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): December 7, 2018

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 December 7, 2018, the Company issued a press release announcing that the U.S. Food and Drug Administration has placed a partial clinical hold on its Phase 1 monotherapy study of MGD009, a B7-H3 × CD3 bispecific DART® molecule as well as on a combination study of MGD009 and MGA012 (anti-PD-1). 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 December 7, 2018

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: December 7, 2018

MACROGENICS, INC.

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

MacroGenics Announces Partial Clinical Hold on MGD009 Phase 1 Studies

ROCKVILLE, Md., December 7, 2018 – 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 on December 6, it received a letter from the U.S. Food and Drug Administration (FDA) indicating that a partial clinical hold has been placed on its Phase 1 monotherapy study of MGD009, a B7-H3 × CD3 bispecific DART® molecule, as well as on a combination study of MGD009 and MGA012 (anti-PD-1). Under the partial clinical hold, no new patients will be enrolled in either study until the partial hold is lifted by the FDA. Current study participants may continue to receive drug at their pre-assigned dose.

The partial clinical hold was initiated following MacroGenics' reporting of hepatic adverse events on the MGD009 monotherapy trial to the FDA, including reversible elevations of transaminases with or without concurrent elevations of bilirubin. Although these events have been otherwise uncomplicated and short-lived in duration, MacroGenics also communicated to the FDA the company's plans to amend the existing MGD009 studies with additional supportive care to mitigate these events. The FDA has placed the trials on partial clinical hold, pending review of additional details regarding these events, and satisfactory review of the planned amendments to the monotherapy and combination study protocols and related documents. MacroGenics will be working closely with the FDA to review these events and seek to resolve this clinical hold.

"MacroGenics' top concern in conducting clinical trials is the safety of study participants," said Scott Koenig, M.D., Ph.D. "As we've identified to the FDA, we believe that transaminitis observed in patients administered MGD009 was likely a cytokine-mediated event. We are working with the FDA and will provide an update when we have additional information. This partial clinical hold does not impact ongoing clinical studies for enoblituzumab and MGC018, our other B7-H3-targeted molecules."

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 (ADC). 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.

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