

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 30, 2020**

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**GENOCEA BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

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**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)

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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.

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**Item 7.01 Regulation FD Disclosure.**

On July 30, 2020, Genocea Biosciences, Inc. issued a press release announcing initial clinical data on GEN-009. A copy of the press release, dated July 30, 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 30, 2020](#)

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**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 30, 2020



**Investor Contact:**

Dan Ferry  
617-430-7576  
daniel@lifesciadvisors.com

**Webcast/conference call scheduled today, July 30th at 8:00 a.m. EDT**

**Three of five patients achieved separate RECIST responses after GEN-009 administration**

**GEN-009 elicited antigen-specific CD4<sup>+</sup> and CD8<sup>+</sup> T cell responses in 100% of treated patients**

**CAMBRIDGE, Mass., July 30, 2020** – **Genocea Biosciences, Inc.** (NASDAQ: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, will present initial clinical data today on the first five patients from Part B of the ongoing Phase 1/2a study, which explores the combination of Genocea's neoantigen vaccine, GEN-009 and checkpoint inhibitor-based regimens (CPI) in advanced solid tumors. The webcast and presentation will feature Dr. Maura L. Gillison, MD, PhD, Professor of Medicine, Department of Thoracic/Head and Neck Medical Oncology at MD Anderson Cancer Center.

The trial combines GEN-009 with a Standard of Care (SOC) CPI-based regimen approximately four months after the SOC CPI-based regimen is started. The preliminary findings from the first five patients show three achieving independent RECIST responses starting from the first GEN-009 dose. These responses show an acceleration of shrinkage beyond that of the CPI regimen, creating a novel response plot that supports the effect being attributable to the addition of GEN-009. One such patient achieved a complete response ("CR"), while two demonstrated partial responses ("PR"). Overall, two of the first five patients achieved CRs and three experienced PRs.

These results are corroborated by the patients' immune responses. Neoantigen-specific CD4<sup>+</sup> and CD8<sup>+</sup> T cell responses were detected in 100% of patients, with all patients responding to multiple vaccinated antigens. Early comparison of T cell responses post-checkpoint (pre-vaccination) and post-vaccination show that T cell responses are specific to GEN-009 and not augmented by checkpoint blockade.

"We are incredibly encouraged by these initial results," said Dr. Gillison. "The breadth and magnitude of immune responses validate the complete and partial responses observed in the five patients evaluated. We believe incorporating GEN-009 into standard-of-care immunotherapy regimens may help boost the effectiveness of immune checkpoint inhibitor therapy in patients with advanced disease."

"We are very pleased this initial data set continues to validate antigen selection using our proprietary ATLAS™ platform," said Chip Clark, President and Chief Executive Officer, Genocea. "We look forward both to reporting data from approximately ten additional patients this fall and to initiating the clinical trial for the neoantigen cell therapy GEN-011, which should similarly benefit from ATLAS to drive anti-tumor responses through T cells targeting the right neoantigens in checkpoint-refractory patients."

**Webcast & Conference Call Information**

Interested participants may access the call by clicking [here](#). For those who are unable to listen in during the event, a replay of the call will be available [here](#).

A replay of the webcast will be archived for 30 days following the presentation by visiting the "Events and Presentations" tab of the investor relations section of the Genocea website at <http://ir.genocea.com>.

**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](http://www.genocea.com).

**Forward-Looking Statement**

*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.*