GENOCEA BIOSCIENCES, INC.

FORM 8-K
(Current report filing)

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Address	100 ACORN PARK DRIVE CAMBRIDGE, MA 02140
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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): **February 16, 2017**

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.)

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:

☐ 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))

Item 2.02 Results of Operations and Financial Condition.

On February 16, 2017, Genocea Biosciences, Inc. announced its financial results for the fiscal 2016 fourth quarter and the full fiscal year ended December 31, 2016. 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 February 16, 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: February 16, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Genocea Biosciences, Inc. on February 16, 2017

Exhibit 99.1

Genocea Reports Fourth Quarter and Year-End 2016 Financial Results

- Positive Phase 2b clinical data confirm attractive profile for GEN-003; expected to start Phase 3 program in 4Q 2017 -

- Neoantigen cancer vaccine program on track to file first IND by end of 2017 -

- Conference call at 9am ET today -

CAMBRIDGE, Mass., February 16, 2017 - Genocea Biosciences, Inc. (NASDAQ: GNCA), a biopharmaceutical company developing T cell-directed vaccines and immunotherapies, today reported corporate highlights and financial results for the fourth quarter and year ended December 31, 2016 . Genocea is developing GEN-003 , a therapeutic vaccine candidate for the treatment of genital herpes expected to enter Phase 3 development in 2017, and is applying its unique and proprietary T cell antigen identification platform, ATLAS™, to immuno-oncology and cancer vaccine development .

“We are proud to report on our 2016 achievements, as we made important advances in both our GEN-003 and immuno-oncology programs,” said Chip Clark, president and chief executive officer of Genocea. “With the announcements of positive virologic and clinical data for GEN-003 from our ongoing Phase 2b trial, we believe we have confirmed a highly attractive clinical profile for GEN-003, which has the potential to be the first new treatment for patients with genital herpes in more than 20 years. We are encouraged by market research indicating that the GEN-003 clinical profile is attractive to both physicians and payers, and, most importantly, to patients, many of whom are dissatisfied with their current treatment options.”

Mr. Clark continued: “In addition to the progress on GEN-003, we announced last fall that we are now focusing our early stage development resources on our immuno-oncology programs. We believe there is a significant opportunity to use our ATLAS platform in immuno-oncology to comprehensively profile T cell responses to cancer. We believe that we can create value by developing novel therapeutic neoantigen cancer vaccines and by developing non-invasive assays to define patient selection for clinical trials and clinical practice. As we presented at our first-ever R&D Day in December, we are making significant progress in both areas and remain on track to file an IND for our first cancer vaccine (GEN-009) by the end of this year.”

Program Highlights

GEN-003 Program Milestones

- March 2016 : Announced positive efficacy data from the Phase 2 dose-optimization trial, demonstrating sustained reductions in the rate of viral shedding and clinical efficacy across secondary clinical endpoints 12 months after dosing
- June 2016 : Presented detailed 6- and 12-month clinical and viral shedding data from the Phase 2 dose-optimization trial at the American Society for Microbiology annual general meeting, ASM Microbe 2016
- September 2016 : Announced the first data from the placebo-controlled Phase 2b trial evaluating a new Phase 3-ready formulation, with GEN-003 demonstrating significant reduction in viral shedding immediately after dosing
- October 2016 : Presented 12-month immunogenicity data from the Phase 2 dose-optimization trial at the Infectious Disease Society of America (IDSA) annual meeting, IDWeek 2016, demonstrating GEN-003 effects clear and robust T and B cell responses
- January 2017 : Announced positive 6-month results from the Phase 2b clinical trial showing statistical significance vs. placebo for multiple clinical endpoints

Immuno-Oncology Program Milestones

- November 2016 : Announced new findings supporting the potential of the proprietary ATLAS technology to identify clinically meaningful neoantigens compared to those identified by predictive algorithms and presented the results at the Society for Immunotherapy of Cancer's 31 st Annual Meeting & Associated Programs, SITC 2016
- December 2016 : Announced two immuno-oncology collaborations, Checkmate Pharmaceuticals, Inc. and US Oncology, each employing ATLAS to characterize T cell responses to optimize clinical development and to discover new antigens, respectively

Anticipated Upcoming Milestones and Events

Milestones

- 1Q 2017: GEN-003 end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) expected; will confirm the design of the GEN-003 Phase 3 program
- 2H 2017: GEN-003 24-month Phase 2 data expected; will inform likely timing of maintenance dosing for GEN-003
- 2H 2017: GEN-003 12-month Phase 2b data anticipated; expected to reconfirm clinical profile of GEN-003 at 1 year post dosing
- 4Q 2017: GEN-003 Phase 3 program start expected
- 4Q 2017: GEN-009 neoantigen cancer vaccine Investigational New Drug (IND) application filing expected

Events

- March 2017: Presentation at the Cowen 37 th Annual Health Care Conference in Boston
- April 2017: Presentation at the Needham & Company 16 th Annual Healthcare Conference in NYC

Financial Guidance

Genocea expects that its existing cash, cash equivalents and investments are sufficient to support its operating expenses and capital expenditure requirements into the first quarter of 2018, without assuming any receipt of proceeds from potential business development partnerships, equity financings or debt drawdowns. This guidance assumes commencing Phase 3 trials for GEN-003 for genital herpes in the fourth quarter 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.

Fourth Quarter and Year-End 2016 Financial Results

- **Cash Position:** Cash, cash equivalents and investments as of December 31, 2016 were $63.4 million compared to $75.5 million as of September 30, 2016.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended December 31, 2016 increased $5.3 million, to $11.8 million, from the same period in 2015, driven by higher manufacturing and clinical costs for GEN-003 together with higher personnel and lab-related costs related to Genocea's immuno-oncology programs. These increases were partially offset by reduced spending on early stage infectious disease programs.
- **General and Administrative (G&A) Expenses:** G&A expenses for the fourth quarter of 2016 were $3.9 million, compared to $3.8 million for the same period in 2015. The slight increase reflects higher personnel costs to support Genocea's expanding R&D operations.
- **Net Loss:** Net loss was $16.0 million for the quarter ended December 31, 2016, compared to a net loss of $10.3 million for the same period in 2015.

Full Year 2016 Financial Results

- **Cash Position:** Cash, cash equivalents and investments as of December 31, 2016 were $63.4 million, compared to $106.4 million as of December 31, 2015.
- **R&D Expenses:** R&D expenses for the year ended December 31, 2016 were $34.6 million, compared to $28.0 million for the same period in 2015, reflecting higher personnel costs, consulting and professional services costs, clinical costs, and lab-related costs to support the continued advancement of GEN-003. These increased costs were partially offset by lower GEN-003 manufacturing costs in 2016 compared to

2015. Increases in personnel and lab related costs across early stage research programs were offset by a reduction in GEN-004 costs for which a clinical trial was completed in late 2015 and further development of this program was suspended.

- **G&A Expenses:** G&A expenses were $15.4 million for the year ended December 31, 2016, compared to $14.0 million for the same period in 2015, reflecting an increase in market research costs to support GEN-003 and higher depreciation costs from facility expansion in late 2015.
- **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 $49.6 million for the year ended December 31, 2016, compared to a net loss of $42.5 million for the same period in 2015.

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 58691835. 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. T cells are increasingly recognized as a critical element of protective immune responses to a wide range of diseases, but traditional discovery methods have proven unable to identify the targets of such protective immunity. Using ATLAS™, its proprietary technology platform, Genocea identifies these targets to potentially enable the rapid development of medicines to address critical patient needs. Genocea's pipeline includes GEN-003, a novel T cell-enabled immunotherapy for genital herpes currently in Phase 2 clinical development, and earlier-stage investments in immuno-oncology. For more information, please visit the company's website a t 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, 2015 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)

	December 31, 2016	December 31, 2015
Cash, cash equivalents and investments	$ 63,362	$ 106,432
Other assets	6,534	5,710
Total assets	$ 69,896	$ 112,142
Debt, current and long-term	$ 16,958	$ 16,477
Accounts payable	3,043	1,757
Accrued expenses and other liabilities	4,354	4,012
Deferred revenue	—	235
Total liabilities	24,355	22,481
Stockholders' equity	45,541	89,661
Total liabilities and stockholders’ equity	$ 69,896	$ 112,142

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

	Three months ended December 31,		Twelve months ended December 31,	
	2016	2015	2016	2015
Grant revenue	$ —	$ 221	$ 235	$ 670
Operating expenses:				
Research and development	11,824	6,513	34,645	28,049
General and administrative	3,858	3,781	15,427	13,987
Refund of research and development expense	—	—	(1,592)	—
Total operating expenses	15,682	10,294	48,480	42,036
Loss from operations	(15,682)	(10,073)	(48,245)	(41,366)
Other income and expense:				
Interest income	87	93	410	163
Interest expense	(439)	(334)	(1,738)	(1,280)
Total other income and expense	(352)	(241)	(1,328)	(1,117)
Net loss	$ (16,034)	$ (10,314)	$ (49,573)	$ (42,483)
Net loss per share - basic and diluted	$ (0.56)	$ (0.37)	$ (1.75)	$ (1.74)
Weighted-average number of common shares used in computing net loss per share	28,394	28,118	28,299	24,460