

GENOCEA BIOSCIENCES, INC.

FORM 8-K (Current report filing)

Filed 08/09/17 for the Period Ending 08/09/17

Address	100 ACORN PARK DRIVE CAMBRIDGE, MA 02140
Telephone	617-876-8191
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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): **August 9, 2017**

GENOCEA BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36289
(Commission
File Number)

51-0596811
(IRS Employer
Identification No.)

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

02140
(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-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 2.02 Results of Operations and Financial Condition.

On August 9, 2017, Genocea Biosciences, Inc. announced its financial results for the second quarter ended June 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 August 9, 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: August 9, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Genocea Biosciences, Inc. on August 9, 2017



Genocea Biosciences Reports Second Quarter 2017 Financial Results

- Recently reported positive top-line 12-month Phase 2b data for GEN-003 in genital herpes -
- IND filing for neoantigen cancer vaccine, GEN-009, expected in Q4 2017 -

CAMBRIDGE, Mass., August 9, 2017 - [Genocea Biosciences, Inc.](#) (NASDAQ: GNCA), a biopharmaceutical company developing novel vaccines and immunotherapies targeting T cell antigens, today reported financial results for the second quarter of 2017. Genocea is developing GEN-003, an investigational immunotherapy for the treatment of genital herpes, and is applying its unique and proprietary T cell antigen identification platform, ATLAS™, to immuno-oncology and cancer vaccine development.

Highlights of the Second Quarter of 2017 and Recent Events

- May 2017 - In its first quarter earnings report, Genocea announced (i) the successful completion of its end-of-Phase 2 meeting for GEN-003 with the U.S. Food & Drug Administration and (ii) data from its prior GEN-003 Phase 2 trial indicating that the initial course of injections sustained clinical and virologic efficacy for at least 24 months.
- June 2017 - Genocea announced its addition to the Russell 3000® and Russell 2000® Indices as part of the annual reconstitution of those indexes.
- July 2017 - Genocea reported positive top-line 12-month Phase 2b data for GEN-003 including statistically significant data on the expected Phase 3 primary endpoint with the Phase 3 dose, and positive results on multiple secondary clinical endpoints.

Chip Clark, president and chief executive officer of Genocea commented: "We are delighted with the recent positive GEN-003 12-month Phase 2b data and continue to explore means of securing capital for this program to enable the start of Phase 3. We believe that, if approved, GEN-003 could become the first new therapy to treat genital herpes in more than 20 years and address serious unmet patient needs.

With respect to our cancer vaccine program, recent scientific publications on neoantigen cancer vaccines suggest that the concept has promise, but we think that there is significant room for improvement. We believe that Genocea's ATLAS platform can enable better neoantigen selection and that, combined with our vaccinology expertise, positions us strongly in this emerging field. We expect to file an IND by the end of 2017 for our neoantigen vaccine, GEN-009, and we are also continuing our pre-clinical work on common antigen cancer vaccines and an EBV-related cancer vaccine."

Financial Guidance

Genocea expects that its existing cash and cash equivalents are sufficient to support its operating expenses and capital expenditure requirements into 2018. Genocea is currently exploring various avenues to secure capital to advance GEN-003 into Phase 3 trials and does not intend to commence Phase 3 development of GEN-003 until it has secured such capital.

Second-Quarter 2017 Financial Results

- **Cash Position:** Cash and cash equivalents as of June 30, 2017 were \$35.2 million compared to cash, cash equivalents and investments of \$48.7 million as of March 31, 2017.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended June 30, 2017 increased \$4.7 million, to \$11.4 million, from the same period in 2016. The increase was primarily driven by higher external manufacturing-related expenses and increases in compensation, consulting and professional services to support both the clinical drug supply and clinical planning activities in support of GEN-003 Phase 3 program readiness. 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 Investigational New Drug (IND) application for GEN-009 in 2017. Increased spending on these programs was offset by lower costs on deprioritized infectious disease programs.

- **General and Administrative (G&A) Expenses:** G&A expenses for the second quarter of 2017 were \$3.6 million, compared to \$4.0 million for the same period in 2016 reflecting lower depreciation costs and lower consulting and professional services costs.
- **Net Loss:** Net loss was \$15.4 million for the quarter ended June 30, 2017, compared to a net loss of \$11.0 million for the same period in 2016.

No Second Quarter 2017 Financial Results Conference Call

As announced during the GEN-003 Phase 2b 12-month results conference call on July 24, 2017, Genocera will not be holding a conference call relating to these results.

About Genocera Biosciences, Inc.

Genocera 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, Genocera has successfully developed ATLAS™, its proprietary technology platform, to identify clinically relevant antigens of T cells based on actual human immune responses. Genocera used ATLAS to identify the antigens in its lead clinical candidate, GEN-003, an investigational immunotherapy to treat genital herpes, and is currently using ATLAS in immuno-oncology applications to develop neoantigen cancer vaccines (with an IND filing expected by the end of 2017), general cancer vaccines and a vaccine targeting cancers caused by Epstein-Barr Virus. For more information, please visit www.genocera.com.

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. Genocera 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 Genocera'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; Genocera'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; Genocera'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 Genocera in its business and the period for which existing cash will be able to fund such operation; Genocera'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 Genocera'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 Genocera's business, financial conditions, and results of operations is contained in Genocera'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 Genocera assumes no duty to update forward-looking statements.

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GENOCEA BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(In thousands)

	June 30, 2017	December 31, 2016
Cash, cash equivalents and investments	\$ 35,225	\$ 63,362
Other assets	7,387	6,534
Total assets	\$ 42,612	\$ 69,896
Debt, current and long-term	\$ 17,214	\$ 16,958
Accounts payable	2,463	3,043
Accrued expenses and other liabilities	3,728	4,354
Total liabilities	23,405	24,355
Stockholders' equity	19,207	45,541
Total liabilities and stockholders' equity	\$ 42,612	\$ 69,896

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Grant revenue	\$ —	\$ —	\$ —	\$ 235
Operating expenses:				
Research and development	11,427	6,678	21,169	14,010
General and administrative	3,571	4,026	7,205	7,950
Refund of research and development expense	—	—	—	(1,592)
Total operating expenses	<u>14,998</u>	<u>10,704</u>	<u>28,374</u>	<u>20,368</u>
Loss from operations	(14,998)	(10,704)	(28,374)	(20,133)
Other income and expense:				
Interest income	71	111	148	220
Interest expense	(448)	(430)	(884)	(861)
Total other income and expense	<u>(377)</u>	<u>(319)</u>	<u>(736)</u>	<u>(641)</u>
Net loss	<u>\$ (15,375)</u>	<u>\$ (11,023)</u>	<u>\$ (29,110)</u>	<u>\$ (20,774)</u>
Net loss per share - basic and diluted	<u>\$ (0.54)</u>	<u>\$ (0.39)</u>	<u>\$ (1.02)</u>	<u>\$ (0.74)</u>
Weighted-average number of common shares used in computing net loss per share	<u>28,541</u>	<u>28,276</u>	<u>28,519</u>	<u>28,214</u>