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 1, 2019

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 1, 2019, the Company announced financial and operating results as of and for the quarter ended March 31, 2019. 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 1, 2019

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 1, 2019

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress and First Quarter 2019 Financial Results

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

ROCKVILLE, Md., May 1, 2019 (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, 2019.

“In February, we reported topline results from SOPHIA showing that in the Phase 3 trial, progression-free survival was prolonged following treatment with margetuximab and chemotherapy compared to trastuzumab with chemotherapy. We look forward to presenting detailed results at ASCO. In addition, we anticipate submitting a BLA for this program to the FDA in the second half of 2019. If approved by regulators, margetuximab could offer the potential of a new treatment option for patients living with HER2-positive metastatic breast cancer in a third line and beyond setting where there are currently no FDA-approved therapies. In seeking to address unmet needs of patients with HER2-postive cancers beyond breast cancer, we plan to initiate in the second half of 2019 a registration-directed trial to evaluate margetuximab for treating gastric cancer patients in the frontline setting,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics.

“Mechanistically, we believe the results achieved in the SOPHIA study have validated our Fc-optimization technology, also used in enoblituzumab, our investigational monoclonal antibody targeting B7-H3,” continued Dr. Koenig. “To date, we have made tremendous progress with our immuno-oncology pipeline of nine clinical product candidates with multiple molecules demonstrating clinical proof of concept to support ongoing and/or planned registration studies.”

Key Pipeline Updates

Margetuximab. Recent updates related to the Company’s investigational Fc-optimized monoclonal antibody (mAb) that targets human epidermal growth factor receptor 2 (HER2) include:

- **Oral Presentation of SOPHIA Data at ASCO; Plans to Submit BLA in 2H2019:** In February 2019, MacroGenics announced that SOPHIA, the Phase 3 clinical trial of margetuximab in patients with HER2-positive metastatic breast cancer, met the trial’s first sequential primary endpoint of prolongation of progression-free survival (PFS) in patients treated with the combination of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy. An abstract containing data from SOPHIA was selected for presentation in an oral session to be held on Tuesday, June 4, 2019 at the American Society of Clinical Oncology (ASCO) Annual Meeting. MacroGenics anticipates submitting a Biologics License Application (BLA) to the U.S. FDA for margetuximab, based on the PFS results, in the second half of 2019.
- **Additional Validating Mechanistic Data in Posters at AACR and ASCO:** Data presented at the American Association for Cancer Research (AACR) Annual Meeting in April 2019 showed improved Fc-dependent activity of margetuximab compared to trastuzumab in vitro. These preclinical data validate the molecule’s underlying mechanism of action and the Company’s Fc-optimization platform. In addition, an abstract containing data describing HER2-specific immunity observed in patients with HER2-positive cancers treated with margetuximab in the Phase 1 trial was selected for presentation in a poster session at ASCO on Sunday, June 2, 2019.

- **Plans to Initiate Front-line Gastric Cancer Trial in 2H2019:** At the ASCO Gastrointestinal Cancers Symposium in January 2019, data were presented demonstrating encouraging anti-tumor activity and acceptable safety and tolerability of margetuximab in combination with an anti-PD-1 mAb in a Phase 2 clinical trial in patients with HER2-positive gastric or gastroesophageal junction cancer. MacroGenics and its partner in Greater China, Zai Lab, expect to initiate a Phase 2/3 registration-directed clinical trial of margetuximab in combination with checkpoint inhibitor molecules, including MGA012 (anti-PD-1 mAb) and MGD013 (bispecific PD-1 x LAG-3 DART® molecule) in the second half of 2019.

B7-H3 Franchise. MacroGenics is developing a portfolio of investigational antibody-based therapeutics that target B7-H3 through complementary mechanisms of action taking advantage of this antigen's broad expression across multiple solid tumor types. Recent program highlights include:

- **Plans to Advance Enoblituzumab in Head and Neck Cancer Study:** Enoblituzumab is an Fc-optimized mAb that targets B7-H3. Encouraging data from the Phase 1 clinical study of enoblituzumab in combination with an anti-PD-1 mAb were presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2018. Based on these data, MacroGenics is planning to initiate a Phase 2 study of enoblituzumab in combination with MGA012 in patients with squamous cell carcinoma of the head and neck (SCCHN) in the second half of 2019.
- **MGD009 Phase 1 Studies Ongoing**: MGD009 is a bispecific DART molecule designed to target B7-H3 expressed on tumor cells and CD3 expressed on normal T cells. MacroGenics is enrolling patients in two Phase 1 clinical trials of MGD009, one as monotherapy and another in combination with MGA012.
- **MGC018 Dose Escalation Ongoing**: MGC018 is an antibody-drug conjugate (ADC) designed to target solid tumors expressing B7-H3. MacroGenics is evaluating MGC018 in a Phase 1 dose escalation study.

PD-1 Franchise. MacroGenics is advancing multiple investigational PD-1-directed programs to provide differentiation from existing PD-1-based treatment options and enable a broad set of combination opportunities across the Company’s portfolio. Recent program highlights include:

- **MGA012 Registration-directed Studies Ongoing**: MGA012 (INCMGA0012) is an anti-PD-1 mAb exclusively licensed to Incyte Corporation on a worldwide basis. Incyte is initially pursuing development of MGA012 monotherapy through three potentially registration-directed trials in MSI-high endometrial cancer, Merkel cell carcinoma and anal cancer and Incyte and MacroGenics are each conducting multiple studies of MGA012 in combination with other agents. MacroGenics retains the right to develop its pipeline of product candidates in combination with MGA012.
- **MGD013 Dose Expansion Ongoing:** MGD013 is a first-in-class bispecific DART molecule designed to provide co-blockade of PD-1 and LAG-3, two immune checkpoint molecules expressed on T cells. MacroGenics is evaluating MGD013 in a Phase 1 dose expansion study in up to nine tumor types and expects to present data from this trial in the second half of 2019.
- **MGD019 Dose Escalation Ongoing:** MGD019 is a bispecific DART molecule designed to provide co-blockade of PD-1 and CTLA-4, two immune checkpoint inhibitors expressed on T cells. MacroGenics is currently evaluating MGD019 in a Phase 1 dose escalation study.

Flotetuzumab. A recent update related to the Company’s investigational, bispecific DART molecule that recognizes both CD123 and CD3, includes:

- **Data from Ongoing Study Expected 2H2019**: Based on data presented at the American Society of Hematology (ASH) Annual Meeting in December 2018 showing anti-leukemic activity and acceptable tolerability of flotetuzumab in patients with relapsed/refractory AML, MacroGenics is enrolling additional patients in a dose expansion cohort enriched for primary refractory patients and expects to announce updated data from the trial in the second half of 2019. The Company’s collaborator, Servier, has development and commercialization rights outside North America, Japan, Korea and India for flotetuzumab, also known as S80880.

First Quarter 2019 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of March 31, 2019, were $320.4 million, compared to $232.9 million as of December 31, 2018.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $9.7 million for the quarter ended March 31, 2019, compared to $4.7 million for the quarter ended March 31, 2018. Revenue from collaborative agreements included revenue received under a clinical supply agreement with Incyte, as well as the recognition of deferred revenue from payments received in previous periods and payments received during the quarter.
- **R&D Expenses**: Research and development expenses were $47.1 million for the quarter ended March 31, 2019, compared to $45.7 million for the quarter ended March 31, 2018. This increase was due to increased clinical trial costs for MGD013, MGC018 and flotetuzumab, as well as increased development/manufacturing costs related to MGA012 (largely offset by revenue from Incyte). These increases were partially offset by decreased expenses related to the SOPHIA and enoblituzumab clinical studies.
- **G&A Expenses**: General and administrative expenses were $10.2 million for the quarter ended March 31, 2019, compared to $9.2 million for the quarter ended March 31, 2018.
- **Net Loss**: Net loss was $45.0 million for the quarter ended March 31, 2019, compared to net loss of $49.5 million for the quarter ended March 31, 2018.
- **Shares Outstanding**: Shares outstanding as of March 31, 2019 were 48,805,008.

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, 2019 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: 8788605.

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, 2019 (unaudited)	December 31, 2018
Cash and cash equivalents	$ 320,391	$ 232,863
Total assets	414,638	332,130
Deferred revenue	35,292	40,722
Total stockholders' equity	320,617	242,877

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

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

	Three Months Ended March 31,	
	2019	**2018**
Revenues:		
Revenue from collaborative agreements	$ 9,497	$ 4,501
Revenue from government agreement	165	194
Total revenues	9,662	4,695
Costs and expenses:		
Research and development	47,060	45,670
General and administrative	10,219	9,235
Total costs and expenses	57,279	54,905
Loss from operations	(47,617)	(50,210)
Other income	2,600	674
Net loss	(45,017)	(49,536)
Other comprehensive loss:		
Unrealized gain on investments	3	39
Comprehensive loss	$ (45,014)	$ (49,497)
Basic and diluted net loss per common share	$ (0.99)	$ (1.34)
Basic and diluted weighted average common shares outstanding	45,606,651	36,936,560

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, 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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