

**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): August 7, 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 August 7, 2018, the Company announced financial and operating results as of and for the quarter ended June 30, 2018. 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 August 7, 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: August 7, 2018

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress and 2nd Quarter 2018 Financial Results

ROCKVILLE, MD, August 7, 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 quarter ended June 30, 2018.

“MacroGenics continues to advance its portfolio of oncology product candidates toward multiple data read-outs,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “We expect to complete enrollment of the SOPHIA Phase 3 metastatic breast cancer study of margetuximab in the next few months and be able to disclose top-line results in the first quarter of 2019. Also in early 2019, we expect to provide an update on the combination study of margetuximab with an anti-PD-1 agent in the treatment of gastric cancer patients in a Phase 2 study. In addition, we will provide updates later this year on both the enoblituzumab plus anti-PD-1 combination study, as well as the flotetuzumab monotherapy dose expansion study in patients with relapsed/refractory acute myeloid leukemia (AML). Finally, we recently submitted an investigational new drug (IND) application for our first antibody-drug conjugate - MGC018, an anti-B7-H3 ADC - and anticipate submitting an IND for MGD019 (PD-1 x CTLA-4 DART® molecule) by year-end.”

Key Pipeline Updates

Margetuximab. Recent highlights related to the Company’s Fc-optimized monoclonal antibody (mAb) 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 to complete enrollment of the study in the next few months, with anticipated disclosure of topline PFS data in the first quarter of 2019.
- **Phase 2 Gastric Cancer Study.** At the 2018 ASCO Annual Meeting in June, MacroGenics presented updated interim clinical data from a Phase 2 study of margetuximab plus an anti-PD-1 agent in patients with HER2-positive gastroesophageal adenocarcinoma. This chemotherapy-free combination, designed to coordinately engage innate and adaptive immunity, demonstrated that margetuximab plus an anti-PD-1 antibody may have enhanced antitumor activity in patients with advanced gastric cancer. The Company expects to complete enrollment of 25 additional gastric cancer patients in the next few months and present data in the first quarter of 2019.

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

- **Monotherapy Study.** MacroGenics has completed the enrollment of its AML dose expansion cohort and plans to present updated clinical data and disclose further development plans in late 2018. The Company’s collaborator, Servier, has development and commercialization rights outside North America, Japan, Korea and India for flotetuzumab, also known as S80880.
 - **Combination Study with MGA012.** MacroGenics has previously presented data supporting the rationale for using checkpoint blockade as an approach to potentially enhance the anti-leukemic activity of flotetuzumab. MacroGenics intends to commence enrollment of a combination study
-

with MGA012, an anti-PD-1 mAb also known as INCMGA0012, later this year.

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.** This humanized, proprietary anti-PD-1 mAb is 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. MacroGenics retains the rights to develop MGA012 in combination with its pipeline assets, and has already initiated clinical combination studies with two separate DART molecules. In June 2018, Incyte announced its intention to pursue monotherapy development of MGA012 in MSI-high endometrial cancer, Merkel cell carcinoma and anal cancer through registration-directed studies, with data anticipated in 2020-2021.
- **MGD013.** This first-in-class DART molecule provides 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 study. MacroGenics expects to establish the dose and schedule for MGD013 administration as well as initiate dose expansion cohorts by year end 2018.
- **MGD019.** This DART molecule is designed to provide co-blockade of both PD-1 and CTLA-4 on T cells. The Company anticipates submitting the IND application for MGD019 by year end 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 completed the recruitment of patients in an ongoing study of this Fc-optimized mAb that targets B7-H3, in combination with an anti-PD-1 mAb and expects to present clinical data from this study as well as disclose further development plans in the fourth quarter of 2018.
- **Orlotamab (formerly known as MGD009):** This DART molecule targeting B7-H3 and CD3 is being evaluated in a Phase 1 study. The Company recently established the dose and schedule for orlotamab administration and initiated monotherapy dose expansion cohorts in six different tumor types. In addition, a combination study of orlotamab and MGA012 was initiated in the first quarter of 2018 and is ongoing.
- **MGC018:** The Company has submitted an IND for this anti-B7-H3 ADC and anticipates initiation of a Phase 1 study in the coming months. This first-in-man study is designed to study MGC018 both as monotherapy and in combination with MGA012 in patients with solid tumors.

Second Quarter 2018 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2018, were \$300.9 million, compared to \$305.1 million as of December 31, 2017.
-

- **Revenue:** Total revenue, consisting primarily of revenue from collaborative agreements, was \$18.8 million for the quarter ended June 30, 2018, compared to \$1.7 million for the quarter ended June 30, 2017. 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 \$52.0 million for the quarter ended June 30, 2018, compared to \$34.5 million for the quarter ended June 30, 2017. This increase was primarily due to the continued enrollment in the Company's two margetuximab studies, flotetuzumab study and increased headcount to support expanded manufacturing and development activities.
- **G&A Expenses:** General and administrative expenses were \$11.1 million for the quarter ended June 30, 2018, compared to \$8.4 million for the quarter ended June 30, 2017. This increase was primarily due to consulting and other costs incurred related to the implementation of the Company's new enterprise resource planning (ERP) system and increased patent expenses.
- **Net Loss:** Net loss was \$43.2 million for the quarter ended June 30, 2018, compared to net loss of \$40.7 million for the quarter ended June 30, 2017.
- **Shares Outstanding:** Shares outstanding as of June 30, 2018 were 42,229,011.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (ET) to discuss financial results for the quarter ended June 30, 2018 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: 9259899.

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)

	<u>June 30, 2018 (unaudited)</u>	<u>December 31, 2017</u>
Cash and cash equivalents	\$ 300,894	\$ 305,121
Total assets	386,891	373,883
Deferred revenue	23,947	20,839
Total stockholders' equity	312,036	299,238

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
Revenue from collaborative agreements	\$ 18,552	\$ 1,081	\$ 23,053	\$ 2,359
Revenue from government agreements	282	585	476	1,361
Total revenues	18,834	1,666	23,529	3,720
Costs and expenses:				
Research and development	52,014	34,461	97,684	67,262
General and administrative	11,134	8,384	20,369	15,846
Total costs and expenses	63,148	42,845	118,053	83,108
Loss from operations	(44,314)	(41,179)	(94,524)	(79,388)
Other income	1,070	525	1,744	1,078
Net loss	(43,244)	(40,654)	(92,780)	(78,310)
Other comprehensive loss:				
Unrealized gain (loss) on investments	40	25	79	(1)
Comprehensive loss	\$ (43,204)	\$ (40,629)	\$ (92,701)	\$ (78,311)
Basic and diluted net loss per common share				
	\$ (1.03)	\$ (1.14)	\$ (2.35)	\$ (2.21)
Basic and diluted weighted average common shares outstanding				
	42,153,813	35,784,804	39,559,599	35,373,799

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.

###

Contacts:

Jim Karrels, Senior Vice President, CFO

MacroGenics, Inc.

1-301-251-5172, info@macrogenics.com

Karen Sharma, Senior Vice President

MacDougall Biomedical Communications

1-781-235-3060, ksharma@macbiocom.com