

**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): January 9, 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)

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 January 9, 2020, MacroGenics, Inc. (the "Company" or "MacroGenics") issued a press release, which included the Company's current expectations with respect to its unaudited cash, cash equivalents, and investments in marketable securities as of December 31, 2019. The press release is attached hereto as Exhibit 99.1.

The information provided under Item 2.02 in this Form 8-K 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 8.01 Other Events

On January 9, 2020, the Company issued a press release announcing program development priorities for 2020, and indicating the upcoming availability of an updated corporate presentation on the Company's website. The press release is attached hereto as Exhibit 99.1 and incorporated by reference (other than the information that is deemed furnished in Item 2.02 above) in this Item 8.01.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

| <u>Exhibit Number</u> | <u>Description of Exhibit</u> |
|------------------------------|---|
| <u>99.1</u> | <u>Press Release, dated January 9, 2020</u> |

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: January 9, 2020

MACROGENICS, INC.

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



MacroGenics Outlines Corporate Priorities for 2020

ROCKVILLE, MD., January 9, 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 announced its corporate and program priorities for 2020.

"Following the submission in 2019 of our first BLA with the FDA, 2020 has the potential to be a transformative year for MacroGenics. As the product candidates in our deep pipeline enter later-stage clinical trials, we are prioritizing certain programs in order to efficiently utilize our financial, human and intellectual capital on programs with the highest commercial and scientific merit and the potential to achieve regulatory approval," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "We are excited to advance multiple product candidates in registration-directed studies and believe our program prioritization positions us to capitalize on what we hope will be a pivotal year for the Company."

Program Prioritization

The Company's research and development priorities for its investigational molecules in 2020 are highlighted below.

Margetuximab is an Fc-engineered, anti-HER2 monoclonal antibody being evaluated for the treatment of patients with advanced HER2-positive cancers.

- *Biologics Licensing Application (BLA) for Metastatic Breast Cancer.* Pending acceptance and review of the BLA submitted in December 2019 to the Food and Drug Administration (FDA) based on the Phase 3 SOPHIA study results, the Company anticipates a Prescription Drug User Fee Act (PDUFA) date by the end of 2020. MacroGenics expects a Standard Review process in which the FDA will likely require an Oncologic Drugs Advisory Committee (ODAC) meeting in the second half of 2020.
- *Phase 2/3 MAHOGANY Study in Advanced Gastric and Gastroesophageal Junction Cancer.* MacroGenics is enrolling patients in this front-line study designed to evaluate the combination of margetuximab with anti-PD-1 based therapies. Initial safety and efficacy data are expected in the second half of 2020 from Module A of this study, which is evaluating a chemotherapy-free regimen. Module A has been designed to support a potential accelerated approval in the U.S. based on evaluation of objective response rate in a single-arm study.

Flotetuzumab is a bispecific CD123 x CD3 DART® molecule being evaluated for the treatment of patients with relapsed or refractory acute myeloid leukemia (AML). MacroGenics intends to define a potential registration path in the U.S. for the treatment of patients with primary induction failure and early relapsed AML in the first half of 2020, pending continued discussions with the FDA.

MGA012 (INCMGA0012) is an anti-PD-1 monoclonal antibody that has been exclusively licensed to Incyte Corporation. There are currently 18 disclosed Phase 1-3 clinical studies evaluating MGA012 in monotherapy and combination regimens across a broad range of tumor types.¹

MGD013 is a first-in-class, bispecific PD-1 x LAG-3 DART molecule being evaluated in a Phase 1 dose expansion study. MacroGenics is selecting indications for further development and expects to submit data from the ongoing study for presentation at a scientific conference in the first half of 2020.

Enoblituzumab is an Fc-engineered, anti-B7-H3 monoclonal antibody. To further inform the development of this molecule, MacroGenics plans to evaluate the activity of both enoblituzumab plus MGA012 and enoblituzumab plus MGD013 as chemotherapy-free regimens in front-line patients with recurrent and metastatic squamous cell carcinoma of the head and neck (SCCHN) before proceeding with the full Phase 2/3 study.

MGC018 is an antibody-drug conjugate (ADC) targeting B7-H3 and **MGD019** is a bispecific PD-1 x CTLA-4 DART molecule. The Company expects to complete dose escalation for each of these molecules in early 2020 and then initiate a focused dose expansion in select tumor types.

MGD009 is a B7-H3 x CD3 DART molecule and **MGD007** is a gpA33 x CD3 DART molecule. In connection with its strategic prioritization, the Company will discontinue development of these programs.

Cash Balance and Cash Runway

The Company's estimated cash, cash equivalents and marketable securities balance as of December 31, 2019 was approximately \$215 million (unaudited), compared to \$232.9 million as of December 31, 2018. Through the prioritization of programs and ongoing realignment of its resources, as well as anticipated and potential collaboration payments, MacroGenics is focused on extending its cash runway through 2021. The Company will provide further guidance in connection with reporting 2019 fourth quarter and annual financial results and company progress in late February 2020.

Slide Presentation

A slide presentation describing these corporate priorities, research and development goals and other information will be available on the Investors page on the Company's website at www.macrogenics.com after the market close on Friday, January 10, 2020.

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.

¹ Clinicaltrials.gov and MacroGenics' website as of January 8, 2020.

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