

MACROGENICS INC

FORM 8-K (Current report filing)

Filed 11/08/17 for the Period Ending 11/08/17

Address	9704 MEDICAL CENTER DRIVE Rockville, MD, 20850
Telephone	301-251-5172
CIK	0001125345
Symbol	MGNX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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 8, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On November 8, 2017, the Company announced financial and operating results as of and for the quarter ended September 30, 2017. 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.

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	Press Release dated November 8, 2017

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 8, 2017

MACROGENICS, INC.

By: /s/ Jeffrey Peters
Jeffrey Peters
Vice President and Acting General Counsel

MacroGenics Provides Update on Corporate Progress and Third Quarter 2017 Financial Results

ROCKVILLE, MD, November 8, 2017 – 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, 2017.

“We continue to be encouraged by data we’ve seen across multiple product candidates in our diverse pipeline. At the Society for Immunotherapy of Cancer (SITC) 32nd Annual Meeting later this week, we will have five posters relating to our various PD-1-based programs, including MGA012 (anti-PD-1) and our two PD-1-based DART® molecules,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “Also, in addition to the Phase 1 flotetuzumab data presented recently at the European Society for Medical Oncology Annual Congress (ESMO), we look forward to having two posters and an oral presentation with updated clinical data, at the 59th Annual Meeting of the American Society of Hematology (ASH) in December. Finally, we are thrilled to work with our new collaboration partner, Incyte, to expand the current development efforts for MGA012 and accelerate our own efforts to investigate combinations of MGA012 with multiple molecules in MacroGenics’ portfolio.”

Key Pipeline Highlights

Flotetuzumab. Enrollment of the Phase 1 dose expansion study of flotetuzumab, a bispecific DART molecule that recognizes both CD123 and CD3, is ongoing in patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). Recent highlights include:

- In September, MacroGenics presented clinical data from its ongoing Phase 1 study of flotetuzumab in an oral session at ESMO. Flotetuzumab demonstrated acceptable tolerability in the dose escalation portion of the study with encouraging initial anti-leukemic activity observed in AML patients. As of the data cut-off date of August 1, of the 14 response-evaluable patients treated at the threshold dose, six (43%) experienced an objective response. This included four (28%) patients who achieved a CR/CRi, with one patient who had a molecular CR.
- MacroGenics will present updated clinical data in an oral presentation at ASH in December 2017.

PD-1-Directed Immuno-Oncology Franchise. MacroGenics is advancing several PD-1-directed programs, which are designed to enable both a broad set of combination opportunities across the Company’s portfolio and provide further differentiation from existing PD-1-based treatment options. The first of these are:

- **MGA012**. Enrollment in the dose escalation portion of the Phase 1 study of this anti-PD-1 antibody has been completed and the data have been accepted for poster presentation at the upcoming SITC meeting. MGA012 is currently being evaluated as monotherapy across four solid tumor types in the dose expansion portion of the Phase 1 study. In October 2017, MacroGenics entered into an exclusive global collaboration and license agreement with Incyte Corporation for MGA012, in which Incyte obtained exclusive worldwide rights for the development and commercialization of MGA012. MacroGenics retains the right to pursue its core strategy to develop its pipeline assets in combination with MGA012. The Company plans to initiate the first study of MGA012 in combination with another internal program by year end 2017.
-

- **MGD013.** MacroGenics is developing MGD013, a DART molecule, to provide co-blockade of two immune checkpoint molecules expressed on T cells, PD-1 and LAG-3, for the potential treatment of a range of malignancies. The Company is enrolling the dose escalation portion of the Phase 1 study and will present a preclinical data poster as well as a Trials-in-Progress poster describing the Phase 1 study at SITC.
- **MGD019 .** MacroGenics continues to advance a preclinical bispecific DART molecule that provides co-blockade of PD-1 and CTLA-4, resulting in enhanced T-cell activation. The Company is conducting activities to support the potential submission of an Investigational New Drug (IND) application for MGD019 in 2018 and will present a preclinical data poster at SITC.

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 that take advantage of this antigen's broad expression across multiple solid tumor types. These molecules include:

- **Enoblituzumab :** The Company and collaborators continue to recruit patients in multiple ongoing studies of enoblituzumab, an Fc-optimized monoclonal antibody that targets B7-H3. These studies include a combination study with an anti-PD-1 antibody and a neoadjuvant prostate cancer study.
- **MGD009 :** This DART molecule targets B7-H3 and CD3 and is being evaluated in a Phase 1 study across multiple solid tumor types. The Company continues to explore the dose and schedule for MGD009 administration.
- **MGC018 :** The Company is conducting activities to support the potential submission of an IND application for this anti-B7-H3 antibody drug conjugate in 2018.

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

- **Phase 3 Metastatic Breast Cancer Study .** The pivotal SOPHIA study is evaluating the efficacy of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in approximately 530 relapsed/refractory HER2-positive metastatic breast cancer patients. MacroGenics believes it is on track to complete and announce the results of an interim futility analysis by year-end 2017 or early 2018 and to complete enrollment of this study by late 2018.
- **Phase 2 Gastric Cancer Study .** The Company continues to enroll advanced HER2-positive gastric and gastroesophageal junction cancer patients in its combination study of margetuximab with an anti-PD-1 antibody. MacroGenics expects to complete enrollment of two 30 patient expansion cohorts in 2017 and present clinical data during the first half of 2018.

Additional DART Clinical Programs. Other DART molecules being led by MacroGenics in Phase 1 clinical development include MGD007 (gpA33 x CD3) for colorectal cancer and MGD014 (HIV x CD3) for HIV. Updates on these programs include:

- **MGD007.** MacroGenics continues to recruit patients with colorectal cancer in a Phase 1 study and is evaluating various expansion cohorts to define a recommended dose and schedule.
- **MGD014.** MacroGenics' IND submission for MGD014 was cleared by FDA and the Company anticipates that a first patient will be dosed in early 2018.

Corporate Update

- **Incyte Collaboration.** In October 2017, MacroGenics and Incyte Corporation entered into an exclusive global collaboration and license agreement for MGA012. Under this agreement, MacroGenics will receive an upfront payment of \$150 million and could receive up to \$750 million in potential development, regulatory and commercial milestones. If MGA012 is approved and commercialized, MacroGenics would be eligible to receive royalties, tiered from 15 percent to 24 percent, on future sales of MGA012 by Incyte. The transaction is expected to close in the fourth quarter of 2017, subject to the early termination or expiration of any applicable waiting periods under the Hart-Scott-Rodino Act and customary closing conditions.
- **GMP Manufacturing.** Construction progress on MacroGenics' GMP manufacturing suite remains on track. The Company anticipates that the 5 x 2,000 liter single-use bioreactor facility will be operational in 2018. As part of the MGA012 collaboration with Incyte, MacroGenics retains the right to manufacture a portion of both companies' global clinical and commercial supply needs of MGA012.

Third Quarter 2017 Financial Results

- **Cash Position** : Cash, cash equivalents and marketable securities as of September 30, 2017, were \$203.6 million, compared to \$285.0 million as of December 31, 2016. MacroGenics anticipates receipt of the \$150 million upfront payment from Incyte upon closing of the transaction in the fourth quarter of 2017.
- **Revenue** : Total revenue, consisting primarily of revenue from collaborative agreements, was \$1.7 million for the quarter ended September 30, 2017, compared to \$3.3 million for the quarter ended September 30, 2016. Revenue from collaborative agreements includes the recognition of deferred revenue from payments received in previous periods as well as payments received during the period.
- **R&D Expenses** : Research and development expenses were \$41.0 million for the quarter ended September 30, 2017, compared to \$30.3 million for the quarter ended September 30, 2016. This increase was primarily due to the initiation of the MGA012 Phase 1 study and continued enrollment in multiple ongoing clinical trials.
- **G&A Expenses** : General and administrative expenses were \$8.4 million for the quarter ended September 30, 2017, compared to \$7.2 million for the quarter ended September 30, 2016. This increase was primarily due to increased professional fees, including consulting expenses, and increased employee compensation and benefit expense to support our overall growth.
- **Net Loss** : Net loss was \$47.0 million for the quarter ended September 30, 2017, compared to net loss of \$33.8 million for the quarter ended September 30, 2016.
- **Shares Outstanding** : Shares outstanding as of September 30, 2017 were 36,807,112.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (EDT) to discuss financial results for the quarter ended September 30, 2017 and provide a corporate update. To participate in the conference call, please dial (877) 303-6253 (domestic) or (+1) (973) 409-9610 (international) five minutes prior to the start of the call and provide the Conference ID: 5477659.

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)

	September 30, 2017	December 31, 2016
Cash, cash equivalents and investments	\$203,647	\$284,982
Total assets	241,845	311,263
Deferred revenue	11,640	14,306
Total stockholders' equity	189,465	268,751

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
Revenue from collaborative agreements	\$ 1,076	\$ 2,014	\$ 3,435	\$ 82,404
Revenue from government agreements	587	1,241	1,948	4,370
Total revenues	1,663	3,255	5,383	86,774
Costs and expenses:				
Research and development	40,984	30,296	108,246	90,982
General and administrative	8,403	7,224	24,249	20,596
Total costs and expenses	49,387	37,520	132,495	111,578
Loss from operations	(47,724)	(34,265)	(127,112)	(24,804)
Other income	681	419	1,759	1,059
Net loss	(47,043)	(33,846)	(125,353)	(23,745)
Other comprehensive loss:				
Unrealized gain (loss) on investments	56	(41)	55	23
Comprehensive loss	\$ (46,987)	\$ (33,887)	\$ (125,298)	\$ (23,722)
Basic and diluted net loss per common share	\$ (1.28)	\$ (0.97)	\$ (3.50)	\$ (0.69)
Basic and diluted weighted average common shares outstanding	36,779,305	34,766,440	35,847,449	34,629,330

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, DART and TRIDENT are trademarks or 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 "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.

###

Contacts:

Jim Karrels, Senior Vice President, CFO
MacroGenics, Inc.
1-301-251-5172, info@macrogenics.com

Karen Sharma, Senior Vice President
MacDougall Biomedical Communications
1-781-235-3060, ksharma@macbiocom.com