens;
- Exploring Inhibigen biology; and
- Further optimizing ATLAS.

Since these other research activities are early stage, we cannot provide specific timelines for if, or when, these activities may result in new clinical candidates.

Business update regarding COVID-19

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly affect our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

To date, we have been able to continue our operations and do not anticipate any material interruptions for the foreseeable future. However, we are continuing to assess the potential impact of the COVID-19 pandemic on our business and operations, including our expenses, supply chain and pre-clinical and clinical trials.

Our third-party contract manufacturing partners continue to operate their manufacturing facilities at or near normal levels. While we currently do not anticipate any interruptions in our supply chain, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our and/or our third-party suppliers and contract manufacturing partners' ability to manufacture our products or the products of our partners.

Financing and business operations

We commenced business operations in August 2006. To date, our operations have been limited to organizing and staffing our company, acquiring and developing our proprietary ATLAS technology, identifying potential product candidates, and undertaking preclinical studies and clinical trials for our product candidates. We have not generated any product revenue and do not expect to do so for the foreseeable future. We have financed our operations primarily through the issuance of our equity securities and through debt financings. As of March 31, 2021, we had received an aggregate of \$447.5 million in net proceeds from the issuance of equity securities, we had outstanding borrowings of \$10.5 million, and our cash and cash equivalents were \$66.0 million.

Since inception, we have incurred significant operating losses. 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 January 2021, we entered into a sublease agreement for one floor of lab and office space through June 2022, with an option for the sublessee to extend the sublease for an additional two months. After the initial option, which is at the sublessee's sole discretion, the sublease agreement contains additional options for us and the sublessee to mutually extend the sublease for up to an additional eighteen months. As we retained our obligations under the sublease, we are recording the payments received from the sublease as a reduction of lease expense. Sublease income was \$0.4 million during the three months ended March 31, 2021.

On February 18, 2021 (the "2021 Loan Closing Date"), we entered into a Loan and Security Agreement (the "2021 Loan Agreement") with Silicon Valley Bank ("SVB") for a \$10 million secured term loan (the "2021 Term Loan"). \$9.0 million of the proceeds from the 2021 Term Loan were used to repay our borrowings that were outstanding at the 2021 Loan Closing Date under our previous loan and security agreement with Hercules Capital, Inc. ("Hercules"), paying off all obligations owing under, and extinguishing, the previous loan and security agreement with Hercules on the 2021 Loan Closing Date. The remaining proceeds from the 2021 Term Loan of \$1.0 million were received by us for working capital and general corporate purposes.

We have an agreement with Cowen and Company, LLC ("Cowen") to establish an at-the-market equity offering program ("ATM") pursuant to which Cowen is able to offer and sell up to \$50.0 million of our common stock at prevailing market prices. In the three months ended March 31, 2021, we sold approximately 1.3 million shares under our ATM program and received net proceeds of \$4.0 million, after deducting commissions. Through March 31, 2021, we have sold an aggregate of approximately 4.2 million shares under the ATM and received \$13.8 million in net proceeds. As of March 31, 2021, we had \$35.8 million in gross proceeds remaining under the ATM.

We have a purchase agreement with Lincoln Park Capital ("LPC") pursuant to which, for a period of 30 months beginning in October 2019, we have the right, at our sole discretion, to sell up to \$27.5 million of our common stock to LPC based on prevailing market prices of our common stock at the time of each sale. The purchase agreement limits our sales of shares of common stock to LPC to approximately 5.2 million shares of common stock, representing 19.99% of the shares of common stock outstanding on the date of the purchase agreement. The purchase agreement also prohibits us from directing LPC to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by LPC and its affiliates, would result in LPC and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of our common stock. As of March 31, 2021, we had \$24.0 million remaining under our agreement with LPC.

As reflected in our condensed consolidated financial statements, we used cash of \$12.4 million to fund operating activities for the three months ended March 31, 2021 and had \$66.0 million available in cash and cash equivalents at March 31, 2021. In addition, we had an accumulated deficit of \$386.7 million and anticipate that we will continue to incur significant operating losses for the foreseeable future as we continue to develop our product candidates. Until such time, if ever, as we attempt to generate substantial product revenue and achieve profitability, we expect to finance our cash needs through a combination of equity offerings and strategic transactions, and other sources of funding. If we are unable to raise additional funds when needed, we may be required to implement cost reduction strategies, including ceasing development of GEN-009, GEN-011 or other corporate programs and activities. Our available cash and cash equivalents at March 31, 2021 are expected to fund operations to mid-2022, and we have strategic plans to extend our operating cash to the end of 2022.

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, GEN-011 or any other product candidate. Accordingly, we will be required to obtain further funding through public or private equity offerings, collaboration and licensing arrangements, or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all, which could result in a decision to pause or delay development or advancement of clinical trials for one or more of our product candidates. Similarly, we may decide to pause or delay development or advancement of clinical trials for one or more of our product candidates if we believe that such development or advancement is imprudent or impractical.

Financial Overview

Revenues

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for the foreseeable future.

Research and development expenses

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

- salary and related expenses;
- expenses incurred under agreements with contract research organizations, contract manufacturing organizations, 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):

	Three Months Ended March 31	
	2021	2020
Phase 1/2a programs	\$ 5,776	\$ 4,793
Discovery and pre-IND	1,786	3,809
Other research and development	1,189	1,385
Total research and development	<u>\$ 8,751</u>	<u>\$ 9,987</u>

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

General and administrative expenses

General and administrative expenses consist primarily of salaries and related expenses for personnel in executive and other administrative functions. Other general and administrative expenses include facility costs, professional fees associated with consulting, corporate and intellectual property legal expenses, and accounting services.

Other income/(expense)

Other income/(expense) consists of the change in the fair value of the warrant liability, transaction expenses, interest expense, net of interest income, gains and losses on sale and disposal of assets, and gains and losses on foreign currency.

Critical Accounting Policies and Significant Judgments and Estimates

Our critical accounting policies have not changed from those described in the 2020 10-K.

Results of Operations

Comparison of the three months ended March 31, 2021 and 2020

Research and development expenses

	Three Months Ended March 31	
	2021	2020
	(in thousands)	
Research and development	\$ 8,751	\$ 9,987

Research and development expenses decreased \$1.2 million in the three months ended March 31, 2021, as compared to the three months ended March 31, 2020. The decrease was largely due to decreased external manufacturing costs of \$1.3 million, lower clinical costs of \$0.3 million and decreased costs for lab supplies of \$0.2 million, partially offset by increased headcount-related costs of \$0.6 million.

General and administrative expenses

	Three Months Ended March 31	
	2021	2020
	(in thousands)	
General and administrative	\$ 3,671	\$ 3,388

General and administrative expenses increased \$0.3 million in the three months ended March 31, 2021, as compared to the three months ended March 31, 2020. The increase was primarily due to an increase in headcount-related costs of \$0.4 million and higher professional services fees of \$0.2 million, partially offset by decreased rent expense, net of sublease income, of \$0.3 million.

Change in fair value of warrants

	Three Months Ended March 31	
	2021	2020
	(in thousands)	
Change in fair value of warrants	\$ 854	\$ 781

Change in fair value of warrants reflects the non-cash change in the fair value of the 2020 Warrants and the 2018 Warrants, which are recorded at their fair value on the date of issuance and then remeasured at the end of each reporting period. In the three months ended March 31, 2021, the change in the fair value of warrants was primarily attributed to the increase in our stock price between December 31, 2020 and March 31, 2021.

Interest expense, net

	Three Months Ended March 31	
	2021	2020
	(in thousands)	
Interest expense, net	\$ 279	\$ 259

Interest expense, net, consists primarily of interest expense on our long-term debt facilities, partially offset by interest earned on our cash equivalents.

Other expense

	Three Months Ended March 31	
	2021	2020
	(in thousands)	
Other expense	\$ 136	\$ —

Other expense consists primarily of debt prepayment and extinguishment costs.

Liquidity and Capital Resources

Overview

Since our inception in 2006, we have funded operations primarily through proceeds from issuances of common stock and long-term debt. As of March 31, 2021, we had \$66.0 million in cash and cash equivalents.

In April 2018, we entered into an amended and restated loan and security agreement, which was subsequently amended in November 2019 (as amended, the “Hercules Loan Agreement”), with Hercules. The Hercules Loan Agreement provided a \$14.0 million secured term loan that was scheduled to mature on May 1, 2021 and that accrued interest at a floating rate per annum equal to the greater of (i) 8.00%, or (ii) the sum of 3.00% plus the prime rate. We were also obligated to pay a final payment charge of \$1.0 million at maturity.

On the 2021 Loan Closing Date, we entered into the 2021 Loan Agreement with SVB for the \$10 million 2021 Term Loan. \$9.0 million of the proceeds from the 2021 Term Loan were used to repay our borrowings that were outstanding at the 2021 Loan Closing Date under the Hercules Loan Agreement, paying off all obligations owing under, and extinguishing, the Hercules Loan Agreement, on the 2021 Loan Closing Date. The remaining proceeds from the 2021 Term Loan of \$1.0 million were received by us for working capital and general corporate purposes.

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for the foreseeable future.

We have an agreement with Cowen to establish an ATM program pursuant to which Cowen is able to offer and sell up to \$50.0 million of our common stock at prevailing market prices. In the three months ended March 31, 2021, we sold approximately 1.3 million shares under our ATM program and received net proceeds of \$4.0 million, after deducting commissions. Through March 31, 2021, we have sold an aggregate of approximately 4.2 million shares under the ATM and received \$13.8 million in net proceeds. As of March 31, 2021, we had \$35.8 million in gross proceeds remaining under the ATM.

We have a purchase agreement with LPC pursuant to which, for a period of 30 months beginning in October 2019, we have the right, at our sole discretion, to sell up to \$27.5 million of our common stock to LPC based on prevailing market prices of our common stock at the time of each sale. The purchase agreement limits our sales of shares of common stock to LPC to approximately 5.2 million shares of common stock, representing 19.99% of the shares of common stock outstanding on the date of the purchase agreement. The purchase agreement also prohibits us from directing LPC to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by LPC and its affiliates, would result in LPC and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of our common stock. As of March 31, 2021, we had \$24.0 million remaining under our agreement with LPC.

Cash flows from operating activities

Cash flows from operating activities consist of our net loss adjusted for various non-cash items, changes in working capital and changes in certain other balance sheet accounts. Cash used in operating activities for the three months ended March 31, 2021 and 2020 was \$12.4 million and \$13.8 million, respectively. Cash used in operating activities decreased \$1.4 million for the three months ended March 31, 2021 compared to the three months ended March 31, 2020, primarily due to a decrease in our research and development expenses due to lower clinical and external development costs for GEN-009.

Cash flows from investing activities

Investing activities consumed \$1.0 million of cash in three months ended March 31, 2021 compared to \$0.2 million in three months ended March 31, 2020. Cash used by investing activities was primarily for purchases of property and equipment in both of the three months ended March 31, 2021 and 2020.

Cash flows from financing activities

Financing activities used \$0.3 million in the three months ended March 31, 2021 compared to \$0.4 million provided in the three months ended March 31, 2020. In the three months ended March 31, 2021, we repaid \$14.0 million in long-term debt and paid deferred financing charges of \$0.3 million, partially offset by the issuance of long-term debt for proceeds of \$10.0 million and the issuance of shares under our ATM program for net proceeds of \$4.0 million. In the three months ended March 31, 2020, we issued shares of common stock to LPC for net proceeds of \$0.4 million.

Operating capital requirements

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

We expect that our existing cash and cash equivalents are sufficient to support our operations to mid-2022, and we have strategic plans to extend our operating cash to the end of 2022. 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 coupled with the global economic uncertainty that has arisen with the outbreak of the coronavirus, or referred to as COVID-19, 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- 011;

- the progress, timing, and costs of manufacturing GEN-011;
- the timing of GEN-011 patient enrollment and dosing;
- the availability of GEN-011 third-party manufacturing capacity;
- the timing and costs we require to perform monitoring activities to support the GEN-009 clinical trial;
- the initiation, progress, timing, costs, and results of preclinical studies and clinical trials for our other product candidates and potential 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;
- the extent to which we in-license or acquire other products and technologies;
- the receipt of marketing approval;
- the costs of commercialization activities for GEN-009, GEN-011 and other product candidates, if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution, and manufacturing capabilities; and
- revenue received from commercial sales of our product candidates.

We will need to obtain substantial additional funding in order to complete clinical trials and receive regulatory approval for GEN-009, GEN-011 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. 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, GEN-011 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, GEN-011 or our other product candidates that we otherwise would seek to develop or commercialize ourselves.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We had cash and cash equivalents of \$66.0 million as of March 31, 2021. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk relates to fluctuations in interest rates, which are affected by changes in the general level of U.S. interest rates. Given the short-term nature of our cash and cash equivalents, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations. We do not own any derivative financial instruments.

We do not believe that our cash and cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

We currently do not have significant exposure to foreign currencies as we hold no foreign exchange contracts, option contracts, or other foreign hedging arrangements. Further, our operations are primarily denominated in U.S. dollars. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our results of operations during the three months ended March 31, 2021.

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, as amended (the "Exchange Act"), 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, 2021 (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). 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, 2021, 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, 2021, 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 Exchange Act that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. 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.

Item 1A. Risk Factors

There have been no material changes from the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2020.

Item 6. Exhibits

Exhibit Number	Exhibit
3.1	Fifth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on February 12, 2014)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on June 25, 2018)
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on May 21, 2019)
3.4	Certificate of Amendment to Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on June 2, 2020)
3.5	Certificate of Correction to the Certificate of Amendment to the Restated Certificate of Incorporation of Genoclea Biosciences, Inc. (incorporated by reference to Exhibit 3.5 to the Company's Quarterly Report on Form 10-Q, File No. 001-36289, filed on July 23, 2020)
10.1*†	Form of Performance-Based Restricted Stock Unit Award Agreement under the Genoclea Biosciences, Inc. 2014 Equity Incentive Plan
31.1*	Rule 13a-14(a) / 15d-14(a) Certification of Principal Executive Officer
31.2*	Rule 13a-14(a) / 15d-14(a) Certification of Principal Financial Officer
32**	Section 1350 Certifications of Principal Executive Officer and Principal Financial Officer
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Date File (embedded within the Inline XBRL document)

* Filed herewith

** Furnished herewith

† Indicates a management contract or compensatory plan

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 29, 2021

By: /s/ WILLIAM D. CLARK

William D. Clark

President and Chief Executive Officer and Director

(Principal Executive Officer)

Date: April 29, 2021

By: /s/ DIANTHA DUVALL

Diantha Duvall

Chief Financial Officer

(Principal Financial and Accounting Officer)

Name of Grantee:	[_____]
Target Number of PSUs:	[_____]
Date of Grant:	[_____]

Genocea Biosciences, Inc.

2014 Equity Incentive Plan

Performance-Based Restricted Stock Unit Award Agreement

This agreement (this “Agreement”) evidences an award (the “Award”) of performance-based restricted stock units granted by Genocea Biosciences, Inc. (the “Company”) to the individual named above (the “Grantee”), pursuant to and subject to the terms of the Genocea Biosciences, Inc. 2014 Equity Incentive Plan (as amended from time to time, the “Plan”).

1. Grant of PSUs. The Company grants to the Grantee on the date set forth above (the “Date of Grant”) the target number of performance-based Restricted Stock Units (the “PSUs”) set forth above (the “Target Award”), giving the Grantee the conditional right to receive, without payment and pursuant to and subject to the terms set forth in this Agreement and in the Plan, one share of Stock (a “Share”) with respect to each PSU forming part of the Award, subject to adjustment pursuant to Section 7(b) of the Plan in respect of transactions occurring after the date hereof. The percentage of the Target Award that may be earned by the Grantee will be determined in accordance with Exhibit A hereto.

2. Meaning of Certain Terms. Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan. The following terms have the following meanings:

(a) “Beneficiary” means, in the event of the Grantee’s death, the beneficiary named in the written designation (in a form acceptable to the Administrator) most recently filed with the Administrator by the Grantee prior to the Grantee’s death and not subsequently revoked, or, if there is no such designated beneficiary, the executor or administrator of the Grantee’s estate. An effective beneficiary designation will be treated as having been revoked only upon receipt by the Administrator, prior to the Grantee’s death, of an instrument of revocation in form acceptable to the Administrator.

3. Earning; Vesting; Cessation of Employment.

(a) Earned PSUs. The PSUs shall become “Earned PSUs” following the end of the Performance Period (as defined in Exhibit A) to the extent earned in accordance with the performance criteria set forth on Exhibit A (the “Performance Criteria”), based on the Administrator’s determination, in its sole discretion, of the level of achievement of the Performance Criteria.

(b) Vesting of Earned PSUs. Unless earlier terminated, forfeited, relinquished or expired, the Earned PSUs will vest in full on the date on or following the end of the Performance Period on which the Administrator determines the extent to which, if any, the Performance Criteria have been met and the number of Earned PSUs (not later than January 31, 2024) (the “Vesting Date”), subject to the Grantee remaining in continuous Employment from the Date of Grant through the Vesting Date except as described in Section 2(c) below.

- (c) Cessation of Employment. Automatically and immediately upon the cessation of the Grantee's Employment, except as expressly provided for in an employment, severance-benefit or other agreement between the Grantee and the Company that is in effect at the time of such termination of Employment, (i) the unvested portion of the Award will terminate and be forfeited for no consideration, and (ii) the vested portion of the Award, if any, will terminate and be forfeited for no consideration if the Grantee's Employment is terminated in connection with an act or failure to act constituting Cause (as the Administrator, in its sole discretion, may determine), or such termination of Employment occurs in circumstances that in the determination of the Administrator would have entitled the Company and its subsidiaries to terminate the Grantee's Employment for Cause.
4. Delivery of Shares. Subject to Section 5 below, the Company shall, as soon as practicable upon the vesting of any PSUs (but in no event later than March 15th of the year following the year in which such PSUs vest), effect delivery of the Shares with respect to such vested PSUs to the Grantee (or, in the event of the Grantee's death following the vesting of such portion of the Award, to the Grantee's Beneficiary). No Shares will be issued pursuant to the Award unless and until all legal requirements applicable to the issuance or transfer of such Shares have been complied with to the satisfaction of the Administrator.
5. Forfeiture; Recovery of Compensation. The Administrator may cancel, rescind, withhold or otherwise limit or restrict the Award at any time if the Grantee is not in compliance with all applicable provisions of this Agreement and the Plan. By accepting, or being deemed to have accepted, the Award, the Grantee expressly acknowledges and agrees that his or her rights, and those of any Beneficiary or permitted transferee of the Award, under the Award, including the right to any Shares acquired under the Award or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). The Grantee further agrees to be bound by the terms of any clawback, recoupment or similar policy of the Company or any of its Affiliates and any policy of the Company or any of its Affiliates that relates to trading on non-public information and permitted transactions with respect to shares of Stock, including limitations on hedging and pledging. Nothing in the preceding sentence will be construed as limiting the general application of Section 10 of this Agreement.
6. Dividends; Other Rights. The Award may not be interpreted to bestow upon the Grantee any equity interest or ownership in the Company or any subsidiary prior to the date on which the Company delivers Shares to the Grantee. The Grantee is not entitled to vote any Shares by reason of the granting of the Award or to receive or be credited with any dividends declared and payable on any Share prior to the date on which any such Share is delivered to the Grantee hereunder. The Grantee will have the rights of a shareholder only as to those Shares, if any, that are actually delivered under the Award.
7. Nontransferability. The Award may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

8. Withholding. The Grantee expressly acknowledges that the vesting or settlement of the PSUs granted hereunder may give rise to “wages” subject to withholding. The Grantee expressly acknowledges and agrees that the Grantee’s rights hereunder, including the right to receive Shares following the vesting of any portion of the Award, are subject to the satisfaction of all taxes required to be withheld with respect to the Award. Unless otherwise determined by the Company, the Company shall automatically satisfy these tax withholding obligations by withholding from the Shares that would otherwise be delivered in connection with such vesting date a number of Shares having a fair market value equal to the minimum statutory amount required to be withheld to satisfy such tax withholding obligations and/or by causing such number of Shares to be sold in accordance with a sell-to-cover arrangement. The Grantee authorizes the Company and its subsidiaries to withhold any amounts due in respect of any required tax withholdings by withholding from the Shares otherwise deliverable in connection with this Award, by causing such Shares to be sold in accordance with a sell-to-cover arrangement and/or by withholding from any amounts otherwise owed to the Grantee. The Grantee acknowledges and agrees that he or she shall be solely responsible for any brokerage or third-party fees associated with any such sell-to-cover arrangement. Nothing in this Section 8 shall be construed as relieving the Grantee of any liability for satisfying his or her tax obligations relating to the Award.

9. Effect on Employment. Neither the grant of the Award, nor the issuance of Shares upon the vesting of the Award, will give the Grantee any right to be retained in the employ or service of the Company or any of its subsidiaries, affect the right of the Company or any of its subsidiaries to terminate the Employment of the Grantee at any time, or affect any right of the Grantee to terminate his or her Employment at any time.

10. Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been furnished to the Grantee. By accepting, or being deemed to have accepted, all or any portion of the Award, the Grantee agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

11. Acknowledgements. The Grantee acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument, (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder, and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Grantee.

[Signature page follows.]

The Company, by its duly authorized officer, and the Grantee have executed this Agreement.

GENOCEA BIOSCIENCES, INC.

By: _____

Name: _____

Title: _____

Agreed and Accepted:

By _____

Signature Page to Performance-Based Restricted Stock Unit Award Agreement

Exhibit A
Performance Criteria

1. General. The Target Award will be eligible to be earned subject to the terms and conditions of Section 3 of this Exhibit A based on the Stock Price at the end of the Performance Period. Stock Price shall be the Performance Criterion under the Award.
2. Definitions. The terms set forth below, as used in this Exhibit A, shall the following meanings:
 - (a) “Performance Period” shall mean the period beginning on the Performance Period Start Date and ending on the Performance Period End Date or, if earlier, the consummation of a Covered Transaction.
 - (b) “Performance Period End Date” shall mean December 31, 2023.
 - (c) “Performance Period Start Date” shall mean the Date of Grant.
 - (d) “Stock Price” means the average closing price of a share of Stock over the sixty (60)-trading days immediately preceding the Performance Period End Date or, if a Covered Transaction is consummated on or before the Performance Period End Date, the closing price of a share of Stock on the date such Covered Transaction is consummated.
3. Earning of PSUs. No PSUs shall become earned unless the Stock Price equals or exceeds \$7.00* as of the end of the Performance Period. If the Stock Price equals or exceeds \$7.00* as of the end of the Performance Period, the number of PSUs that become Earned PSUs shall be equal to the number of PSUs subject to the Target Award multiplied by the “Applicable Percentage” set forth in the table below. In the event that the Stock Price falls between two of the prices listed in the table below at the end of the Performance Period, the Applicable Percentage shall be interpolated on a straight-line basis and the percentage of the Target Award earned shall be based on such interpolated percentage. If Stock Price equals or exceeds \$12.00* as of the end of the Performance Period, the Applicable Percentage shall be one hundred and fifty percent (150%).

Stock Price*	Applicable Percentage
\$7.00	75%
\$8.00	100%
\$10.00	125%
\$12.00	150%

*Subject to adjustment in accordance with the Plan.

4. Determinations by Administrator. At the end of the Performance Period, the Administrator shall determine the extent to which, if any, the Performance Criterion have been met and the number of PSUs that are earned hereunder. Any PSUs that are earned hereunder or that are deemed earned are referred to as “Earned PSUs”. Other than in connection with a Covered Transaction as set forth in the Plan, no PSUs shall be earned and shall vest until the Administrator determines that the Performance Criteria have been met and determines the extent to which they have so been met. The Administrator shall make such determination not later than January 31st following the end of the Performance Period. Earned PSUs shall vest and be settled as set forth in the Agreement. All determinations under this Exhibit A shall be made by the Administrator and will be final and binding on the Grantee.

PRINCIPAL EXECUTIVE OFFICER CERTIFICATION

I, William D. Clark, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Genocera Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ WILLIAM D. CLARK

William D. Clark

President and Chief Executive Officer and Director

(Principal Executive Officer)

Date: April 29, 2021

PRINCIPAL FINANCIAL OFFICER CERTIFICATION

I, Diantha Duvall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Genocera Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ DIANTHA DUVALL

Diantha Duvall
Chief Financial Officer

Date: April 29, 2021

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

I, William D. Clark, certify to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Genoclea Biosciences, Inc. on Form 10-Q for the three months ended March 31, 2021 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-Q fairly presents in all material respects the financial condition and results of operations of Genoclea Biosciences, Inc. at the dates and for the periods indicated.

/s/ WILLIAM D. CLARK

William D. Clark

President and Chief Executive Officer and Director

Date: April 29, 2021

I, Diantha Duvall, certify to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Genoclea Biosciences, Inc. on Form 10-Q for the three months ended March 31, 2021 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-Q fairly presents in all material respects the financial condition and results of operations of Genoclea Biosciences, Inc. at the dates and for the periods indicated.

/s/ DIANTHA DUVALL

Diantha Duvall

Chief Financial Officer

Date: April 29, 2021