

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 2, 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 November 2, 2016, the Company announced financial and operating results as of and for the period ended September 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) 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 2, 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: November 2, 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 November 2, 2016
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MacroGenics Provides Update on Corporate Progress and Third Quarter 2016 Financial Results

- *Continued expansion and advancement of product candidates*
- *Portfolio update planned for upcoming R&D Day on December 13, 2016*

ROCKVILLE, MD, November 2, 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 September 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. "During the third quarter, an IND for MGA012 cleared the FDA and we remain on track to submit two DART molecule INDs in 2017, which would result in a total of eight DART molecules in clinical development. We look forward to providing an update on multiple clinical and preclinical programs at our R&D Day on December 13."

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 90% of the anticipated study sites have been activated as of September 30, 2016.
- **Phase 1b/2 Gastric Cancer Study:** MacroGenics continues to recruit and dose patients in a 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 the combination regimen being explored avoids 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 North America. We anticipate the start of this study in Asia by year-end.

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. An additional monotherapy study is planned for children with neuroblastoma and other tumors, and we also anticipate an investigator-sponsored monotherapy study in neo-adjuvant prostate cancer.
- **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 or duvortuxizumab) and PF-06671008 (P-cadherin x CD3).

During the third quarter and as previously reported, MacroGenics and Takeda Pharmaceutical Company Limited announced the conclusion of their License and Option Agreement for MGD010, a bispecific molecule targeting CD32B and CD79B. MacroGenics regained the worldwide rights to MGD010, for which the Company plans to continue to advance development based on the encouraging study results reported to date.

An Investigational New Drug (IND) application for MGA012, a monoclonal antibody, recently cleared the FDA and the Company plans to submit INDs for 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.

Corporate Update

- **R&D Day:** MacroGenics plans to host an R&D Day in New York on Tuesday, December 13, 2016. At this meeting, the Company plans to both provide an update on its clinical pipeline as well as preview its next set of development candidates.
- **Universal Shelf Registration Statement Filing:** MacroGenics has filed a shelf registration statement with the SEC and believes that this filing provides the Company with the flexibility to access the equity or debt capital markets most efficiently should the need arise. However, the Company

has no immediate plan to undertake an offering.

Third Quarter 2016 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2016, were \$314.1 million, compared to \$339.0 million as of December 31, 2015.
- **Revenue:** Total revenue, consisting primarily of revenue from collaborative agreements, was \$3.3 million for the quarter ended September 30, 2016, compared to \$14.7 million for the quarter ended September 30, 2015. This decrease was primarily due to recognition of a one-time milestone received from Janssen Biotech, Inc. in 2015.
- **R&D Expenses:** Research and development expenses were \$30.3 million for the quarter ended September 30, 2016, compared to \$24.1 million for the quarter ended September 30, 2015. This increase was due primarily to increased activity in the Company's preclinical immune checkpoint programs, including MGD013, MGD014 (funded by NIAID/NIH) 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 September 30, 2016, compared to \$6.0 million for the quarter ended September 30, 2015. This increase was primarily due to increased staff, recruiting costs and stock-based compensation expense.
- **Net Income/Loss:** Net loss was \$33.9 million for the quarter ended September 30, 2016, compared to net loss of \$15.4 million for the quarter ended September 30, 2015.
- **Shares Outstanding:** Shares outstanding as of September 30, 2016 were 34,813,334.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (EDT) to discuss the third 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: 2781761.

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>September 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Cash, cash equivalents and investments	\$ 314,124	\$ 339,049
Total assets	339,864	359,269
Deferred revenue	13,577	18,497
Total stockholders' equity	300,102	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 September</u> <u>30,</u>		<u>Nine Months Ended September</u> <u>30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenues:				
Revenue from collaborative agreements	\$ 2,014	\$ 14,681	\$ 82,404	\$ 91,444
Revenue from government agreements	1,241	-	4,370	1,232
Total revenues	<u>3,255</u>	<u>14,681</u>	<u>86,774</u>	<u>92,676</u>
Costs and expenses:				
Research and development	30,296	24,103	90,982	68,227
General and administrative	7,224	6,021	20,596	16,050
Total costs and expenses	<u>37,520</u>	<u>30,124</u>	<u>111,578</u>	<u>84,277</u>
Income (loss) from operations	(34,265)	(15,443)	(24,804)	8,399
Other income (expense)	419	1	1,059	(88)
Net income (loss)	<u>(33,846)</u>	<u>(15,442)</u>	<u>(23,745)</u>	<u>8,311</u>
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	(41)	-	23	-
Comprehensive income (loss)	<u>\$ (33,887)</u>	<u>\$ (15,442)</u>	<u>\$ (23,722)</u>	<u>\$ 8,311</u>
Basic net income (loss) per common share	\$ (0.97)	\$ (0.46)	(0.69)	0.27
Diluted net income (loss) per common share	\$ (0.97)	\$ (0.46)	(0.69)	0.25
Basic weighted average number of common shares	34,766,440	33,339,163	34,629,330	30,952,458
Diluted weighted average number of common shares	34,766,440	33,339,163	34,629,330	32,960,233

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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