

**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): **July 23, 2020**



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.)

100 Acorn Park Drive, 5th Floor
Cambridge, MA 02140
(Address of principal executive offices, including zip code)

(617) 876-8191
(Registrant's telephone number, including area code)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value per share	GNCA	Nasdaq Capital Market

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 July 23, 2020, Genocea Biosciences, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 2020. 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 July 23, 2020](#)
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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/ DIANTHA DUVALL

Diantha Duvall

Chief Financial Officer

(Principal Financial Officer)

Date: July 23, 2020



Investor Contact:

Dan Ferry
617-430-7576
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Genocea Provides Second Quarter 2020 Corporate Update

***Upcoming GEN-009 data update planned for July 30th at 8 a.m. EDT
Filed IND application for GEN-011 and is working with the FDA to provide additional information
Private Placement with Leading Life Science Investment Funds***

Conference call today at 8:30 a.m. EDT

CAMBRIDGE, Mass., July 23, 2020 - [Genocea Biosciences, Inc.](#) (NASDAQ: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, today reported its operating and financial results for the second quarter ended June 30, 2020. Genocea had an active and productive second quarter, demonstrating important progress across the Company:

GEN-009

- On July 30, 2020, the Company plans to present initial clinical data on the first 5 patients from Part B with Dr. Maura L. Gillison, MD, PhD, Professor of Medicine, Department of Thoracic/Head and Neck Medical Oncology at MD Anderson Cancer Center. Part B of the study is exploring the combination of GEN-009 and immune checkpoint inhibitor-based regimens in advanced solid tumors.
- Presented long-term follow-up data from Part A of the ongoing Phase 1/2a clinical trial at ASCO20 Virtual Scientific Program that evaluates eight participants for duration of immune responses and clinical outcomes.
 - Seven out of eight patients treated on Part A of the study are without disease progression at one-year median follow-up.
 - ATLAS™-identified neoantigens generate broad, sustained T cell responses starting after only 4 weeks and lasting for up to 1 year after the last vaccination.

GEN-011

- Hosted a virtual KOL symposium introducing GEN-011 – a neoantigen cell therapy that uses peripheral blood T cells and is powered by ATLAS™ to target the right tumor neoantigens. The event featured commentary from Dr. Eric Tran, Assistant Member at the Earle A. Chiles Research Institute in the Providence Cancer Institute and members of the Genocea management team on GEN-011 as a new category of T cell therapy designed to improve on current limitations of TIL therapy.
- Filed an Investigational New Drug (IND) application to initiate a Phase 1/2a clinical study of GEN-011 evaluating patient safety, T cell proliferation and persistence, and clinical activity. The trial expects to enroll up to 24 patients and will assess GEN-011 in a range of tumor types, with a focus on patients who have failed standard-of-care checkpoint inhibitor therapy. The Company has received verbal notification from the U.S. Food and Drug Administration (FDA) that the agency has completed its review of the Company's IND for GEN-011. In this verbal feedback, the FDA informed Genocea that it is placing the IND on clinical hold until it receives additional information pertaining to certain third-party reagents used in the GEN-011 manufacturing process. These reagents are not a component of the final cell therapy product. The Company expects to receive official written communication from the FDA regarding the hold and the FDA's position in the near future and plans to work with the FDA to resolve their questions as quickly as possible.

Private Placement

- On July 22, 2020 the Company entered into a private placement led by an undisclosed leading U.S. public investment fund specializing in life sciences as well as certain existing and new investors providing for the purchase of up to approximately \$80 million of its common stock and warrants to purchase shares of Genoclea common stock (before deducting fees to the placement agent and other offering expenses payable by Genoclea). Genoclea will offer 21.4 million shares of common stock and 12.2 million pre-funded warrants to purchase common stock, along with accompanying warrants to purchase one share of common stock for each share of common stock or pre-funded warrant purchased by an investor. The warrants will be exercisable immediately upon issuance, in whole or in part, at an exercise price of \$2.25 per share and will have a 4-year term. The closing of the private placement is expected to occur on or about July 24, 2020, subject to customary closing conditions.

Shionogi Material Transfer Agreement (“MTA”)

- Entered into an MTA and exclusive license option with Shionogi & Co., Ltd. (“Shionogi”) to develop a novel HSV-2 vaccine using Genoclea's proprietary HSV-2 antigens from the GEN-003 program, which the company discontinued in 2017. As part of this agreement, the Company received \$2 million for the exclusive option to evaluate the HSV-2 antigens and to negotiate a license prior to expiration of the MTA. Upon exercise of Shionogi's option, terms of the license are expected to include an upfront payment, regulatory and sales milestones, as well as tiered royalties. Final terms of the license agreement will be based on results of the MTA evaluation and overall diligence. If licensed, Shionogi will assume responsibility for global development and commercialization of the HSV-2 vaccine product.

Inhibigens

- Presented preclinical data at the AACR Virtual Annual Meeting II that furthers understanding of inhibitory antigen (Inhibigen™) function and builds on previous research demonstrating that the presence of an Inhibigen in an otherwise protective immunotherapy can be detrimental to anti-tumor responses.
 - Inhibigens were found to alter the tumor microenvironment and drive tumor hyperprogression and also abolished both global and tumor antigen-specific T cell activity to beneficial anti-tumor antigens.
 - Findings suggest that Inhibigens must be identified and excluded from the rational design of cancer immunotherapies to achieve more favorable patient outcomes.

“We continue to advance our clinical programs for patients living with cancer,” said Chip Clark, President and Chief Executive Officer, Genoclea. “I am pleased by our ability to remain on track during these uncertain times, meeting our highest priority milestones and working to deliver on the promise of developing effective immunotherapies through our unique and differentiated approach.”

Second Quarter 2020 Financial Results

- Cash position: As of June 30, 2020, cash and cash equivalents were \$22.1 million versus \$40.1 million as of December 31, 2019.
- Research and Development (R&D) expenses: R&D expenses were \$8.6 million for the quarter ended June 30, 2020, compared to \$6.8 million for the same period in 2019.
- General and Administrative (G&A) expenses: G&A expenses were \$3.5 million for the quarter ended June 30, 2020, compared to \$3.2 million for the same period in 2019.
- Net loss: Net loss was \$11.3 million for the quarter ended June 30, 2020, compared to \$6.5 million for the same period in 2019.

Guidance

Genoclea expects that its existing cash and cash equivalents inclusive of the private placement proceeds are sufficient to support its operations to mid-2022.

Conference Call

Genoclea will host a conference call and webcast today at 8:30 a.m. EDT. Interested participants may access the conference call by dialing (844) 826-0619 (domestic) or (315) 625-6883 (international) and referring to conference ID number 8894505. To join the live webcast, please visit the presentation page of the investor relations section of the Genoclea website at <https://ir.genoclea.com/events-and-presentations>. 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 90 days.

GEN-009 Clinical Update Registration

Genocea will present a clinical update on GEN-009 on Thursday, July 30 at 8 a.m. EDT. Interested participants may access this event by registering [here](#).

About Genocea Biosciences, Inc.

Genocea's mission is to conquer cancer by developing personalized cancer immunotherapies in multiple tumor types. Our unique ATLAS™ platform comprehensively profiles each patient's T cell responses to potential targets, or antigens, on the tumor. ATLAS enables us to optimize the neoantigens for inclusion in our immunotherapies and exclude inhibitory antigens that can exert an immunosuppressive effect. We are advancing two ATLAS-enabled programs: GEN-009, our neoantigen vaccine for which we are conducting a Phase 1/2a clinical trial and expect preliminary clinical results in the third quarter of 2020, and GEN-011, our neoantigen-specific cell therapy using T cells derived from peripheral blood for which we expect to conduct a Phase 1/2a clinical trial. To learn more, please visit www.genocea.com.

Forward-Looking Statements

This press release includes forward-looking statements, including statements relating to GEN-009 and GEN-011, within the meaning of the Private Securities Litigation Reform Act. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Genocea cautions that these forward-looking statements are subject to numerous assumptions, risks and uncertainties that change over time. Applicable risks and uncertainties include those identified under the heading "Risk Factors" included in Genocea's Annual Report on Form 10-K for the year ended December 31, 2019 and any subsequent SEC filings. These forward-looking statements speak only as of the date of this press release and Genocea assumes no duty to update forward-looking statements, except as may be required by law.

(Tables to follow)

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

	June 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 22,108	\$ 40,127
Right of use assets	11,265	6,306
Other assets	7,143	6,178
Total assets	\$ 40,516	\$ 52,611
Debt, current and long-term	\$ 13,627	\$ 13,407
Accounts payable and accrued expenses	4,749	5,164
Deferred revenue	1,094	—
Lease liabilities	11,526	6,512
Warrant liability	1,483	2,486
Total liabilities	32,479	27,569
Stockholders' equity	8,037	25,042
Total liabilities and stockholders' equity	\$ 40,516	\$ 52,611

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
License revenue	\$ 906	\$ —	\$ 906	\$ —
Operating expenses:				
Research and development	8,587	6,849	18,574	13,309
General and administrative	3,480	3,217	6,868	6,234
Total operating expenses	12,067	10,066	25,442	19,543
Loss from operations	(11,161)	(10,066)	(24,536)	(19,543)
Other (expense) income	(160)	3,571	362	(2,519)
Net loss	\$ (11,321)	\$ (6,495)	\$ (24,174)	\$ (22,062)
Net loss per share - basic and diluted	\$ (0.39)	\$ (0.42)	\$ (0.84)	\$ (1.57)
Weighted-average number of common shares used in computing net loss per share	29,142	15,344	28,642	14,035