

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): **August 3, 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))
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Item 2.02 Results of Operations and Financial Condition

On August 3, 2016, the Company announced financial and operating results as of and for the period ended June 30, 2016. 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) is being furnished and 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 August 3, 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: August 3, 2016

MACROGENICS, INC.

By: /s/Atul Saran

Atul Saran

Senior Vice President and General Counsel

EXHIBIT INDEX

Exhibit Number

99.1

Description of Exhibit

Press release dated August 3, 2016

MacroGenics Provides Update on Corporate Progress and Second Quarter 2016 Financial Results

- **MGD010 Phase 1 clinical DART® data presented at EULAR**
- **Entered into collaboration with Janssen to develop MGD015**
- **On track for three new IND submissions in 2016-2017**

ROCKVILLE, MD, August 3, 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 quarter ended June 30, 2016.

"MacroGenics continues to make progress across its broad pipeline of clinical compounds, including margetuximab, our Fc-optimized anti-HER2 monoclonal antibody, our two clinical programs targeting B7-H3 as well as several bispecific product candidates based on our DART platform," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "Of note during the second quarter, we presented promising Phase 1 clinical data for one of our DART programs, MGD010, at EULAR 2016. We look forward to providing data on other programs later this year, including additional clinical data from our enoblituzumab monotherapy study."

"In terms of our preclinical projects, we expect to continue our pace of generating promising clinical development candidates based on MacroGenics' technology platforms. We remain on track to submit one IND later this year and two additional INDs in 2017," commented Dr. Koenig. "Finally, during the second quarter of 2016, we were very pleased to enter into a second collaboration with Janssen Biotech, Inc. for the development of MGD015, a DART program being developed for the treatment of various hematological malignancies and solid tumors."

Pipeline Update

Margetuximab. Recent highlights related to the Company's Fc-optimized monoclonal antibody that targets the human epidermal growth factor receptor 2, or HER2, include:

- **SOPHIA Study:** MacroGenics' 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 relapsed/refractory patients. Approximately three-quarters of the anticipated study sites have been activated as of June 30, 2016. The Company expects to provide an update on patient enrollment and the expected timing of trial completion after all sites are activated and actively enrolling.
- **Phase 1b/2 Gastric Cancer Study:** MacroGenics continues to recruit and dose patients 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 this proposed combination regimen would avoid chemotherapy while exploiting the potential for enhancing the antitumor immune response. This trial is being conducted in collaboration with Merck and is currently recruiting patients in the United States, with plans to expand into Asia later this year.

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. Current ongoing clinical-stage development programs include:

- **Enoblituzumab:** The Company continues to recruit patients in three ongoing studies of enoblituzumab, an Fc-optimized monoclonal antibody that targets B7-H3. These studies include one monotherapy study and two combination studies with each of ipilimumab and pembrolizumab. As previously reported, the monotherapy study was expanded to include additional prostate and bladder cancer cohorts.
- **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 Phase 1 clinical development, including MGD006 (CD123 x CD3, also known as S80880), MGD007 (gpA33 x CD3), MGD009 (B7-H3 x CD3), MGD010 (CD32B x CD79B), MGD011 (CD19 x CD3, also known as JNJ-64052781) and PF-06671008 (P-cadherin x CD3). Highlights during the second quarter include:

- **MGD010 Clinical Data Presentation:** MacroGenics presented clinical data from its Phase 1 study of MGD010 at the Annual European Congress of Rheumatology (EULAR 2016) in London, England. MGD010, a DART molecule, was designed to simultaneously target the B-cell surface proteins, CD32B and CD79B, and is being developed for the treatment of autoimmune disorders. Data from the first-in-human, double-blind, placebo-controlled study in healthy volunteers showed that MGD010 was well tolerated at all dose levels. MGD010 demonstrated linear pharmacokinetics and modulation of B-cell function without depletion.
- **PF-06671008 Phase 1 Study Commencement:** Pfizer commenced the Phase 1 clinical study of PF-06671008, which targets P-cadherin and CD3. The dosing of the first patient in the study triggered a \$2 million milestone payment to MacroGenics under the companies' 2010 agreement.

MacroGenics expects to submit IND applications for MGA012, a monoclonal antibody, in 2016 as well as two DART molecules in 2017. These two DART molecules are:

- **MGD013:** MacroGenics is developing MGD013 to simultaneously block two immune checkpoint molecules, PD-1 and LAG-3.
- **MGD014:** MGD014 is a DART molecule that is being developed to eliminate latent HIV infection.

Beyond MGD013 and MGD014, MacroGenics continues to generate and evaluate multiple other candidates that target a range of immune regulatory and other molecules using its proprietary platforms.

Second Quarter 2016 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2016, were \$265.6 million, compared to \$339.0 million as of December 31, 2015. The MGD015 collaboration agreement with Janssen closed during the second quarter of 2016; however, the \$75 million upfront payment from them was not received until early in the third quarter.
- **Revenue:** Total revenue, consisting primarily of revenue from collaborative agreements, was \$80.7 million for the quarter ended June 30, 2016, compared to \$6.7 million for the quarter ended June 30, 2015. This increase is primarily due to the \$75 million in revenue recognized under the Janssen MGD015 collaboration announced in the second quarter of 2016 and the \$2 million milestone received from Pfizer.
- **R&D Expenses:** Research and development expenses were \$33.3 million for the quarter ended June 30, 2016, compared to \$22.7 million for the quarter ended June 30, 2015. This increase was due primarily to increased activity in the Company's preclinical immune checkpoint programs, including MGD013, the initiation of a Phase 1 clinical trial of MGD009 and the initiation of two Phase 1 clinical trials combining enoblituzumab with other compounds.
- **G&A Expenses:** General and administrative expenses were \$7.2 million for the quarter ended June 30, 2016, compared to \$5.3 million for the quarter ended June 30, 2015. This increase is primarily due to increased professional fees, recruiting costs and stock-based compensation expense.
- **Net Income/Loss:** Net income was \$40.5 million for the quarter ended June 30, 2016, compared to net loss of \$21.4 million for the quarter ended June 30, 2015. The change from net loss to net income was primarily due to the recognition of the \$75 million upfront payment from Janssen.
- **Shares Outstanding:** Shares outstanding as of June 30, 2016 were 34,694,039.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (EDT) to discuss the second quarter of 2016 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: 54065731.

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.
SELECTED CONSOLIDATED BALANCE SHEET DATA

(Amounts in thousands)

	<u>June 30, 2016</u>	<u>December 31, 2015</u>
Cash, cash equivalents and investments	\$ 265,624	\$ 339,049
Total assets	368,850	359,269
Deferred revenue	15,318	18,497
Total stockholders' equity	329,976	313,337

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenues:				
Revenue from collaborative agreements	\$ 78,497	\$ 5,598	\$ 80,390	\$ 76,763
Revenue from government agreements	2,176	1,118	3,129	1,232
Total revenues	<u>80,673</u>	<u>6,716</u>	<u>83,519</u>	<u>77,995</u>
Costs and expenses:				
Research and development	33,340	22,660	60,686	44,124
General and administrative	7,239	5,346	13,372	10,029
Total costs and expenses	<u>40,579</u>	<u>28,006</u>	<u>74,058</u>	<u>54,153</u>
Income (loss) from operations	40,094	(21,290)	9,461	23,842
Other income (expense)	370	(86)	640	(89)
Net income (loss)	<u>40,464</u>	<u>(21,376)</u>	<u>10,101</u>	<u>23,753</u>
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	7	-	64	-
Comprehensive income (loss)	<u>\$ 40,471</u>	<u>\$ (21,376)</u>	<u>\$ 10,165</u>	<u>\$ 23,753</u>
Basic net income (loss) per common share	\$ 1.17	\$ (0.71)	0.29	0.80
Diluted net income (loss) per common share	\$ 1.12	\$ (0.71)	0.28	0.75
Basic weighted average number of common shares	34,616,197	30,059,329	34,560,021	29,739,326
Diluted weighted average number of common shares	36,017,411	30,059,329	35,966,987	31,797,332

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. MacroGenics, the MacroGenics logo, and DART 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 "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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