UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **July 29, 2021**

GENOCEA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36289**	**51-0596811**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

100 Acorn Park Drive, 5th Floor

Cambridge, MA 02140

(Address of principal executive offices, including zip code)

(617) 876-8191

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	GNCA	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (230.405 of this chapter) or Rule 12b-2of the Securities Exchange Act of 1934 (§ 240 12b-2 of this chapter).

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On July 29, 2021, Genocea Biosciences, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2021. A full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by Genocea Biosciences, Inc. on July 29, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

GENOCEA BIOSCIENCES, INC.

By: /s/ DIANTHA DUVALL
Diantha Duvall
Chief Financial Officer
(Principal Financial Officer)

Date: July 29, 2021

Investor Contact:
Dan Ferry
daniel@lifesciadvisors.com

Media Contact:
Sarah O'Connell
soconnell@vergescientific.com

Genocea Provides Second Quarter 2021 Corporate Update

GEN-011 neoantigen-targeted peripheral T cell therapy clinical trial continues

GEN-009 neoantigen vaccine candidate shows promising long-term clinical results

Conference call today at 8:30 a.m. E.T.

CAMBRIDGE, Mass., July 29, 2021 - Genocea Biosciences, Inc. (Nasdaq: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, today provided a business update for the second quarter ended June 30, 2021.

"I am pleased with the GEN-011 program progress. We continue to believe that GEN-011 has the potential to represent a major advancement in solid tumor T cell therapies based on the use of optimal T cells and targets. These T cells are derived from easily accessible peripheral blood as opposed to the tumor itself and are activated to pursue the surface-presented neoantigens of anti-tumor $CD8^+$ and $CD4^+$ T cell responses, prioritized by our proprietary *ex vivo* discovery platform, ATLAS™," said Chip Clark, Genocea's President and Chief Executive Officer.

Clinical updates

GEN-011 (investigational neoantigen-targeted peripheral T cell therapy – or NPT)

- Genocea previously announced dosing of the first patient in its GEN-011 TiTAN™ clinical trial. GEN-011 is a next-generation solid tumor therapy comprised of neoantigen-targeted peripheral T cells ("NPTs") selectively expanded on neoantigens of anti-tumor $CD8^+$ and $CD4^+$ T cell responses identified by ATLAS. The TiTAN trial is an open-label, multi-center Phase1/2a trial evaluating safety, tolerability, T cell persistence and proliferation and clinical efficacy. Preliminary clinical response data from an initial subset of patients is expected in late Q4 2021 or Q1 2022.

GEN-009 (investigational neoantigen vaccine)

- At the American Society of Clinical Oncology ("ASCO") 2021 Annual Meeting in June, the Company presented long-term follow-up clinical and immunogenicity data from its ongoing Phase 1/2a clinical study demonstrating that GEN-009 continues to generate broad immune responses against neoantigens that can lead to sustained clinical responses. In Part B of the clinical trial, of the nine CPI-sensitive patients, the data show four patients experienced novel reduction in tumor volume post-GEN-009 dosing and achieved independent RECIST responses after vaccination, including three partial responses ("PRs") and one complete response ("CR"). This is an increase from the two PRs and one CR previously reported at the Society for Immunotherapy of Cancer's ("SITC") 2020 Annual Meeting. The remaining five CPI-sensitive patients all achieved disease stabilization. Across the CPI-sensitive cohort, the median duration without disease progression after initial GEN-009 vaccination was 15 months. Of the seven CPI-refractory patients, two achieved stable disease after initial GEN-009 vaccination for up to 10 months. Expanded immunogenicity data revealed that vaccine-specific T cell responses were detected *ex vivo* after the first dose of the vaccine and continued to rise with each subsequent dose. Vaccine-specific T cell responses remained significantly elevated over baseline and post-CPI, pre-vaccine timepoints for at least 6 months, showing persistence of the vaccine response.

Research updates

Strengthened Scientific Advisory Board

- Marcela Maus, M.D., Ph.D. joined the Company's Scientific Advisory Board. Dr. Maus, the Director of the Cellular Immunotherapy Program at Mass General Cancer Center and an Associate Professor of Medicine at Harvard Medical School, is internationally known for her work as a translational physician-scientist in the field of immunology, particularly T cell immunotherapies and cellular therapies in the treatment of cancer.

Upcoming presentations

Bioprocessing Summit - Event Details

- Presentation Title: GEN-011 PLANET Process: A Robust and Rapidly Scalable Manufacturing Process to Generate Neoantigen-Targeted Peripheral T Cells (NPTs)
  Date/Time: Thursday, August 19 - 12:40 p.m. ET

Financial and other updates

Second quarter 2021 financial results

- Cash position: As of June 30, 2021, cash and cash equivalents were $60.4 million compared to $79.8 million as of December 31, 2020.
- Net loss: Net loss was $4.3 million or $0.20 diluted net loss per share for the quarter ended June 30, 2021, compared to $11.3 million or $0.39 per share for the same period in 2020. Net loss was $16.3 million or $0.37 diluted net loss per share for the six months ended June 30, 2021, compared to $24.2 million or $0.84 per share for the same period in 2020.
- Research and Development ("R&D") expenses: R&D expenses were $10.5 million for the quarter ended June 30, 2021, compared to $8.6 million for the same period in 2020. R&D expenses were $19.3 million for the six months ended June 30, 2021, compared to $18.6 million for the same period in 2020.

  The increase in R&D expenses for the three months ended June 30, 2021 is mainly due to growth in our internal research and manufacturing teams and GEN-011 manufacturing and clinical costs.

  The increase in R&D expenses for the six months ended June 30, 2021 is mainly due to growth in our internal research and manufacturing teams, partially offset by the timing of GEN-011 engineering and clinical manufacturing costs.
- General and Administrative ("G&A") expenses: G&A expenses were $4.0 million for the quarter ended June 30, 2021, compared to $3.5 million for the same period in 2020. G&A expenses were $7.7 million for the six months ended June 30, 2021, compared to $6.9 million for the same period in 2020.

  The increase in G&A expenses for both periods is mainly due to growth in our internal G&A team, partially offset by decreased facility costs.
- Other income (expense): Other income (expense) was income of $10.2 million for the quarter ended June 30, 2021, compared to expense of $0.2 million for the same period in 2020. Other income (expense) was income of $10.7 million for the six months ended June 30, 2021, compared to income of $0.4 million for the same period in 2020.

  The increase in other income (expense) for both periods is mainly due to the non-cash impact of the fair-value adjustment for the 33.6 million liability-classified warrants issued in connection with our July 2020 private placement.

Guidance

- Genocea's operating plan extends its cash runway to the end of 2022.

Conference Call

Genocea will host a conference call and webcast today at 8:30 a.m. E.T. Interested participants may access the conference call by dialing (844) 826-0619 (domestic) or (315) 625-6883 (international) and referring to conference ID number 6789021. To join the live webcast, please visit the presentation page of the investor relations section of the Genocea website at https://ir.genocea.com/events-and-presentations. A webcast replay of the conference call will be available on the Genocea website beginning approximately two hours after the event and will be archived for 90 days.

About Genocea Biosciences, Inc.

Genocea's mission is to identify the right tumor targets to develop life-changing immunotherapies for people suffering from cancer. Our proprietary ATLAS™ platform can comprehensively profile each patient's T cell responses to potential targets, or antigens, on that patient's tumor. ATLAS zeroes in on both antigens that activate anti-tumor T cell responses and inhibitory antigens, Inhibigens™, that drive pro-tumor immune responses. We are conducting a Phase 1/2a clinical trial for GEN-011, our investigational adoptive T cell therapy comprising neoantigen-targeted peripheral cells. We continue to monitor patients in our phase 1/2a clinical trial for GEN-009, our investigational neoantigen vaccine. In addition to our two clinical programs, we are conducting research in several areas where we believe ATLAS could be a key tool in optimizing antigen selection for therapies across a number of diseases. To learn more, please visit https://www.genocea.com.

Forward-Looking Statements

This press release includes forward-looking statements related to GEN-011, GEN-009 and research updates within the meaning of the Private Securities Litigation Reform Act, including statements related to the anticipated timing of top-line results from Genocea's Phase 1/2a clinical trial of GEN-011. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Genocea cautions that these forward-looking statements are subject to numerous assumptions, risks and uncertainties that change over time. These factors include, but are not limited to, risks related to the potential failure of our active product candidates which are in an early stage of clinical development; our ability to obtain regulatory approval for our current and future product candidates; potential delays in enrolling patients in our clinical trials; our reliance on third parties to conduct technical development, non-clinical studies and clinical trials for our product candidates; our reliance on third parties to conduct some or all aspects of our product manufacturing; our ability to obtain or protect intellectual property rights related to our product candidates; the potential impacts of COVID-19 on our business and financial results; changes in law, regulations, or interpretations and enforcement of regulatory guidance; our need for additional financing and the risks listed under "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2020 and any subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release and Genocea assumes no duty to update forward-looking statements, except as may be required by law.

(Tables to follow)

GENOCEA BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(In thousands)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 60,399	$ 79,769
Property and equipment, net	5,214	5,123
Right of use assets	8,371	9,308
Other assets	3,399	4,293
Total assets	$ 77,383	$ 98,493
Accounts payable and accrued expenses	$ 7,690	$ 7,878
Deferred revenue	1,641	1,641
Debt, current and long-term	9,777	13,862
Warrant liabilities	44,747	56,118
Lease liabilities	9,473	10,012
Total liabilities	73,328	89,511
Stockholders' equity	4,055	8,982
Total liabilities and stockholders’ equity	$ 77,383	$ 98,493

GENOCEA BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

(In thousands, except per share data)

	Three Months Ended June 30		Six Months Ended June 30	
	2021	2020	2021	2020
License revenue	$ —	$ 906	$ —	$ 906
Operating expenses:				
Research and development	10,513	8,587	19,264	18,574
General and administrative	4,033	3,480	7,704	6,868
Total operating expenses	14,546	12,067	26,968	25,442
Loss from operations	(14,546)	(11,161)	(26,968)	(24,536)
Other income (expense)	10,235	(160)	10,674	362
Net loss	$ (4,311)	$ (11,321)	$ (16,294)	$ (24,174)
Net loss per share:				
Basic	$ (0.06)	$ (0.39)	$ (0.24)	$ (0.84)
Diluted	$ (0.20)	$ (0.39)	$ (0.37)	$ (0.84)
Weighted-average number of shares used in computing net loss per share:				
Basic	67,970	29,142	67,074	28,642
Diluted	70,202	29,142	72,467	28,642