

**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 13, 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.)

Cambridge Discovery Park
100 Acorn Park Drive, 5th Floor
Cambridge, MA 02140
(Address of principal executive offices, including zip code)
(Registrant's telephone number, including area code): **(617) 876-8191**

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 February 13, 2020, Genocea Biosciences, Inc. (the “Company”) announced its financial results for the fiscal 2019 fourth quarter and the full fiscal year ended December 31, 2019. 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 13, 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: February 13, 2020



Investor Contact:

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Genocea Provides Fourth Quarter 2019 Corporate Update

***ATLAS™ identifies Inhibigens™ that can undermine immunotherapy
Dosed first patient in Part B of GEN-009 neoantigen vaccine Phase 1/2a trial
Progressed GEN-011 neoantigen cell therapy - IND filing expected in Q2 2020
Appointed Dr. Gisela Schwab to Genocea's Board of Directors***

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

CAMBRIDGE, Mass., February 13, 2020 - [Genocea Biosciences, Inc.](#) (NASDAQ: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, today reported its operating and financial results for the fourth quarter and fiscal year ended December 31, 2019.

Genocea presented new inhibigen (inhibitory antigen) data at the Society for Immunotherapy of Cancer (SITC) 2019 in National Harbor, Maryland. In one presentation, preclinical data demonstrated that the presence of an inhibigen reversed anti-tumor responses of an otherwise protective neoantigen vaccine, confirming the importance of excluding inhibigens from neoantigen cancer immunotherapies. A separate presentation showed data suggesting that the ratio of a patient's inhibigens to stimulatory (anti-tumor) neoantigens may predict response to immune checkpoint inhibitor (ICI) therapy. Only Genocea's proprietary neoantigen discovery platform, ATLAS, can systematically find inhibigens. As previously disclosed, GEN-009 immunogenicity data confirm that ATLAS identifies neoantigens optimized both to patients' T cell responses and their tumors. These new data offer an additional dimension to the advantages of ATLAS for neoantigen selection.

The company also completed patient dosing in Part A of its GEN-009 neoantigen vaccine phase 1/2a trial with no disease recurrence in vaccinated study participants to date. GEN-009 was highly immunogenic and well-tolerated by the entire cohort. Genocea has begun dosing patients for Part B, testing GEN-009 in combination with standard-of-care ICI therapy, with preliminary clinical results expected in Q2/Q3 2020.

Genocea also made important progress developing a robust manufacturing process for GEN-011, an adoptive T cell therapy using T cells derived from peripheral blood against ATLAS-identified neoantigens. The company intends to file an Investigational New Drug Application (IND) for GEN-011 in Q2 2020 with preliminary clinical results expected in 1H 2021.

"Genocea made critical scientific and clinical progress in the last quarter," said Chip Clark, President and Chief Executive Officer, Genocea. "The discovery and understanding of inhibigens has the potential to transform the process of antigen discovery for cancer immunotherapies, and even the therapeutic landscape for cancer. The GEN-009 immunogenicity results are unprecedented in neoantigen vaccines. Meanwhile, GEN-011 is progressing rapidly toward the clinic. We look forward to continuing - and capitalizing on - this strong progress in 2020."

Genocea also appointed Gisela Schwab, M.D., President, Product Development and Medical Affairs and Chief Medical Officer of Exelixis to its board of directors effective February 14, 2020. "I am delighted to welcome Gisela to our board. Her broad oncology drug development expertise and her proven company-building track record will provide us valued counsel and insights in the coming years," said Clark.

Fourth Quarter 2019 Financial Results

- Cash position: As of December 31, 2019, cash and cash equivalents were \$40.1 million versus \$26.4 million as of December 31, 2018.
- Research and Development (R&D) expenses: R&D expenses were \$6.8 million for the quarter ended December 31, 2019, compared to \$6.3 million for the same period in 2018.
- General and Administrative (G&A) expenses: G&A expenses were \$3.0 million for the quarter ended December 31, 2019, compared to \$2.6 million for the same period in 2018.
- Net income/loss: Net loss was \$9.4 million for the quarter ended December 31, 2019, compared to a net income of \$0.4 million for the same period in 2018.

Guidance

Genocea expects that its existing cash and cash equivalents are sufficient to support its operations into the first quarter of 2021.

Conference Call

Genocea will host a conference call and webcast today at 8:30 a.m. EST. Interested participants may access the conference call by dialing (844) 826-0619 (domestic) or (315) 625-6883 (international) and referring to conference ID number 7319557. To join the live webcast, please visit the presentation page of the investor relations section of the Genocea website at <https://ir.genocea.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.

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 Q2/Q3 2020, and GEN-011, our neoantigen-specific cell therapy using T cells derived from peripheral blood, for which we intend to file an Investigational New Drug Application in the second quarter of 2020. 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, 2018 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)

| | December 31, 2019 | | December 31, 2018 | |
|--|-------------------|--------|-------------------|--------|
| Cash and cash equivalents | \$ | 40,127 | \$ | 26,361 |
| Other assets | | 12,484 | | 4,754 |
| Total assets | \$ | 52,611 | \$ | 31,115 |
| Debt, current and long-term | \$ | 13,407 | \$ | 14,822 |
| Accounts payable, accrued expenses and other liabilities | | 11,676 | | 5,486 |
| Warrant liability | | 2,486 | | 3,472 |
| Total liabilities | | 27,569 | | 23,780 |
| Stockholders' equity | | 25,042 | | 7,335 |
| Total liabilities and stockholders' equity | \$ | 52,611 | \$ | 31,115 |

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

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|------------------------------------|----------|-------------------------------------|-------------|
| | 2019 | 2018 | 2019 | 2018 |
| Operating expenses: | | | | |
| Research and development | \$ 6,817 | \$ 6,259 | \$ 26,952 | \$ 25,209 |
| General and administrative | 3,045 | 2,627 | 12,037 | 14,309 |
| Total operating expenses | 9,862 | 8,886 | 38,989 | 39,518 |
| Loss from operations | (9,862) | (8,886) | (38,989) | (39,518) |
| Other income | 506 | 9,236 | 39 | 11,707 |
| Net income (loss): | \$ (9,356) | \$ 350 | \$ (38,950) | \$ (27,811) |
| Net income (loss) per share - basic and diluted | \$ (0.34) | \$ 0.03 | \$ (1.89) | \$ (2.69) |
| Weighted-average number of common shares used in computing net loss per share | 27,620 | 10,846 | 20,644 | 10,321 |