

**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 5, 2020

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)

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|------------------------------------------|--------------------------|--------------------------------------------------|
| Common Stock, par value \$0.01 per share | MGNX | Nasdaq Global Select Market |

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 5, 2020, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended March 31, 2020. 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 5, 2020 |
| 104 | Cover Page Interactive Data (embedded within the Inline XBRL document) |

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 5, 2020

MACROGENICS, INC.

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



MacroGenics Provides Update on Corporate Progress and First Quarter 2020 Financial Results

– *Conference call scheduled for today at 4:30 p.m. ET.*

ROCKVILLE, MD., May 5, 2020 (GLOBE NEWSWIRE) -- 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 an update on its corporate progress and reported financial results for the quarter ended March 31, 2020.

“We are encouraged by the progress and clinical activity that we continue to observe across our broad portfolio of seven antibody-based product candidates, and we anticipate presenting clinical data from all these molecules this year. In the near-term, we look forward to sharing the initial data from our Phase 1 studies of MGD013 and MGC018 at ASCO and our plans for further development of these promising candidates,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “While we expect some near-term impact on clinical trial site initiation and patient enrollment due to the unprecedented challenges posed by the COVID-19 pandemic, we have not changed our guidance for the timing of anticipated 2020 clinical data read-outs or regulatory events.”

Recent and Anticipated Presentation of Clinical Data

- At the recent American Association for Cancer Research (AACR) Virtual Annual Meeting I held April 27-28, an academic collaborator presented data during a plenary session suggesting that TP53 mutational status in patients with acute myeloid leukemia (AML) correlated with an immune-infiltrated tumor microenvironment that was associated with response to flotetuzumab, an investigational, bispecific CD123 x CD3 DART® molecule.
- At the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting in May, MacroGenics plans to present the following clinical data:
 - An oral presentation covering dose escalation and select expansion cohorts from the ongoing Phase 1 study of MGD013, an investigational, bispecific PD-1 x LAG-3 DART molecule;
 - A poster presentation covering initial dose escalation data from the ongoing Phase 1/2 study of MGC018, an investigational antibody-drug conjugate targeting B7-H3; and
 - A poster presentation covering results stratified by chemotherapy from the Phase 3 SOPHIA study of chemotherapy plus margetuximab, an investigational, Fc-engineered, anti-HER2 monoclonal antibody, compared to chemotherapy plus trastuzumab in patients with HER2-positive metastatic breast cancer.

- MacroGenics also anticipates the presentation of the following clinical data in the second half of 2020:
 - Final overall survival (OS) analysis for the Phase 3 SOPHIA study of margetuximab;
 - Initial data from the Phase 2/3 MAHOGANY study of margetuximab plus checkpoint blockade in patients with advanced gastric cancer;
 - Data from the Phase 1 dose escalation study of MGD019, an investigational, bispecific, PD-1 x CTLA-4 DART molecule;
 - Additional data on flotetuzumab in AML patients who are refractory to induction treatment (primary induction failure); and
 - Incyte expects to present data from its study of retifanlimab (formerly known as MGA012 or INCMGA0012) in patients with anal cancer, which is now fully enrolled, and is one of three ongoing potentially registration-enabling monotherapy studies. Retifanlimab is an investigational anti-PD-1 monoclonal antibody invented by MacroGenics and licensed to Incyte.

Regulatory Interactions and Events

- MacroGenics anticipates a Prescription Drug User Fee Act (PDUFA) target action date in December 2020 for margetuximab in combination with chemotherapy as a treatment for patients with metastatic HER2-positive breast cancer. The Food and Drug Administration (FDA) has indicated its plan to schedule an Oncologic Drugs Advisory Committee (ODAC) meeting in the second half of 2020.
- MacroGenics will meet with the FDA this quarter to gain feedback on the planned registration path in the U.S. for flotetuzumab for the treatment of patients with AML who are refractory to induction treatment (primary induction failure).

Clinical Trial Updates and Status

- In consideration of current global and domestic COVID-19 pandemic, the planned Phase 2 study initiation of enoblituzumab will be delayed. Enoblituzumab is an investigational, Fc-engineered, anti-B7-H3 monoclonal antibody which is being studied in combination with checkpoint blockade for the treatment of patients with advanced head and neck cancer. The Company expects to provide updates on the timing for initiating the study in the second half of 2020.
- MacroGenics has stopped enrollment in an ex-U.S. Phase 1/2 study combining flotetuzumab with retifanlimab in patients with relapsed or refractory AML. The decision was not due to any safety finding or lack of activity, and the Company plans to resume the study in the U.S. in the future.
- MacroGenics continues to open clinical sites globally to enroll patients in the Phase 2/3 MAHOGANY study evaluating the combination of margetuximab and retifanlimab as a front-line treatment for advanced gastric and gastroesophageal junction cancer. Zai Lab, MacroGenics'

regional partner in Greater China, has stated that it expects sites in its territory to enroll patients starting in the second half of 2020.

- MacroGenics and Zai Lab, its regional partner in Greater China, are continuing to broadly explore the development of MGD013 across multiple indications. MGD013 is being studied both as a monotherapy and in combination with other pipeline assets. Zai Lab has initiated combination studies with niraparib, a PARP inhibitor, and brivanib, a dual target tyrosine kinase inhibitor of the VEGF and FGF receptors, for the study of advanced gastric cancer and hepatocellular carcinoma, respectively.

First Quarter 2020 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2020, were \$170.8 million, compared to \$215.8 million as of December 31, 2019.
- **Revenue:** Total revenue, consisting primarily of revenue from collaborative agreements, was \$13.7 million for the quarter ended March 31, 2020, compared to \$9.7 million for the quarter ended March 31, 2019. This increase was primarily due to revenue recognized for manufacturing services under the Clinical Supply Agreements with Incyte and Zai Lab, as well as milestone payments under the Zai Lab Agreement for clinical trial initiations in Greater China.
- **R&D Expenses:** Research and development expenses were \$48.9 million for the quarter ended March 31, 2020, compared to \$47.1 million for the quarter ended March 31, 2019. This increase was primarily due to an increase in development and clinical trial costs for multiple programs.
- **G&A Expenses:** General and administrative expenses were \$10.2 million for the quarter ended March 31, 2020, compared to \$10.2 million for the quarter ended March 31, 2019.
- **Net Loss:** Net loss was \$44.7 million for the quarter ended March 31, 2020, compared to net loss of \$45.0 million for the quarter ended March 31, 2019.
- **Shares Outstanding:** Shares outstanding as of March 31, 2020 were 49,131,150.
- **Cash Runway Guidance:** MacroGenics anticipates that its cash, cash equivalents and marketable securities as of March 31, 2020, combined with anticipated and potential collaboration payments, should enable it to fund its operations into 2022, assuming the Company's programs and collaborations advance as currently contemplated.

Conference Call Information

MacroGenics will host a conference call today at 4:30 p.m. ET to discuss financial results for the quarter ended March 31, 2020 and provide a corporate update. To participate in the conference call, please dial (877) 303-6253 (domestic) or (973) 409-9610 (international) ten minutes prior to the start of the call and provide the Conference ID: 2993147.

The 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, 2020 (unaudited) | December 31, 2019 |
|--------------------------------------------------|-------------------------------|-------------------|
| Cash, cash equivalents and marketable securities | \$ 170,849 | \$ 215,756 |
| Total assets | 265,413 | 312,501 |
| Deferred revenue | 17,606 | 19,853 |
| Total stockholders' equity | 190,573 | 230,628 |

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

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

| | Three Months Ended March 31, | |
|--------------------------------------------------------------|------------------------------|-------------|
| | 2020 | 2019 |
| Revenues: | | |
| Revenue from collaborative and other agreements | \$ 12,967 | \$ 9,497 |
| Revenue from government agreements | 715 | 165 |
| Total revenues | 13,682 | 9,662 |
| Costs and expenses: | | |
| Research and development | 48,894 | 47,060 |
| General and administrative | 10,233 | 10,219 |
| Total costs and expenses | 59,127 | 57,279 |
| Loss from operations | (45,445) | (47,617) |
| Other income | 721 | 2,600 |
| Net loss | (44,724) | (45,017) |
| Other comprehensive income: | | |
| Unrealized gain on investments | 56 | 3 |
| Comprehensive loss | \$ (44,668) | \$ (45,014) |
| Basic and diluted net loss per common share | \$ (0.91) | \$ (0.99) |
| Basic and diluted weighted average common shares outstanding | 49,012,663 | 45,606,651 |

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 the timing and steps required in the regulatory review process, expectations for regulatory approvals, the impact of competitive products, our ability to enter into agreements with strategic partners and other matters that could affect the availability or commercial potential of the Company's product candidates, business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises such as the novel coronavirus (referred to as COVID-19), 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:

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