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 September 30, 2021

OR

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

For the transition period from to

Commission File Number: 001-36289

GENOCEA BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**51-0596811**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

100 Acorn Park Drive, Cambridge, MA 02140
(Address of principal executive offices, including zip code)

(617) 876-8191
(Registrant's telephone number, including area code)

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

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 October 25, 2021 was 57,445,391.

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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)

	September 30, 2021	December 31, 2020
Current assets:		
Cash and cash equivalents	$ 48,908	$ 79,769
Prepaid expenses and other current assets	1,706	2,458
Total current assets	50,614	82,227
Property and equipment, net	5,519	5,123
Right-of-use assets	7,901	9,308
Restricted cash	631	631
Other non-current assets	253	1,204
Total assets	$ 64,918	$ 98,493
Current liabilities:		
Accounts payable	$ 978	$ 534
Accrued expenses and other current liabilities	6,861	7,344
Current portion of long-term debt	4,584	13,862
Lease liabilities	2,281	1,614
Deferred revenue	—	1,641
Total current liabilities	14,704	24,995
Non-current liabilities:		
Lease liabilities, net of current portion	6,660	8,398
Long-term debt, net of current portion	5,327	—
Warrant liabilities	398	56,118
Total liabilities	27,089	89,511
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; (25,000,000 shares authorized at September 30, 2021 and December 31, 2020; — shares issued and outstanding at September 30, 2021 and December 31, 2020)	—	—
Common stock, $0.001 par value; (225,000,000 shares authorized at September 30, 2021 and 170,000,000 shares authorized at December 31, 2020, 57,224,551 shares issued and outstanding at September 30, 2021 and 53,018,813 shares issued and outstanding at December 31, 2020)	57	53
Additional paid-in capital	432,356	383,597
Accumulated deficit	(394,584)	(374,668)
Total stockholders' equity	37,829	8,982
Total liabilities and stockholders' equity	$ 64,918	$ 98,493

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
License revenue	$ 1,641	$ 453	$ 1,641	$ 1,359
Operating expenses:				
Research and development	9,473	7,548	28,737	26,123
General and administrative	3,884	3,644	11,588	10,511
Total operating expenses	13,357	11,192	40,325	36,634
Loss from operations	(11,716)	(10,739)	(38,684)	(35,275)
Other income (expense):				
Change in fair value of warrants	8,382	10,767	19,753	11,770
Interest expense, net	(290)	(377)	(851)	(1,001)
Other income (expense)	2	(4,206)	(134)	(4,223)
Total other income (expense)	8,094	6,184	18,768	6,546
Net loss	$ (3,622)	$ (4,555)	$ (19,916)	$ (28,729)
Comprehensive loss	$ (3,622)	$ (4,555)	$ (19,916)	$ (28,729)
Net loss per share:				
Basic	$ (0.05)	$ (0.08)	$ (0.29)	$ (0.76)
Diluted	$ (0.05)	$ (0.26)	$ (0.54)	$ (1.01)
Weighted average number of shares used in computing net loss per share:				
Basic	69,807	55,492	67,998	37,657
Diluted	69,807	61,130	70,616	39,550

See accompanying notes to the condensed consolidated financial statements.

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

	Common Stock		Preferred Stock	Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	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
Issuance of common stock, net	2,500	3	—	5,512	—	5,515
Stock-based compensation expense	—	—	—	1,014	—	1,014
Issuance of common stock under employee benefit plans	145	—	—	75	—	75
Net loss	—	—	—	—	(4,311)	(4,311)
Balance at June 30, 2021	57,014	57	—	394,960	(390,962)	4,055
Issuance of common stock, net	198	—	—	397	—	397
Stock-based compensation expense	—	—	—	1,030	—	1,030
Reclassification of 2020 Warrants	—	—	—	35,967	—	35,967
Issuance of common stock under employee benefit plans	13	—	—	2	—	2
Net loss	—	—	—	—	(3,622)	(3,622)
Balance at September 30, 2021	57,225	$ 57	$ —	$ 432,356	$ (394,584)	$ 37,829

	Common Stock		Preferred Stock	Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Amount	Capital	Deficit	Equity
Balance at December 31, 2019	27,453	$ 27	$ 701	$ 355,268	$ (330,954)	$ 25,042
Issuance of common stock, net	187	1	—	439	—	440
Stock-based compensation expense	—	—	—	384	—	384
Issuance of common stock under employee benefit plans	4	—	—	—	—	—
Net loss	—	—	—	—	(12,853)	(12,853)
Balance at March 31, 2020	27,644	28	701	356,091	(343,807)	13,013
Issuance of common stock, net	2,287	2	—	5,797	—	5,799
Stock-based compensation	—	—	—	486	—	486
Issuance of common stock under employee benefit plans	33	—	—	60	—	60
Net loss	—	—	—	—	(11,321)	(11,321)
Balance at June 30, 2020	29,964	30	701	362,434	(355,128)	8,037
Issuance of common stock, net	21,391	22	—	16,162	—	16,184
Conversion of preferred stock to common stock	205	—	(701)	701	—	—
Stock-based compensation expense	—	—	—	533	—	533
Issuance of common stock under employee benefit plans	4	—	—	6	—	6
Net loss	—	—	—	—	(4,555)	(4,555)
Balance at September 30, 2020	51,564	$ 52	$ —	$ 379,836	$ (359,683)	$ 20,205

See accompanying notes to the condensed consolidated financial statements.

Genocea Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30	
	2021	**2020**
Operating activities		
Net loss	$ (19,916)	$ (28,729)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	(19,753)	(11,770)
Stock-based compensation	2,624	1,403
Depreciation and amortization	1,149	867
Non-cash interest expense	378	336
Allocation of proceeds to transaction expenses	—	4,219
Other	101	97
Changes in operating assets and liabilities	1,152	1,568
Net cash used in operating activities	(34,265)	(32,009)
Investing activities		
Purchases of property and equipment	(2,353)	(1,214)
Proceeds from sale of equipment	65	26
Net cash used in investing activities	(2,288)	(1,188)
Financing activities		
Repayment of long-term debt	(13,960)	—
Proceeds from long-term debt	10,000	—
Proceeds from issuance of common stock, net	9,891	80,740
Payment of deferred financing costs	(289)	—
Proceeds from issuance of common stock under employee benefit plans	161	66
Debt prepayment costs	(88)	—
Payments on finance lease	(23)	(111)
Net cash provided by financing activities	5,692	80,695
Net (decrease) increase in cash, cash equivalents and restricted cash	(30,861)	47,498
Cash, cash equivalents and restricted cash at beginning of period	80,400	40,758
Cash, cash equivalents and restricted cash at end of period	$ 49,539	$ 88,256
Non-cash financing activities and supplemental cash flow information		
Property and equipment included in accounts payable and accrued expenses	$ 486	$ 181
Right-of-use asset obtained in exchange for lease liabilities	$ —	$ 5,931
Cash paid in connection with operating lease liabilities	$ 2,156	$ 1,800
Cash paid for interest	$ 432	$ 787

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. Genocea operates as one segment, which is discovering, researching, developing and commercializing novel cancer immunotherapies.

GEN-011 is an investigational adoptive T cell therapy comprising neoantigen-targeted peripheral T cells ("NPTs"). NPTs are peripheral blood-derived T cells targeted to ATLAS-identified neoantigens. By employing ATLAS to optimize neoantigen selection and by using T cells derived from peripheral blood, Genocea believes GEN-011 will enable potential patient efficacy, accessibility and cost advantages over other autologous T cell therapies. The Company is conducting a first-in-human clinical trial for GEN-011 (the "TiTAN™ trial"), and in the second quarter of 2021, Genocea dosed its first patient in the trial. GEN-009 is an investigational neoantigen vaccine delivering adjuvanted synthetic long peptides from ATLAS-identified neoantigens. Genocea reported long-term immunogenicity and clinical response data from its GEN-009 neoantigen Phase 1 clinical trial in June 2021, and the Company continues to monitor patients to further evaluate these efficacy signals.

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

The Company regularly evaluates whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the financial statements are issued. The Company had available cash and cash equivalents of $48.9 million at September 30, 2021. As of September 30, 2021, Genocea had an accumulated deficit of $394.6 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 $38.7 million and cash used in operating activities of $34.3 million for the nine months ended September 30, 2021. 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. If the Company is unable to raise additional funds when needed, it may be required to implement cost reduction strategies, including ceasing development of GEN-011 or other research programs and activities, including the Inhibigens and COVID-19 programs. Genocea expects to finance its cash needs through a combination of equity offerings, strategic transactions, or other sources of funding, including utilization of the Lincoln Park Capital ("LPC") purchase agreement and the at-the-market ("ATM") equity offering program with Cowen and Company, LLC ("Cowen"). Although management plans to pursue additional funding, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, or at all.

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, 2020 (the "2020 10-K").

Basis of presentation

The condensed consolidated financial statements include the accounts of the Company and a wholly owned subsidiary. Intercompany accounts and transactions have been eliminated. In the opinion of the Company's management, the condensed consolidated financial statements reflect all adjustments, which are normal and recurring in nature, 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 2020 10-K.

Recently adopted accounting standards

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

Recent accounting pronouncements

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 will adopt this standard on January 1, 2022.

3. Revenue

In May 2020, Genocea entered into a material transfer agreement (the "MTA") with Shionogi & Co., Ltd. ("Shionogi") pursuant to which the Company agreed to transfer certain herpes simplex type 2 ("HSV-2") antigens from its GEN-003 program to Shionogi to evaluate the potential development of a novel HSV-2 vaccine. In connection with the agreement, Genocea provided Shionogi with an option to negotiate an exclusive development and commercialization license for the HSV-2 antigens prior to the expiration of the MTA. Under the terms of the MTA, Shionogi paid the Company a total of $3.0 million in non-refundable, creditable (with respect to the up-front fee pursuant to a development and commercialization agreement) fees.

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

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

During both the three and nine months ended September 30, 2021, the Company recorded license revenue of $1.6 million associated with the expiration of the material right due to the termination of the MTA. During the three and nine months ended September 30, 2020, the Company recorded license revenue of $0.5 million and $1.4 million, respectively, related to the MTA with Shionogi.

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) in active markets for identical assets or liabilities that the Company has the ability to access;
- Level 2—Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates, yield curves and foreign currency spot rates; and
- Level 3—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The Company's financial assets and liabilities measured at fair value consist of cash equivalents and warrant liabilities, respectively.

The fair value of 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 in calculating the estimated fair value. The Company's warrant liabilities are classified as Level 3.

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2021 and December 31, 2020 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2021				
Assets				
Cash equivalents	$ 33,672	$ 33,672	$ —	$ —
Total assets	$ 33,672	$ 33,672	$ —	$ —
Liabilities				
Warrant liabilities	$ 398	$ —	$ —	$ 398
Total liabilities	$ 398	$ —	$ —	$ 398
December 31, 2020				
Assets				
Cash equivalents	$ 76,866	$ 76,866	$ —	$ —
Total assets	$ 76,866	$ 76,866	$ —	$ —
Liabilities				
Warrant liabilities	$ 56,118	$ —	$ —	$ 56,118
Total liabilities	$ 56,118	$ —	$ —	$ 56,118

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

	Warrant Liabilities
Balance at December 31, 2020	$ 56,118
Change in fair value	(19,753)
Reclassification to equity	(35,967)
Balance at September 30, 2021	$ 398

As of September 30, 2021 and December 31, 2020, the carrying value of Genocea's long-term debt approximated its fair value, as it reflected interest rates currently available to the Company.

5. Accrued expenses and other current liabilities

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

	September 30, 2021	December 31, 2020
Research and development costs	$ 3,151	$ 2,592
Payroll and other headcount-related costs	2,639	2,779
Other current liabilities	1,071	1,973
Total	$ 6,861	$ 7,344

6. Commitments and contingencies

Operating leases

As of September 30, 2021, Genocea has 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 September 30, 2021.

In January 2021, Genocea entered into a sublease agreement for one floor of lab and office space through June 2022, with an option for the sublessee to extend the sublease for an additional two months. After the initial option, which is at the sublessee's sole discretion, the sublease agreement contains additional options for the Company and the sublessee to mutually extend the sublease for up to an additional eighteen months. As Genocea retained its obligations under the sublease, it will record the payments received under the sublease as a reduction of lease expense. For the three and nine months ended September 30, 2021, the Company recorded sublease income of $0.4 million and $1.1 million, respectively, as a reduction of lease expense.

For the three months ended September 30, 2021 and 2020, the Company recorded lease expense, net of sublease income, of $0.3 million and $0.7 million, respectively. For the nine months ended September 30, 2021 and 2020, the Company recorded lease expense, net of sublease income, of $0.9 million and $2.0 million, respectively.

The weighted average remaining lease term and weighted average discount rate of the Company's operating leases are as follows:

	September 30, 2021	December 31, 2020
Weighted average remaining lease term (in years)	3.41	4.17
Weighted average discount rate	8.13 %	8.12 %

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

	Classification	September 30, 2021	December 31, 2020
Assets			
Operating	Right-of-use assets	$ 7,901	$ 9,278
Finance	Right-of-use assets	—	30
Total lease assets		$ 7,901	$ 9,308
Liabilities			
Current:			
Operating	Lease liabilities	$ 2,281	$ 1,592
Finance	Lease liabilities	—	22
Non-current:			
Operating	Lease liabilities, net of current portion	6,660	8,398
Total lease liabilities		$ 8,941	$ 10,012

The minimum lease payments related to the Company's operating leases as of September 30, 2021 were as follows (in thousands):

Remainder of 2021	$ 721
2022	2,943
2023	3,017
2024	3,092
2025	517
Total lease payments	10,290
Less: Imputed interest	(1,349)
Total	$ 8,941

At September 30, 2021 and December 31, 2020, the Company had an outstanding letter of credit of $0.6 million with a financial institution related to a security deposit for the office and lab space lease, which is secured by cash on deposit and expires in February 2025.

Contractual obligations

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

Harvard University license agreement

Genocea has an exclusive license agreement with Harvard University (“Harvard”), granting the Company an exclusive, worldwide, royalty-bearing, sublicensable license to three patent families, to develop, make, have made, use, market, offer for sale, sell, have sold and import licensed products and to perform licensed services related to the ATLAS discovery platform. Genocea is also obligated to pay Harvard milestone payments up to $1.6 million in the aggregate upon the achievement of certain development and regulatory milestones. As of September 30, 2021, the Company has paid $0.4 million in aggregate milestone payments. Genocea is obligated under this license agreement to use commercially reasonable efforts to develop, market and sell licensed products in compliance with an agreed-upon development plan. In addition, the Company is obligated to achieve specified development milestones, and in the event Genocea is unable to meet its development milestones for any type of product or service, absent any reasonable proposed extension or amendment thereof, Harvard has the right, depending on the type of product or service, to terminate this agreement with respect to such products or to convert the license to a non-exclusive, non-sublicensable license with respect to such products and services.

Upon commercialization of the Company's products covered by the licensed patent rights or discovered using the licensed methods, Genocea is obligated to pay Harvard royalties on the net sales of such products and services sold by the Company, the Company's affiliates, and the Company's sublicensees. This royalty varies depending on the type of product or service 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 revenue (cash or non-cash) under any sublicense, it must pay Harvard a percentage of such revenue, excluding certain categories of payments, varying from the low single digits to up to the low double digits depending on the scope of the license that includes the sublicense.

The license agreement with Harvard will expire on a product-by-product or service-by-service and country-by-country basis until the expiration of the last-to-expire valid claim under the licensed patent rights. The Company may terminate the agreement at any time by giving Harvard advance written notice. Harvard may also terminate the agreement (i) in the event of a material breach by the Company that remains uncured; (ii) in the event of the Company's insolvency, bankruptcy, or similar circumstances; (iii) or if Genocea 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 the Company's technology (the “Combination Product”). Hiltonol is the adjuvant component of GEN-009, which will consist of synthetic long peptides or neoantigens identified using the Company's proprietary ATLAS platform, formulated with Hiltonol.

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

Under this agreement, 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.

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

7. Debt

In April 2018, the Company entered into an amended and restated loan and security agreement 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.

On February 18, 2021 (the "2021 Loan Closing Date"), Genocea entered into a loan and security agreement (the "2021 Loan Agreement") with Silicon Valley Bank ("SVB") for a $10.0 million secured term loan (the "2021 Term Loan"). $9.0 million of the proceeds from the 2021 Term Loan were used to repay the Company's borrowings that were outstanding at the 2021 Loan Closing Date under its previous loan and security agreement with Hercules, paying off all obligations owing under, and extinguishing, the Hercules Loan Agreement on the 2021 Loan Closing Date. The remaining proceeds from the 2021 Term Loan of $1.0 million were received by the Company for working capital and general corporate purposes.

The 2021 Term Loan will mature on September 1, 2023. The 2021 Term Loan accrues interest at a floating per annum rate equal to the greater of (i) 6.25% or (ii) the sum of 3.0% plus the prime rate. The 2021 Term Loan provides for interest-only payments until September 30, 2021. Thereafter, amortization payments will be payable monthly in equal installments of principal and interest (subject to recalculation upon a change in prime rates) upon expiration of the interest-only period through maturity. The 2021 Term Loan is subject to a final payment charge of $0.5 million that will be amortized as a debt issuance cost over the expected term of the loan. The 2021 Term Loan may be prepaid in whole (but not in part), subject to a prepayment charge of 3.0%, if prepaid in any of the first twelve (12) months following the Closing Date, 2.0%, if prepaid after twelve (12) months following the Closing Date but on or prior to twenty four (24) months following the Closing Date, and 1.0% thereafter.

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

The 2021 Loan Agreement contains customary covenants and representations, including a financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries. There are no financial covenants. As of September 30, 2021, the Company was in compliance with all covenants under the 2021 Loan Agreement.

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

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

As of September 30, 2021 and December 31, 2020, the Company had outstanding borrowings, net of unamortized debt issuance costs, of $9.9 million and $13.9 million, respectively. Interest expense was $0.3 million and $0.4 million for the three months ended September 30, 2021 and 2020, respectively. Interest expense was $0.9 million and $1.1 million for the nine months ended September 30, 2021 and 2020, respectively.

Future principal payments, including final payment charges, as of September 30, 2021 are as follows:

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

8. Stockholders' equity

Effective June 24, 2021, the Company increased the number of authorized shares of common stock from 170.0 million shares to 225.0 million shares.

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 nine months ended September 30, 2021, the Company sold approximately 4.0 million shares under the ATM and received net proceeds of $9.9 million, after deducting commissions. Cumulatively through September 30, 2021, the Company has sold an aggregate of approximately 6.9 million shares under the ATM and received $19.8 million in net proceeds. As of September 30, 2021, the Company had $29.7 million in gross proceeds remaining under the ATM.

Agreement with Lincoln Park Capital

Genocea has a purchase agreement with LPC pursuant to which, for a period of 30 months beginning in October 2019, the Company has the right, at its sole discretion, to sell up to $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. The purchase agreement limits the Company's sales of shares of common stock to LPC to approximately 5.2 million shares of common stock, representing 19.99% of the shares of common stock outstanding on the date of the purchase agreement. The purchase agreement also prohibits the Company from directing LPC to purchase any shares of common stock if those shares, when aggregated with all other shares of the Company's common stock then beneficially owned by LPC and its affiliates, would result in LPC and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of the Company's common stock. As of September 30, 2021, the Company had $24.0 million remaining under its agreement with LPC.

2020 Private Placement

In July 2020, the Company completed a private placement (the “2020 Private Placement”) and received net cash proceeds of $74.5 million. In connection with the 2020 Private Placement, the Company issued approximately 21.4 million shares of its common stock, pre-funded warrants to purchase approximately 12.2 million additional shares of its common stock (the “2020 Pre-Funded Warrants”) and warrants to purchase approximately 33.6 million shares of its common stock (the “2020 Warrants”). See **Note 10. Warrants.**

In connection with the 2020 Private Placement, the Company incurred $5.4 million of issuance costs. The Company allocated $1.2 million of the issuance costs to the common stock and 2020 Pre-Funded Warrants within additional paid-in capital and immediately expensed $4.2 million of the issuance costs allocated to the liability-classified 2020 Warrants as other expenses.

Preferred stock

In July 2020, 1,635 shares of the Company's preferred stock, which represented the entirety of the outstanding preferred stock balance, were converted to common stock. Each share of preferred stock was convertible into 125 shares of common stock.

9. Warrants

As of September 30, 2021, the Company had the following potentially issuable shares of common stock related to unexercised warrants outstanding (shares in thousands):

	Shares	Exercise Price	Expiration Date	Classification
Hercules Warrant	41	$ 6.80	Q2 2023	Equity
2018 Warrants	3,617	$ 9.60	Q1 2023	Liability
2019 Warrants	933	$ 4.52	Q1 2024	Equity
2019 Pre-Funded Warrants	531	$ 0.08	Q1 2039	Equity
2020 Warrants	33,613	$ 2.25	Q3 2024	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 $0.7 million and expense of $0.3 million for the three months ended September 30, 2021 and 2020, respectively, and income of $1.3 million and $0.7 million for the nine months ended September 30, 2021 and 2020, respectively. The fair value of the warrant liability related to the 2018 Warrants was $0.4 million and $1.7 million as of September 30, 2021 and December 31, 2020, respectively.

The following table details the assumptions used in the Monte Carlo simulation models used to estimate the fair value of the 2018 Warrants as of September 30, 2021 and December 31, 2020, respectively:

	September 30, 2021	December 31, 2020
Stock price	$ 1.92	$ 2.42
Volatility	50.0% - 94.7%	50.0% - 101.5%
Remaining term (in years)	1.3	2.0
Expected dividend yield	— %	— %
Risk-free rate	0.15 %	0.13 %
Acquisition event probability	18.0 %	25.0 %

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 shareholder approval for the adjustment to the exercise price as a result of any common stock issuance at a price per share less than $2.25, 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 $7.7 million and $18.5 million for the three and nine months ended September 30, 2021, respectively, and income of $11.1 million for both the three and nine months ended September 30, 2020. The fair value of the warrant liability related to the 2020 Warrants was $54.5 million as of December 31, 2020. 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 and December 31, 2020, respectively:

	July 25, 2021		December 31, 2020	
Stock price	$ 2.04		$ 2.42	
Volatility	96.2	%	119.1	%
Remaining term (in years)	3.0		3.6	
Expected dividend yield	—		—	
Risk-free rate	0.38	%	0.22	%
Acquisition event probability	35.0	%	40.0	%

SVB Warrant

In connection with the 2021 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 September 30, 2021, there were approximately 0.6 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.

Determining the fair value of market-based RSUs

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

The following table details the assumptions used in the Monte Carlo simulation model used to estimate the fair value of the market-based RSUs granted during the nine months ended September 30, 2021:

	Nine Months Ended September 30
	2021
Stock price	$ 3.01
Volatility	97.65 %
Remaining term (in years)	2.8
Risk-free rate	0.29 %
Acquisition event probability	33.0 %

Stock-based compensation expense

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
Research and development	$ 416	$ 222	$ 1,099	$ 600
General and administrative	614	311	1,525	803
Total	$ 1,030	$ 533	$ 2,624	$ 1,403

Stock options

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	2,329	$ 7.05		$ 505
Granted	1,855	$ 2.91		
Exercised	(40)	$ 2.19		
Forfeited/cancelled	(241)	$ 6.41		
Outstanding at September 30, 2021	3,903	$ 5.18	8.1	$ 143
Exercisable at September 30, 2021	1,383	$ 9.36	7.0	$ 48

RSUs

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

	Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	550	$ 2.13
Granted[1]	1,996	$ 2.52
Vested	(130)	$ 2.13
Forfeited/cancelled	(88)	$ 2.49
Outstanding at September 30, 2021	2,328	$ 2.45

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"), issues shares of common stock to participating eligible employees during two six-month offering periods each year. As of September 30, 2021, there were approximately 0.1 million shares remaining for future issuance under the ESPP.

11. Net loss per share

Basic and diluted net loss per share were calculated as follows for the three and nine months ended September 30, 2021 and 2020 (in thousands, except per share amounts):

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
Numerator				
Net loss	$ (3,622)	$ (4,555)	$ (19,916)	$ (28,729)
Less: Change in fair value of 2020 Warrants[1]	—	11,092	18,488	11,092
Adjusted net loss	$ (3,622)	$ (15,647)	$ (38,404)	$ (39,821)
Denominator				
Weighted average common stock outstanding – basic	69,807	55,492	67,998	37,657
Dilutive effect of common stock issuable from assumed exercise of warrants[1]	—	5,638	2,618	1,893
Weighted average common stock outstanding – diluted	69,807	61,130	70,616	39,550
Net loss per share				
Basic	$ (0.05)	$ (0.08)	$ (0.29)	$ (0.76)
Diluted	$ (0.05)	$ (0.26)	$ (0.54)	$ (1.01)

1. The 2020 Warrants have been included in the calculation of diluted net loss per share for the nine months ended September 30, 2021 and for the three and nine months ended September 30, 2020 as the warrants were in-the-money during those periods 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 nine months ended September 30, 2021 and 2020 (in thousands):

	Nine Months Ended September 30	
	2021	2020
Warrants	4,627	4,591
Stock options	3,903	2,385
RSUs	2,328	545
Total	10,858	7,521

FORWARD-LOOKING STATEMENTS

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

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed in our Annual Report on Form 10-K for the year ended December 31, 2020 (the "2020 10-K") and other filings with the Securities Exchange Commission (the “SEC”), including the following:

- the timing and amount of funds we require to conduct clinical trials for GEN-011 and to perform research in support of pipeline development;
- 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;
- future expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing;
- the availability and timing of additional financing;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the timing of, and our ability to obtain and maintain, regulatory approvals for our product candidates;
- the effect of the novel coronavirus ("COVID-19") pandemic on the economy generally and on our business and operations specifically, including our research and development efforts, our clinical trials and our employees, and the potential disruptions in supply chains and to our third-party manufacturers, including the availability of materials and equipment;
- the potential benefits of strategic partnership agreements and our ability to enter into strategic partnership arrangements;
- our ability to obtain and maintain intellectual property protection for our manufacturing methods and product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- our ability to quickly and efficiently identify and develop product candidates; and
- our commercialization, marketing and manufacturing capabilities and strategy.

These factors are discussed more fully in our 2020 10-K and elsewhere in this and other reports we file with the SEC. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and investors should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make or collaborations or strategic partnerships we may enter into. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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

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

Overview

We are a biopharmaceutical company dedicated to discovering and developing novel cancer immunotherapies using our proprietary ATLAS™ platform. The ATLAS platform can profile each patient's $CD4^+$ and $CD8^+$ T cell immune responses to every potential target or "antigen" identified by next-generation sequencing of that patient's tumor. ATLAS zeroes in on both antigens that activate anti-tumor T cell responses and inhibitory antigens, 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.

GEN-011 is an investigational adoptive T cell therapy comprising neoantigen-targeted peripheral T cells ("NPTs"). NPTs are peripheral blood-derived T cells targeted to ATLAS-identified neoantigens. By employing ATLAS to optimize neoantigen selection and by using T cells derived from peripheral blood, we believe GEN-011 will enable potential patient efficacy, accessibility and cost advantages over other autologous T cell therapies. We are conducting a first-in-human clinical trial (the "TiTAN™ trial") for GEN-011, and in the second quarter of 2021, we dosed our first patient in the trial. 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 June 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 have also demonstrated that classical antigen prediction methodologies often mischaracterize Inhibigens as stimulatory. 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 could have beneficial uses beyond cancer. We have previously demonstrated its effectiveness in identifying novel protective antigens for infectious disease therapies, and we believe it also could provide benefits in autoimmune and other disease therapies. While we believe Inhibigens should be avoided in cancer immunotherapies, they could prove to be beneficial in other therapies. ATLAS could be a key tool in optimizing antigen selection for therapies across a number of diseases.

Intellectual property

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

GEN-011 differs from TIL therapy in two critical ways. First, we use ATLAS to design the product to be highly specific for the antigens of anti-tumor T cell responses. Second, we rely on T cells extracted from peripheral blood, which are readily available and we believe have greater potential for proliferation and activity than TILs. We believe these differences may result in GEN-011, if approved, offering 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, often limiting their clinical utility to certain subsets of western Caucasians; and
- The GEN-011 cell expansion process does not require T cell receptor ("TCR") vector design or transduction.

Across more than 15 development and engineering runs in blood derived from cancer patients and healthy donors, we have demonstrated that GEN-011 NPTs:

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

We are conducting the TiTAN trial, treating patients with GEN-011 as monotherapy for tumors that have not achieved an adequate response after CPI therapy. Our target indications include melanoma, non-small cell lung cancer, small cell lung cancer, squamous cell carcinoma of the head and neck, urothelial carcinoma, renal cell carcinoma, cutaneous squamous cell carcinoma, and anal squamous cell carcinoma. In the second quarter of 2021, we dosed our first patient.

The TiTAN trial will contain two patient cohorts:

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

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

GEN-009

GEN-009 is a neoantigen vaccine candidate delivering adjuvanted synthetic long peptides spanning ATLAS-identified anti-tumor neoantigens. We are conducting a Phase 1/2a clinical trial for GEN-009 across a range of solid tumor types. Part A of the trial is assessing the monotherapy GEN-009 for safety, immunogenicity and ability to prevent disease relapse in certain cancer patients with no detectable tumor at the time of vaccination but with a risk of relapse. Part B of the trial is assessing the safety, immunogenicity and preliminary 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 American Society of Clinical Oncology Annual Meeting in June 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.

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 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.

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

Other research activities

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

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

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

Business update regarding COVID-19

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

To date, we have been able to continue our operations and do not anticipate any material interruptions for the foreseeable future. However, we are continuing to assess the potential impact of the COVID-19 pandemic on our business and operations, including our expenses, supply chain and preclinical 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 September 30, 2021, we had received an aggregate of $453.5 million in net proceeds from the issuance of equity securities, we had outstanding borrowings of $10.5 million, and our cash and cash equivalents were $48.9 million.

Since inception, we have incurred significant operating losses. We expect to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year. We will need to generate significant revenue to achieve profitability, and we may never do so.

In January 2021, we entered into a sublease agreement for one floor of lab and office space through June 2022, with an option for the sublessee to extend the sublease for an additional two months. After the initial option, which is at the sublessee’s sole discretion, the sublease agreement contains additional options for us and the sublessee to mutually extend the sublease for up to an additional eighteen months. As we retained our obligations under the sublease, we are recording the payments received from the sublease as a reduction of lease expense. Sublease income of $0.4 million and $1.1 million was recorded as a reduction of lease expense during the three and nine months ended September 30, 2021, respectively.

On February 18, 2021 (the "2021 Loan Closing Date"), we entered into a loan and security agreement (the "2021 Loan Agreement") with Silicon Valley Bank ("SVB") for a $10.0 million secured term loan (the "2021 Term Loan"). $9.0 million of the proceeds from the 2021 Term Loan were used to repay our borrowings that were outstanding at the 2021 Loan Closing Date under our previous loan and security agreement with Hercules Capital, Inc. (“Hercules”), paying off all obligations owing under, and extinguishing, the previous loan and security agreement with Hercules on the 2021 Loan Closing Date. The remaining proceeds from the 2021 Term Loan of $1.0 million were received by us for working capital and general corporate purposes. The 2021 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.

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 nine months ended September 30, 2021, we sold approximately 4.0 million shares under our ATM and received net proceeds of $9.9 million, after deducting commissions. Through September 30, 2021, we have sold an aggregate of approximately 6.9 million shares under our ATM and received $19.8 million in net proceeds. As of September 30, 2021, we had $29.7 million in gross proceeds remaining under our ATM.

We have a purchase agreement with Lincoln Park Capital (“LPC”) pursuant to which, for a period of 30 months beginning in October 2019, we have the right, at our sole discretion, to sell up to $30.0 million of our common stock to LPC based on prevailing market prices of our common stock at the time of each sale. The purchase agreement limits our sales of shares of common stock to LPC to approximately 5.2 million shares of common stock, representing 19.99% of the shares of common stock outstanding on the date of the purchase agreement. The purchase agreement also prohibits us from directing LPC to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by LPC and its affiliates, would result in LPC and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of our common stock. As of September 30, 2021, we had $24.0 million remaining under our agreement with LPC.

As reflected in our condensed consolidated financial statements, we used cash of $34.3 million to fund operating activities during the nine months ended September 30, 2021 and had $48.9 million available in cash and cash equivalents at September 30, 2021. In addition, we had an accumulated deficit of $394.6 million and anticipate that we will continue to incur significant operating losses for the foreseeable future as we continue to develop our product candidates. Until such time, if ever, as we attempt to generate substantial product revenue and achieve profitability, we expect to finance our cash needs through a combination of equity offerings and strategic transactions, and other sources of funding. If we are unable to raise additional funds when needed, we may be required to implement cost reduction strategies, including ceasing development of GEN-011 or other corporate programs and activities, including our Inhibigens and COVID-19 programs. We expect that our available cash and cash equivalents at September 30, 2021 should be sufficient to fund operations into the third quarter of 2022.

Costs related to clinical trials can be unpredictable, and there can be no guarantee that our current balances of cash and cash equivalents, combined with proceeds received from other sources, will be sufficient to fund our trials or operations through this period. These funds will not be sufficient to enable us to conduct pivotal clinical trials for, seek marketing approval for, or commercially launch GEN-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 and nine months ended September 30, 2021 and 2020 was derived from a material transfer agreement (the "MTA") with Shionogi & Co., Ltd. ("Shionogi"). In July 2021, Shionogi informed us that their studies under the MTA were successful and demonstrated that GEN-003 antigen vaccination was protective in animal models of genital herpes. However, due to a change in Shionogi's corporate focus, Shionogi allowed its option to negotiate an exclusive development and commercialization license for the HSV-2 antigens prior to the expiration of the MTA to lapse. 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 preclinical and clinical 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 and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
Phase 1/2a programs	$ 6,526	$ 2,135	$ 19,777	$ 10,544
Discovery and pre-IND	1,496	3,722	4,960	11,075
Other research and development	1,451	1,691	4,000	4,504
Total research and development	$ 9,473	$ 7,548	$ 28,737	$ 26,123

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 2020 10-K.

Results of Operations

Comparison of the three and nine months ended September 30, 2021 and 2020

License revenue

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
	(in thousands)			
License revenue	$ 1,641	$ 453	$ 1,641	$ 1,359

License revenue increased $1.2 million in three months ended September 30, 2021, as compared to the three months ended September 30, 2021, and increased $0.3 million in the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020. The increase in both periods relates to revenue recognized in connection with the expiration of the MTA with Shionogi during the three and nine months ended September 30, 2021.

Research and development expenses

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
	(in thousands)			
Research and development	$ 9,473	$ 7,548	$ 28,737	$ 26,123

Research and development expenses increased $1.9 million in the three months ended September 30, 2021, as compared to the three months ended September 30, 2020. The increase was largely due to higher manufacturing and clinical costs of $1.3 million and higher headcount and headcount-related costs of $0.7 million.

Research and development expenses increased $2.6 million in the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020. The increase was largely due to higher headcount and headcount-related costs of $2.1 million and higher manufacturing and clinical costs of $0.6 million.

General and administrative expenses

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
	(in thousands)			
General and administrative	$ 3,884	$ 3,644	$ 11,588	$ 10,511

General and administrative expenses increased $0.2 million in the three months ended September 30, 2021, as compared to the three months ended September 30, 2020. The increase was primarily due to higher headcount and headcount-related costs of $0.6 million, partially offset by lower facilities costs, net of sublease income, of $0.6 million.

General and administrative expenses increased $1.1 million in the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020. The increase was primarily due to higher headcount and headcount-related costs of $1.9 million, increased professional services fees of $0.4 million and higher depreciation expense of $0.3 million, partially offset by lower facilities costs, net of sublease income, of $1.8 million.

Change in fair value of warrants

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
	(in thousands)			
Change in fair value of warrants	$ 8,382	$ 10,767	$ 19,753	$ 11,770

Change in fair value of warrants reflects the non-cash change in the fair value of 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. At the expiration of the down-round protection feature on July 25, 2021, the 2020 Warrants were remeasured to their fair value and subsequently reclassified to equity. The increase in both the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, was primarily due to the July 2020 issuance of liability-classified warrants for 33.6 million shares of our common stock in connection with our 2020 private placement.

Interest expense, net

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
	(in thousands)			
Interest expense, net	$ (290)	$ (377)	$ (851)	$ (1,001)

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

Other income (expense)

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
	(in thousands)			
Other income (expense)	$ 2	$ (4,206)	$ (134)	$ (4,223)

Other expense during the nine months ended September 30, 2021 consists primarily of debt prepayment and extinguishment costs. Other expense during the three and nine months ended September 30, 2020 consists primarily of transaction costs incurred in connection with our 2020 private placement.

Liquidity and Capital Resources

Overview

Since our inception in 2006, we have funded operations primarily through proceeds from issuances of common stock and long-term debt.

As of September 30, 2021, we had $48.9 million in cash and cash equivalents.

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

On the 2021 Loan Closing Date, we entered into the 2021 Loan Agreement with SVB for the $10.0 million 2021 Term Loan. $9.0 million of the proceeds from the 2021 Term Loan were used to repay our borrowings that were outstanding at the 2021 Loan Closing Date under the Hercules Loan Agreement, paying off all obligations owing under, and extinguishing, the Hercules Loan Agreement, on the 2021 Loan Closing Date. The remaining proceeds from the 2021 Term Loan of $1.0 million were received by us for working capital and general corporate purposes. The 2021 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 2021 Loan Agreement contains customary covenants and representations, including a financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries. There are no financial covenants. As of September 30, 2021, we were in compliance with all covenants under the 2021 Loan Agreement.

The 2021 Loan Agreement also includes customary events of default, including payment defaults, breaches of covenants, change of control and occurrence of a material adverse effect. Amounts outstanding during an event of default shall be payable on demand and shall accrue interest at an additional rate of 4.0% per annum of the past due amount outstanding. We have 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.

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

We have an agreement with Cowen to establish an ATM 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 nine months ended September 30, 2021, we sold approximately 4.0 million shares under our ATM and received net proceeds of $9.9 million, after deducting commissions. Cumulatively through September 30, 2021, we have sold an aggregate of approximately 6.9 million shares under the ATM and received $19.8 million in net proceeds. As of September 30, 2021, we had $29.7 million in gross proceeds remaining under the ATM.

We have a purchase agreement with LPC pursuant to which, for a period of 30 months beginning in October 2019, we have the right, at our sole discretion, to sell up to $30.0 million of our common stock to LPC based on prevailing market prices of our common stock at the time of each sale. The purchase agreement limits our sales of shares of common stock to LPC to approximately 5.2 million shares of common stock, representing 19.99% of the shares of common stock outstanding on the date of the purchase agreement. The purchase agreement also prohibits us from directing LPC to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by LPC and its affiliates, would result in LPC and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of our common stock. As of September 30, 2021, we had $24.0 million remaining under our agreement with LPC.

Cash flows from operating activities

Cash flows from operating activities consist of our net loss adjusted for various non-cash items, changes in working capital and changes in certain other balance sheet accounts. Cash used in operating activities for the nine months ended September 30, 2021 and 2020 was $34.3 million and $32.0 million, respectively. Cash used in operating activities for the nine months ended September 30, 2021 increased by $2.3 million when compared to the nine months ended September 30, 2020. This increase was primarily due to increased research and development expenses for GEN-011 and growth of our corporate infrastructure.

Cash flows from investing activities

Investing activities used $2.3 million and $1.2 million of cash in nine months ended September 30, 2021 and 2020, respectively. Cash used by investing activities was primarily for purchases of property and equipment in both of the nine months ended September 30, 2021 and 2020.

Cash flows from financing activities

Financing activities provided $5.7 million and $80.7 million of cash in the nine months ended September 30, 2021 and 2020, respectively. In the nine months ended September 30, 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 of our common stock under our ATM for net proceeds of $9.9 million. In the nine months ended September 30, 2020, the 2020 private placement generated net proceeds of $74.5 million, we issued shares of common stock to LPC for net proceeds of $3.5 million, and we issued shares of common stock under our ATM for net proceeds of $2.7 million.

Operating capital requirements

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

We expect that our cash and cash equivalents as of September 30, 2021 of $48.9 million should be sufficient to fund operations into the third quarter of 2022. These funds may 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 its operations. If we are unable to raise additional funds when needed, we may be required to implement cost reduction strategies, including ceasing development of GEN-011 or other research programs and activities, including our Inhibigens and COVID-19 programs. We expect to finance our cash needs through a combination of equity offerings, strategic transactions, or other sources of funding, including utilization of our purchase agreement with LPC and our ATM equity offering program with Cowen. We expect that our operating plan, which includes these funding sources, extends operations to the end of 2022. Although we plan to pursue additional funding, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, or at all.

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 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.

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 $48.9 million as of September 30, 2021. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk relates to fluctuations in interest rates, which are affected by changes in the general level of U.S. interest rates. Given the short-term nature of our cash and cash equivalents, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations. We do not own any derivative financial instruments.

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

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

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our results of operations during the nine months ended September 30, 2021.

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 September 30, 2021 (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the three months ended September 30, 2021, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. We do not believe we are currently party to any pending legal action, arbitration proceeding or governmental proceeding, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business or operating results. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

Item 1A. Risk Factors

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

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

We had available cash and cash equivalents as of September 30, 2021 of $48.9 million. As of September 30, 2021, we had an accumulated deficit of $394.6 million and anticipate that we will continue to incur significant operating losses for the foreseeable future as we continue to develop our product candidates. In addition, we had a loss from operations of $38.7 million and cash used in operating activities of $34.3 million for the nine months ended September 30, 2021. 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 condensed 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 these condensed consolidated financial statements is dependent on our ability to raise additional capital to finance our operations. If we are unable to raise additional funds when needed, we may be required to implement cost reduction strategies, including ceasing development of GEN-011 or other research programs and activities, including our Inhibigens and COVID-19 programs. We expect to finance our cash needs through a combination of equity offerings, strategic transactions, or other sources of funding, including utilization of the Lincoln Park Capital purchase agreement and the at-the-market equity offering program with Cowen and Company, LLC. We expect that our operating plan, which includes these funding sources, extends operations to the end of 2022. Although management plans to pursue additional funding, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, or at all.

We believe that we will continue to expend substantial resources for the foreseeable future developing GEN-011. These expenditures will include costs associated with research and development, manufacturing, clinical trials, potentially acquiring new technologies, and potentially obtaining regulatory approvals. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development of our product candidates. Furthermore, because of the significant expense associated with conducting clinical trials, we cannot be certain we will have sufficient capital to complete such trials for a given product candidate.

Our future capital requirements depend on many factors, including:

- the timing and costs of our planned clinical trials for GEN- 011;
- the progress, timing, and costs of manufacturing GEN-011;
- the timing of GEN-011 patient enrollment and dosing;
- the availability of GEN-011 third-party manufacturing capacity;
- the 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.

Our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us when needed, we would be required to delay, limit, reduce or terminate non-clinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

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 By-laws (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: October 28, 2021

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: October 28, 2021

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: October 28, 2021

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 September 30, 2021 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-Q fairly presents in all material respects the financial condition and results of operations of 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: October 28, 2021

I, Diantha Duvall, certify to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Genocea Biosciences, Inc. on Form 10-Q for the three months ended September 30, 2021 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-Q fairly presents in all material respects the financial condition and results of operations of Genocea Biosciences, Inc. at the dates and for the periods indicated.

/s/ DIANTHA DUVALL
Diantha Duvall
Chief Financial Officer

Date: October 28, 2021