

**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, 2017

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))

Item 2.02 Results of Operations and Financial Condition

On February 28, 2017, the Company announced financial and operating results as of and for the year ended December 31, 2016. 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.

99.1 Press Release issued by the Company on February 28, 2017

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 28, 2017

MACROGENICS, INC.

By: /s/ Atul Saran
Atul Saran
Senior Vice President and General Counsel

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	Press Release dated February 28, 2017

MacroGenics Provides Update on Corporate Progress and 2016 Financial Results

ROCKVILLE, MD, February 28, 2017 – MacroGenics, Inc. (NASDAQ: MGNX), a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, as well as autoimmune disorders and infectious diseases, today provided a corporate progress update and reported financial results for the year ended December 31, 2016.

“MacroGenics continues to advance its broad pipeline of clinical compounds, including those in our HER2, B7-H3 and PD-1 franchises as well as the many bispecific product candidates based on our DART® platform,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “Across our portfolio of proprietary antibody and DART-based oncology programs, we now have initial evidence of on-target engagement, manageable safety and anti-tumor activity. In addition, I am very encouraged by the biological activity observed in subjects treated with MacroGenics’ autoimmune DART molecule, MGD010. We will continue to advance our robust pipeline in 2017, including defining future development strategies for multiple programs based on data expected later this year.”

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. MacroGenics continues to expect to complete enrollment of this study by late 2018. In addition, in consultation with the U.S. Food and Drug Administration (FDA) and the Committee for Medicinal Products for Human Use of the European Medicines Agency, the patient population eligible for participation in SOPHIA has been further expanded to include ado-trastuzumab emtansine-naïve patients.
- **Phase 2 Gastric Cancer Study.** The Company continues to enroll advanced HER2-positive gastric and gastroesophageal junction cancer patients in its combination study of margetuximab with an anti-PD-1 antibody. Preliminary data from the dose escalation portion of the study, including patients with objective response following progression on previous lines of treatment with trastuzumab and chemotherapy, was presented at the Company’s R&D Day in December 2016. MacroGenics expects to complete enrollment of this study in 2017.

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 in multiple ongoing studies of enoblituzumab, an Fc-optimized monoclonal antibody that targets B7-H3. These studies include one monotherapy study expanded to include additional bladder and prostate cancer cohorts and two combination studies with either an anti-CTLA-4 mAb (ipilimumab) or anti-PD-1 mAb (pembrolizumab). In addition, two monotherapy Phase 1 studies were recently initiated: a study for children with various solid tumors, including neuroblastoma, and an investigator-sponsored study in men with localized intermediate and high-risk prostate cancer in the neoadjuvant setting.

- **MGD009:** This DART molecule targeting B7-H3 and CD3 is being evaluated in a Phase 1 study across multiple solid tumor types. Adverse events have been manageable to date and initial signs of antitumor activity have been observed, as previously disclosed at the Company's R&D Day in December 2016. The Company expects to establish the dose and schedule for MGD009 administration as well as initiate dose expansion cohorts in 2017.
- **MGC018:** The Company is conducting Investigational New Drug (IND)-enabling activities to support an IND application for this anti-B7-H3 antibody drug conjugate (ADC) in 2018. The Company will feature a poster presentation on MGC018 at the upcoming American Association for Cancer Research (AACR) Annual Meeting in April.

PD-1-Directed Immuno-Oncology Franchise. MacroGenics is advancing several PD-1-directed programs, which will enable both a broad set of combination opportunities across the Company's portfolio and provide further differentiation from existing PD-1-based treatment options. The first of these are:

- **MGA012.** The Company's Phase 1 clinical study of its proprietary anti-PD-1 monoclonal antibody was initiated in November 2016. With anti-PD-1 therapy becoming a mainstay of cancer treatment across multiple tumor types, MacroGenics believes MGA012 will be the basis for combination therapy with several of the molecules in its pipeline.
- **MGD013.** MacroGenics is developing the 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 malignancies. The Company has completed IND-enabling studies and plans to submit an IND for MGD013 in the first half of 2017.

Additional DART Clinical Programs. Additional DART molecules in Phase 1 clinical development include flotetuzumab (CD123 x CD3, also known as MGD006 and S80880); MGD007 (gpA33 x CD3); MGD010 (CD32B x CD79B); duvortuxizumab (CD19 x CD3, also known as MGD011), which is being developed by Janssen; and PF-06671008 (P-cadherin x CD3), which is being developed by Pfizer. At its R&D Day in December 2016, MacroGenics provided an in-depth update on its portfolio of proprietary, clinical DART programs. The Company highlighted the promising features of these DART molecules, including on-target engagement, manageable safety as well as preliminary evidence of biological activity. Updates on three of these programs for which MacroGenics leads development include:

- **Flotetuzumab.** MacroGenics continues to recruit patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) in the U.S. and Europe in the Phase 1 study of flotetuzumab. The Company expects to establish the dose and schedule as well as initiate dose expansion cohorts for this study in 2017. In late 2016, the FDA granted orphan drug designation to flotetuzumab for the treatment of AML.
- **MGD007.** MacroGenics continues to recruit patients with colorectal cancer in the Phase 1 study of MGD007. The Company expects to establish the dose and schedule for this study in 2017.
- **MGD010.** During the fourth quarter of 2016, MacroGenics completed the Phase 1 study of MGD010 in healthy subjects. This DART molecule is being developed for the potential treatment of autoimmune disorders. The Company plans to report updated clinical pharmacodynamic activity results from this study in 2017.

Corporate Update

- **New Board Members:** In January 2017, MacroGenics announced the expansion of its Board of Directors from six to eight members and the appointments of Karen J. Ferrante, M.D., and Scott Jackson to fill the newly

created vacancies. Dr. Ferrante, a hematologist-oncologist, most recently served as Chief Medical Officer and Head of Research and Development at Tokai Pharmaceuticals. Mr. Jackson served as Chief Executive Officer and as a member of the Board of Directors of Celator Pharmaceuticals, Inc. until its acquisition in July 2016.

- **Commenced Build-out of GMP Manufacturing Suite:** In January 2017, the Company began the expansion of its manufacturing capacity by commencing the construction of a GMP suite in its headquarters building in Rockville, MD to support larger-scale clinical and commercial manufacturing.

2016 Financial Results and Cash Runway Guidance

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2016, were \$285.0 million, compared to \$339.0 million as of December 31, 2015.
- **Revenue:** Total revenue, consisting primarily of revenue from collaborative agreements, was \$91.9 million for the year ended December 31, 2016, compared to \$100.9 million for the year ended December 31, 2015. 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 \$122.1 million for the year ended December 31, 2016, compared to \$98.3 million for the year ended December 31, 2015. This increase was due primarily to increased activity in the Company's preclinical immune checkpoint programs, including MGD013 and MGA012, MGD014 (funded by NIAID/NIH) and the initiation of two Phase 1 clinical trials combining enoblituzumab with other compounds. These increases were partially offset by decreased manufacturing costs for margetuximab.
- **G&A Expenses:** General and administrative expenses were \$29.8 million for the year ended December 31, 2016, compared to \$22.8 million for the year ended December 31, 2015. This increase was primarily due to increased staff, recruiting costs and stock-based (non-cash) compensation expense and patent expense.
- **Net Loss:** Net loss was \$58.5 million for the year ended December 31, 2016, compared to net loss of \$20.1 million for the year ended December 31, 2015.
- **Shares Outstanding:** Shares outstanding as of December 31, 2016 were 34,870,607.
- **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 through late 2018.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (EDT) to discuss the 2016 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: 58247768.

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,	
	2016	2015
Cash, cash equivalents and marketable securities	\$ 284,982	\$ 339,049
Total assets	311,263	359,269
Deferred revenue	14,306	18,497
Total stockholders' equity	268,751	313,337

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

	Year Ended December 31,		
	2016	2015	2014
Revenues:			
Revenue from collaborative agreements	\$ 86,582	\$ 99,368	\$ 47,264
Revenue from government agreements	5,298	1,486	533
Total revenues	91,880	100,854	47,797
Costs and expenses:			
Research and development	122,091	98,271	70,186
General and administrative	29,831	22,765	15,926
Total costs and expenses	151,922	121,036	86,112
Loss from operations	(60,042)	(20,182)	(38,315)
Other income	1,514	42	2
Net loss	(58,528)	(20,140)	(38,313)
Other comprehensive loss:			
Unrealized loss on investments	(77)	(5)	—
Comprehensive loss	\$ (58,605)	\$ (20,145)	\$ (38,313)
Basic and diluted net loss per common share	\$ (1.69)	\$ (0.63)	\$ (1.40)
Basic and diluted weighted average number of common shares	34,685,274	31,801,645	27,384,990

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, as well as autoimmune disorders and infectious diseases. The Company generates its pipeline of product candidates primarily from its proprietary suite of next-generation antibody-based technology platforms. 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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