GENOCEA BIOSCIENCES, INC.

FORM 8-K
(Current report filing)

Filed 09/25/17 for the Period Ending 09/19/17

Address	100 ACORN PARK DRIVE
	CAMBRIDGE, MA, 02140
Telephone	617-876-8191
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Symbol	GNCA
SIC Code	2836 - Biological Products, (No Diagnostic Substances)
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): **September 19, 2017**

GENOCEA BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36289**	**51-0596811**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Cambridge Discovery Park 100 Acorn Park Drive, 5th Floor Cambridge, MA	**02140**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(617) 876-8191**

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

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 (*see* General Instruction A.2. below):

☐ 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))

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 2.05 Costs Associated With Exit or Disposal Activities.

On September 19, 2017, Genocea Biosciences, Inc., (the "Company") committed to an approximate 40% reduction in headcount as part of a corporate restructuring following its strategic shift to immuno-oncology and focus on the development of neoantigen cancer vaccines. The Company estimates that it will incur charges for one-time termination benefits in connection with this corporate restructuring of approximately $1.1 million for employee severance, benefits and related costs in the third quarter of 2017, all of which are expected to result in cash expenditures. After the headcount reduction, the Company expects to have approximately 55 employees.

Item 7.01 Regulation FD Disclosure

On September 25, 2017, the Company issued a press release announcing its commitment to a corporate restructuring. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

See Exhibit Index attached hereto.

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/ JONATHAN POOLE
Jonathan Poole
Chief Financial Officer

Date: September 25, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Genocea Biosciences, Inc. on September 25, 2017

Genocea Announces Strategic Shift to Immuno-oncology and the Development of Neoantigen Cancer Vaccines

- Superior ATLAS ™ platform for neoantigen selection (1) -
- Exploring strategic alternatives for GEN-003 -
- Announces corporate restructuring -

CAMBRIDGE, Mass., September 25, 2017 - Genocea Biosciences, Inc. (NASDAQ: GNCA), a biopharmaceutical company discovering and developing novel vaccines and immunotherapies targeting T cell antigens, today announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009, its lead candidate for which it expects to file an Investigational New Drug (IND) application by early 2018. Genocea also announced it is exploring strategic alternatives for GEN-003, its Phase 3-ready investigational immunotherapy for the treatment of genital herpes. Consequently, Genocea is ceasing GEN-003 spending and activities and is reducing its workforce by approximately 40 percent.

Genocea has confidence that it is positioned for leadership in the development of neoantigen cancer vaccines through its unique antigen identification capabilities and vaccinology expertise. More specifically, the company believes that antigen selection is a crucial determinant of neoantigen vaccine efficacy and that previously presented head-to-head data show that ATLAS, the only platform to comprehensively identify the actual neoantigens to which a patient's $CD4^+$ and $CD8^+$ T cells respond, is a superior approach for identifying neoantigens for personalized vaccines compared to methods used by others developing similar products.

The company plans to initiate a Phase 1 clinical trial for GEN-009 in a range of tumor types in the first half of 2018 and expects to report initial immunogenicity data in the first half of 2019. GEN-009 is an adjuvanted peptide vaccine designed to direct a patient's T cells to attack their tumor. Antigens in a patient's vaccine are selected by Genocea's proprietary ATLAS platform.

Chip Clark, president and chief executive officer of Genocea, commented: "With our research and development efforts now focused entirely on neoantigen cancer vaccines, we believe the power of ATLAS to identify the right vaccine antigens, combined with our vaccinology expertise, gives us the opportunity to create value for our shareholders by developing best-in-class vaccines for cancer patients and achieving leadership in this exciting field.

"To our teammates who've given so much to advance GEN-003, we offer our profound thanks for their dedication. Due to their efforts, GEN-003 has the potential to serve as a cornerstone treatment for genital herpes infections. We see this strategic process, which is already underway, as the best way to drive to commercial launch of and maximize shareholder value from GEN-003."

Financial Guidance
As a result of the workforce restructuring, which is anticipated to be completed by the end of the third quarter, Genocea estimates annualized savings of approximately $6.5 million in personnel-related costs, with estimated one-time severance and related costs of approximately $1.1 million in the third quarter of 2017. Genocea now expects that its existing cash and cash equivalents are sufficient to support its operating expenses and capital expenditure requirements into the middle of 2018.

About Genocea Biosciences, Inc.
Genocea is harnessing the power of T cell immunity to develop life-changing vaccines and immunotherapies. While traditional immunotherapy discovery methods have largely used predictive methods to propose T cell targets, or antigens, Genocea has successfully developed ATLAS™, its proprietary technology platform, to identify clinically relevant antigens of T cells based on actual human immune responses. Genocea is currently

using ATLAS in immuno-oncology applications to develop neoantigen cancer vaccines and exploring partnership opportunities for general cancer vaccines and a vaccine targeting cancers caused by Epstein-Barr Virus. Genocea is exploring strategic alternatives for GEN-003, its Phase 3-ready immunotherapy candidate for the treatment of genital herpes. For more information, please visit www.genocea.com .

About Neoantigen Cancer Vaccines and GEN-009

Neoantigens are personalized tumor mutations that are seen as 'foreign' by an individual's immune system [(2)] . Data published in recent years have indicated that an individual's response to neoantigens drives checkpoint inhibitor efficacy [(3)] and that it is possible to vaccinate an individual against their own neoantigens [(4)] ,

GEN-009 is an adjuvanted neoantigen peptide vaccine that is designed to direct a patient's immune system to attack their tumor. GEN-009's neoantigen peptides are identified by Genocea's proprietary ATLAS platform, which recalls a patient's pre-existing $CD4^+$ and $CD8^+$ T cell immune responses to their tumor. Following ATLAS neoantigen identification, Genocea will manufacture a personal vaccine for each patient.

References (1) https://www.genocea.com/assets/Kaufmann_AACR2017.pdf *; (2) Yadav, Gubin, 2015; (3) Schumacher, Schreiber, 2015; (4) Ott, Sahin, 2017*

Forward-Looking Statements

Statements herein relating to future business performance, conditions or strategies and other financial and business matters, including statements regarding Genocea's product candidates, and its ability to finance contemplated development activities and fund operations for a specified period, the cause, size, timing and impact of Genocea's workforce reduction and related activities, including costs and annual savings anticipated in connection with the reduction, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act. Genocea cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties that change over time. Factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including Genocea's ability to progress any product candidates in preclinical or clinical trials; the ability of ATLAS to identify promising oncology vaccine and immunotherapy product candidates; the scope, rate and progress of its preclinical studies and clinical trials and other research and development activities; anticipated clinical trial results; anticipated timing for initiation of new clinical trials; even if the data from preclinical studies or clinical trials is positive, regulatory authorities may require additional studies for approval and the product may not prove to be safe and efficacious; Genocea's ability to enter into future collaborations with industry partners and the government and the terms, timing and success of any such collaboration; risks associated with the manufacture and supply of clinical and commercial product; the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; Genocea's ability to obtain rights to technology; competition for clinical resources and patient enrollment from drug candidates in development by other companies with greater resources and visibility; the rate of cash utilized by Genocea in its business and the period for which existing cash will be able to fund such operation; Genocea's ability to obtain adequate financing in the future to continue its clinical programs through product licensing, co-promotional arrangements, public or private equity or debt financing or otherwise; general business conditions; competition; business abilities and judgment of personnel; the availability of qualified personnel and other factors set forth under "Risk Factors" in Genocea's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and other filings with the Securities and Exchange Commission (the "SEC"). Further information on the factors and risks that could affect Genocea's business, financial conditions, and results of operations is contained in Genocea's filings with the SEC, which are available at www.sec.gov. These forward-looking statements speak only as of the date of this press release and Genocea assumes no duty to update forward-looking statements.

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