

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): **May 6, 2015**

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 May 6, 2015, the Company announced financial and operating results for the period ended March 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 May 6, 2015.

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: May 6, 2015

MACROGENICS, INC.

By: /s/James Karrels
James Karrels
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number

Description of Exhibit

99.1

Press release dated May 6, 2015

MacroGenics Provides Update on Corporate Progress and First Quarter 2015 Financial Results

-- *Company's third bi-specific DART® molecule, MGD010, in clinical testing*

-- *FDA clears IND for fourth DART, MGD011 – Janssen to initiate clinical testing*

-- *Margetuximab Phase 3 SOPHIA study in metastatic breast cancer to initiate 3Q 2015*

ROCKVILLE, Md., May 6, 2015 (GLOBE NEWSWIRE) -- 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 first quarter ended March 31, 2015.

"I am very pleased to announce the clearance for clinical testing of MGD011, following our recent IND submission to the FDA. With the anticipated clinical initiation of this molecule by our collaboration partner, Janssen Biotech, Inc., and our recent Phase 1 initiation of MGD010, MGD011 will represent the fourth Dual-Affinity Re-Targeting molecule, or DART, to enter the clinic. Our mission to harness the power of the immune system to fight cancer and autoimmune disorders has continued to advance," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "In addition to our DART molecules, both of our Fc-optimized product candidates, margetuximab and MGA271, continue to progress in the clinic and we look forward to sharing Phase 1 data with you later this year for these two programs. In addition to the high level of clinical activity underway at MacroGenics, we continue to make significant progress on earlier-stage molecules that will serve as the basis for new INDs we intend to submit later this year and in subsequent years."

Pipeline Update

Margetuximab is an Fc-optimized monoclonal antibody that targets HER2. Recent highlights include:

- **Phase 3 Metastatic Breast Cancer Study:** The Company remains on track to commence SOPHIA, a Phase 3 pivotal study in approximately 530 subjects, in the third quarter of 2015. This study is planned to evaluate margetuximab plus chemotherapy against trastuzumab plus chemotherapy in third-line metastatic breast cancer patients with HER2 expression at the 3+ level by immunohistochemistry (IHC) or 2+ level by IHC with gene amplification, subject to completion of further regulatory review. MacroGenics projects that it will take approximately three years to complete this study, which will include an interim fertility analysis.
- **ASCO Presentation of Phase 1 Data:** MacroGenics plans to present margetuximab Phase 1 clinical data at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting in a poster discussion.
- **Gastroesophageal Cancer Opportunity:** The Company remains on track to initiate a Phase 1/2 combination study in gastroesophageal cancer starting in the fourth quarter of 2015.

MGA271 is an Fc-optimized monoclonal antibody that targets B7-H3, a member of the B7 family of molecules involved in immune regulation. Recent highlights include:

- **Recruiting Additional Monotherapy Expansion Cohorts:** As previously disclosed, the Company is recruiting patients in multiple additional MGA271 monotherapy expansion cohorts across various tumor types, including triple-negative breast cancer, head and neck cancer, renal cell cancer, melanoma (in patients who have failed a checkpoint inhibitor), non-small cell lung cancer and bladder cancer.
- **Combination Studies:** MacroGenics is currently enrolling a study of MGA271 in combination with ipilimumab in patients with B7-H3 positive melanoma, lung, and head and neck cancers. In addition, the Company will be initiating a study of MGA271 in combination with an anti-PD-1 antibody in patients with melanoma, non-small cell lung carcinoma and squamous cell carcinoma of the head and neck later this year.
- **Presentation of Phase 1 Data:** In the second half of 2015, MacroGenics plans to present Phase 1 clinical data for MGA271.

MGD006 is a humanized DART molecule that recognizes both CD123 and CD3. CD123, the Interleukin-3 receptor alpha chain, is expressed on leukemia and leukemic stem cells. The primary mechanism of action of MGD006 is its ability to redirect T cells, via their CD3 component, to kill CD123-expressing cells. MacroGenics continues to enroll patients in the dose escalation portion of a Phase 1 study of MGD006 for the treatment of acute myeloid leukemia.

MGD007 is a humanized DART molecule that recognizes both the glycoprotein A33 antigen, or gpA33, and CD3. gpA33 is a gastrointestinal antigen with high expression in colorectal cancer. The primary mechanism of action of MGD007 is its ability to redirect T cells, via their CD3 component, to kill gpA33-expressing cells. MacroGenics continues to enroll patients in the dose escalation portion of a Phase 1 study of MGD007 for the treatment of colorectal cancer.

MGD010 is a humanized DART molecule that simultaneously targets CD32B and CD79B, two B-cell surface proteins. MGD010 is being developed for the treatment of autoimmune disorders and is designed to inhibit B-cell activation by exploiting the

inhibitory function of CD32B, a checkpoint molecule expressed by B cells. MacroGenics initiated a Phase 1a study in normal healthy volunteers during the first quarter of 2015, which triggered a milestone payment of \$3 million by our global collaboration partner, Takeda Pharmaceuticals Company Limited.

MGD011 is a humanized DART molecule that targets both CD19 and CD3 and is being developed for the treatment of B-cell hematological malignancies. MGD011 is designed to redirect T cells, via their CD3 component, to eliminate cells expressing CD19, a specific marker expressed in B-cell hematological malignancies. MGD011 has been engineered to address half-life challenges posed by other programs targeting CD19 and CD3, allowing for convenient dosing regimens in the clinical setting.

MacroGenics submitted an investigational new drug (IND) application for MGD011 that has been cleared by the U.S. Food and Drug Administration (FDA) to allow initiation of clinical testing. Pursuant to the Company's collaboration and license agreement with Janssen Biotech, Inc., Janssen will develop the product candidate, subject to MacroGenics' options to co-promote the product in the United States and Canada and to invest in later-stage development in exchange for a profit-share.

MacroGenics continues to advance several additional antibody and DART-based pre-clinical molecules, including MGD009, for which MacroGenics retains worldwide development and commercialization rights.

First Quarter 2015 Financial Results

- **Cash Position:** Cash and cash equivalents as of March 31, 2015 were \$263.1 million, compared to \$157.6 million as of December 31, 2014. In the first quarter of 2015, MacroGenics closed a previously announced global collaboration and license agreement for MGD011 with Janssen and received a \$50 million upfront license fee. Johnson & Johnson Innovation - JJDC, Inc. also invested \$75 million with the purchase of new shares of MacroGenics common stock at a price of \$39.00 per share.
- **Revenue:** Total revenues, consisting primarily of revenue from collaborative research, were \$71.3 million for the quarter ended March 31, 2015, including \$62.3 million associated with the Janssen collaboration, compared to \$14.7 million for the quarter ended March 31, 2014. Collaborative research revenue 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 \$21.5 million for the quarter ended March 31, 2015, compared to \$14.6 million for the quarter ended March 31, 2014. This increase was primarily due to the clinical study preparations for two product candidates and increased activity related to IND preparation for a preclinical program.
- **G&A Expenses:** General and administrative expenses were \$4.7 million for the quarter ended March 31, 2015, compared to \$3.3 million for the quarter ended March 31, 2014. This increase was primarily due to higher stock-based compensation expense and labor costs as well as information technology-related expenses.
- **Net Income (Loss):** Net income was \$45.1 million for the quarter ended March 31, 2015, compared to net loss of \$3.1 million for the quarter ended March 31, 2014. Excluding the effects of the Janssen collaboration, the Company would have had a net loss of \$17.2 million for the quarter ended March 31, 2015.
- **Shares Outstanding:** Shares outstanding as of March 31, 2015 were 30,024,535, including the 1,923,077 shares issued to Johnson & Johnson Innovation - JJDC, Inc., in January 2015.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (EDT) 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: 37744154.

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)

	<u>March 31, 2015</u>	<u>December 31, 2014</u>
Cash and cash equivalents	\$ 263,134	\$ 157,591
Total assets	278,070	173,886
Deferred revenue	26,771	30,720
Total stockholders' equity	230,993	121,286

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(Amounts in thousands, except share and per share data)

	<u>Three Months Ended March 31,</u>	
	<u>2015</u>	<u>2014</u>
Revenues:		
Revenue from collaborative research	\$ 71,165	\$ 14,401
Grant revenue	114	318
Total revenues	<u>71,279</u>	<u>14,719</u>

Costs and expenses:		
Research and development	21,464	14,569
General and administrative	4,683	3,258
Total costs and expenses	<u>26,147</u>	<u>17,827</u>
Income (loss) from operations	45,132	(3,108)
Other income (expense)	(3)	–
Net comprehensive income (loss)	<u>\$ 45,129</u>	<u>\$ (3,108)</u>
Basic net income (loss) per common share	\$ 1.53	\$ (0.12)
Diluted net income (loss) per common share	\$ 1.42	\$ (0.12)
Basic weighted average common shares outstanding	29,415,768	26,262,356
Diluted weighted average common shares outstanding	31,684,174	26,262,356

SUMMARY OF NON-GAAP ADJUSTMENTS
(Amounts in thousands, except share and per share data)

	<u>GAAP</u>	<u>Revenue from Janssen Agreements</u>	<u>Non-GAAP</u>
Three months ended March 31, 2015:			
Total revenues	\$ 71,279	\$ 62,308	\$ 8,971
Income (loss) from operations	45,132	(62,308)	(17,176)
Net comprehensive income (loss)	45,129	(62,308)	(17,179)
Basic net income (loss) per common share	\$ 1.53	\$ (2.12)	\$ (0.58)
Diluted net income (loss) per common share	\$ 1.42	\$ (2.12)	\$ (0.58)

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 and DART are 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 "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 risk factors 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. 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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