

**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): **October 29, 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 October 29, 2020, Genocea Biosciences, Inc. (the "Company") announced its financial results for the third quarter ended September 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 October 29, 2020](#)

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: October 29, 2020



Investor Contact:

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Genocea Provides Third Quarter 2020 Corporate Update

Initiated GEN-011 Phase 1/2a clinical trial

Presented positive follow-up GEN-009 Part B data at ESMO Virtual Congress 2020 demonstrating potential added benefit to PD-1 inhibitor therapy

Closed financing with net proceeds of \$74.5 million

Upcoming presentations at SITC 2020 Virtual Conference on GEN-009, Inhibigens™ and GEN-011

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

CAMBRIDGE, Mass., October 29, 2020 - [Genocea Biosciences, Inc.](#) (NASDAQ: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, today reported its operating and financial results for the third quarter ended September 30, 2020.

GEN-011 Phase 1/2a clinical trial initiation

Genocea recently announced the U.S. Food and Drug Administration (FDA) accepted the company's Investigational New Drug (IND) Application for GEN-011, an adoptive neoantigen T cell therapy designed to improve upon the limitations of TIL and TCR therapies. The company initiated a Phase 1/2a clinical study of GEN-011 in patients who have failed standard-of-care checkpoint inhibitor therapy to evaluate safety, T cell proliferation and persistence as well as clinical activity. Genocea plans to enroll up to 24 patients across several tumor types in the trial.

Scientific and clinical presentations: ESMO Congress, upcoming SITC meeting and conference call

Genocea presented clinical response and immunogenicity data on the first five patients from Part B of the ongoing GEN-009 Phase 1/2a trial at the European Society for Medical Oncology (ESMO) Virtual Congress 2020. The incremental follow-up findings demonstrated tumor reductions or stable outcomes for all five patients, suggesting GEN-009 vaccination could be used in conjunction with CPI-based therapies to augment their effects. In addition, 100% of patients demonstrated immune responses to ATLAS™-identified neoantigens.

Genocea will report additional clinical and immunogenicity data from the remaining GEN-009 Part B patients during the 2020 virtual Society for Immunotherapy of Cancer (SITC) annual meeting from November 9-14. The company will also provide a detailed introduction to GEN-011 and will share new insights on the utility of ATLAS-identified Inhibigens to inform future immunotherapy development.

Genocea will also host a conference call on Monday, November 9 at 8:30 a.m. EST to discuss the new GEN-009 clinical and immunogenicity data reported at SITC.

Private placement

In July, Genocea completed a private placement with \$74.5 million in net proceeds. The proceeds will be used to fund continued development of GEN-009, GEN-011 and ATLAS.

"In the third quarter, our team achieved important clinical, scientific and financial progress. We provided what we believe to be differentiated immunogenicity and efficacy data from an initial look at our GEN-009 Part B clinical trial and secured critical fresh capital," said Chip Clark, president and chief executive officer Genocera. "Using these proceeds to advance GEN-011 into the clinic and to further our investigation into ATLAS and its applications represents an exciting opportunity."

Third Quarter 2020 Financial Results

- Cash position: As of September 30, 2020, cash and cash equivalents were \$87.6 million versus \$40.1 million as of December 31, 2019.
- Research and Development (R&D) expenses: R&D expenses were \$7.5 million for the quarter ended September 30, 2020, compared to \$6.8 million for the same period in 2019.
- General and Administrative (G&A) expenses: G&A expenses were \$3.6 million for the quarter ended September 30, 2020, compared to \$2.8 million for the same period in 2019.
- Net loss: Net loss was \$4.6 million for the quarter ended September 30, 2020, compared to \$7.5 million for the same period in 2019.

Guidance

Genocera expects that its existing cash and cash equivalents are sufficient to support its operations to mid-2022.

Conference Call

Genocera 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 5951388. To join the live webcast, please visit the presentation page of the investor relations section of the Genocera website at <https://ir.genocera.com/events-and-presentations>. A webcast replay of the conference call will be available on the Genocera website beginning approximately two hours after the event and will be archived for 90 days.

About Genocera Biosciences, Inc.

Genocera'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 GEN-011, our neoantigen-specific cell therapy using T cells derived from peripheral blood for which we are commencing a Phase 1/2a clinical trial. To learn more, please visit www.genocera.com.

Forward-Looking Statements

This press release includes forward-looking statements 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. Genocera 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 Genocera'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 Genocera 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)

	September 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 87,625	\$ 40,127
Right of use assets	10,737	6,306
Other assets	7,836	6,178
Total assets	\$ 106,198	\$ 52,611
Accounts payable and accrued expenses	\$ 6,351	\$ 5,164
Deferred revenue	1,641	—
Debt, current and long-term	13,743	13,407
Warrant liabilities	53,237	2,486
Lease liabilities	11,021	6,512
Total liabilities	85,993	27,569
Stockholders' equity	20,205	25,042
Total liabilities and stockholders' equity	\$ 106,198	\$ 52,611

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
License revenue	\$ 453	\$ —	\$ 1,359	\$ —
Operating expenses:				
Research and development	7,548	6,826	26,123	20,135
General and administrative	3,644	2,758	10,511	8,992
Total operating expenses	11,192	9,584	36,634	29,127
Loss from operations	(10,739)	(9,584)	(35,275)	(29,127)
Other income (expense)	6,184	2,052	6,546	(467)
Net loss	\$ (4,555)	\$ (7,532)	\$ (28,729)	\$ (29,594)
Net loss per share:				
Basic	\$ (0.08)	\$ (0.28)	\$ (0.76)	\$ (1.62)
Diluted	\$ (0.26)	\$ (0.28)	\$ (1.01)	\$ (1.62)
Weighted-average number of shares used in computing net loss per share:				
Basic	55,492	26,681	37,657	18,297
Diluted	61,130	26,681	39,550	18,297