

GENOCEA BIOSCIENCES, INC.

FORM 8-K (Current report filing)

Filed 01/31/18 for the Period Ending 01/31/18

Address	100 ACORN PARK DRIVE CAMBRIDGE, MA, 02140
Telephone	617-876-8191
CIK	0001457612
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): **January 26, 2018**

GENOCEA BIOSCIENCES, INC.

(Exact name of registrant as specified in its 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:

- 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 1.01. Entry into a Material Definitive Agreement.

On January 26, 2018, Genocea Biosciences, Inc. (the “*Company*”) entered into a License and Supply Agreement (the “*Agreement*”) with Oncovir, Inc. (“*Oncovir*”). The Agreement relates to the manufacture and supply of Hiltonol® (poly-ICLC) (“*Hiltonol*”), an immunomodulator and vaccine adjuvant. Hiltonol is the adjuvant component of GEN-009, the Company’s investigational personal neoantigen cancer vaccine which will consist of synthetic long peptides of neoantigens identified using the Company’s proprietary ATLAS™ platform, formulated with Hiltonol. When paired with synthetic long peptides, Hiltonol has shown the ability to induce T cell responses, which the Company believes will be important for driving clinical efficacy of GEN-009. Hiltonol is manufactured under Good Manufacturing Practice conditions, has an existing Drug Master File and has an extensive tolerability record when used alone and in combination with vaccine antigens.

The Agreement provides the terms and conditions under which Oncovir will manufacture and supply Hiltonol to the Company for use in connection with the research, development, use, sale, manufacture, commercialization and marketing of products combining the Hiltonol with the Company’s technology (the “*Combination Product*”), including GEN-009. The Company is not required to purchase any minimum quantity of Hiltonol from Oncovir.

Oncovir granted the Company a non-exclusive, assignable, royalty-bearing worldwide license, with the right to grant sublicenses through one tier, to certain of Oncovir’s intellectual property in connection with the research, development or commercialization of Combination Products, including the use of Hiltonol, but not the use of Hiltonol for manufacturing or the use or sale of Hiltonol alone. The license shall become perpetual, fully paid-up and royalty-free on the later of January 25, 2028 or the date on which the last valid claim of any patent licensed to the Company under the Agreement expires.

Under this Agreement, the Company is obligated to pay Oncovir (i) an up-front payment in the mid-six figures in consideration of the license granted to Genocea and for the initial supply of Hiltonol for the planned GEN-009 Phase 1/2 trial, (ii) a supply price for Hiltonol in the low-three figures per vial of Hiltonol for use in clinical trials or commercial use, (iii) a milestone payment in the low-six figures upon the achievement of certain clinical trial milestones for each Combination Product, (iv) a milestone payment in the mid-six figures upon the first marketing approval of commercial sales for each Combination Product in certain territories, and (v) tiered royalties in the low-single digits on a product-by-product basis based on the net sales of Combination Products.

The Company may terminate the Agreement upon a decision to discontinue the development of the Combination Product or upon a determination by the Company or an applicable regulatory authority that Hiltonol or Combination Product is not clinically safe or effective. The Agreement may also be terminated by either party due to a material uncured breach by the other party, or due to the other party’s bankruptcy, insolvency or dissolution.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 30, 2018, Seth Hetherington, M.D. delivered his resignation as Chief Medical Officer of the Company, effective immediately. Dr. Hetherington, an infectious disease expert, is leaving the Company in connection with the Company’s strategic shift to focus on oncology and the development of cancer vaccines. The Company has commenced a search for a new Chief Medical Officer with an executive search firm.

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: January 31, 2018