

**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 27, 2018

MACROGENICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36112
(Commission
File Number)

06-1591613
(IRS Employer
Identification No.)

**9704 Medical Center Drive,
Rockville, Maryland**
(Address of Principal Executive Offices)

20850
(Zip Code)

Registrant's telephone number, including area code: **(301) 251-5172**

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 (see General Instruction A.2. below):

- 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 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 27, 2018, the Company announced financial and operating results as of and for the year ended December 31, 2017. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information provided under this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	Press Release dated February 27, 2018

SIGNATURE

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.

Date: February 27, 2018

MACROGENICS, INC.

By: /s/ Jeffrey Peters
Jeffrey Peters
Vice President and General Counsel

MacroGenics Provides Update on Corporate Progress and 2017 Financial Results

ROCKVILLE, MD, February 27, 2018 – MacroGenics, Inc. (NASDAQ: MGNX), a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, today provided a corporate progress update and reported financial results for the year ended December 31, 2017.

“We have had multiple advances in our portfolio of product candidates recently,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “In addition to margetuximab passing an interim futility analysis for the SOPHIA Phase 3 metastatic breast cancer study, a combination of margetuximab with an anti-PD-1 agent has shown encouraging activity in the treatment of gastric cancer patients in a Phase 2 study. Furthermore, we continue to enroll relapsed/refractory acute myeloid leukemia (AML) patients in the flotetuzumab dose expansion study following the promising results that were presented at recent medical conferences. As we continue to advance these and our other candidates, we look forward to presenting additional data in 2018 and defining future development strategies across our portfolio.”

Key Pipeline Updates

Margetuximab. Recent highlights related to the Company’s Fc-optimized monoclonal antibody that targets the human epidermal growth factor receptor 2, or HER2, include:

- **Phase 3 Metastatic Breast Cancer Study.** The pivotal SOPHIA study is evaluating the efficacy of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in approximately 530 relapsed/refractory HER2-positive metastatic breast cancer patients. In January 2018, the Company announced the completion of a pre-planned interim futility analysis with the recommendation of an independent data safety monitoring committee to continue SOPHIA as planned without modification. This analysis was based on a pre-specified assessment of progression-free survival as determined by independent central review. The Company also announced that the U.S. FDA had granted Fast Track designation for the investigation of margetuximab for treatment of patients with metastatic or locally advanced HER2 positive breast cancer who have previously been treated with anti-HER2-targeted therapy. MacroGenics remains on track to complete enrollment of the study by the end of 2018.
- **Phase 2 Gastric Cancer Study.** In January 2018, MacroGenics presented interim clinical data from a Phase 2 study of margetuximab plus an anti-PD-1 agent in patients with gastric and gastroesophageal junction (GEJ) cancer. These results included encouraging tolerability, a 32% objective response rate and median progression-free survival of 5.5 months in a subpopulation of 25 patients with gastric cancer. Based on these results, MacroGenics is expanding the study by enrolling 25 additional gastric cancer patients and will continue to evaluate biomarkers to determine the patients who are most likely to benefit from margetuximab plus anti-PD-1 therapy.

Flotetuzumab. Recent highlights of the Company’s bispecific, humanized DART molecule that recognizes both CD123 and CD3, include:

- **Monotherapy Study.** Updated data from an ongoing dose expansion study of flotetuzumab in patients with AML and myelodysplastic syndrome (MDS) were presented at the Annual American Society of Hematology (ASH) Meeting in December 2017. Consistent with previously disclosed

earlier dose escalation data, flotetuzumab demonstrated acceptable tolerability as well as evidence of anti-leukemic activity. MacroGenics continues to enroll the AML and MDS dose-expansion cohorts and anticipates presenting updated clinical data in 2018. The Company's collaborator, Servier, has development and commercialization rights outside North America, Japan, Korea and India for flotetuzumab, also known as S80880.

- **Planned Combination Study with anti-PD-1.** At the Annual ASH Meeting in December 2017, MacroGenics presented data supporting the rationale for using checkpoint blockade as an approach to potentially enhance the anti-leukemic activity of flotetuzumab. MacroGenics intends to initiate a combination study with MGA012, an anti-PD-1 monoclonal antibody (mAb), by mid-2018.

Other Pipeline Assets Update

Additional programs that the Company is advancing include the following:

PD-1-Directed Immuno-Oncology Franchise. MacroGenics is advancing multiple PD-1-directed programs to enable both a broad set of combination opportunities across the Company's portfolio and provide further differentiation from existing PD-1-based treatment options. These programs include:

- **MGA012.** MGA012 is a humanized, proprietary anti-PD-1 monoclonal antibody being developed for use as monotherapy as well as in combination with other potential cancer therapeutics. MGA012 was licensed to Incyte Corporation in 2017 under a global collaboration and license agreement. Patients are being enrolled across multiple dose expansion cohorts in a Phase 1 study.
- **MGD013.** MacroGenics designed a DART molecule, MGD013, to provide co-blockade of two immune checkpoint molecules expressed on T cells, PD-1 and LAG-3, for the potential treatment of a range of solid tumors and hematological malignancies. MGD013 is currently being evaluated in a Phase 1 dose escalation study. MacroGenics expects to establish the dose and schedule for MGD013 administration as well as initiate dose expansion cohorts in 2018.
- **MGD019.** This DART molecule is designed to provide co-blockade of both PD-1 and CTLA-4 on T cells. The Company is completing Investigational New Drug (IND)-enabling studies and anticipates submitting the IND application for MGD019 in 2018.

B7-H3 Franchise. MacroGenics is developing a portfolio of therapeutics that target B7-H3, a member of the B7 family of molecules involved in immune regulation. The Company is advancing multiple programs that target B7-H3 through complementary mechanisms of action that take advantage of this antigen's broad expression across multiple solid tumor types. These molecules include:

- **Enoblituzumab:** The Company continues to recruit patients with various solid tumors in an ongoing study of this Fc-optimized monoclonal antibody that targets B7-H3, in combination with an anti-PD-1 mAb. The Company expects to present clinical data from this study in 2018.
- **MGD009:** This DART molecule targeting B7-H3 and CD3 is being evaluated in a Phase 1 study across multiple solid tumor types. The Company expects to establish the dose and schedule for MGD009 administration as well as initiate monotherapy dose expansion cohorts in 2018. In addition, a combination study of MGD009 and MGA012 was recently initiated.
- **MGC018:** The Company is completing IND-enabling activities to support submission of an IND application for this anti-B7-H3 antibody drug conjugate (ADC) in 2018.

Additional DART Clinical Programs. Additional DART molecules in Phase 1 clinical development being led by MacroGenics include the following:

- **MGD007.** The Company is completing a monotherapy study of MGD007, a DART molecule that recognizes gpA33 and CD3, and anticipates commencing a combination study with MGA012 in 2018.
- **MGD014.** MacroGenics' first DART molecule designed to target an infectious agent, MGD014 recognizes the envelope protein of HIV-infected cells (Env) and the T cells' CD3 component, to redirect the immune system's T cells to kill HIV-infected cells. The Company expects to commence the Phase 1 study in 2018.

Corporate Update

- **Incyte Collaboration.** In October 2017, MacroGenics announced that it had entered into a global collaboration and license agreement with Incyte. The Company received an upfront payment of \$150 million upon closing in December 2017 and is eligible to receive milestones and royalties on any future sales of MGA012. MacroGenics retains the right to develop its own pipeline assets in combination with MGA012, with Incyte commercializing MGA012 and MacroGenics commercializing its combinatorial asset(s), if any such potential combinations are approved. In addition, MacroGenics retains the right to manufacture a portion of both companies' global clinical and commercial supply needs of MGA012.
- **Roche Collaboration.** In January 2018, MacroGenics announced that it had entered into a research collaboration and license agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. ("Roche") to jointly discover and develop novel bispecific molecules to undisclosed targets. MacroGenics received an upfront payment of \$10 million from Roche in January 2018 and is eligible to receive potential milestone payments and royalties on future sales.
- **GMP Manufacturing Suite Build-out:** The Company began the expansion of its manufacturing capacity in early 2017 by commencing the build-out of a GMP suite in its headquarters building in Rockville, Maryland to support larger-scale clinical and commercial manufacturing. MacroGenics expects this manufacturing suite to be fully operational in 2018.
- **Dr. Jay Siegel Added to Board.** In November 2017, MacroGenics announced the appointment of Jay Siegel, M.D., former Chief Biotechnology Officer and Head of Scientific Strategy and Policy at Johnson & Johnson, to its Board of Directors.

2017 Financial Results and Cash Runway Guidance

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2017, were \$305.1 million, compared to \$285.0 million as of December 31, 2016.
- **Revenue:** Total revenue, consisting primarily of revenue from collaborative agreements, was \$157.7 million for the year ended December 31, 2017, compared to \$91.9 million for the year ended December 31, 2016. Revenue from collaborative agreements includes the recognition of deferred revenue from payments received in previous periods as well as payments received during the year.

- **R&D Expenses:** Research and development expenses were \$147.2 million for the year ended December 31, 2017, compared to \$122.1 million for the year ended December 31, 2016. This increase was primarily due to continued or expanded enrollment across multiple clinical trials as well as IND-enabling activities related to two preclinical product candidates.
- **G&A Expenses:** General and administrative expenses were \$32.7 million for the year ended December 31, 2017, compared to \$29.8 million for the year ended December 31, 2016. This increase was primarily due to labor-related costs, including stock-based compensation expense, and information technology-related expenses, partially offset by lower patent expenses.
- **Net Loss:** Net loss was \$19.6 million for the year ended December 31, 2017, compared to net loss of \$58.5 million for the year ended December 31, 2016.
- **Shares Outstanding:** Shares outstanding as of December 31, 2017 were 36,859,077.
- **Cash Runway Guidance:** MacroGenics expects that its current cash, cash equivalents and marketable securities, combined with anticipated funding under its current strategic collaborations, should fund the Company's operations for approximately two years.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (EST) to discuss the 2017 financial results and provide a corporate update. To participate in the conference call, please dial (877) 303-6253 (domestic) or (973) 409-9610 (international) five minutes prior to the start of the call and provide the Conference ID: 6481429.

The recorded, listen-only webcast of the conference call can be accessed under "Events & Presentations" in the Investor Relations section of the Company's website at <http://ir.macrogenics.com/events.cfm>. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company's website for 30 days following the call.

MACROGENICS, INC.
SELECTED CONSOLIDATED BALANCE SHEET DATA

(Amounts in thousands)

	As of December 31,	
	2017	2016
Cash, cash equivalents and marketable securities	\$ 305,121	\$ 284,982
Total assets	373,883	311,263
Deferred revenue	20,839	14,306
Total stockholders' equity	299,238	268,751

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Amounts in thousands, except share and per share data)

	Year Ended December 31,		
	2017	2016	2015
Revenues:			
Revenue from collaborative agreements	\$ 155,516	\$ 86,582	\$ 99,368
Revenue from government agreements	2,226	5,298	1,486
Total revenues	157,742	91,880	100,854
Costs and expenses:			
Research and development	147,232	122,091	98,271
General and administrative	32,653	29,831	22,765
Total costs and expenses	179,885	151,922	121,036
Loss from operations	(22,143)	(60,042)	(20,182)
Other income	2,517	1,514	42
Net loss	(19,626)	(58,528)	(20,140)
Other comprehensive loss:			
Unrealized loss on investments	(21)	(77)	(5)
Comprehensive loss	\$ (19,647)	\$ (58,605)	\$ (20,145)
Basic and diluted net loss per common share	\$ (0.54)	\$ (1.69)	\$ (0.63)
Basic and diluted weighted average number of common shares	36,095,080	34,685,274	31,801,645

About MacroGenics, Inc.

MacroGenics is a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer. The Company generates its pipeline of product candidates primarily from its proprietary suite of next-generation antibody-based technology platforms, which have applicability across broad therapeutic domains. The combination of MacroGenics' technology platforms and protein engineering expertise has allowed the Company to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. For more information, please see the Company's website at www.macrogenics.com. MacroGenics, the MacroGenics logo and DART are trademarks or registered trademarks of MacroGenics, Inc.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development of the Company's therapeutic candidates, milestone or opt-in payments from the Company's collaborators, the Company's anticipated milestones and future expectations and plans and prospects for the Company and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions, or by discussions of strategy constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and enrollment of future clinical trials, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company's product candidates and other risks described in the Company's filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, except as may be required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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