# GENOCEA BIOSCIENCES, INC.

## FORM 8-K
(Current report filing)

Filed 05/04/17 for the Period Ending 05/04/17

| | |
|---|---|
| Address | 100 ACORN PARK DRIVE<br>CAMBRIDGE, MA 02140 |
| Telephone | 617-876-8191 |
| CIK | 0001457612 |
| Symbol | GNCA |
| SIC Code | 2836 - Biological Products, Except 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): **April 11, 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**<br>**100 Acorn Park Drive, 5th Floor**<br>**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 May 4, 2017, Genocea Biosciences, Inc. (the "Company") announced its financial results for the first quarter ended March 31, 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 7.01 Regulation FD Disclosure.**

On May 4, 2017, the Company announced positive data from its GEN-003 Phase 2 trial indicating an initial course of injections sustains clinical and virologic efficacy for at least 24 months. 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 May 4, 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: May 4, 2017

## EXHIBIT INDEX

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release issued by Genocea Biosciences, Inc. on May 4, 2017 |

# Genocea Reports First Quarter 2017 Financial Results and Positive Clinical Developments on Lead Candidate GEN-003 in Genital Herpes

*- Data from GEN-003 Phase 2 trial indicate initial course of injections sustains clinical and virologic efficacy for at least 24 months -*

*- End of Phase 2 meeting successfully completed for GEN-003; expect to be Phase 3-ready by end of 2017 -*

*- Neoantigen cancer vaccine candidate GEN-009 IND filing expected by end of 2017 -*

*- Conference call today at 9am ET -*

**CAMBRIDGE, Mass., May 4 , 2017** - Genocea Biosciences, Inc. (NASDAQ: GNCA), a biopharmaceutical company developing T cell-directed vaccines and immunotherapies, today reported financial results for the first quarter of 2017 and announced several positive clinical developments on GEN-003 , the company's candidate immunotherapy for the treatment of genital herpes.

In a Phase 2 study, GEN-003 demonstrated sustained reductions compared to baseline in the genital lesion rate (percent of days with genital lesions) and the viral shedding rate (percent of days with detectable virus) in genital herpes patients 24 months after dosing across multiple dose groups (see detailed data below). In addition, Genocea has now successfully completed its End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and continues to expect GEN-003 to be ready for Phase 3 development by the end of 2017.

Chip Clark, president and chief executive officer of Genocea commented on the results: "These long-term durability data reinforce our conviction that GEN-003 could become the cornerstone treatment for patients with genital herpes. We believe the data suggest a single course of treatment of GEN-003 could offer significant clinical, virologic and convenience benefits to patients generally, and especially those dissatisfied with current treatments, for at least 2 years with no maintenance dosing. Given our successful End of Phase 2 meeting with the FDA, we continue to plan a Phase 3 program design consistent with previous guidance. We believe that these new data, together with the body of positive clinical results to date and these FDA discussions, give us momentum to advance our pioneering product candidate to Phase 3 readiness this year."

"Since our last earnings announcement," Mr. Clark added, "we have also progressed our immuno-oncology programs. Together with our advisory board of prominent immuno-oncology experts, we reviewed and refined our development plans for GEN-009, our lead neoantigen cancer vaccine candidate, and we remain confident in our plans to file an IND for this differentiated vaccine candidate this year. Furthermore, we recently presented data on our ATLAS™ antigen identification platform at two important oncology conferences - the Keystone Symposium on immuno-oncology and at AACR 2017 - as well as at the World Vaccine Congress, where we were invited to give an oral presentation on the potential benefits that ATLAS can bring to neoantigen identification and immune response profiling for immuno-oncology."

**GEN-003 Phase 2 Clinical Results**

The 24-month clinical results announced today come from an extension of a Phase 2 dose-optimization study that started in 2014 and enrolled 310 subjects from 17 institutions in the United States. Subjects were randomized to one of six dosing groups of either 30 µg or 60 µg of each of two protein antigens paired with one of three Matrix-M ™ adjuvant doses (25 µg, 50 µg, or 75 µg). A seventh group received placebo. Subjects received three doses of GEN-003 or placebo at 21-day intervals and no maintenance doses were given. Baseline viral shedding and genital lesion rates were established for each subject in a 28-day observation period prior to the commencement of dosing. This 28-day observation period was repeated immediately after the completion of dosing and at six, 12,

and 24 months following dosing. After the 28-day observation period immediately after dosing, patients in the placebo arm were rolled over across the six active dose groups under a separate protocol. Throughout the trial, GEN-003 continued to demonstrate a safety profile appropriate for its therapeutic setting, as determined by the trial's independent Drug Monitoring Committee.

Genocea has already advanced the two most promising doses (60 µg per protein combined with either 50 or 75 µg of adjuvant) from this Phase 2 trial into an ongoing Phase 2b efficacy trial, from which positive 6-month, placebo-controlled clinical efficacy data were announced in January 2017 . The efficacy of GEN-003 at these two dose levels over the course of this Phase 2 extension study is as follows:

| Endpoint | 60 µg per protein / 50 µg of Matrix-M | | | | 60 µg per protein / 75 µg of Matrix-M | | | |
|---|---|---|---|---|---|---|---|---|
| | Post dose 3 | 6 months | 12 months | 24 months | Post dose 3 | 6 Months | 12 months | 24 months |
| n | 42 | 38 | 36 | 21 | 41 | 39 | 34 | 25 |
| Viral shedding rate reduction* | 41% (p<0.01) | 47% (p<0.0004) | 66% (p<0.0001) | 58% NA** | 55% (p<0.006) | 58% (p<0.0001) | 55% (p<0.01) | 69% NA** |
| Genital lesion rate reduction* | 69% (p<0.0005) | 50% (p<0.01) | 65% (p<0.003) | 77% NA** | 60% (p<0.02) | 43% (p<0.03) | 47% (p<0.02) | 39% NA** |

Notes:
* Mean rate reduction vs. pre-dosing baseline levels. Statistical analysis performed using a Poisson mixed effect model with empirical variance: Magaret, Amalia, "Models for HSV shedding must account for two levels of overdispersion" ((January 2016). UW Biostatistics Working Paper Series. Working Paper 410)
** Per prospectively defined clinical trial protocol, descriptive results only, no statistical testing performed.

**Anticipated Upcoming Milestones and Events**

- May 12-16, 2017: AAI's IMMUNOLOGY 2017™ - Genocea will be presenting the first data from its Epstein-Barr Virus (EBV)-related cancer program, highlighting that ATLAS has identified novel and unexpected antigens of T cell responses in the widely studied, cancer-causing virus.
- June 13, 2017: Annual Meeting of Shareholders at the offices of Ropes & Gray in Boston
- July 29 - August 2, 2017: 42 nd Annual International Herpesvirus Workshop ( IHW 2017 ) - Genocea will be presenting data on its GEN-003 Phase 2b clinical trial
- Mid-2017: GEN-003 12-month Phase 2b data anticipated
- 4Q 2017: GEN-003 expected to be ready for Phase 3 development
- 4Q 2017: GEN-009 neoantigen cancer vaccine Investigational New Drug (IND) application filing expected

**Financial Guidance**

Genocea expects that its existing cash, cash equivalents and investments are sufficient to support its operating expenses, capital expenditure requirements and debt obligations into the first quarter of 2018, without assuming any receipt of proceeds from potential business development partnerships or equity financings. This guidance assumes commencing Phase 3 trials for GEN-003 for genital herpes around the end of 2017 and filing an IND for GEN-009 for cancer by the end of the year, however it is Genocea's strategy to secure additional sources of financing in advance of starting GEN-003 Phase 3 clinical trials.

**First-Quarter 2017 Financial Results**

- **Cash Position:** Cash, cash equivalents and investments as of March 31, 2017 were $48.7 million compared to $63.4 million as of December 31, 2016.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended March 31, 2017 increased $2.4 million, to $9.7 million, from the same period in 2016. The increase was driven by higher compensation, consulting and professional services costs in support of the GEN-003 program and increases in manufacturing costs related to supply for Genocea's anticipated Phase 3 clinical program. Spending increases on GEN-009 and immuno-oncology programs were more than offset by lower costs on deprioritized infectious disease programs.
- **General and Administrative (G&A) Expenses:** G&A expenses for the first quarter of 2017 were $3.6 million, compared to $3.9 million for the same period in 2016 reflecting improved operating leverage.

- **Refund of Research and Development Expense:** A gain of $1.6 million for the quarter ended March 31, 2016 resulted from cash received pursuant to contractual obligations under a collaboration agreement with Isconova AB (“Isconova”) (since acquired by Novavax, Inc.) to refund R&D expenses paid by Genocea to Isconova between 2009 and 2011 relating to the development of the Matrix-M adjuvant technology.
- **Net Loss:** Net loss was $13.7 million for the quarter ended March 31, 2017, compared to a net loss of $9.8 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 13446635. 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 successfully developed ATLAS™, its proprietary technology platform, to identify clinically relevant antigens of T cells based on actual human immune responses. Genocea 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 and to identify T cell response signatures of cancer patients treated with checkpoint blockade therapies to potentially improve clinical practice. Genocea expects GEN-003 to be ready to begin Phase 3 development and to file an IND for its neoantigen cancer vaccine candidate GEN-009 by the end of 2017. For more information, please visit the company's website at www.genocea.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. Genocea cautions that these forward-looking statements are subject to numerous assumptions, risks and uncertainties, which 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; 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 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)**

| | March 31, 2017 | December 31, 2016 |
|---|---|---|
| Cash, cash equivalents and investments | $ 48,675 | $ 63,362 |
| Other assets | 6,970 | 6,534 |
| Total assets | $ 55,645 | $ 69,896 |
| | | |
| Debt, current and long-term | $ 17,083 | $ 16,958 |
| Accounts payable | 2,875 | 3,043 |
| Accrued expenses and other liabilities | 2,603 | 4,354 |
| Total liabilities | 22,561 | 24,355 |
| Stockholders' equity | 33,084 | 45,541 |
| Total liabilities and stockholders’ equity | $ 55,645 | $ 69,896 |

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

| | Three months ended March 31, | |
|---|---|---|
| | 2017 | 2016 |
| Grant revenue | $ — | $ 235 |
| Operating expenses: | | |
| Research and development | 9,742 | 7,332 |
| General and administrative | 3,634 | 3,924 |
| Refund of research and development expense | — | (1,592) |
| Total operating expenses | 13,376 | 9,664 |
| Loss from operations | (13,376) | (9,429) |
| Other income and expense: | | |
| Interest income | 77 | 109 |
| Interest expense | (436) | (431) |
| Total other income and expense | (359) | (322) |
| **Net loss** | $ (13,735) | $ (9,751) |
| Net loss per share - basic and diluted | $ (0.48) | $ (0.35) |
| Weighted-average number of common shares used in computing net loss per share | 28,496 | 28,152 |