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 25, 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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 8.01. Other Events.

On January 25, 2019, the Company issued a press release announcing that the U.S. Food and Drug Administration has lifted the partial clinical hold on its Phase 1 monotherapy and combination studies of MGD009, a B7-H3 x CD3 bispecific DART® molecule. A copy of the press release ("the Press Release") is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1 Press Release, dated January 25, 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: January 25, 2019

MACROGENICS, INC.

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

MacroGenics Announces Removal of Partial Clinical Hold on MGD009 Program by FDA

ROCKVILLE, Md., January 25, 2019 – 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 that the U.S. Food and Drug Administration (FDA) has lifted the partial clinical hold on its Phase 1 monotherapy and combination studies of MGD009, a B7-H3 × CD3 bispecific DART® molecule. Enrollment of new patients in the U.S. has been cleared to proceed with these trials. MacroGenics previously announced on December 7, 2018, that the FDA had placed the program on partial clinical hold following MacroGenics' reporting of hepatic adverse events on the MGD009 trials to the FDA. During the partial clinical hold, previously enrolled study participants were allowed to continue to receive drug at their pre-assigned dose.

"The MacroGenics team worked diligently and rapidly to provide a comprehensive response to the FDA in late December. As a result, we have been able to resolve the partial clinical hold without significant delay to this clinical program," stated Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "The partial clinical hold did not involve our other B7-H3 programs, and, in fact, during the partial hold, we completed enrollment of the first dose escalation cohort for MGC018, our B7-H3-targeted ADC."

About MGD009

MGD009 is a humanized, bispecific DART molecule that recognizes both B7-H3 and CD3 and has a prolonged serum half-life. B7-H3 is a member of the B7 family of molecules involved in immune regulation and is over-expressed on a wide variety of cancer cells, including cancer stem cells, as well as on the supporting tumor vasculature and underlying tissues, or stroma. The intended mechanism of action of MGD009 is its ability to redirect T cells, via their CD3 component, to kill B7-H3-expressing cells.

In addition to MGD009, MacroGenics' comprehensive B7-H3 franchise includes enoblituzumab, an Fc-optimized monoclonal antibody, as well as MGC018, an antibody-drug conjugate. These clinical molecules target B7-H3. MacroGenics retains worldwide rights to its franchise of three B7-H3-based molecules.

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 risk of delays or failure in reaching an agreement with the FDA regarding the release of a clinical hold, 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.

###

Contacts:
Jim Karrels, Senior Vice President, CFO
MacroGenics, Inc.
1-301-251-5172, info@macrogenics.com

Karen Sharma, Managing Director
MacDougall Biomedical Communications
1-781-235-3060, ksharma@macbiocom.com