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): **November 9, 2020**

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 November 9, 2020, Genocea Biosciences, Inc. issued a press release announcing four posters highlighting clinical and preclinical data that collectively validate the company's unique and differentiated approach to identifying clinically meaningful immunotherapy targets at The Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting taking place virtually November 9th – 14th. A copy of the press release, dated November 9, 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 November 9, 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: November 9, 2020

Investor Contact:
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Genocea Presents Positive GEN-009 Clinical Results, Update on GEN-011 Program and New Inhibigen™ Mechanism of Action Data at Virtual SITC 2020

Novel clinical and durable immune response patterns suggest addition of GEN-009 may offer additive clinical benefit in combination with PD-1-based therapies

GEN-011, a neoantigen-targeted peripheral T cell ("NPT") product, addresses several critical adoptive T cell therapy challenges

ATLAS™-identified Inhibigens decrease anti-tumor T cell responses, cannot be overcome by powerful checkpoint blockade immunotherapy

CAMBRIDGE, Mass., November 9, 2020 - Genocea Biosciences, Inc. (NASDAQ: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, today presented four posters that collectively validate the company's unique and differentiated approach to identifying clinically meaningful immunotherapy targets at The Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting taking place virtually November 9th – 14th.

GEN-009

In follow up to data shared at the European Society for Medical Oncology (ESMO) Virtual Congress 2020, the company shared expanded clinical and immunogenicity findings from Part B of its ongoing GEN-009 Phase 1/2a trial, which evaluates GEN-009, Genocea's neoantigen vaccine, in combination with PD-1 inhibitors in advanced cancers. Posters 390 and 413 outline the clinical and immune responses elicited by GEN-009 in 16 checkpoint inhibitor (CPI) therapy sensitive and resistant patients. Poster 413 was a highly scored abstract selected for a "Poster Walk."

Of the nine CPI-sensitive patients, three patients experienced a novel reduction in tumor volume post-GEN-009 dosing and achieved independent RECIST responses after vaccination, including 2 PRs and 1 CR. Five additional CPI-sensitive patients have shown disease control post-vaccination for up to 11 months. Within the CPI-resistant population, five of seven patients appear to have stabilized disease lasting up to seven months. GEN-009 elicited strong anti-tumor immune responses with both $CD4^+$ and $CD8^+$ T cell responses observed at day 50 post-vaccination and with peak *ex vivo* responses occurring Day 92. Early data from two patients tested so far show a complete absence of circulating tumor DNA by day 50, which is consistent with a vaccine clinical effect. There was also emerging evidence of epitope spreading in patients who successfully responded to therapy. GEN-009 was safe and well tolerated.

"We are highly encouraged by the response patterns observed in this clinical cohort, which are a novel signal that further support the possibility that GEN-009 administration can significantly decrease tumor burden in certain patients" said Thomas Davis, M.D., Chief Medical Officer of Genocea. "Augmenting the breadth of immune response against relevant cancer specific targets through GEN-009 can deepen CPI response in patients with advanced disease. We will continue to monitor these patients to measure the GEN-009 impact on longer-term disease stabilization. While we await these data, we do not intend to dose additional patients. We believe the

cumulative GEN-009 data set establishes a differentiated clinical profile based on superior neoantigen selection and also provides a strong foundation for GEN-011, which also utilizes ATLAS selected targets to generate a potent cell therapy."

Inhibigens

One distinguishing feature of Genocea's proprietary ATLAS technology is its ability not only to identify the stimulatory neoantigens to include in GEN-009 and GEN-011, but also to reveal Inhibigens – peptides that elicit T cell responses with the capacity to compromise anti-tumor immunity. Poster 526 delves further into the biology of Inhibigen-specific responses and reveals important insights that add to the company's growing body of knowledge beyond data previously shared at the AACR Virtual Annual Meeting II. Findings in mice and humans confirmed the presence of Inhibigens in nearly every sample screened, and mouse data show the abrogation of anti-tumor activity in response to otherwise protective vaccines is associated with decreased $CD4^+$ and $CD8^+$ T cell, macrophage and dendritic cell infiltration into tumors. This outcome may be attributed to abolished cytokine activity in response to tumor-specific vaccine antigens. The data also show that vaccination with an Inhibigen renders CPI co-administration ineffective.

"Our understanding of Inhibigens' mechanism of action and their translational relevance will be critical as we advance Genocea's vaccine and adoptive T cell therapy products through the clinic," said Jessica Baker Flechtner, Chief Scientific Officer of Genocea. "Immunotherapies targeting PD-1 and CTLA-4 have become standard of care across multiple cancer indications with remarkable yet variable effects. Learning more about Inhibigen biology may be critical to improving standard-of-care treatments for patients. We believe that Inhibigens must be identified and excluded from the rational design of immunotherapies, including GEN-011, the company's NPT product."

GEN-011

Poster 149 highlights important advantages of GEN-011 over TIL and TCR-T therapies. GEN-011 has been developed with 100% manufacturing success at clinical scale via PLANET™, a process designed to deliver billions of NPTs for every patient. The 16 PLANET runs conducted to date have confirmed GEN-011 comprises over 98% of highly functional, non-exhausted T cells with a mean neoantigen breadth of response nearing 90% of intended targets. In contrast, recent reported data from TIL products showed responses to less than 10% of intended neoantigens. GEN-011 NPTs have an unparalleled breadth of neoantigen coverage, targeting up to 30 relevant antigens. The drug product also avoids pro-tumor Inhibigens that may hinder clinical responses and the PLANET process does not require extra surgery or viable tumor.

"I am pleased by the body of work shared today," said Chip Clark, President and Chief Executive Officer of Genocea. "Our proprietary ATLAS platform has played an integral role in the development of GEN-009 and GEN-011, and we remain eager to continue using ATLAS-based insights to identify both the right targets and Inhibigens to advance these programs in 2021 and beyond."

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 and GEN-011, our neoantigen-specific cell therapy using T cells derived from peripheral blood. To learn more, please visit www.genocea.com.

Forward-Looking Statements
This press release includes forward-looking statements, including statements related to the possibility that GEN-009 administration can significantly decrease tumor burden in certain patients and the use of ATLAS-based insights to potentially identify both the right targets and Inhibigens to advance programs in 2021 and beyond. 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.

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