# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

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# 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 7, 2018

# MACROGENICS, INC.

(Exact Name of Registrant as Specified in Charter)

| **Delaware** | **001-36112** | **06-1591613** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **9704 Medical Center Drive, Rockville, Maryland** | **20850** |
|---|---|
| (Address of Principal Executive Offices) | (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 7, 2018, the Company announced financial and operating results as of and for the quarter ended March 31, 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.**

| Exhibit Number | Description of Exhibit |
|---|---|
| 99.1 | Press Release dated May 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: May 7, 2018

MACROGENICS, INC.

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

**MacroGenics Provides Update on Corporate Progress and 1st Quarter 2018 Financial Results**

ROCKVILLE, MD, May 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 March 31, 2018.

"Our momentum continues to build in 2018, as our multiple product candidates advance toward data read-outs," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "During the first quarter, margetuximab passed an interim futility analysis for the SOPHIA Phase 3 metastatic breast cancer study. We also presented clinical data for the combination of margetuximab with an anti-PD-1 agent showing encouraging activity in the treatment of gastric cancer patients in a Phase 2 study. We plan to provide an update on this study, including presentation of biomarker data, at the upcoming ASCO meeting. During the second half of the year, we expect to provide clinical updates on both flotetuzumab in patients with relapsed/refractory acute myeloid leukemia (AML), and on the combination of enoblituzumab with an anti-PD-1 agent. In addition, we anticipate that two of our oncology product candidates will move into our clinical pipeline this year: MGD019 (PD-1 x CTLA-4 DART® molecule) and MGC018 (B7-H3 ADC), the planned investigational new drug (IND) application submissions for which are both on track."

## 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. 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 in the fourth quarter of 2018, with anticipated disclosure of topline progression-free survival data in the first half of 2019.

- **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 and anti-tumor activity in a subpopulation of 25 gastric cancer patients. Based on these results, MacroGenics expanded the study and is enrolling 25 additional gastric cancer patients. The Company will present updated clinical and biomarker data at the 2018 ASCO Annual Meeting in June.

**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. The Company anticipates presenting updated clinical data and defining a potential registration path during the second half of 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 an anti-PD-1**. 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 initiate a combination study with INCMGA0012, an anti-PD-1 mAb also known as MGA012, during the third quarter of 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:

- **INCMGA0012**. INCMGA0012 is a humanized, proprietary anti-PD-1 mAb being developed for use as monotherapy as well as in combination with other potential cancer therapeutics. INCMGA0012 was licensed to Incyte Corporation in 2017 under a global collaboration and license agreement. MacroGenics transferred the INCMGA0012 U.S. IND to Incyte during the first quarter of 2018.

- **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 the second half of 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 IND-enabling studies and anticipates submitting the IND application for MGD019 in the second half of 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 with four solid tumor types 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 in the second half of 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 the second half of 2018. In addition, a combination study of MGD009 and INCMGA0012 was initiated during the first quarter of 2018.

- **MGC018**: The Company is completing IND-enabling activities to support submission of an IND application for this anti-B7-H3 antibody drug conjugate (ADC) and anticipates initiation of a Phase 1 study in the second half of 2018.

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

- **MGD007.** The Company recently completed a monotherapy study of MGD007, a DART molecule that recognizes gpA33 and CD3, and anticipates commencing a combination study with INCMGA0012 in the second quarter of 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 during the second quarter of 2018.

**Corporate Update**

- **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 is expanding its manufacturing capacity by completing the build-out of a GMP suite in its headquarters building in Rockville, Maryland to support larger-scale clinical and commercial manufacturing. MacroGenics expects to commence GMP production runs in this facility in the third quarter of 2018.
- **Common Stock Financing**. On April 2, 2018, the Company closed its public offering of 5,175,000 shares of common stock. Net proceeds to MacroGenics, after deducting underwriting discounts and commissions and offering expenses, were $103 million.

**First Quarter 2018 Financial Results**

- **Cash Position**: Cash, cash equivalents and marketable securities as of March 31, 2018, were $260.1 million, compared to $305.1 million as of December 31, 2017.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $4.7 million for the quarter ended March 31, 2018, compared to $2.1 million for the quarter ended March 31, 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 $45.7 million for the quarter ended March 31, 2018, compared to $32.8 million for the quarter ended March 31, 2017. This increase was primarily due to the continued enrollment in the Company's two margetuximab studies and the INCMGA0012 monotherapy clinical trial.
- **G&A Expenses**: General and administrative expenses were $9.2 million for the quarter ended March 31, 2018, compared to $7.5 million for the quarter ended March 31, 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.

- **Net Loss**: Net loss was $49.5 million for the quarter ended March 31, 2018, compared to net loss of $37.7 million for the quarter ended March 31, 2017.
- **Shares Outstanding**: Shares outstanding as of March 31, 2018 were 37,024,623.

**Conference Call Information**

MacroGenics will host a conference call today at 4:30 pm (ET) to discuss financial results for the quarter ended March 31, 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: 1647389.

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, 2018 | December 31, 2017 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 260,081 | $ 305,121 |
| Total assets | 326,078 | 373,883 |
| Deferred revenue | 25,883 | 20,839 |
| Total stockholders' equity | 247,276 | 299,238 |

**MACROGENICS, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2018** | **2017** |
| Revenues: | | |
| Revenue from collaborative agreements | $ 4,501 | $ 1,278 |
| Revenue from government agreements | 194 | 777 |
| Total revenues | 4,695 | 2,055 |
| | | |
| Costs and expenses: | | |
| Research and development | 45,670 | 32,801 |
| General and administrative | 9,235 | 7,462 |
| Total costs and expenses | 54,905 | 40,263 |
| | | |
| Loss from operations | (50,210) | (38,208) |
| | | |
| Other income | 674 | 553 |
| Net loss | (49,536) | (37,655) |
| | | |
| Other comprehensive loss: | | |
| Unrealized gain (loss) on investments | 39 | (26) |
| Comprehensive loss | $ (49,497) | $ (37,681) |
| | | |
| Basic and diluted net loss per common share | ($1.34) | ($1.08) |
| Basic and diluted weighted average number of common shares | 36,936,560 | 34,958,228 |

**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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