

**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 20, 2020**



GENOCEA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation)

001-36289

(Commission File Number)

51-0596811

(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-2 of 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 20, 2020, Genocea Biosciences, Inc. issued a press release announcing clinical updates on GEN-009 and GEN-011. A copy of the press release, dated July 20, 2020, 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 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 20, 2020](#)

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 20, 2020



Investor Contact:

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GENOCEA BIOSCIENCES PROVIDES CLINICAL UPDATE

CAMBRIDGE, Mass., July 20, 2020 - Genocea Biosciences, Inc. (NASDAQ: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, today announced updates to its clinical programs, the neoantigen vaccine GEN-009 and the neoantigen cell therapy, GEN-011.

GEN-009

On July 30, 2020, the Company will share initial clinical data on the first 5 patients from Part B of the ongoing Phase 1/2a clinical trial exploring the combination of GEN-009 and immune checkpoint inhibitor-based regimens in advanced solid tumors. The lead investigator, Dr. Maura L. Gillison, MD, PhD, Professor of Medicine, Department of Thoracic/Head and Neck Medical Oncology at MD Anderson Cancer Center, will present.

GEN-011

In June 2020, the Company submitted the IND to support the initiation of a Phase 1/2 clinical trial and the 30-day FDA review period has just ended. The Company has received verbal notification from the U.S. Food and Drug Administration (FDA) that the agency has completed its review of the Company's Investigational New Drug Application (IND) for GEN-011. In this verbal feedback, the FDA informed Genocea that it is placing the IND on clinical hold until it receives additional information pertaining to certain third-party reagents used in the GEN-011 manufacturing process. These reagents are not a component of the final cell therapy product. The Company expects to receive official written communication from the FDA regarding the hold and the FDA's position in the near future and will work with the FDA to resolve their questions as quickly as possible.

About Genocea Biosciences, Inc.

Genocea's mission is to conquer cancer by developing personalized cancer immunotherapies in multiple tumor types. Our unique ATLAS™ platform comprehensively profiles each patient's T cell responses to potential targets, or antigens, on the tumor. ATLAS enables us to optimize the neoantigens for inclusion in our immunotherapies and exclude inhibitory antigens that can exert an immunosuppressive effect. We are advancing two ATLAS-enabled programs: GEN-009, our neoantigen vaccine for which we are conducting a Phase 1/2a clinical trial and expect preliminary clinical results in the third quarter of 2020, and GEN-011, our neoantigen-specific cell therapy using T cells derived from peripheral blood for which we expect to conduct a Phase 1/2a clinical trial. To learn more, please visit www.genocea.com.

Forward-Looking Statements

This press release includes forward-looking statements, including statements relating to GEN-009 and GEN-011, within the meaning of the Private Securities Litigation Reform Act. 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. Applicable risks and uncertainties include those identified under the heading "Risk Factors" included in Genocea's Annual Report on Form 10-K for the year ended December 31, 2019 and any subsequent SEC filings. 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.