

**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 28, 2019

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 2.02 Results of Operations and Financial Condition.

On February 28, 2019, Genocea Biosciences, Inc. (the “Company”) announced its financial results for the fiscal 2018 fourth quarter and the full fiscal year ended December 31, 2018. 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On February 28, 2019, Genocea Biosciences, Inc. announced the appointment of Diantha Duvall, age 47, as Chief Financial Officer, effective March 5, 2019. Ms. Duvall will also be designated as the Company’s Principal Financial Officer and Principal Accounting Officer.

Prior to her appointment as Chief Financial Officer, Ms. Duvall was Vice President, Controller and Chief Accounting Officer at Bioverativ, Inc. (2017-2019). Prior to that, she worked at Biogen Inc., serving as Global Commercial Controller (2016-2017) and U.S. Commercial Controller (2015-2016). She also held a number of positions at Merck and Co. (2009-2015). Her experiences at Merck spanned roles in venture investment, business development, joint ventures, and alliances, as well as operational controls and technical accounting. She also has extensive experience in SEC reporting, Sarbanes Oxley compliance, transaction support and risk management, having held multiple health industries positions within PricewaterhouseCoopers (1996-2009). Ms. Duvall has a Master of Science in Accounting and Master of Business Administration from Northeastern University and a Bachelor of Arts from Colby College.

In connection with Ms. Duvall’s appointment, the Company entered into a letter agreement (the “Agreement”) with Ms. Duvall governing the terms of Ms. Duvall’s employment for an indefinite term. This Agreement became effective on March 5, 2019, the first day of Ms. Duvall’s employment with the Company. Under the Agreement, Ms. Duvall will receive an initial annual base salary of \$360,000 and is eligible for an annual bonus target of 40% of her base salary. In addition, pursuant to the terms of the Agreement and the Company’s Amended and Restated 2014 Equity Incentive Plan, the Company granted Ms. Duvall an award of stock options to purchase 475,000 shares of the Company’s common stock. The options have a term of ten years and will have an exercise price equal to the closing price of the Company’s common stock as reported by the NASDAQ Capital Market on March 5, 2019. The options are scheduled to vest as to 25% of the shares on the first anniversary of the date that Ms. Duvall’s appointment becomes effective (March 5, 2019) and, thereafter, in ratable monthly installments for 36 months. Vesting of the award is subject to Ms. Duvall’s continued service with the Company through the relevant date.

Upon execution and effectiveness of a release of claims, Ms. Duvall will be entitled to severance payments if the Company terminates her employment without cause or Ms. Duvall terminates her employment for good reason, each as defined in the Agreement.

In connection with the execution of the Agreement, Ms. Duvall has entered into a Confidential Information and Invention Assignment Agreement with the Company.

A press release announcing Ms. Duvall’s employment is filed as Exhibit 99.1 hereto.

The foregoing summary of the Agreement is qualified in its entirety by the copy of such agreement filed as Exhibit 10.1 and incorporated herein by this reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Genocea Biosciences, Inc. on February 28, 2019

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/ WILLIAM D. CLARK

William D. Clark

*President and Chief Executive Officer and Director
(Principal Executive Officer)*

Date: February 28, 2019



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Genocea Reports Fourth Quarter 2018 Results and Announces Hiring of
New Chief Financial Officer

Company advancing lead clinical-stage neoantigen cancer vaccine candidate and
expanding pipeline into adoptive cell therapy

Diantha Duvall to join as CFO, bringing broad life science financial leadership experience

Conference call today at 9:00 am ET

CAMBRIDGE, Mass., February 28, 2018 – [Genocea Biosciences, Inc.](#) (NASDAQ: GNCA), a biopharmaceutical company developing neoantigen cancer immunotherapies, today reported its operating and financial results for the fourth quarter and fiscal year ended December 31, 2018. The company also announced the appointment of a new Chief Financial Officer, Diantha Duvall, a seasoned life science industry professional. Ms. Duvall will join the company on March 5th.

"We are very pleased to welcome Diantha to Genocea," said Chip Clark, president & CEO of Genocea. "She joins us at a truly exciting time. With our recently completed equity financing and advancing pipeline, we look forward to an eventful 2019. We foresee important near-term milestones in two programs, each driven by our unique ATLAS™ neoantigen identification platform: first, our Phase 1/2a clinical program for our neoantigen cancer vaccine candidate, GEN-009, from which we expect to see the first immunogenicity data in mid-2019, and second, our GEN-011 program, a neoantigen adoptive T cell therapy, for which we plan to file an IND in the first half of 2020."

Ms. Duvall joins Genocea from Bioerativ, Inc., where she served as Vice President, Controller and Chief Accounting Officer since the company's spin out from Biogen, where she had served as U.S. and then Global Commercial Controller. Prior to Biogen, Ms. Duvall held a variety of financial and accounting positions at Merck and Co. and PricewaterhouseCoopers.

Recent Operational Highlights

- Strengthened senior management team, adding Thomas Davis, M.D., as Chief Medical Officer and Derek Meisner, J.D., as General Counsel in the Fall of 2018, Girish Aakalu, Ph.D. as Chief Business Officer in December 2018, and, as announced today, Diantha Duvall as CFO.
- Completed a private placement financing in mid-February, the first closing of which resulted in aggregate gross proceeds of \$15.0 million (before deducting fees to the placement agents and other expenses).
- Announced a major clinical milestone in early January, dosing the first patients and completing enrollment in Part A of its Phase 1/2a clinical trial for GEN-009. The first immunogenicity data from this study are expected in mid-2019.
- Presented additional ATLAS data at the Society for Immunotherapy of Cancer (SITC) meeting in November 2018. The posters further highlighted the advantages of Genocea's ATLAS platform over in silico methods in identifying both neoantigens for vaccine inclusion and "inhibitory" neoantigens for exclusion, and presented, for the first time, data in a mouse model providing evidence that these neoantigen-specific inhibitory responses could be tumor-promoting.

Fourth-Quarter 2018 Financial Results

- Cash position: As of December 31, 2018, cash and cash equivalents were \$26.4 million compared to \$12.3 million, as of December 31, 2017; this does not include approximately \$15.0 million in aggregate gross proceeds (before deducting fees to the placement agents and other expenses) from the company's recently closed private placement.
- Research and Development (R&D) expenses: R&D expenses were \$6.3 million for the quarter ended December 31, 2018, compared to \$7.9 million for the same period in 2017.
- General and Administrative (G&A) expenses: G&A expenses were \$2.6 million for the quarter ended December 31, 2018, compared to \$2.5 million for the same period in 2017.
- Net income/loss: Net income was \$0.4 million for the quarter ended December 31, 2018, compared to a net loss of \$1.7 million for quarter ended December 31, 2017.

Full-Year 2018 Financial Results

- Research and Development (R&D) expenses: R&D expenses were \$25.2 million for the year ended December 31, 2018, compared to \$39.2 million for the year ended December 31, 2017.
- General and Administrative (G&A) expenses: G&A expenses were \$14.3 million for the year ended December 31, 2018, compared to \$13.4 million for the year ended December 31, 2017.
- Net loss: Net loss was \$27.8 million for the year ended December 31, 2018, compared to a net loss of \$56.7 million for year ended December 31, 2017.

Guidance

Genocea expects that its existing cash and cash equivalents are sufficient to support its operations into the first quarter of 2020.

Genocea continues to explore strategic alternatives for GEN-003, its Phase 3-ready investigational immunotherapy for the treatment of genital herpes.

Genocea's Board of Directors has adopted a resolution approving and recommending that stockholders support a proposal in the company's upcoming proxy statement to effect a reverse stock split of the company's issued and outstanding common stock, if necessary, to maintain the company's NASDAQ Capital Market listing.

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 (domestic) or (315) 625-6883 (international) and referring to conference ID number 6953999. 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 90 days.

About Genocea Biosciences, Inc.

Genocea's mission is to help conquer cancer by designing and delivering targeted cancer vaccines and immunotherapies. While traditional immunotherapy discovery methods have largely used predictive methods to propose T cell targets, or antigens, Genocea has developed ATLAS™, its proprietary technology platform, to identify clinically relevant antigens of T cells based on individual patient immune responses. Genocea's lead neoantigen vaccine candidate, GEN-009, is currently being evaluated in a Phase 1/2a clinical trial. Genocea is also developing GEN-011, an investigational adoptive T cell therapy. For more information, please visit www.genocea.com.

Forward-Looking Statements

This press release includes forward-looking statements, including statements relating to the near-term milestones for GEN-009 and GEN-011, expected increased investments in the Genocea's clinical pipeline, and the period for which existing cash will be able to fund operations, 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, 2017 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, 2018	December 31, 2017
Cash, cash equivalents and investments	\$ 26,361	\$ 12,273
Other assets	4,754	5,215
Total assets	<u>\$ 31,115</u>	<u>\$ 17,488</u>
Debt, current and long-term	\$ 14,822	\$ 14,311
Accounts payable	1,659	3,516
Accrued expenses and other liabilities	3,827	5,711
Total liabilities	<u>23,780</u>	<u>23,538</u>
Stockholders' equity (deficit)	<u>7,335</u>	<u>(6,050)</u>
Total liabilities and stockholders' equity	<u>\$ 31,115</u>	<u>\$ 17,488</u>

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

	Three months ended December 31,		Twelve months ended December 31,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	6,259	7,880	25,209	39,204
General and administrative	2,627	2,478	14,309	13,433
Restructuring costs	—	27	—	2,618
Total operating expenses	<u>8,886</u>	<u>10,385</u>	<u>39,518</u>	<u>55,255</u>
Loss from operations	(8,886)	(10,385)	(39,518)	(55,255)
Other income (expense):				
Change in fair value of warrants	11,664	—	14,757	—
Interest expense, net	(313)	(347)	(1,021)	(1,441)
Other expense	(2,115)	—	(2,029)	(14)
Total other income (expense)	<u>9,236</u>	<u>(347)</u>	<u>11,707</u>	<u>(1,455)</u>
Net income (loss)	<u>\$ 350</u>	<u>\$ (10,732)</u>	<u>\$ (27,811)</u>	<u>\$ (56,710)</u>
Net loss per share - basic and diluted	<u>\$ 0.00</u>	<u>\$ (0.37)</u>	<u>\$ (0.34)</u>	<u>\$ (1.98)</u>
Weighted-average number of common shares used in computing net loss per share - basic and diluted	<u>86,771</u>	<u>28,705</u>	<u>82,561</u>	<u>28,603</u>

