# 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): March 3, 2015

#### MACROGENICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware001-3611206-1591613(State or Other Jurisdiction<br/>of Incorporation)(Commission<br/>File Number)(IRS Employer<br/>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))

## Item 2.02 Results of Operations and Financial Condition.

On March 3, 2015, the Company announced financial and operating results as of and for the year ended December 31, 2014. 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 9.01Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1 Press release issued by the company on March 3, 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: March 3, 2015 MACROGENICS, INC.

By: <u>/s/James Karrels</u> James Karrels

Chief Financial Officer

# EXHIBIT INDEX

**Exhibit Number** 

99.1

**Description of Exhibit**Press release dated March 3, 2015

MacroGenics Provides Update on Corporate Progress and 2014 Financial Results
-- Four oncology molecules in clinical development, including two bi-specific DART® molecules
-- Margetuximab Phase 3 SOPHIA study in metastatic breast cancer to initiate 3Q 2015
-- Cash runway extends into 2018

**ROCKVILLE, Md., March 3, 2015** – 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, 2014.

"This past year was critical for advancing our mission to harness the power of the immune system to fight cancer and autoimmune diseases," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "We achieved significant traction with our bi-specific Dual-Affinity Re-Targeting, or DART, antibody platform with the initiation of clinical testing of our first two DART product candidates in both hematological malignancies and solid tumors. In addition, we entered into three DART collaborations during the year that, combined with the completion of our February 2014 follow-on offering, further strengthened our financial position to enable us to advance our proprietary pipeline of immuno-therapeutics."

"Looking forward, in 2015, we will continue to invest in our immuno-oncology pipeline through the expansion of our growing portfolio of clinical development programs. We plan to initiate SOPHIA, a Phase 3 study of margetuximab in patients with metastatic breast cancer, in the third quarter. In addition, we expect to add to the growing body of MGA271 clinical data by enrolling monotherapy expansion cohorts representing six different tumor types and commencing studies in combination with other immuno-oncology agents. By the end of the year, we expect that a total of five DART molecules will be in the clinic, including those we've recently partnered," concluded Dr. Koenig.

#### **Development Pipeline Update**

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

- **Phase 3 Metastatic Breast Cancer Study**: The Company expects 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 futility analysis.
- **Presentation of Phase 1 Data**: In mid-2015, MacroGenics plans to present margetuximab Phase 1 clinical data for patients with breast cancer in expansion cohorts testing once-every-three-week dosing regimens.

**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**: During the fourth quarter of 2014, the Company initiated recruitment of patients in multiple additional 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), and a cohort consisting of non-small cell lung cancer and bladder cancer patients with the highest level of B7-H3 expression.
- · **Presentation of Phase 1 MGA271 Data**: In the second half of 2015, MacroGenics plans to present Phase 1 clinical data for MGA271.
- **Combination Studies**: MacroGenics plans to initiate studies of MGA271 in combination with other immuno-oncology agents in 2015, including a combination study with ipilimumab in B7-H3 positive melanoma, lung, and head and neck cancers.

**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. 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.

**MacroGenics' pipeline of earlier DART candidates continues to progress.** In addition to MGD011, which was recently licensed to Janssen Biotech, Inc., the Company expects that both MGD010 and MGD009 will start in Phase 1 clinical studies in 2015. Details of these programs include:

- · **MGD010 Nearing Phase 1 Clinical Initiation:** MGD010 is a DART molecule for the treatment of autoimmune disorders that simultaneously targets CD32B and CD79B, which are two B-cell surface proteins. MGD010 is designed to inhibit B-cell activation by exploiting the inhibitory function of CD32B, a checkpoint molecule expressed by B cells. MacroGenics expects to initiate a Phase 1a study in normal healthy volunteers in the first half of 2015. This product candidate is subject to a global collaboration with Takeda.
- **Introducing MGD009:** In late 2015, MacroGenics anticipates initiating a Phase 1 clinical study of MGD009, a humanized DART molecule that recognizes both CD3 and an undisclosed antigen expressed on many solid tumor types. MacroGenics retains worldwide development and commercialization rights to this molecule.

#### 2014 Partnering Highlights

- Janssen Biotech, Inc.: In December 2014, MacroGenics entered into a global collaboration and license agreement with Janssen Biotech, Inc. for MGD011. Johnson & Johnson Innovation JJDC, Inc. concurrently agreed to make an equity investment in MacroGenics. Upon closing of these agreements in 2015, MacroGenics received a total of \$125 million. MGD011 is a humanized CD19 x CD3 bi-specific DART protein being developed for the treatment of B-cell hematological malignancies. Janssen will be fully responsible for developing MGD011 following submission of the IND, which is planned for 2015. MacroGenics may elect to fund a portion of late-stage clinical development in exchange for a profit share in the U.S. and Canada.
- **Takeda**: In May 2014, MacroGenics announced that it had entered into an option agreement with Takeda Pharmaceutical Company Limited for the development and commercialization of MGD010. In September 2014, MacroGenics announced that it had entered into a second strategic alliance with Takeda. The second collaboration was for the development and commercialization of additional DART molecules.
- **Servier**: In February 2014, MacroGenics announced that Servier had exercised its exclusive option to develop and commercialize MGD006. MacroGenics has retained exclusive development and commercial rights in the U.S., Canada, Mexico, Japan, South Korea and India. Servier has rights in all other countries.

#### 2014 Financial Results and 2015 Financial Guidance

- Cash Position: Cash and cash equivalents as of December 31, 2014 were \$157.6 million, compared to \$116.5 million as of December 31, 2013. 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, and Johnson & Johnson Innovation JJDC, Inc. 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 \$47.8 million for the year ended December 31, 2014, compared to \$58.0 million for the year ended December 31, 2013. 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 \$70.2 million for the year ended December 31, 2014, compared to \$46.6 million for the year ended December 31, 2013. This increase was primarily due to the initiation of clinical manufacturing activities for two product candidates and the advancement of the Company's clinical and pre-clinical programs.
- **G&A Expenses**: General and administrative expenses were \$15.9 million for the year ended December 31, 2014, compared to \$11.1 million for the year ended December 31, 2013. This increase was primarily due to higher stock-based compensation expense as well as an increase in professional fees and other costs associated with public company operations.
- **Net Loss**: Net loss was \$38.3 million for the year ended December 31, 2014, compared to net loss of \$0.3 million for the year ended December 31, 2013.
- · **Shares Outstanding**: Shares outstanding as of December 31, 2014 were 27,995,638 million. This excludes the 1,923,077 shares issued to Johnson & Johnson Innovation JJDC, Inc., in January 2015.
- **Financial Guidance:** MacroGenics expects that its current cash and cash equivalents, 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: 92691132.

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,				
	 2014		2013		
Cash and cash equivalents	\$ 157,591	\$	116,481		
Total assets	173,886		125,782		
Deferred revenue	30,720		27,403		
Total stockholders' equity	121,286		78,914		

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

#### Year Ended December 31,

	 2014		2013		2012
Revenues:					
Revenue from collaborative research	\$ 47,264	\$	56,753	\$	59,646
Grant revenue	 533		1,282		4,180
Total revenues	47,797		58,035		63,826
Costs and expenses:					
Research and development	70,186		46,582		45,433
General and administrative	15,926		11,087		10,188
Total costs and expenses	86,112		57,669		55,621
Income (loss) from operations	(38,315)		366		8,205
Other income (expense)	2		(627)		157
Net comprehensive income (loss)	\$ (38,313)	\$	(261)	\$	8,362
Basic and diluted net income (loss) per common share	\$ (1.40)	\$	(0.04)	\$	0.00
Basic and diluted weighted average number of common shares	27,384,990		6,847,697		1,083,276

#### 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 is a registered trademark 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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