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): **October 28, 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 October 28, 2021, Genocea Biosciences, Inc. (the "Company") announced its financial results for the quarter ended September 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 October 28, 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: October 28, 2021

Investor Contact:
Dan Ferry
daniel@lifesciadvisors.com

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

Genocea Provides Third Quarter 2021 Corporate Update

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

Strong presence at the SITC 36th Annual Meeting

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

CAMBRIDGE, Mass., October 28, 2021 - Genocea Biosciences, Inc. (Nasdaq: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, today provided a business update for the third quarter ended September 30, 2021.

"We continue to make significant progress. Most notably, we are very excited about our TiTAN™ clinical trial for GEN-011, our neoantigen-targeted peripheral T cell therapy (NPT) candidate, from which we expect to have initial data from a small subset of patients in the first quarter or early in the second quarter next year," said Chip Clark, Genocea's President and Chief Executive Officer. "We are also pleased that our SITC presentations will continue to showcase the neoantigen selection capabilities of our ATLAS™ platform, through differentiated long-term immunogenicity and clinical response data for GEN-009, our neoantigen-targeted vaccine candidate, and through its potential application to novel autoimmune disease treatments."

Operational updates

Strengthened Board of Directors

- Jennifer Herron was appointed to the Company's Board of Directors, effective September 8, 2021. Ms. Herron is currently Senior Vice President and Chief Commercial Officer at ADC Therapeutics SA ("ADCT"), leading global commercialization strategy and execution including the launch of ADCT's first commercial product. She is a seasoned biopharmaceutical leader with extensive oncology experience.

Upcoming presentations

Festival of Biologics November 9-11, 2021 *https://www.terrapinn.com/conference/festival-of-biologics/agenda.stm*

- Keynote panel discussion: What does the future of Immunotherapy hold for Oncology and Infectious Diseases
  Date/Time: Tuesday, November 9, 2021 at 10:00 a.m. C.E.T.
- Presentation: Unleashing the TiTANs: the GEN-011 neoantigen-targeted peripheral T cell therapy for solid tumors
  Date/Time: Tuesday, November 9, 2021 at 4:50 p.m. C.E.T.

Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting November 10-14, 2021 *https://sitc.sitcancer.org/2021/abstracts/titles/*

- Poster Presentation #475: GEN-011-101 (the TiTAN-1 trial): Phase 1 study to evaluate the safety, proliferation and persistence of GEN-011, an autologous neoantigen-targeted peripheral T cell therapy in solid tumors
- Poster Presentation #485: Long term results from a phase 1 trial of GEN-009, a personalized neoantigen vaccine, combined with PD-1 inhibition in advanced solid tumors
- Poster Presentation #521: GEN-009, a personalized neoantigen vaccine candidate, elicits diverse and durable immune responses associated with clinical efficacy outcomes
- Poster Presentation #753: Inhibigen™ administration promotes aberrant T cell responses in cancer but may be beneficial for amelioration of autoimmune disease
- Poster Presentation #248: Empiric profiling of peripheral T cell recall responses to tumor mutanomes versus in silico predictions in NSCLC patients undergoing pembrolizumab treatment ± chemotherapy

Date/Time: ePosters will be on display on the SITC 2021 virtual meeting platform on Friday, November 12, 2021 at 7:00 a.m. E.T.

Cellular Immunotherapies for Solid Tumors Summit November 16-18, 2021 *https://solid-tumors-summit.com/whats-on/day-two/*

- Presentation: GEN-011 PLANET Process: A Robust and Rapidly Scalable Manufacturing Process to Generate Neoantigen-targeted Peripheral T cells (NPTs)
  Date/Time: Wednesday, November 17, 2021 at 4:30 pm E.T.

World Vaccine & Immunotherapy Congress November 30-December 2, 2021 *https://www.terrapinn.com/conference/world-vaccine-immunotherapy-congress-west-coast/agenda.stm*

- Panel discussion: Are neoantigens living up to their initial promise? What questions remain unanswered?
  Date/Time: Wednesday, December 1, 2021 at 11:40 a.m. P.T.

Financial updates

Third quarter 2021 financial results

- Cash position: As of September 30, 2021, cash and cash equivalents were $48.9 million compared to $79.8 million as of December 31, 2020.
- Net loss: Net loss was $3.6 million or $0.05 diluted net loss per share for the quarter ended September 30, 2021, compared to $4.6 million or $0.26 per share for the same period in 2020. Net loss was $19.9 million or $0.54 diluted net loss per share for the nine months ended September 30, 2021, compared to $28.7 million or $1.01 per share for the same period in 2020.
- Research and Development ("R&D") expenses: R&D expenses were $9.5 million for the quarter ended September 30, 2021, compared to $7.5 million for the same period in 2020. R&D expenses were $28.7 million for the nine months ended September 30, 2021, compared to $26.1 million for the same period in 2020.

  The increase in R&D expenses for both periods is mainly due to growth in our internal research and manufacturing teams and GEN-011 manufacturing and clinical costs.
- General and Administrative ("G&A") expenses: G&A expenses were $3.9 million for the quarter ended September 30, 2021, compared to $3.6 million for the same period in 2020. G&A expenses were $11.6 million for the nine months ended September 30, 2021, compared to $10.5 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: Other income was $8.1 million for the quarter ended September 30, 2021, compared to $6.2 million for the same period in 2020. Other income was $18.8 million for the nine months ended September 30, 2021, compared to $6.5 million for the same period in 2020.

  The increase in other income 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 the Company's July 2020 private placement (the "2020 Warrants"). During the quarter ended September 30, 2021, the 2020 Warrants were remeasured to their fair value of $36.0 million and subsequently reclassified to equity.

Guidance

- Genocea's operating plan extends its cash runway into the third quarter 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 8729366. 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-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)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 48,908	$ 79,769
Property and equipment, net	5,519	5,123
Right of use assets	7,901	9,308
Other assets	2,590	4,293
Total assets	$ 64,918	$ 98,493
Accounts payable and accrued expenses	$ 7,839	$ 7,878
Debt, current and long-term	9,911	13,862
Lease liabilities	8,941	10,012
Warrant liabilities	398	56,118
Deferred revenue	—	1,641
Total liabilities	27,089	89,511
Stockholders' equity	37,829	8,982
Total liabilities and stockholders’ equity	$ 64,918	$ 98,493

GENOCEA BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (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	8,094	6,184	18,768	6,546
Net 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