

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): **February 29, 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.)

9640 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))
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Item 2.02 Results of Operations and Financial Condition

On February 29, 2016, the Company announced financial and operating results as of and for the year ended December 31, 2015. 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 99.1 Press release issued by the Company on February 29, 2016

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: February 29, 2016

MACROGENICS, INC.

By: /s/Atul Saran

Atul Saran

Senior Vice President and General Counsel

EXHIBIT INDEX

Exhibit Number

Description of Exhibit

99.1	Press release dated February 29, 2016
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MacroGenics Provides Update on Corporate Progress and 2015 Financial Results

- *Eight molecules in clinical development, including six in immuno-oncology*
- *Multi-national Phase 1b/2 gastric cancer study initiated evaluating the combination of margetuximab and pembrolizumab*
- *Strong balance sheet supports continued advancement of pipeline*

ROCKVILLE, MD, February 29, 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 a corporate progress update and reported financial results for the year ended December 31, 2015.

"I am thrilled with MacroGenics' progress towards advancing breakthrough biologics and life-changing medicines, and particularly our industry leadership in creating bi-specific molecules," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "There are now six Dual-Affinity Re-Targeting, or DART®, molecules based on our proprietary platform, in or entering clinical development – four led by MacroGenics and two led by our collaborators, Janssen Biotech and Pfizer. In addition, we are actively enrolling patients with metastatic breast cancer in SOPHIA, our Phase 3 study of our Fc-optimized HER2 antibody, margetuximab. During 2015, in addition to updating our Phase 1 margetuximab data at the ASCO annual meeting, we also reported encouraging initial results from an ongoing Phase 1 study of enoblituzumab, our Fc-optimized B7-H3 antibody, at the SITC annual meeting. Finally, given the strength of our cash and investments balance, we continue to be well positioned to advance our proprietary pipeline of immunotherapeutic product candidates."

"For 2016, we have already initiated a Phase 1b/2 study combining margetuximab and pembrolizumab in advanced HER2-positive gastric cancer," added Dr. Koenig. "Later this year, we plan to share additional enoblituzumab clinical data and provide clinical updates on multiple DART molecules being evaluated in Phase 1 studies. We also expect to submit an Investigational New Drug (IND) application for MGA012. Over the next few years, we intend to continue to advance at least one additional IND per year."

Pipeline Update

Margetuximab is an Fc-optimized monoclonal antibody that targets the human epidermal growth factor receptor 2, or HER2. Recent highlights include:

- **Phase 1b/2 Gastric Cancer Study:** MacroGenics recently dosed the first patient in a Phase 1b/2 clinical trial of margetuximab in combination with pembrolizumab, an anti-PD-1 therapy, in patients with advanced HER2-positive gastric cancer. Treatment options for these patients are limited and our proposed combination regimen would avoid chemotherapy while exploiting the expected enhanced immune-mediated killing properties of both margetuximab and pembrolizumab. We recently elected to expand the scope of this trial to include centers in both Asia and the United States. This study is being conducted in collaboration with Merck.
- **SOPHIA Study:** The Company's Phase 3 pivotal study in patients with HER2-positive metastatic breast cancer is ongoing, as the Company continues to initiate sites and enroll patients. This study is evaluating the efficacy of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in approximately 530 patients following progression after at least two lines of previous therapy. The Company is targeting completion of this study in 2018.

B7-H3 Franchise. MacroGenics is developing a portfolio of therapeutics that target B7-H3, a member of the B7 family of molecules involved in immune regulation. The Company is advancing multiple programs that target B7-H3 through complementary mechanisms of action and take advantage of this antigen's broad expression across multiple solid tumor types. Recent highlights of ongoing clinical programs include:

- **Enoblituzumab (MGA271):** Data from the ongoing monotherapy study of enoblituzumab, an Fc-optimized monoclonal antibody that targets B7-H3, was presented in a late-breaking abstract session at the 2015 Society for Immunotherapy of Cancer (SITC) Annual Meeting in November. Enoblituzumab has been generally well tolerated in patients and has shown encouraging initial single-agent, anti-tumor activity in heavily pre-treated patients, including those with prostate and bladder cancer as well as melanoma. In addition, evidence of T-cell immunomodulatory function has been observed in patients treated with enoblituzumab. The Company has expanded its development program to include two combination studies with either ipilimumab or pembrolizumab.
- **MGD009:** This DART molecule targeting B7-H3 and CD3 is being evaluated in a Phase 1 study across multiple solid tumor types.

DART Product Candidates. There are currently six DART molecules in or entering Phase 1 clinical development, including MGD006 (CD123 x CD3, also known as S80880), MGD007 (gpA33 x CD3), MGD011 (CD19 x CD3, also known as JNJ-64052781), MGD010 (CD32B x CD79B), MGD009 (B7-H3 x CD3) and PF-06671008 (P-cadherin x CD3). The Company expects to submit IND applications for two additional DART molecules in 2017. These two product candidates are:

- **MGD013:** MacroGenics is developing an Fc-bearing DART molecule, MGD013, to simultaneously block two immune checkpoint molecules, PD-1 and LAG-3. The Company has presented promising pre-clinical data demonstrating the activity of a DART molecule with these specificities and expects that this bi-specific combination may be useful for treatment of a wide range of solid tumors and hematological malignancies.
- **MGD014:** In 2015, MacroGenics presented pre-clinical data on MGD014, a DART molecule that is being developed to eliminate latent HIV infection. MGD014 is being developed under a contract awarded to MacroGenics by the National Institute of Allergy and Infectious Diseases for up to \$24.5 million. This is the first infectious disease DART program planned for clinical testing.

Beyond MGD013 and MGD014, MacroGenics is generating and evaluating multiple other candidates that target a range of immune regulatory and other molecules using both its DART and Trident™ platforms, the latter for generating tri-specific molecules.

Corporate Update

- **Commercial Preparation:** Tom Farrell recently joined MacroGenics as Vice President, Market Development and Strategy and will lead the Company's effort in preparing for commercialization of its lead product candidates. Tom was most recently at Genentech, a Member of the Roche Group, where he was Global Pricing & Market Access Head (Oncology/Hemophilia), and responsible for leading the development and implementation of global pricing and payer strategies for all oncology (including Perjeta® and Kadcyła®) and hemophilia molecules from early-through late-stage development.
- **Pfizer's DART Molecule Advances:** MacroGenics' collaboration partner, Pfizer, recently advanced PF-06671008, a DART molecule that targets P-cadherin and CD3, by submitting an IND application that has been cleared by the FDA. Increased levels of the protein P-cadherin have been reported in various tumors, including breast, gastric, endometrial, colorectal and pancreatic cancers, and is correlated with poor survival of patients.

2015 Financial Results and Financial Guidance

- **Cash Position:** Cash, cash equivalents and investments as of December 31, 2015 were \$339.0 million, compared to \$157.6 million as of December 31, 2014. In the first quarter of 2015, MacroGenics closed a global collaboration and license agreement for MGD011 with Janssen Biotech, Inc. and received a \$50 million upfront license fee. Johnson & Johnson Innovation - JJDC, Inc. also purchased \$75 million of newly issued shares of MacroGenics common stock. In July 2015, MacroGenics completed an equity offering that raised net proceeds of \$141 million.
- **Revenue:** Total revenues, consisting primarily of revenue from collaborative agreements, were \$100.9 million for the year ended December 31, 2015, compared to \$47.8 million for the year ended December 31, 2014. Revenue from collaborative agreements includes the recognition of deferred revenue from payments received in previous periods as well as payments received during the year.
- **R&D Expenses:** Research and development expenses were \$98.3 million for the year ended December 31, 2015, compared to \$70.2 million for the year ended December 31, 2014. This increase was due primarily to the initiation of SOPHIA, a margetuximab Phase 3 study, and a Phase 1b/2 study of margetuximab in combination with pembrolizumab, increased activity in our pre-clinical immune checkpoint programs, including MGD013, and the initiation of a Phase 1a study of MGD010.
- **G&A Expenses:** General and administrative expenses were \$22.8 million for the year ended December 31, 2015, compared to \$15.9 million for the year ended December 31, 2014. This increase was primarily due to higher labor-related costs, including stock-based compensation expense and information technology-related expenses.
- **Net Loss:** Net loss was \$20.1 million for the year ended December 31, 2015, compared to a net loss of \$38.3 million for the year ended December 31, 2014.
- **Shares Outstanding:** Shares outstanding as of December 31, 2015 were 34,345,754.
- **Financial Guidance:** MacroGenics expects that its current cash, cash equivalents and investments, combined with anticipated funding under its strategic collaborations, should fund the Company's operations into 2018.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (EST) to discuss the year 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: 53370315.

The recorded, 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.
CONSOLIDATED BALANCE SHEET DATA
(Amounts in thousands)

	As of December 31,	
	2015	2014
Cash, cash equivalents and investments	\$ 339,049	\$ 157,591
Total assets	359,269	173,886
Deferred revenue	18,497	30,720
Total stockholders' equity	313,337	121,286

MACROGENICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

	Year Ended December 31,		
	2015	2014	2013
Revenues:			
Revenue from collaborative agreements	\$ 99,368	\$ 47,264	\$ 56,753
Revenue from government agreements	1,486	533	1,282
Total revenues	<u>100,854</u>	<u>47,797</u>	<u>58,035</u>
Costs and expenses:			
Research and development	98,271	70,186	46,582
General and administrative	22,765	15,926	11,087
Total costs and expenses	<u>121,036</u>	<u>86,112</u>	<u>57,669</u>
Income (loss) from operations	(20,182)	(38,315)	366
Other income (expense)	42	2	(627)
Net loss	<u>(20,140)</u>	<u>(38,313)</u>	<u>(261)</u>
Other comprehensive loss:			
Unrealized loss on investments	(5)	-	-
Comprehensive loss	<u>\$ (20,145)</u>	<u>\$ (38,313)</u>	<u>\$ (261)</u>
Basic and diluted net loss per common share	\$ (0.63)	\$ (1.40)	\$ (0.04)
Basic and diluted weighted average number of common shares	31,801,645	27,384,990	6,847,697

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 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. MacroGenics, the MacroGenics logo, DART and Trident are trademarks or registered trademarks of MacroGenics, Inc.

The development of one or more DART molecules targeting HIV is being funded in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services under Contract No. HHSN272201500032C.

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 "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. 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 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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