

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): **November 4, 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 November 4, 2015, the Company announced financial and operating results as of and for the period ended September 30, 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 November 4, 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: November 4, 2015

MACROGENICS, INC.
By: /s/James Karrels
James Karrels
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number

Description of Exhibit

99.1 Press release dated November 4, 2015

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

- **Bi-specific antibody leadership – fifth DART® molecule (MGD009) enters clinical testing**
- **B7-H3 franchise advances – Encouraging initial clinical results from ongoing enoblituzumab (MGA271) Phase 1 trial and regional rights regained**
- **Recent collaboration with Merck on immuno-oncology study evaluating margetuximab in combination with KEYTRUDA® (pembrolizumab)**
- **Balance sheet strengthened with \$141M net proceeds from July equity offering**

ROCKVILLE, Md., Nov. 04, 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 third quarter ended September 30, 2015.

"As we strive to create breakthrough biologics and life-changing medicines, the team at MacroGenics was proud to share our progress at our recent R&D Day in New York," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "We reported encouraging initial clinical trial results from an ongoing Phase 1 study of enoblituzumab, our Fc-optimized monoclonal antibody that targets B7-H3. We also extended our B7-H3 franchise by advancing MGD009, a DART molecule directed against B7-H3 and CD3, into a Phase 1 study. Furthermore, we recently announced a collaboration with Merck to evaluate margetuximab in combination with Merck's anti-PD-1 therapy, KEYTRUDA, in patients with advanced gastric cancer. This combination of therapeutics could exploit complementary immune-based mechanisms for targeting tumors and provide an important alternative for patients who do not respond to currently available regimens."

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 in Collaboration with Merck:** The Company recently announced a collaboration to evaluate the combination of margetuximab with Merck's anti-PD-1 therapy, KEYTRUDA (pembrolizumab), in a Phase 1b/2 clinical trial in patients with HER2-positive advanced gastric cancer. Trial startup activities are underway, and the Company expects to begin enrolling patients by the first quarter of 2016.
- **SOPHIA Study Continues:** The Company's Phase 3 pivotal study in patients with HER2-positive metastatic breast cancer is continuing enrollment. This three-year study is evaluating the efficacy of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy following progression after at least two lines of previous therapy in approximately 530 patients.

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's three programs target B7-H3 through complementary mechanisms of action and take advantage of this target's broad expression across multiple solid tumor types. Recent highlights include:

- **Enoblituzumab (MGA271):** The Company provided an overview of initial data from its ongoing Phase 1 monotherapy clinical study of enoblituzumab, an Fc-optimized monoclonal antibody that targets B7-H3. To date, enoblituzumab has been well tolerated in patients and has shown encouraging, initial single-agent activity, including tumor regression in multiple, heavily pre-treated patients. In addition, evidence of T-cell immunomodulatory function has been observed in patients treated with enoblituzumab. The Company continues to enroll patients in additional monotherapy Phase 1 study cohorts as well as in two combination studies with either ipilimumab or pembrolizumab. Data from the ongoing monotherapy study will be presented in a late-breaking abstract session at the 2015 Society for Immunotherapy of Cancer (SITC) Annual Meeting on November 7, 2015.
- **Regains European and Other Regional Rights to Enoblituzumab:** In October 2015, Les Laboratoires Servier, or Servier, provided notice that it would not be exercising its option under a 2011 agreement to develop and commercialize enoblituzumab in Europe and other countries. Accordingly, the agreement with Servier regarding enoblituzumab has expired and MacroGenics now controls worldwide development and commercialization rights to enoblituzumab. The agreement between MacroGenics and Servier for development of DART molecules is unaffected by this decision.
- **MGD009 in Phase 1:** MGD009, a Dual-Affinity Re-Targeting, or DART, molecule targeting B7-H3 and CD3, is being tested in a Phase 1 study in patients and is being evaluated across multiple solid tumor types.
- **B7-H3 Antibody-Drug Conjugate:** The Company continues to evaluate antibody drug conjugate (ADC) molecules to induce direct killing of B7-H3 positive tumor cells.

DART Product Candidates—There are currently five DART molecules in 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) and MGD009 (B7-H3 x CD3).

Each of these DART molecules is being evaluated in a Phase 1 clinical study. At its R&D Day, the Company disclosed for the first time two DART molecules that it expects to advance into clinical development in the first half of 2017. These two product candidates include:

- **MGD013:** MacroGenics is developing an Fc-bearing DART molecule, MGD013, to simultaneously block two immune checkpoint molecules, PD-1 and LAG-3. The company 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. Beyond MGD013, MacroGenics is generating and evaluating multiple other candidates that target a range of immune regulatory molecules using its DART platform as well as its Trident™ platform for generating tri-specific molecules.
- **MGD014:** MacroGenics presented pre-clinical data on MGD014, a DART molecule that is being developed to eliminate latent HIV infection. MGD014 will be developed under a contract recently awarded 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.

Corporate Update

- **Equity Offering:** In July, the Company completed an equity offering, raising \$141 million in net proceeds, which included exercise of the underwriters' over-allotment option in full. MacroGenics is using the proceeds of this offering to expand its manufacturing capacity and accelerate development of immune regulatory-based product candidates, including MGD013, advance other research and development programs, in-license or acquire other products or technologies, and for general corporate purposes.
- **Partners' DART Molecules Advance:** As previously announced, MacroGenics' collaboration partner, Janssen Biotech, Inc., paid the Company a \$10 million milestone during the third quarter of 2015 after dosing a first patient in an open-label Phase 1 study of MGD011. Also, in October 2015, MacroGenics' collaboration partner, Boehringer Ingelheim, selected a DART molecule for further pre-clinical development. This triggers a \$5 million milestone payment to MacroGenics under an October 2010 agreement to discover, develop and commercialize DART therapeutics.
- **Manufacturing Expansion:** During the third quarter, the Company signed a lease for additional space with a focus on expanding its commercial manufacturing capabilities.

Third Quarter 2015 Financial Results

- **Cash Position:** Cash and cash equivalents as of September 30, 2015 were \$365.8 million, compared to \$157.6 million as of December 31, 2014. The Company expects that its cash balance should fund operations into 2018.
- **Revenue:** Total revenues, consisting primarily of revenue from collaborative research, were \$14.7 million for the three-month period ended September 30, 2015 compared to \$18.4 million for the three-month period ended September 30, 2014. Collaborative research revenue includes the recognition of deferred revenue from payments received in previous periods as well as payments received during the quarter.
- **R&D Expenses:** Research and development expenses were \$24.1 million for the three-month period ended September 30, 2015, compared to \$18.6 million for the three-month period ended September 30, 2014. This increase was primarily due to preparations for and launch of the margetuximab SOPHIA Phase 3 study, increased activity to prepare for the MGD009 Investigational New Drug (IND) application submission, and costs of other ongoing clinical studies.
- **G&A Expenses:** General and administrative expenses were \$6.0 million for the three-month period ended September 30, 2015, compared to \$3.7 million for the three-month period ended September 30, 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 \$15.4 million for the three-month period ended September 30, 2015, compared to net loss of \$3.9 million for the three-month period ended September 30, 2014.
- **Shares Outstanding:** Shares outstanding as of September 30, 2015 were 34,248,240.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (EST) to discuss the third quarter 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: 67542492.

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)

	September 30, 2015	December 31, 2014
Cash and cash equivalents	\$ 365,767	\$ 157,591
Total assets	384,089	173,886
Deferred revenue	19,052	30,720
Total stockholders' equity	339,326	121,286

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
Revenue from collaborative research	\$ 14,681	\$ 18,283	\$ 91,444	\$ 41,886
Grant revenue	-	99	1,232	435
Total revenues	<u>14,681</u>	<u>18,382</u>	<u>92,676</u>	<u>42,321</u>
Costs and expenses:				
Research and development	24,103	18,632	68,227	50,536
General and administrative	6,021	3,678	16,050	11,081
Total costs and expenses	<u>30,124</u>	<u>22,310</u>	<u>84,277</u>	<u>61,617</u>
Income (loss) from operations	(15,443)	(3,928)	8,399	(19,296)
Other income (expense)	1	-	(88)	1
Net comprehensive income (loss)	<u>\$ (15,442)</u>	<u>\$ (3,928)</u>	<u>\$ 8,311</u>	<u>\$ (19,295)</u>
Basic net income (loss) per common share	\$ (0.46)	\$ (0.14)	\$ 0.27	\$ (0.71)
Diluted net income (loss) per common share	\$ (0.46)	\$ (0.14)	\$ 0.25	\$ (0.71)
Basic weighted average number of common shares	33,339,163	27,751,437	30,952,458	27,227,151
Diluted weighted average number of common shares	33,339,163	27,751,437	32,960,233	27,227,151

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

The development of a DART molecule targeting HIV is funded in part by NIAID under contract no. HHSN272201500032C.

KEYTRUDA® is a registered trademark of Merck & Co., 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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