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, 2022

OR

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

For the transition period from to

Commission File Number: 001-36289

GENOCEA BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**51-0596811**
(State or Other Jurisdiction of Incorporation or Organization)	(I.RS. 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:

Title of each class	Trading symbol	Name of each exchange on which registered
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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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 29, 2022 was 58,783,503.

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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, 2022	December 31, 2021
Current assets:		
Cash and cash equivalents	$ 20,137	$ 37,148
Prepaid expenses and other current assets	4,271	4,674
Total current assets	24,408	41,822
Property and equipment, net	6,562	5,841
Right-of-use assets	6,934	7,420
Restricted cash	631	631
Other non-current assets	253	253
Total assets	$ 38,788	$ 55,967
Current liabilities:		
Accounts payable	$ 594	$ 500
Accrued expenses and other current liabilities	8,760	9,496
Current portion of long-term debt	4,700	4,641
Lease liabilities	2,412	2,346
Deferred revenue	1,564	1,700
Total current liabilities	18,030	18,683
Non-current liabilities:		
Lease liabilities, net of current portion	5,426	6,052
Long-term debt, net of current portion	2,947	4,146
Warrant liabilities	—	11
Total liabilities	26,403	28,892
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; (25,000,000 shares authorized at March 31, 2022 and December 31, 2021; — shares issued and outstanding at March 31, 2022 and December 31, 2021)	—	—
Common stock, $0.001 par value; (225,000,000 shares authorized at March 31, 2022 and December 31, 2021, 58,733,759 shares issued and outstanding at March 31, 2022 and 58,225,170 shares issued and outstanding at December 31, 2021)	59	58
Additional paid-in capital	436,168	434,881
Accumulated deficit	(423,842)	(407,864)
Total stockholders' equity	12,385	27,075
Total liabilities and stockholders' equity	$ 38,788	$ 55,967

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	
	2022	2021
License revenue	$ 270	$ —
Operating expenses:		
Research and development	12,444	8,751
General and administrative	3,599	3,671
Total operating expenses	16,043	12,422
Loss from operations	(15,773)	(12,422)
Other income (expense)	(205)	439
Net loss	$ (15,978)	$ (11,983)
Comprehensive loss	$ (15,978)	$ (11,983)
Net loss per share:		
Basic	$ (0.22)	$ (0.18)
Diluted	$ (0.22)	$ (0.17)
Weighted average number of shares used in computing net loss per share:		
Basic	71,120	66,158
Diluted	71,120	74,220

See accompanying notes to the condensed consolidated financial statements.

Genocea Biosciences, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands)

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2021	58,225	$ 58	$ 434,881	$ (407,864)	$ 27,075
Issuance of common stock, net	354	1	386	—	387
Stock-based compensation expense	—	—	901	—	901
Issuance of common stock under employee benefit plans	155	—	—	—	—
Net loss	—	—	—	(15,978)	(15,978)
Balance at March 31, 2022	58,734	$ 59	$ 436,168	$ (423,842)	$ 12,385

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	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	54,369	$ 54	$ 388,359	$ (386,651)	$ 1,762

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	
	2022	**2021**
Operating activities		
Net loss	$ (15,978)	$ (11,983)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	901	580
Depreciation and amortization expense	400	381
Non-cash interest expense	110	117
Change in fair value of warrant liability	(11)	(854)
Other	(15)	101
Changes in operating assets and liabilities	(616)	(735)
Net cash used in operating activities	(15,209)	(12,393)
Investing activities		
Purchases of property and equipment	(961)	(1,109)
Proceeds from sale of equipment	22	65
Net cash used in investing activities	(939)	(1,044)
Financing activities		
Repayment of long-term debt	(1,250)	(13,960)
Proceeds from issuance of common stock, net	387	3,979
Proceeds from long-term debt	—	10,000
Payment of deferred financing costs	—	(289)
Debt prepayment costs	—	(88)
Proceeds from issuance of common stock under employee benefit plans	—	84
Payments on finance lease	—	(23)
Net cash used by financing activities	(863)	(297)
Net decrease in cash, cash equivalents and restricted cash	(17,011)	(13,734)
Cash, cash equivalents and restricted cash at beginning of period	37,779	80,400
Cash, cash equivalents and restricted cash at end of period	$ 20,768	$ 66,666
Non-cash financing activities and supplemental cash flow information		
Property and equipment included in accounts payable and accrued expenses	$ 508	$ 306
Cash paid in connection with operating lease liabilities	$ 733	$ 709
Cash paid for interest	$ 130	$ 166

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, or Inhibigens™, that drive pro-tumor immune responses. Genocea believes this approach ensures that cancer immunotherapies, such as cellular therapies and vaccines, focus T cell responses on the tumor antigens most vulnerable to T cell targeting. Consequently, the Company believes that ATLAS may enable more immunogenic and efficacious cancer immunotherapies.

On April 28, 2022, the Company announced that it had initiated a process to explore a range of strategic alternatives to maximize shareholder value and engaged professional advisors, including an investment bank, to support this process. Strategic alternatives include the sale of all or part of the Company, merger or reverse merger. As the Company pursues strategic alternatives, it put into place a restructuring plan which includes an approximate 65% reduction in workforce in the second quarter of 2022. As part of further cost reduction measures, the Company has since made the decision to voluntarily terminate the TiTAN™ clinical study of GEN-011 and continues to review its other research programs and collaborations to determine an appropriate course of action.

Genocea has devoted 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. Genocea had available cash and cash equivalents of $20.1 million at March 31, 2022. As of March 31, 2022, Genocea had an accumulated deficit of $423.8 million and anticipates that it will continue to incur significant operating losses for the foreseeable future as it continues to develop its product candidates.

In addition, the Company had a loss from operations of $15.8 million and used $15.2 million of cash for operating activities during the three months ended March 31, 2022. These factors, combined with the Company's forecast of cash required to fund operations for a period of at least one year from the date of issuance of these condensed consolidated financial statements, raise substantial doubt about the Company's ability to continue as a going concern. The future viability of the Company beyond one year from the date of issuance of these condensed consolidated financial statements is dependent on its ability to raise additional capital to finance its operations. As announced on April 28, 2022, Genocea is exploring strategic alternatives that include the sale of all or part of the Company, merger or reverse merger. The Company's existing cash and cash equivalents, including the impact of the restructuring plan, are sufficient to support its current operations into Q3 2022.

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

2. Summary of significant accounting policies

Genocea's significant accounting policies have not changed materially from those disclosed in its Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "2021 10-K").

Basis of presentation

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. Intercompany accounts and transactions have been eliminated. Genocea operates as one segment, which is discovering, researching, developing and commercializing novel cancer immunotherapies.

In the opinion of the Company's management, the condensed consolidated financial statements reflect all adjustments, which are normal and recurring in nature, and 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 the 2021 10-K.

Recently adopted accounting standards

In May 2021, the FASB issued a new standard that clarifies an issuer's accounting for certain modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The new standard is effective on a prospective basis for fiscal years beginning after December 15, 2021, and early adoption is permitted. The Company adopted this standard on January 1, 2022. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures at the time of adoption, and the impact on later periods is not known or reasonably estimable.

3. Revenue

In December 2021, the Company entered into a collaboration and option agreement (the "Janssen Agreement") with Janssen Biotech, Inc. ("Janssen"), one of the Janssen Pharmaceutical Companies of Johnson and Johnson, to use the Company's proprietary ATLAS platform to explore the immunogenicity of neoantigens and the role and impact of Inhibigens in the context of vaccine therapies for cancer. Under the Janssen Agreement, the Company received a non-refundable and non-creditable upfront fee of $1.7 million for research relating to an identified tumor type and is eligible to receive additional research and development funding up to a potential total of $3.3 million.

Management evaluated the promised goods and services within the Janssen Agreement and determined those which represented separate performance obligations. The Company identified its potential performance obligations, including (i) its grant of a limited-use research license to Janssen to certain of its intellectual property subject to certain conditions, (ii) its conduct of research and development services ("R&D Services"), (iii) an option, at Janssen's sole discretion, for the Company to conduct additional research and development services at pre-negotiated rates ("R&D Option") and (iv) an option for Janssen to negotiate a future strategic partnership ("Strategic Partnership Option") to develop non-personalized vaccine products relating to two tumor types using Genocea's ATLAS platform and expertise on Inhibigens.

The Company determined that its grant of a limited-use research license to Janssen and its conduct of R&D Services should be accounted for as a combined performance obligation as they are not capable of being distinct, and that the combined performance obligation will be transferred over the expected term of the conduct of the R&D Services. The Company determined that the R&D Option is a material right as the consideration for the R&D Option represents a discount that would otherwise not be available to the customer without entering into the Janssen Agreement. Additionally, the Company determined that the Strategic Partnership Option did not constitute a performance obligation and is instead a marketing offer.

The Company estimated the standalone selling price of the R&D Services 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 Janssen will exercise its R&D Option.

The transaction price as of March 31, 2022 was comprised of fixed consideration of $1.7 million and variable consideration of $1.5 million. The transaction price was allocated to each of the performance obligations based on the relative standalone selling prices. The Company concluded that the variable consideration of $1.8 million related to additional services to be performed upon the exercise of the R&D Option was constrained as of March 31, 2022 and therefore did not allocate variable consideration from the R&D Option to any of the performance obligations.

The amount allocated to the R&D Services will be recognized in an amount proportional to the actual costs incurred during the period in which the R&D Services are performed by the Company. The amount allocated to the material right will be recognized either (i) in an amount proportional to the actual costs incurred during the period in which the additional services under the R&D Option are performed by the Company or (ii) upon a decision by Janssen not to proceed with the additional services under the R&D Option. In the three months ended March 31, 2022, the Company recognized $0.3 million in license revenue for R&D Services performed during the period.

The Company had not provided any services under the Janssen Agreement as of December 31, 2021, and as such, the upfront fee of $1.7 million was recorded as deferred revenue at December 31, 2021. $0.1 million of the upfront fee was allocated to the revenue recognized during the three months ended March 31, 2022, and therefore $1.6 million of the upfront fee was recorded as deferred revenue at March 31, 2022.

4. Fair value of financial instruments

Genocea 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) for identical assets or liabilities in active markets 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 recorded at fair value consist of cash equivalents, and the Company's financial liabilities recorded at fair value consist of warrant liabilities.

The fair value of Genocea'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 Genocea's warrant liabilities is determined using a Monte Carlo simulation. See **Note 9. Warrants** for the assumptions and methodologies used to calculate the estimated fair value of the Company's warrant liabilities. Genocea'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, 2022 and December 31, 2021 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2022				
Assets				
Cash equivalents	$ 19,324	$ 19,324	$ —	$ —
Total assets	$ 19,324	$ 19,324	$ —	$ —
Liabilities				
Warrant liabilities	$ —	$ —	$ —	$ —
Total liabilities	$ —	$ —	$ —	$ —
December 31, 2021				
Assets				
Cash equivalents	$ 33,673	$ 33,673	$ —	$ —
Total assets	$ 33,673	$ 33,673	$ —	$ —
Liabilities				
Warrant liabilities	$ 11	$ —	$ —	$ 11
Total liabilities	$ 11	$ —	$ —	$ 11

The following table reflects the change in Genocea's Level 3 warrant liabilities for the three months ended March 31, 2022 (in thousands):

	Warrant Liabilities
Balance at December 31, 2021	$ 11
Change in fair value	(11)
Balance at March 31, 2022	$ —

5. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following as of March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Research and development costs	$ 6,696	$ 5,223
Payroll and other headcount-related costs	854	3,022
Other current liabilities	1,210	1,251
Total	$ 8,760	$ 9,496

6. Commitments and contingencies

Operating leases

As of March 31, 2022, the Company had a lease for two floors of lab and office space in a multi-tenant building in Cambridge, Massachusetts through February 2025. Genocea has the option to extend the lease term for an additional five years, which was not included in the Company's right-of-use ("ROU") assets and associated lease liabilities as of March 31, 2022.

Genocea has a sublease agreement for one floor of lab and office space through February 2023. The sublease agreement contains options for the Company and the sublessee to mutually extend the sublease for up to an additional twelve months. As Genocea retained its obligations under the sublease, it will record the payments received under the sublease as a reduction of lease expense. For both the three months ended March 31, 2022 and 2021, the Company recorded sublease income of $0.4 million, as a reduction of lease expense.

Genocea's lease expense, net of sublease income, was $0.3 million for both the three months ended March 31, 2022 and 2021.

The weighted-average remaining lease term and weighted-average discount rate of the Company's operating leases as of March 31, 2022 and December 31, 2021 were as follows:

	March 31, 2022	December 31, 2021
Weighted-average remaining lease term (in years)	2.91	3.17
Weighted-average discount rate	8.12 %	8.12 %

The following table summarizes the presentation of leases in Genocea's condensed consolidated balance sheets as of March 31, 2022 and December 31, 2021 (in thousands):

	Classification	March 31, 2022	December 31, 2021
Assets			
Operating	Right-of-use assets	$ 6,934	$ 7,420
Total lease assets		$ 6,934	$ 7,420
Liabilities			
Current:			
Operating	Lease liabilities	$ 2,412	$ 2,346
Non-current:			
Operating	Lease liabilities, net of current portion	5,426	6,052
Total lease liabilities		$ 7,838	$ 8,398

The minimum lease payments related to the Company's operating leases as of March 31, 2022 were as follows (in thousands):

Remainder of 2022	$ 2,216
2023	3,017
2024	3,092
2025	517
Total lease payments	8,842
Less: Imputed interest	(1,004)
Total	$ 7,838

At March 31, 2022 and December 31, 2021, Genocea 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

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

Harvard license agreement

Genocea has an exclusive license agreement with the President and Fellows of Harvard College (“Harvard”), granting the Company an exclusive, worldwide, royalty-bearing, sublicensable license to one patent family, 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, 2022, the Company has paid or accrued $0.3 million in aggregate milestone payments.

Upon commercialization of Genocea's products covered by the licensed patent rights or discovered using the licensed methods, the Company is obligated to pay Harvard royalties on the net sales of such products and services sold by Genocea, its affiliates, and its sublicensees. This royalty varies depending on the type of product or service and 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 Genocea 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 ten 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 consideration (cash or non-cash) under any sublicense, it must pay Harvard a percentage of the value of such consideration, excluding certain categories of consideration, varying from the low single digits 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. Genocea may terminate the agreement at any time by giving Harvard advance written notice. Harvard may also terminate the agreement (i) in the event of a material breach by the Company that remains uncured; (ii) in the event of Genocea's insolvency, bankruptcy, or similar circumstances; or (iii) if the Company challenges the validity of any patents licensed to it.

Oncovir license and supply agreement

Genocea 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 Genocea's technology (the “Combination Product”). Hiltonol is the adjuvant component of GEN-009, which will consist of synthetic long peptides of neoantigens identified using the Company's proprietary ATLAS platform, formulated with Hiltonol.

Oncovir granted Genocea 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, Genocea 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.

The Company may terminate the agreement upon a decision to discontinue the development of the Combination Product or upon a determination by Genocea 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 with Hercules Capital, Inc. ("Hercules"), which was subsequently amended in November 2019 (as amended, the "Hercules Loan Agreement"). 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.

In February 2021, Genocea entered into a loan and security agreement (the "SVB Loan Agreement") with Silicon Valley Bank ("SVB") for a $10.0 million secured term loan (the "SVB Term Loan"). $9.0 million of the proceeds from the SVB Term Loan were used to repay the borrowings that were outstanding at the SVB Loan Agreement closing date under the Company's previous loan and security agreement with Hercules, paying off all obligations owing under, and extinguishing, the Hercules Loan Agreement on the SVB Term Loan closing date. The remaining proceeds from the SVB Term Loan of $1.0 million were received by the Company for working capital and general corporate purposes.

The SVB Term Loan will mature on September 1, 2023. The SVB 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 SVB Term Loan provided for interest-only payments until September 30, 2021; thereafter, payments are due monthly in equal installments of principal and interest (subject to recalculation upon a change in prime rates) through maturity. The SVB Term Loan is subject to a final payment charge of $0.5 million that will be amortized as a debt issuance cost over the expected term of the loan. The SVB Term Loan may be prepaid in whole (but not in part), subject to a prepayment charge of 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 SVB 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 SVB 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, 2022, the Company was in compliance with all covenants under the SVB Loan Agreement.

The SVB 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. As of March 31, 2022, the Company has determined that the risk of subjective acceleration under the material adverse effects clause was remote and therefore has classified the long-term portion of the outstanding principal in non-current liabilities.

In connection with the SVB Loan Agreement, Genocea issued to SVB a warrant (the "SVB Warrant") in February 2021 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 SVB Term Loan that will be amortized over the expected term of the loan.

As of March 31, 2022 and December 31, 2021, the Company had outstanding borrowings, net of unamortized debt issuance costs, of $7.6 million and $8.8 million, respectively. Interest expense was $0.2 million and $0.3 million for the three months ended March 31, 2022 and 2021, respectively.

Future principal payments, including the final payment charge, as of March 31, 2022 were as follows:

	Principal Payments on Long-Term Debt
Remainder of 2022	$ 3,750
2023	4,250
	$ 8,000

8. Stockholders' equity

At-the-market equity offering program

Genocea has an agreement with Cowen to establish an ATM equity offering program 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, 2022, the Company sold approximately 0.4 million shares under the ATM and received net proceeds of $0.4 million, after deducting commissions. Cumulatively through March 31, 2022, the Company has sold an aggregate of approximately 8.2 million shares under the ATM and received $21.6 million in net proceeds. As of March 31, 2022, the Company had $27.8 million in gross proceeds remaining under the ATM.

Agreement with Lincoln Park Capital

Genocea had a purchase agreement with Lincoln Park Capital ("LPC") pursuant to which, for a period of 30 months beginning in October 2019, the Company had the right, at its sole discretion, to sell up to $30.0 million of the Company's common stock to LPC based on prevailing market prices of its common stock at the time of each sale. Cumulatively through March 31, 2022, the Company had sold an aggregate of approximately 2.7 million shares to LPC under the agreement and received $6.0 million in net proceeds. The agreement expired in April 2022.

9. Warrants

As of March 31, 2022, 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	Equity
2020 Pre-Funded Warrants	12,223	$ 0.01	N/A	Equity
SVB Warrant	43	$ 3.45	Q1 2026	Equity
	51,001			

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. Genocea 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, Genocea 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, Genocea will settle the 2018 Warrants in cash and if the Company’s stockholders are to receive stock in the Acquisition, Genocea 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. Genocea 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 less than $0.1 million and $0.2 million for the three months ended March 31, 2022 and 2021, respectively. The fair value of the warrant liability related to the 2018 Warrants was not significant as of both March 31, 2022 and December 31, 2021.

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, 2022 and December 31, 2021, respectively:

	March 31, 2022	December 31, 2021
Stock price	$ 1.25	$ 1.16
Volatility	50.0% - 59.8%	50.0% - 79.9%
Remaining term (in years)	0.8	1.0
Expected dividend yield	— %	— %
Risk-free rate	1.39 %	0.41 %
Acquisition event probability	11.3 %	14.6 %

2019 Warrants and 2019 Pre-Funded Warrants

The exercise price of the 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. Genocea 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. Genocea 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 were entitled to down-round protection through July 24, 2021. The Company was required to obtain stockholder 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, which resulted in the 2020 Warrants being liability-classified for the period from issuance through July 24, 2021. While the 2020 Warrants were liability-classified, the Company remeasured the fair value at each reporting date. Genocea 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. At the expiration of the down-round protection feature on July 25, 2021, the 2020 Warrants were remeasured to their fair value of $36.0 million and subsequently reclassified to equity.

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 July 25, 2021:

	July 25, 2021	
Stock price	$ 2.04	
Volatility	96.2	%
Remaining term (in years)		3.0
Expected dividend yield	—	
Risk-free rate	0.38	%
Acquisition event probability	35.0	%

SVB Warrant

In connection with the SVB Loan Agreement, Genocea 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

Genocea grants equity awards in the form of stock options and 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 (the "2014 Equity Incentive Plan"). As of March 31, 2022, there were approximately 0.8 million shares remaining for future grants 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 Genocea’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 awarded, if any, when a market-based 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 grant date using the Black-Scholes option pricing model. The fair value of the service-based RSUs is the closing market price of Genocea's common stock on the grant date. The Company measures the fair value of market-based RSUs on the grant date using a Monte Carlo simulation model.

Stock-based compensation expense

Total stock-based compensation expense recognized for stock options and RSUs during the three months ended March 31, 2022 and 2021 was as follows (in thousands):

	Three Months Ended March 31	
	2022	2021
Research and development	$ 372	$ 258
General and administrative	529	322
Total	$ 901	$ 580

Stock options

The following table summarizes stock option activity during the three months ended March 31, 2022 (shares and aggregate intrinsic value in thousands):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2021	3,743	$ 5.18		
Granted	1,661	$ 1.11		
Cancelled	(109)	$ 4.06		
Outstanding at March 31, 2022	5,295	$ 3.93	8.3	$ 233
Exercisable at March 31, 2022	1,722	$ 7.91	6.8	$ —

RSUs

The following table summarizes RSU activity during the three months ended March 31, 2022 (shares in thousands):

	Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2021	2,245	$ 2.43
Granted[(1)]	790	$ 1.11
Vested	(155)	$ 2.93
Cancelled	(69)	$ 2.66
Outstanding at March 31, 2022	2,811	$ 2.03

1. 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") authorizes the issuance shares of common stock to participating eligible employees and provides for two six-month offering periods each year. As of March 31, 2022, there were less than 0.1 million shares remaining for future issuance under the ESPP.

11. Net loss per share

Basic and diluted net loss per share were calculated as follows for the three months ended March 31, 2022 and 2021 (in thousands, except per share amounts):

	Three Months Ended March 31	
	2022	2021
Numerator		
Net loss	$ (15,978)	$ (11,983)
Less: Change in fair value of 2020 Warrants[(1)]	—	673
Adjusted net loss	$ (15,978)	$ (12,656)
Denominator		
Weighted average common stock outstanding – basic	71,120	66,158
Dilutive effect of common stock issuable from assumed exercise of warrants[(1)]	—	8,062
Weighted average common stock outstanding – diluted	71,120	74,220
Net loss per share		
Basic	$ (0.22)	$ (0.18)
Diluted	$ (0.22)	$ (0.17)

1. 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 were in-the-money during that period and were liability-classified for the period from issuance through July 24, 2021.

The Company used the treasury stock method to determine the number of dilutive shares. 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, 2022 and 2021 (in thousands):

	Three Months Ended March 31	
	2022	2021
Warrants	38,247	4,634
Stock options	5,295	3,839
RSUs	2,811	2,434
Total	46,353	10,907

12. Other income (expense)

Other income (expense) consisted of the following during the three months ended March 31, 2022 and 2021 was as follows (in thousands):

	Three Months Ended March 31	
	2022	2021
Other income (expense):		
Change in fair value of warrants	$ 11	$ 854
Interest expense, net	(231)	(279)
Other income (expense)	15	(136)
Other income (expense)	$ (205)	$ 439

13. Subsequent event

On April 28, 2022, the Company implemented a plan to reduce its workforce by approximately 65% with the objective of preserving capital as it explores a range of strategic alternatives to maximize shareholder value. This workforce reduction will take place during the second quarter of 2022. As a result of these actions, the Company expects to incur personnel-related restructuring charges of approximately $4 million in connection with one-time employee termination costs, including severance and other benefits, which are expected to be incurred in the second quarter of 2022. In addition, as part of further cost reduction measures, the Company has since made the decision to voluntarily terminate the TiTAN clinical study of GEN-011 and continues to review its other research programs and collaborations to determine an appropriate course of action. The Company may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the workforce reduction or retention efforts. These estimates of the costs that the Company expects to incur, and the timing thereof, are subject to a number of assumptions and actual results may differ.

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, 2021 (the "2021 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 for our clinical trial;
- 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, as well as the response of our company and governments to COVID-19, including the associated containment, remediation and vaccination efforts;
- 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 2021 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 together with our 2021 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, or Inhibigens™, that drive pro-tumor immune responses. We believe this approach ensures that cancer immunotherapies, such as cellular therapies and vaccines, focus T cell responses on the tumor antigens most vulnerable to T cell targeting. Consequently, we believe that ATLAS may enable more immunogenic and efficacious cancer immunotherapies.

On April 28, 2022, we announced that we have initiated a process to explore a range of strategic alternatives to maximize shareholder value and engaged professional advisors, including an investment bank, to support this process. Strategic alternatives include the sale of all or part of the Company, merger or reverse merger. As we pursue strategic alternatives, we put into place a restructuring plan which includes an approximate 65% reduction in workforce in the second quarter of 2022.

Since then, in an effort to further reduce costs while assessing strategic alternatives to maximize shareholder value, we have also decided to voluntarily terminate the TiTAN™ clinical study of GEN-011 and continue to review our other research programs and collaborations to determine an appropriate course of action.

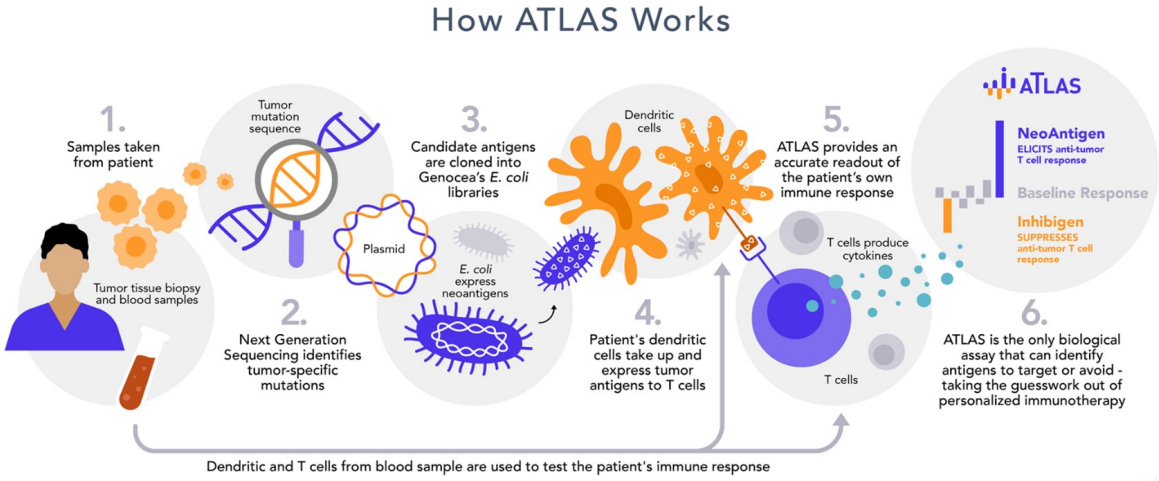
GEN-011 is an investigational next-generation solid tumor cell therapy candidate comprised of $CD4^+$ and $CD8^+$ neoantigen-targeted peripheral T cells ("NPTs") which are specific for up to 30 antigens, designed to limit tumor escape. GEN-011 is comprised of T cells extracted from the patient's peripheral blood and specific for ATLAS-prioritized neoantigens. NPTs have minimal bystander, non-tumor-specific cells, and are designed to be devoid of Inhibigen-specific cells which may be detrimental to clinical response. GEN-011 has the potential to be differentiated from other cell therapies because of the breadth of surface-presented neoantigens it targets and the ease of manufacturing tumor-relevant T cells extracted from readily accessible peripheral blood. TiTAN is an open-label, multi-center Phase 1/2a trial evaluating the safety, tolerability, T cell persistence and proliferation, and clinical efficacy of GEN-011. The TiTAN clinical trial was testing two dosing regimens.

GEN-009 is an investigational neoantigen vaccine delivering adjuvanted synthetic long peptides from ATLAS-identified neoantigens. We reported long-term immunogenicity and clinical response data from our GEN-009 neoantigen vaccine Phase 1 clinical trial in November 2021, and we continue to monitor patients to further evaluate these efficacy signals.

ATLAS platform

Harnessing and directing T cells to kill tumor cells is increasingly viewed as having potential to treat many cancers. Cellular therapies or vaccines employing this approach may be most effective when targeting 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 ("CPI"). We therefore believe that both by identifying the optimal antigens and by excluding Inhibigens, ATLAS enables differentiated immune responses and clinical efficacy.



We believe ATLAS has the potential to be a key tool in optimizing antigen selection for therapies across a number of diseases beyond cancer. We have previously demonstrated its effectiveness in identifying novel protective antigens for infectious disease therapies. In addition, while we believe Inhibigens should be avoided in cancer immunotherapies, they could prove to be beneficial in other therapies such as treatment of autoimmune disease.

Intellectual property

Our ATLAS and immuno-oncology intellectual property portfolio comprises nine patent families and two additional potential patent families, all but one of which are wholly owned by us. The first patent family, in-licensed from the President and Fellows of Harvard College ("Harvard"), 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 three further families and two additional potential families currently comprise a pending U.S. patent application, 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.

Immuno-oncology programs

GEN-011

We believe that GEN-011 represents a new category of adoptive T cell therapy for solid tumors, 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 *ex vivo* in the presence of high dose interleukin-2 ("IL-2") 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.

We believe that GEN-011, if approved, may offer efficacy, patient accessibility and cost advantages over other neoantigen-targeting solid tumor adoptive 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 Inhibigens 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.

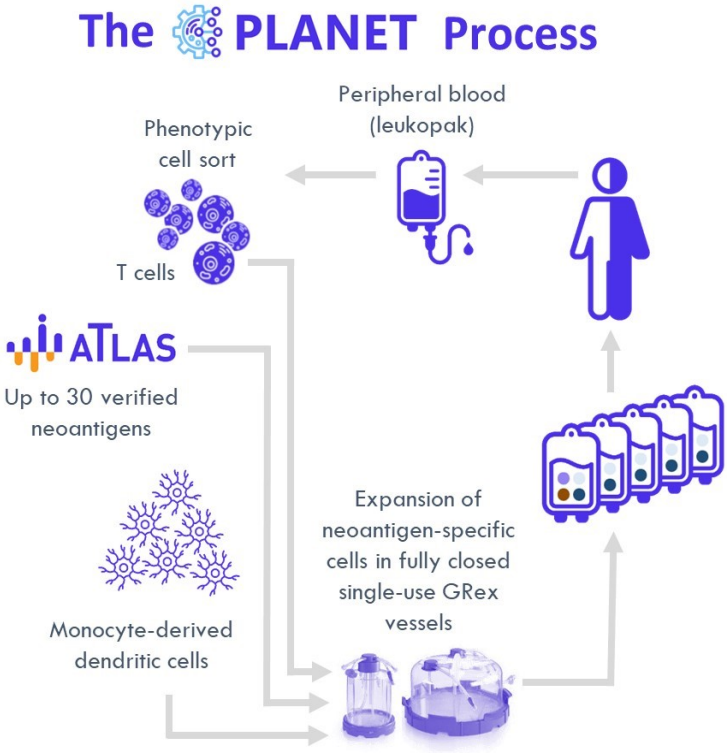
The potential patient accessibility and cost advantages derive from the fact that:

- 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 and specific tumor-associated antigens, often limiting their clinical utility to certain subsets of western Caucasians with tumors that express specific targets; and
- The GEN-011 cell expansion process does not require T cell receptor ("TCR") vector design or transduction.

We believe our PLANET process also has some key advantages as it:

- Uses peripheral blood, potentially expanding accessible patient population;
- Has a robust process designed for reliable production; and
- Is a single-use technology for modularity and rapid scalability.

The following is a summary of our PLANET process:



The Phase 1/2a TiTAN trial investigates the safety, tolerability, T cell persistence and proliferation, and clinical activity of GEN-011 in patients with refractory solid tumors. Our target indications include melanoma, non-small cell lung cancer, small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck (SCCHN), urothelial carcinoma (UC), renal cell carcinoma (RCC), cutaneous squamous cell carcinoma (CSCC), and anal squamous cell carcinoma (ASCC). The trial includes 2 dosing cohorts. Cohort A patients received a lower intensity regimen without lymphodepletion with fractional GEN-011 doses monthly, and with post-infusion intermediate dose IL-2 (125K IU/kg daily s.c.). In Cohort B, patients received GEN-011 as a single infusion after lymphodepletion, followed by IL-2. This Cohort includes one of three escalating lymphodepletion and IL-2 dose regimens.

The early results presented at the American Association for Cancer Research ("AACR") Annual Meeting 2022 show anti-tumor activity despite the lower intensity regimens and heavily pretreated tumors. Two patients were in Cohort A and three patients were in the lower Cohort B lymphodepletion and IL-2 dose regimens. Stable disease was seen at the initial Day 57 scan in 4 of the 5 patients. While all patients had progressive disease (PD) at their Day 113 scan, 3 of the 5 experienced clear biologic changes after infusion. These included palpable improvement in peripheral nodal disease and resolution of severe neuropathy causing arm paralysis and pain in patients with refractory SCCHN. A patient with metastatic NSCLC experienced a 10% reduction in tumor diameters (approx. 30% reduction in volume), also with resolution of tumor-associated cough. The potential for drug product proliferation and persistence for months is supported by translational assays, and clinical activity is associated with declines in detectable circulating tumor DNA (ctDNA) after treatment in some patients. None of the initial patients have experienced dose-limiting toxicities, with no evidence of self-reactivity or autoimmune toxicity. Overall, the range of Grade 2 and Grade 3 treatment emergent adverse events (TEAEs) aligned with expected toxicity from cell therapy regimens.

Since we presented data at AACR from five patients, one additional patient with an initial Day 57 scan showed progressive disease (PD). Another dosed patient experienced a Suspected Unexpected Serious Adverse Reaction (“SUSAR”) that resulted in a fatality, which was timely reported to the FDA.

In an effort to further reduce costs while assessing strategic alternatives to maximize shareholder value, following the restructuring announced on April 28, 2022, we made the decision to voluntarily terminate the TiTAN clinical study of GEN-011. This decision was unrelated to the clinical results in the study.

GEN-009

GEN-009 is a neoantigen vaccine candidate delivering adjuvanted synthetic long peptides spanning ATLAS-identified anti-tumor neoantigens. The phase 1/2a clinical trial evaluating GEN-009 is currently collecting long-term data 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 anti-tumor activity of GEN-009 in combination with CPI therapy in patients with advanced or metastatic tumors.

We have observed the following from our data, most recently presented at the Society for Immunotherapy of Cancer's ("SITC") Annual Meeting in November 2021:

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 two of the eight vaccinated patients have developed a recurrence of their targeted tumor, with up to 36 months of follow-up.

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, four have independent RECIST criteria responses after administration of GEN-009 that appear to be attributable to GEN-009.
    - Of those four patients, one patient achieved a complete response and three 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, one patient achieved a partial response and two achieved prolonged disease stabilization lasting up to 12 months, longer than their prior duration of disease control.

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

Other research activities

In addition to our two clinical programs, we are exploring the immunogenicity of neoantigens and the role and impact of Inhibigens, in collaboration with Janssen Biotech, Inc. ("Janssen"), in the context of vaccine therapies for cancer.

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 or treat COVID-19, and its 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 attributable to COVID-19 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 supply chain, research activities 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 us 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, 2022, we had received an aggregate of $455.4 million in net proceeds from the issuance of equity securities, we had outstanding borrowings, net of unamortized debt issuance costs, of $7.6 million, and our cash and cash equivalents were $20.1 million.

On April 28, 2022, we announced that we have initiated a process to explore a range of strategic alternatives to maximize shareholder value and engaged professional advisors, including an investment bank, to support this process. Strategic alternatives include the sale of all or part of the Company, merger or reverse merger. As we pursue strategic alternatives, we put into place a restructuring plan which includes an approximate 65% reduction in workforce in the second quarter of 2022. Also, as part of further cost reduction measures, we have since made the decision to voluntarily terminate the TiTAN clinical study of GEN-011 and continue to review our other research programs and collaborations to determine an appropriate course of action.

We have a sublease agreement for one floor of lab and office space through February 2023. The sublease agreement contains options for us and the sublessee to mutually extend the sublease for up to an additional twelve 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 of $0.4 million was recorded as a reduction of lease expense during the three months ended March 31, 2022.

We have a loan and security agreement with Silicon Valley Bank ("SVB") for a $10.0 million secured term loan (the "SVB Term Loan"). The SVB Term Loan will mature on September 1, 2023. The SVB 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 SVB Term Loan provided for interest-only payments until September 30, 2021; thereafter, payments are due monthly in equal installments of principal and interest (subject to recalculation upon a change in prime rates) through maturity. The SVB Term Loan is subject to a final payment charge of $0.5 million. The SVB Term Loan may be prepaid in whole (but not in part), subject to a prepayment charge of 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.

We have an agreement with Cowen and Company, LLC ("Cowen") to establish an at-the-market (“ATM”) equity offering 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, 2022, we sold approximately 0.4 million shares under our ATM and received net proceeds of $0.4 million, after deducting commissions. Through March 31, 2022, we have sold an aggregate of approximately 8.2 million shares under our ATM and received $21.6 million in net proceeds. As of March 31, 2022, we had $27.8 million in gross proceeds remaining under our ATM.

We had a purchase agreement with Lincoln Park Capital ("LPC") pursuant to which, for a period of 30 months beginning in October 2019, we had the right, at our sole discretion, to sell up to $30.0 million of our common stock to LPC based on prevailing market prices of our common stock at the time of each sale. Cumulatively through March 31, 2022, we had sold an aggregate of approximately 2.7 million shares to LPC under the agreement and received $6.0 million in net proceeds. The agreement expired in April 2022.

As of March 31, 2022, we had an accumulated deficit of $423.8 million, and we anticipate that we will continue to incur significant operating losses for the foreseeable future as we continue to develop our product candidates. 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 addition, we had a loss from operations of $15.8 million and used $15.2 million of cash for operating activities during the three months ended March 31, 2022.

These factors, combined with our forecast of cash required to fund operations for a period of at least one year from the date of issuance of these consolidated financial statements, raise substantial doubt about our ability to continue as a going concern. Our future viability beyond one year from the date of issuance of the consolidated financial statements is dependent on our ability to raise additional capital to finance our operations. As announced on April 28, 2022, we are exploring strategic alternatives that include the sale of all or part of the Company, merger or reverse merger. Our existing cash and cash equivalents, including the impact of the restructuring plan, are sufficient to support our current operations into Q3 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. These funds will not be sufficient to enable us to conduct pivotal clinical trials for, seek marketing approval for, or commercially launch GEN-011, GEN-009 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. Our license revenue in the three months ended March 31, 2022 was derived from a collaboration and option agreement (the "Janssen Agreement") with Janssen Biotech, Inc. ("Janssen"), one of the Janssen Pharmaceutical Companies of Johnson and Johnson, to use our proprietary ATLAS platform to explore the immunogenicity of neoantigens and the role and impact of Inhibigens in the context of vaccine therapies for cancer. Under the Janssen Agreement, we received a non-refundable and non-creditable upfront fee of $1.7 million for research relating to an identified tumor type and are eligible to receive additional research and development funding up to a potential total of $3.3 million. See **Note 3. Revenue** within the notes to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Research and development expenses

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

- payroll and other headcount-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 summarizes research and development expenses for our product candidates for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31	
	2022	2021
Phase 1/2a programs	$ 10,067	$ 5,776
Discovery and pre-IND	879	1,786
Other research and development	1,498	1,189
Total research and development	$ 12,444	$ 8,751

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 facility costs, depreciation expense, and other costs.

General and administrative expenses

General and administrative expenses consist primarily of payroll and other headcount-related expenses for 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 the 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 2021 10-K.

Results of Operations

Comparison of the three months ended March 31, 2022 and 2021

License revenue

	Three Months Ended March 31	
	2022	2021
	(in thousands)	
License revenue	$ 270	$ —

During the three months ended March 31, 2022, we recorded license revenue of $0.3 million for research and development services provided under the Janssen Agreement.

Research and development expenses

	Three Months Ended March 31	
	2022	2021
	(in thousands)	
Research and development	$ 12,444	$ 8,751

Research and development expenses increased $3.7 million in the three months ended March 31, 2022, as compared to the three months ended March 31, 2021. The increase was largely due to higher manufacturing costs associated with GEN-011 of $3.3 million.

General and administrative expenses

	Three Months Ended March 31	
	2022	2021
	(in thousands)	
General and administrative	$ 3,599	$ 3,671

General and administrative expenses were relatively consistent for the three months ended March 31, 2022 and 2021.

Other income (expense)

	Three Months Ended March 31	
	2022	2021
	(in thousands)	
Other income (expense)	$ (205)	$ 439

The change in other income (expense) for the three months ended March 31, 2021, as compared to the three months ended March 31, 2021 is mainly due to the non-cash impact of the fair-value adjustment for our liability-classified warrants, which were recorded at their fair value on the date of issuance and are remeasured at the end of each reporting period. The fair value of our warrant liabilities is determined using a Monte Carlo simulation. See **Note 9. Warrants** for the assumptions and methodologies used in calculating the estimated fair value. Changes in fair value of warrants are primarily attributed to changes in the price of our common stock and in the remaining term of our liability-classified warrants.

Liquidity and Capital Resources

Overview

As of March 31, 2022, we had $20.1 million in cash and cash equivalents. Since our inception in 2006, we have financed our operations primarily through the issuance of our equity securities and through debt financings. 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.

On April 28, 2022, we announced that we have initiated a process to explore a range of strategic alternatives to maximize shareholder value and engaged professional advisors, including an investment bank, to support this process. Strategic alternatives include the sale of all or part of the Company, merger or reverse merger. As we pursue strategic alternatives, we put into place a restructuring plan which includes an approximate 65% reduction in workforce in the second quarter of 2022. Also, as part of further cost reduction measures, we have since made the decision to voluntarily terminate the TiTAN clinical study of GEN-011 and continue to review our other research programs and collaborations to determine an appropriate course of action.

We have a loan and security agreement ("the SVB Loan Agreement") with SVB for the $10.0 million SVB Term Loan. The SVB Term Loan will mature on September 1, 2023. The SVB 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 SVB Term Loan provided for interest-only payments until September 30, 2021; thereafter, payments are due monthly in equal installments of principal and interest (subject to recalculation upon a change in prime rates) through maturity. The SVB Term Loan is subject to a final payment charge of $0.5 million. The SVB Term Loan may be prepaid in whole (but not in part), subject to a prepayment charge of 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 SVB 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, 2022, we were in compliance with all covenants under the SVB Loan Agreement.

The SVB 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. As of March 31, 2022, we have determined that the risk of subjective acceleration under the material adverse effects clause was remote and therefore have classified the long-term portion of the outstanding principal in non-current liabilities. As of March 31, 2022, we had outstanding borrowings, net of unamortized debt issuance costs, of $7.6 million.

We have an agreement with Cowen to establish an ATM equity offering 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, 2022, we sold approximately 0.4 million shares under our ATM and received net proceeds of $0.4 million, after deducting commissions. Cumulatively through March 31, 2022, we have sold an aggregate of approximately 8.2 million shares under our ATM and received $21.6 million in net proceeds. As of March 31, 2022, we had $27.8 million in gross proceeds remaining under our ATM.

We had a purchase agreement with LPC pursuant to which, for a period of 30 months beginning in October 2019, we had the right, at our sole discretion, to sell up to $30.0 million of our common stock to LPC based on prevailing market prices of our common stock at the time of each sale. Cumulatively through March 31, 2022, we had sold an aggregate of approximately 2.7 million shares to LPC under the agreement and received $6.0 million in net proceeds. The agreement expired in April 2022.

Cash flows from operating activities

Cash flows from operating activities consist of our net loss adjusted for various non-cash items and changes in operating assets and liabilities. Cash used in operating activities for the three months ended March 31, 2022 and 2021 was $15.2 million and $12.4 million, respectively. Cash used in operating activities for the three months ended March 31, 2022 increased by $2.8 million when compared to the three months ended March 31, 2021. This increase was primarily due to increased research and development expenses for GEN-011.

Cash flows from investing activities

Investing activities used $0.9 million and $1.0 million of cash in three months ended March 31, 2022 and 2021, respectively. Cash used by investing activities was primarily for purchases of property and equipment in both of the three months ended March 31, 2022 and 2021.

Cash flows from financing activities

Financing activities used $0.9 million and $0.3 million of cash in the three months ended March 31, 2022 and 2021, respectively. In the three months ended March 31, 2022, we repaid $1.3 million in long-term debt, partially offset by the issuance of shares of our common stock under our ATM for net proceeds of $0.4 million. 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 for net proceeds of $4.0 million.

Operating capital requirements

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

We had available cash and cash equivalents of $20.1 million at March 31, 2022. These funds will not be sufficient to fund operations for at least the next twelve months from the date of issuance of these condensed consolidated financial statements which raises substantial doubt about our ability to continue as a going concern. Our future viability beyond one year from the date of issuance of the condensed consolidated financial statements is dependent on our ability to raise additional capital to finance our operations. As announced on April 28, 2022, we are exploring strategic alternatives that include the sale of all or part of the Company, merger or reverse merger. Our existing cash and cash equivalents, including the impact of the restructuring plan, are sufficient to support our current operations into Q3 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 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 ongoing and 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 availability and timing of additional financing;
- the initiation, progress, timing, costs, and results of preclinical studies and clinical trials for our 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 costs to manufacture material for clinical trials;
- the costs to seek regulatory approvals for any product candidates that successfully complete clinical trials;
- the costs to attract and retain skilled personnel; and
- the costs to create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

On April 28, 2022, we implemented a plan to reduce our workforce by approximately 65% with the objective of preserving capital as we explore a range of strategic alternatives to maximize shareholder value. This workforce reduction will take place during the second quarter of 2022. As a result of these actions, we expect to incur personnel-related restructuring charges of approximately $4 million in connection with one-time employee termination costs, including severance and other benefits, which are expected to be incurred in the second quarter of 2022. In addition, as part of further cost reduction measures, we have since made the decision to voluntarily terminate the TiTAN clinical study of GEN-011 and continue to review our other research programs and collaborations to determine an appropriate course of action. We may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the workforce reduction or retention efforts. These estimates of the costs that we expect to incur, and the timing thereof, are subject to a number of assumptions and actual results may differ.

We will need to obtain substantial additional funding in order to complete clinical trials and receive regulatory approval for GEN-011, GEN-009 and our other product candidates. To the extent that we raise additional capital through the sale of our common stock, convertible securities, or other equity securities, the ownership interests of our existing stockholders may be materially diluted, and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. 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-011, GEN-009 or our other product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to GEN-011, GEN-009 or our other product candidates that we otherwise would seek to develop or commercialize ourselves.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We had cash and cash equivalents of $20.1 million as of March 31, 2022. 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, 2022.

Item 4. Controls and Procedures

Evaluation of 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, 2022 (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, 2022, 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, 2022, 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 results of operations. 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, 2021, except for the following:

Interim, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.

From time to time we may disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial, or subsequent results may differ. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

We have disclosed interim data from our clinical trials. Interim or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and treatment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. For example, in April 2022 we reported interim data from 5 patients that was presented at AACR for GEN-011. Subsequent to that release of data, an additional patient experienced progressive disease, and an additional patient experienced a SUSAR that resulted in a fatality that was reported to FDA. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and investors or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Results from previous or ongoing studies are not necessarily predictive of our future clinical study results, and initial or interim results may not continue or be confirmed upon completion of the study. There is limited data concerning long-term safety and efficacy following treatment with our product candidates. These data, or other positive data, may not continue or occur for these patients or for any future patients in our ongoing or future clinical trials, and may not be repeated or observed in ongoing or future studies involving our product candidates. Furthermore, our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical trials. There can be no assurance that any of these studies will ultimately be successful or support further clinical advancement or marketing approval of our product candidates.

Risks Related to Strategic Alternative Process and Potential Strategic Transaction

We may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transactions that we may consummate in the future could have negative consequences. If a strategic transaction is not consummated, our Board may decide to pursue a dissolution and liquidation. In the event of such liquidation or other wind-down event, holders of our securities will likely suffer a total loss of their investment.

In addition to our efforts, if any, to pursue clinical development of our product candidates, we also continue to evaluate all potential strategic options for the company, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction. However, there can be no assurance that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business.

There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. If we are unable to consummate a strategic transaction, our Board may decide to pursue a dissolution and liquidation. In the event of such liquidation or other wind-down event, holders of our securities will likely suffer a total loss of their investment.

We may not realize any additional value in a strategic transaction.

Potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets. Further, the development and any potential commercialization of our product candidates will require substantial additional cash. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development of our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

Any of the following risks could have a material adverse effect on our business, financial condition and prospects.

Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction.

Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In April 2022, we undertook an organizational restructuring that reduced our workforce in order to conserve our capital resources. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

The impact and results of our ongoing strategic process are uncertain and may not be successful.

Our board of directors remains dedicated to diligently deliberating upon and making informed decisions that the directors believe are in the best interests of the company and its stockholders. There can be no assurance, however, that the company's current strategic direction, or the board's evaluation of strategic alternatives, will result in any initiatives, agreements, transactions or plans that will further enhance stockholder value.

We may become involved in securities litigation that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit
3.1	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 24, 2021)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, File No. 001-36289, filed on February 12, 2014)
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

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: May 5, 2022

By: /s/ DIANTHA DUVALL

Diantha Duvall

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 31.1

PRINCIPAL EXECUTIVE OFFICER CERTIFICATION

I, William D. Clark, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Genocea Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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: May 5, 2022

Exhibit 31.2

PRINCIPAL FINANCIAL OFFICER CERTIFICATION

I, Diantha Duvall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Genocea Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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: May 5, 2022

Exhibit 32

**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 Genocea Biosciences, Inc. on Form 10-Q for the three months ended March 31, 2022 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 Genocea 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: May 5, 2022

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 Genocea Biosciences, Inc. on Form 10-Q for the three months ended March 31, 2022 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 Genocea Biosciences, Inc. at the dates and for the periods indicated.

/s/ DIANTHA DUVALL
Diantha Duvall
Chief Financial Officer

Date: May 5, 2022