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): July 31, 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)

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 July 31, 2019, the Company announced financial and operating results as of and for the quarter ended June 30, 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 July 31, 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: July 31, 2019

MACROGENICS, INC.

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

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

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

ROCKVILLE, Md., July 31, 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 June 30, 2019.

“We have made significant progress in the first half of the year, during which we reported positive results from the Phase 3 SOPHIA study of margetuximab in metastatic HER2-positive breast cancer and enrolled patients into our Phase 1 studies. We believe this progress positions us favorably to achieve several important milestones for our Company during the remainder of 2019,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “Continuing our focus on execution, in the second half of the year, we are planning to submit the BLA for margetuximab, initiate two registration-directed Phase 2/3 clinical trials, and provide clinical updates for several key programs.”

Key Pipeline Updates

Margetuximab. MacroGenics is advancing an investigational, Fc-optimized monoclonal antibody (mAb) that targets human epidermal growth factor receptor 2 (HER2). Highlights include:

- **SOPHIA Phase 3 Data Presented at ASCO; Second Interim OS Data Expected in 4Q2019; Plans to Submit BLA in 4Q2019:** At the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2019, MacroGenics presented data from SOPHIA, the Phase 3 clinical trial of margetuximab in patients with HER2-positive metastatic breast cancer. The trial met the 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. The Company expects to present the results from a pre-specified interim OS analysis and submit a Biologics License Application (BLA) to the U.S. FDA in the fourth quarter of 2019.
- **MAHOGANY Phase 2/3 Study Advancing in Front-line Gastric Cancer:** MacroGenics and Zai Lab, the Company’s partner in Greater China, plan 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 patients with HER2-positive gastric or gastroesophageal junction cancer in the third quarter 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. Program updates include:

- **Advancing Enoblituzumab Study in Head and Neck Cancer:** Enoblituzumab is an investigational, Fc-optimized mAb that targets B7-H3. MacroGenics recently met with FDA to discuss its plans regarding a Phase 2/3 registration-directed study of enoblituzumab in combination with MGA012 in patients with squamous cell carcinoma of the head and neck (SCCHN) and anticipates initiating the trial in the fourth quarter of 2019.

- **MGD009 Program Prioritization:** MGD009 is an investigational, bispecific DART molecule designed to target B7-H3 expressed on tumor cells and CD3 expressed on normal T cells. The company is prioritizing the development of the combination of MGD009 with MGA012, including plans to add a new dose expansion cohort in patients with melanoma who have previously been treated with a checkpoint inhibitor. MacroGenics has closed patient enrollment in the MGD009 monotherapy study.
- **Continued MGC018 Dose Escalation:** MGC018 is an investigational, antibody-drug conjugate (ADC) designed to target solid tumors expressing B7-H3 and has advanced through multiple dose levels in the Phase 1 monotherapy dose escalation.

Flotetuzumab. MacroGenics is advancing an investigational, bispecific DART molecule that recognizes both CD123 and CD3. Updates include:

- **Completed Enrollment of Monotherapy Study in Acute Myeloid Leukemia (AML); Data Expected 2H2019; Requested End of Phase 1 Meeting with FDA:** MacroGenics has completed enrollment of 50 patients at the recommended Phase 2 dose in the Phase 1 monotherapy study, including 30 patients with primary refractory AML. The Company plans to submit updated data from the trial for presentation at the 2019 American Society for Hematology (ASH) Annual Meeting. MacroGenics plans to meet with the FDA in the third quarter to discuss the flotetuzumab program, and to define a potential registration path for this molecule.
- **Plans to Initiate MGA012 Combination Study:** MacroGenics plans to initiate a Phase 1 study in combination with MGA012 in relapsed or refractory AML in the third quarter.
- **Regaining Full Global Rights:** MacroGenics will regain full global rights to develop and commercialize flotetuzumab following Servier's notification of its intent to terminate the collaboration and license agreement with the Company.

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. Program highlights include:

- **MGA012 Registration-directed Studies**: MGA012 (INCMGA0012) is an anti-PD-1 mAb exclusively licensed to Incyte Corporation on a worldwide basis. Incyte is pursuing development of MGA012 monotherapy in three ongoing potentially registration-directed trials. Incyte and MacroGenics are each conducting multiple studies of MGA012 in combination with other agents.
- **MGD013 Dose Expansion; Data Expected 2H2019:** 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 has enrolled approximately 100 patients in the Phase 1 dose expansion study in up to nine tumor types and expects to submit data from this monotherapy trial for presentation at a scientific conference in the second half of 2019.
- **MGD019 Dose Escalation:** 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. MGD019 has advanced through multiple dose levels in a Phase 1 dose escalation study.

MGD007. MacroGenics is evaluating an investigational, bispecific DART molecule that recognizes both gpA33 and CD3. MacroGenics completed the enrollment of 26 patients in the Phase 1 expansion cohort of MGD007 in combination with MGA012. The Company expects to provide a clinical update regarding this study in the first quarter of 2020.

Recent Corporate Developments

- **Collaboration with I-Mab Biopharma:** In July 2019, MacroGenics entered into an exclusive collaboration and license agreement with I-Mab Biopharma (I-Mab) to develop and commercialize enoblituzumab. I-Mab obtains rights in mainland China, Hong Kong, Macau and Taiwan. MacroGenics will receive an upfront payment of $15 million and will also be eligible to receive milestone payments of up to $135 million. In addition, I-Mab will pay tiered royalties ranging from mid-teens to twenty percent based on annual net sales in its territories.

Second Quarter 2019 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of June 30, 2019, were $272.1 million, compared to $232.9 million as of December 31, 2018.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $10.6 million for the quarter ended June 30, 2019, compared to $18.8 million for the quarter ended June 30, 2018. The decrease was primarily due to decreased revenue recognized under the collaboration and license agreement with Incyte, as well as revenue recognized during the three months ended June 30, 2018 under the license agreement and asset purchase agreement with Provention Bio. The decrease was partially offset by the revenue recognized from the deferred upfront payment under the collaboration and license agreement with Zai Lab.
- **R&D Expenses**: Research and development expenses were $51.4 million for the quarter ended June 30, 2019, compared to $52.0 million for the quarter ended June 30, 2018.
- **G&A Expenses**: General and administrative expenses were $12.1 million for the quarter ended June 30, 2019, compared to $11.1 million for the quarter ended June 30, 2018. This increase was primarily due to consulting expenses and other professional service fees.
- **Net Loss**: Net loss was $31.8 million for the quarter ended June 30, 2019, which included Other Income of $19.6 million related to the revaluation of the warrants received from Provention Bio, compared to net loss of $43.2 million for the quarter ended June 30, 2018.
- **Shares Outstanding**: Shares outstanding as of June 30, 2019 were 48,893,451.

Conference Call Information

MacroGenics will host a conference call today at 4:30 p.m. ET to discuss financial results for the quarter ended June 30, 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: 3046407.

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)

	June 30, 2019 (unaudited)	December 31, 2018
Cash and cash equivalents	$ 272,136	$ 232,863
Total assets	383,677	332,130
Deferred revenue	29,862	40,722
Total stockholders' equity	294,451	242,877

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,	
	2019	2018	2019	2018
Revenues:				
Revenue from collaborative and other agreements	$ 9,987	$ 18,552	$ 19,484	$ 23,053
Revenue from government agreements	606	282	771	476
Total revenues	10,593	18,834	20,255	23,529
Costs and expenses:				
Research and development	51,440	52,014	98,500	97,684
General and administrative	12,122	11,134	22,341	20,369
Total costs and expenses	63,562	63,148	120,841	118,053
Loss from operations	(52,969)	(44,314)	(100,586)	(94,524)
Other income	21,202	1,070	23,802	1,744
Net loss	(31,767)	(43,244)	(76,784)	(92,780)
Other comprehensive income:				
Unrealized gain on investments	34	40	37	79
Comprehensive loss	$ (31,733)	$ (43,204)	$ (76,747)	$ (92,701)
Basic and diluted net loss per common share	$ (0.65)	$ (1.03)	$ (1.63)	$ (2.35)
Basic and diluted weighted average common shares outstanding	48,845,234	42,153,813	47,234,889	39,559,599

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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