

MACROGENICS INC

FORM 8-K (Current report filing)

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Address	9704 MEDICAL CENTER DRIVE Rockville, MD 20850
Telephone	301-251-5172
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Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): May 3, 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))

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 May 3, 2017, the Company announced financial and operating results as of and for the quarter ended March 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.

99.1 Press Release issued by the Company on May 3, 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: May 3, 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 May 3, 2017

MacroGenics Provides Update on Corporate Progress and 1st Quarter 2017 Financial Results

ROCKVILLE, MD, May 3, 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 quarter ended March 31, 2017.

“MacroGenics’ broad pipeline of clinical compounds continues to make encouraging progress. In addition to advancing our HER2 and B7-H3-based franchises, our PD-1-targeted franchise has matured with the submission of an IND related to MGD013, the first of our next-generation PD-1-based bispecific molecules with the potential for enhanced anti-tumor activity. By targeting the two different checkpoint molecules, PD-1 and LAG-3, MGD013 has demonstrated enhanced T-cell response in vitro versus what has been observed with targeting PD-1 or LAG-3 alone or in combination,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “I look forward to sharing updates on our other clinical programs and further defining our future development strategies over the course of the year.”

Key Pipeline Highlights

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 remains on track for completing enrollment of this study by late 2018.
- **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. 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 a monotherapy study expanded to include additional bladder and prostate cancer cohorts and a combination study with an anti-PD-1 antibody.
- **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 expansion cohorts in multiple tumor types in 2017.
- **MGC018** : The Company is conducting activities to support an Investigational New Drug (IND) application for this anti-B7-H3 antibody drug conjugate in 2018. The Company’s poster on MGC018 at the recent American Association for Cancer Research (AACR) Annual Meeting showed that this molecule had potent in vivo antitumor activity.

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 proprietary anti-PD-1 monoclonal antibody is enrolling patients in the dose escalation segment of its Phase 1 clinical study and expects to define a target dose and schedule in 2017. With anti-PD-1 therapy becoming a mainstay of cancer treatment across multiple tumor types, MacroGenics believes MGA012 will be the basis for potential combination therapy with several of the molecules in its pipeline.
- **MGD013**. MacroGenics is developing MGD013, a DART molecule, 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 recently submitted an IND for MGD013.
- **PD-1 x CTLA-4** . At the recent AACR meeting, MacroGenics featured a poster showing preclinical bispecific DART and trispecific TRIDENT™ molecules that bind to and inhibit ligand interaction with PD-1 and CTLA-4, resulting in enhanced T-cell activation. Combinatorial blockade of PD-1 and CTLA-4 has shown improved anti-tumor activity in the clinic. By targeting these clinically validated checkpoint molecules simultaneously, MacroGenics' DART and TRIDENT proteins hold the promise of enhanced anti-tumor activity.

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); duvortuzumab (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. Updates on three of these programs for which MacroGenics leads development include:

- **Flotetuzumab.** MacroGenics continues to recruit patients with acute myeloid leukemia or myelodysplastic syndrome in the U.S. and Europe in the Phase 1 study of flotetuzumab. The Company expects to establish a recommended dose and schedule as well as initiate expansion cohorts for this study in 2017.
- **MGD007.** MacroGenics continues to recruit patients with colorectal cancer in a Phase 1 study. The Company expects to establish a recommended dose and schedule for MGD007 in 2017.
- **MGD010.** MacroGenics expects to present updated pharmacodynamic activity results from the completed Phase 1 study of MGD010 in June.

First Quarter 2017 Financial Results

- **Cash Position** : Cash, cash equivalents and marketable securities as of March 31, 2017, were \$248.1 million, compared to \$285.0 million as of December 31, 2016. On May 2, 2017, the Company completed the sale of 1,100,000 shares of its common stock at a purchase price of \$21.50 per share to an institutional healthcare investor in a registered direct offering. Gross proceeds to the Company, before deducting estimated offering expenses, were \$23.7 million.
 - **Revenue** : Total revenue, consisting primarily of revenue from collaborative agreements, was \$2.1 million for the quarter ended March 31, 2017, compared to \$2.8 million for the quarter ended March 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 period.
 - **R&D Expenses** : Research and development expenses were \$32.8 million for the quarter ended March 31, 2017, compared to \$27.3 million for the quarter ended March 31, 2016. This increase was primarily due to the initiation of a Phase 1 clinical trial of MGA012 in late 2016, continued enrollment in the margetuximab SOPHIA study and increased activity in the Company's other preclinical and clinical programs. These increases were partially offset by a decrease in duvortuzumab manufacturing costs, which are reimbursed by our collaborator.
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- **G&A Expenses** : General and administrative expenses were \$7.5 million for the quarter ended March 31, 2017, compared to \$6.1 million for the quarter ended March 31, 2016. This increase was primarily due to increased professional fees, including consulting expenses, and increased employee compensation and benefit expense to support our overall growth.
- **Net Loss** : Net loss was \$37.7 million for the quarter ended March 31, 2017, compared to net loss of \$30.4 million for the quarter ended March 31, 2016.
- **Shares Outstanding** : Shares outstanding as of March 31, 2017 were 34,980,433.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (EDT) to discuss financial results for the quarter ended March 31, 2017 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: 9279413.

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)

	March 31, 2017	December 31, 2016
Cash, cash equivalents and marketable securities	\$ 248,081	\$ 284,982
Total assets	274,721	311,263
Deferred revenue	13,250	14,306
Total stockholders' equity	234,638	268,751

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

	Three Months Ended March 31,	
	2017	2016
Revenues:		
Revenue from collaborative agreements	\$ 1,278	\$ 1,893
Revenue from government agreements	777	953
Total revenues	2,055	2,846
Costs and expenses:		
Research and development	32,801	27,346
General and administrative	7,462	6,133
Total costs and expenses	40,263	33,479
Loss from operations	(38,208)	(30,633)
Other income	553	270
Net loss	(37,655)	(30,363)
Other comprehensive income (loss):		
Unrealized gain (loss) on investments	(26)	57
Comprehensive loss	\$ (37,681)	\$ (30,306)
Basic and diluted net loss per common share	\$ (1.08)	(\$0.88)
Basic and diluted weighted average number of common shares	34,958,228	34,503,845

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, DART and TRIDENT 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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