

**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 13, 2016**

**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))



**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 13, 2016

MACROGENICS, INC.

By: /s/ Atul Saran

Atul Saran

Senior Vice President and General Counsel



## MacroGenics Highlights Progress at 2016 R&D Day

- **Advancement of HER2 franchise led by margetuximab**
- **Expansion and progression of B7-H3 franchise**
- **Introduction of PD-1 directed immuno-oncology franchise**
- **Clinical updates on multiple DART® studies underscore platform progress**
- **Pipeline poised to expand with at least 3 new INDs from internal R&D in 2017-2018**

ROCKVILLE, Md., December 13, 2016 -- MacroGenics, Inc. (NASDAQ: MGNX), a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, as well as autoimmune disorders and infectious diseases, today provided an update on several of the Company's product candidates and technology platforms.

"At today's R&D Day, MacroGenics highlighted the continued progress our team is making to advance our growing portfolio of potential treatment options for patients with cancer, autoimmune disorders and infectious diseases," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "Today, we reviewed our expanded strategy for pursuing a balanced approach across novel and validated targets to develop three immuno-oncology franchises centered around HER2, B7-H3 and PD-1. This approach underscores our belief that cancer patients may significantly benefit from combinatorial and multi-specific strategies that are directly addressed by our core scientific expertise in creating and developing antibody, DART and TRIDENT™ therapeutics. The promising updates we provided on 11 of our programs today underscore the potential of our approach."

### Program Updates and Highlights:

**HER2 Franchise.** MacroGenics provided an update regarding its most advanced franchise targeting the human epidermal growth factor receptor 2, or HER2, led by margetuximab, its Fc-optimized monoclonal antibody:

- **Phase 3 Metastatic Breast Cancer Study.** The pivotal SOPHIA study is evaluating the efficacy of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in approximately 530 relapsed/refractory HER2-positive metastatic breast cancer patients. MacroGenics today confirmed that it expects to complete enrollment of this study by late 2018.
- **Phase 2 Gastric Cancer Combination of Margetuximab with Anti-PD-1 mAb.** The Company presented initial clinical data from a Phase 1b/2 trial of margetuximab in combination with an anti-PD-1 monoclonal antibody (pembrolizumab) in advanced HER2-positive gastric and gastroesophageal junction cancer patients. Preliminary data from the dose escalation portion of the study includes patients with objective response following progression on previous lines of treatment with trastuzumab and chemotherapy.
- **Pre-Clinical DART Program.** MacroGenics presented preliminary non-clinical data from a DART program designed to engage both HER2 and CD137 (4-1BB), a costimulatory molecule, allowing for tumor-targeted immune cell activation.

**B7-H3 Franchise.** MacroGenics highlighted its industry-leading franchise related to the therapeutic targeting of B7-H3, a member of the B7 family of molecules involved in immune regulation, that is broadly expressed in multiple solid tumors:

- **Enoblituzumab.** The Company provided clinical updates on ongoing monotherapy and combination studies with enoblituzumab, an Fc-optimized monoclonal antibody. In the Phase 1 monotherapy study, the antibody continues to be well-tolerated and the most promising activity to-date has been observed in prostate, bladder and

post-checkpoint melanoma patients, consistent with what has been previously reported. Combination studies of enoblituzumab with either an anti-CTLA-4 mAb (ipilimumab) or anti-PD-1 mAb (pembrolizumab) indicate a manageable safety profile to date as well as initial signs of antitumor activity.

- **MGD009.** MacroGenics presented initial data from the ongoing Phase 1 dose escalation study of MGD009, a bispecific B7-H3 x CD3 DART molecule. Adverse events have been manageable to date and initial signs of antitumor activity have been observed in three patients with triple negative breast cancer, renal cell carcinoma and mesothelioma.
- **MGC018.** The Company introduced MGC018, an anti-B7-H3 antibody drug conjugate (ADC) based on a duocarmycin payload with cleavable peptide linker licensed from Synthron Biopharmaceuticals. The Company plans to submit an Investigational New Drug (IND) application for MGC018 in 2018.

**PD1-Directed Immuno-Oncology Franchise.** MacroGenics introduced several new programs in its pipeline directed towards PD-1, which will enable both a broad set of combination opportunities across its portfolio and further differentiation from existing PD-1-based treatment options:

- **MGA012.** The Company introduced MGA012, an anti-PD-1 monoclonal antibody that recently began a Phase 1 clinical study. With anti-PD-1 therapy becoming a mainstay of cancer treatment across multiple tumors, MacroGenics believes this molecule will be the basis for combination therapy with several of its proprietary molecules.
- **MGD013.** MacroGenics is developing MGD013 to provide co-blockade of two immune checkpoint molecules expressed on T cells, PD-1 and LAG-3, for potential treatment of diseases spanning a range of solid tumors as well as hematological malignancies. The Company has observed synergistic immunoregulatory activity in vitro, demonstrating that co-blockade with a PD-1 x LAG-3 DART molecule exceeds the effects achieved by combining two separate antibodies against these targets. The Company is completing IND-enabling studies and plans to submit an IND for MGD013 in the first half of 2017.
- **PD-1 x CTLA-4 Program.** MacroGenics is developing a multi-specific therapeutic to address the co-blockade of PD-1 and CTLA-4, two clinically validated co-inhibitory molecules expressed on T cells.

**Update on DART Clinical Programs.** Across its portfolio of clinical DART programs, the Company highlighted the promising features of its DART platform, including on-target engagement, manageable safety and preliminary evidence of biological activity. These DART programs include MGD009 and the following:

- **MGD006.** MacroGenics presented elements of its initial clinical experience from the ongoing Phase 1 dose escalation study of MGD006, a CD123 x CD3 DART molecule, in patients with AML (acute myeloid leukemia) or MDS (myelodysplastic syndrome). Supportive care regimens have been refined to enable significant limitations in the severity of cytokine release syndrome (CRS). In addition, the Company has characterized predictable pharmacokinetic properties of MGD006 and established biological and preliminary clinical activity in AML patients. The Company is now recruiting patients with AML or MDS in the U.S. and Europe.
- **MGD007.** MacroGenics presented its initial clinical experience from the ongoing Phase 1 dose escalation study of MGD007, a gpA33 x CD3 DART, in patients with primary and metastatic colorectal cancers. In this study, gastrointestinal and constitutional symptoms have been reversible and consistent with the known target distribution of gpA33. Translational findings to date have included dose-dependent binding to CD4+ and CD8+ T cells in patients' peripheral blood as well as histological demonstration of MGD007 binding to tumor cells in tumor biopsy specimens.
- **MGD010.** The Company presented data from the fully enrolled Phase 1 study of MGD010, a CD32B x CD79B DART molecule, being developed for potential treatment of autoimmune disorders. MGD010 was well tolerated in healthy subjects in the single ascending dose study. In addition, MGD010 was shown to down-modulate B-cell function at multiple levels and preliminary data indicated that MGD010 was able to inhibit antibody response to Hepatitis A vaccination, providing clinical evidence consistent with the molecule's expected mechanism of action.

## R&D Day Webcast

To view the recorded webcast of the Company's R&D Day event as well as download the presentation, please visit the Investor Relations section of MacroGenics' website at <http://ir.macrogenics.com/events.cfm>.

## **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, as well as autoimmune disorders and infectious diseases. The Company generates its pipeline of product candidates primarily from its proprietary suite of next-generation antibody-based technology platforms. 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](http://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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