GENOCEA BIOSCIENCES, INC.

FORM 8-K
(Current report filing)

Filed 11/02/17 for the Period Ending 11/02/17

Address	100 ACORN PARK DRIVE CAMBRIDGE, MA, 02140
Telephone	617-876-8191
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SIC Code	2836 - Biological Products, (No Diagnostic Substances)
Industry	Biotechnology & Medical Research
Sector	Healthcare
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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 2, 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 2.02 Results of Operations and Financial Condition.

On November 2, 2017, Genocea Biosciences, Inc. announced its financial results for the third quarter ended September 30, 2017. A full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 2, 2017

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: November 2, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Genocea Biosciences, Inc. on November 2, 2017

Genocea Reports Third Quarter 2017 Financial Results

- SITC presentation to highlight ATLAS™ ability in neoantigen selection -
- IND filing for neoantigen cancer vaccine, GEN-009, expected in Q1 2018 -
- Conference call today at 9 am ET -

CAMBRIDGE, Mass., November 2, 2017 - Genocea Biosciences, Inc. (NASDAQ: GNCA), a biopharmaceutical company developing neoantigen cancer vaccines, today reported financial results for the third quarter of 2017 and announced upcoming data presentations at a leading immuno-oncology conference.

"We believe our proprietary ATLAS ™ technology sets us apart among developers of neoantigen cancer vaccines, as it offers a potential solution to one of the most significant challenges in the field - namely, identifying true neoantigens for those vaccines from up to thousands of potential candidates," said Chip Clark, president and chief executive officer of Genocea. "ATLAS uses a patient's own T cells to identify, rather than predict, which of the many personal mutations found in cancerous tumors are true neoantigens, which we believe will enable us to develop more immunogenic and efficacious cancer vaccines. Our upcoming data presentations at the SITC Annual Meeting continue to support the potential of ATLAS in neoantigen identification for personalized vaccines, including our lead program, GEN-009, for which we expect to file an IND application early next year."

GEN-009 Progress
GEN-009 is a personalized vaccine consisting of adjuvanted synthetic long peptides of true neoantigens identified by ATLAS.

- The company expects to file an Investigational New Drug (IND) application in the first quarter of 2018.
- Genocea plans to initiate a Phase 1 clinical trial in patients with a range of tumor types in the first half of 2018, and expects to report initial immunogenicity data in the first half of 2019.

Upcoming Scientific Presentations
Genocea announced today that it will present three posters at the upcoming Society for Immunotherapy of Cancer (SITC) 32 nd Annual Meeting taking place November 8 to 12, 2017 at the Gaylord National Hotel & Convention Center in National Harbor, Maryland.

- **Poster #430** entitled " *Neoantigen identification using ATLAS™ across multiple tumor types highlights limitations of prediction algorithms* ," will be presented during the session on Personalized Vaccines and Technologies/Personalized Medicine on Saturday, November 11, 2017 ,
- **Poster #8** entitled " *T cell response profiling in colorectal carcinoma patients reveals an enrichment in responses to specific tumor-associated antigens* , " and
- **Poster #28** entitled " *Profiling of T cell responses to tumor-associated antigens in lung cancer patients treated with checkpoint inhibitors* ," will both be presented during the session on Biomarkers and Immune Monitoring on Saturday, November 11, 2017 .

Corporate Update
Following its announced restructuring at the end of the third quarter, Genocea continues to explore, alongside its advisors, strategic alternatives for GEN-003, the company's Phase 3-ready investigational immunotherapy to treat the large patient population infected with genital herpes, many of whom are dissatisfied with their current treatment options.

Financial Guidance
Genocea expects that its existing cash and cash equivalents are sufficient to support its operating expenses and capital expenditure requirements into the middle of 2018.

Third-Quarter 2017 Financial Results

- **Cash Position:** Cash and cash equivalents as of September 30, 2017 were $22.0 million compared to $35.2 million as of June 30, 2017.
- **Restructuring:** A corporate restructuring was implemented following the Company's strategic shift to immuno-oncology, resulting in a charge of approximately $1.1 million for employee severance, benefits , and related costs. These amounts will be paid in the fourth quarter of 2017. In addition, Genocea incurred approximately $0.5 million of expense due to contract termination clauses that the Company anticipates will result in future cash payments and approximately $1.0 million in non-cash asset impairment charges.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended September 30, 2017 increased $1 . 3 million, to $10 . 2 million from the same period in 2016. The increase was primarily driven by higher external manufacturing-related expenses and increases in compensation to support both the clinical drug supply and clinical trial planning activities in support of the previously planned GEN-003 Phase 3 program, partially offset by reduced clinical costs, due to timing of activities in support of clinical trials. Spending increases on Genocea's immuno-oncology and cancer vaccine programs were driven primarily by increased manufacturing and compensation, consulting and professional services in anticipation of Genocea's expected filing of an IND application for GEN-009 in the first quarter of 2018. Increased spending on these programs was offset by lower costs on infectious disease programs previously discontinued in 2016 .
- **General and Administrative (G&A) Expenses:** G&A expenses for the third quarter of 2017 were $3.8 million, compared to $3.6 million for the same period in 2016 , reflecting marginal increases in consulting and professional services offset by reductions in depreciation expense , with all other expenditures across various activities remaining consistent with the same quarter in the prior year.
- **Net Loss:** Net loss was $16.9 million for the quarter ended September 30, 2017, compared to a net loss of $12.8 million for the same period in 2016.

Conference Call
Genocea will host a conference call and webcast today at 9:00 a.m. ET. The conference call may be accessed by dialing (844) 826-0619 for domestic participants and (315) 625-6883 for international callers and referencing the conference ID number 95267931. A live webcast of the conference call will be available online from the investor relations section of the Company's website at http://ir.genocea.com. A webcast replay of the conference call will be available on the Genocea website beginning approximately two hours after the event, and will be archived for 30 days.

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 developed ATLAS™, its proprietary technology platform, to identify clinically relevant antigens of T cells based on actual human immune responses. Genocea is using ATLAS in immuno-oncology applications to develop neoantigen cancer vaccines while also exploring partnership opportunities for general cancer vaccines and a vaccine targeting cancers caused by Epstein-Barr Virus. Genocea expects to begin clinical development of its first neoantigen cancer vaccine, GEN-009, in early 2018. 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. Data published in recent years have indicated that an individual's response to neoantigens drives checkpoint inhibitor efficacy and that it is possible to vaccinate an individual against their own neoantigens . Genocea's lead immuno-oncology program, GEN-009 , is an adjuvanted neoantigen peptide vaccine candidate 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.

Forward-Looking Statements
Statements herein relating to future business performance, conditions or strategies and other financial and business matters, including expectations regarding clinical developments, 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; current results may not be predictive of future results; 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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GENOCEA BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(In thousands)

	September 30, 2017	December 31, 2016
Cash, cash equivalents and investments	$ 21,983	$ 63,362
Other assets	6,061	6,534
Total assets	$ 28,044	$ 69,896
Debt, current and long-term	$ 15,782	$ 16,958
Accounts payable	2,129	3,043
Accrued expenses and other liabilities	6,447	4,354
Total liabilities	24,358	24,355
Stockholders' equity	3,686	45,541
Total liabilities and stockholders’ equity	$ 28,044	$ 69,896

GENOCEA BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Grant revenue	$ —	$ —	$ —	$ 235
Operating expenses:				
Research and development	10,155	8,811	31,324	22,821
General and administrative	3,750	3,619	10,955	11,569
Restructuring costs	2,591	—	2,591	—
Refund of research and development expense	—	—	—	(1,592)
Total operating expenses	16,496	12,430	44,870	32,798
Loss from operations	(16,496)	(12,430)	(44,870)	(32,563)
Other income and expense:				
Interest income	63	103	211	323
Interest expense	(435)	(438)	(1,319)	(1,299)
Total other income and expense	$ (372)	$ (335)	$ (1,108)	$ (976)
Net loss	(16,868)	(12,765)	(45,978)	(33,539)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	$ —	$ (9)	$ —	$ 15
Comprehensive loss	$ (16,868)	$ (12,774)	$ (45,978)	$ (33,524)
Net loss per share - basic and diluted	$ (0.59)	$ (0.45)	$ (1.61)	$ (1.18)
Weighted-average number of common shares used in computing net loss per share	$ 28,666	$ 28,370	$ 28,568	$ 28,267