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 13, 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 7.01 Regulation FD Disclosure.

On July 13, 2021, Genocea Biosciences, Inc. issued a press release announcing the dosing of the first patient in its TiTAN™ study, a Phase 1/2a clinical trial testing its GEN-011 therapy. A copy of the press release, dated July 13, 2021, is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

The information contained in this Item 7.01 of this Current Report on Form 8-K, including the exhibits 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, regardless of any general incorporation language in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press release issued by Genocea Biosciences, Inc. on July 13, 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 13, 2021

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Genocea Doses First Patient in Phase 1/2a TiTAN Clinical Trial for GEN-011 Neoantigen-Targeted T cell Therapy

CAMBRIDGE, Mass., July 13, 2021 - Genocea Biosciences, Inc. (Nasdaq: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, today announced the dosing of the first patient in its TiTAN study, a Phase 1/2a clinical trial testing its GEN-011 therapy. GEN-011 represents a new category of autologous solid tumor cell therapy: neoantigen-targeted peripheral T cells ("NPTs").

"Dosing the first patient with GEN-011 represents an exciting milestone for Genocea and the field of neoantigen-targeted T cell therapy," said Thomas Davis, M.D., the company's Chief Medical Officer. "We believe our GEN-011 therapy employs better targeting – using our ATLAS™ platform to select optimal neoantigen targets that drive anti-tumor immune responses and avoid immunosuppressive Inhibigens™ - and better T cells, derived from easily accessible peripheral blood as opposed to the tumor itself. We are grateful to the patients eager to participate in our trial, to our investigators, and to our colleagues here at Genocea for their great dedication to improve patients' outcomes. We look forward to reporting top-line results from this study on a subset of patients late in the fourth quarter of 2021 or the first quarter of 2022."

About GEN-011

GEN-011 is a next-generation solid tumor therapy comprised of NPTs $CD4^+$ and $CD8^+$ which are specific for up to 30 antigens to limit tumor escape. NPTs have minimal bystander, non-tumor-specific cells, and are devoid of Inhibigen-specific cells which may be detrimental to clinical response.

About the GEN-011 TiTAN clinical trial

TiTAN is an open-label, multi-center Phase1/2a trial evaluating safety, tolerability, T cell persistence and proliferation and clinical efficacy. The TiTAN clinical trial is testing two dosing regimens, a repeated lower dose regimen of GEN-011 without lymphodepletion and a single high dose administration of GEN-011 after lymphodepletion. Both groups will receive interleukin-2 after GEN-011 dosing to maximize the tumor-killing potential of the infused cells. Initial data from the TiTAN trial is expected in late Q4 2021 or Q1 2022.

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 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 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.

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