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 7, 2018

MACROGENICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36112**	**06-1591613**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

9704 Medical Center Drive, Rockville, Maryland	**20850**
(Address of Principal Executive Offices)	(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 7, 2018, the Company announced financial and operating results as of and for the quarter ended September 30, 2018. 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 Number	**Description of Exhibit**
99.1	Press Release dated November 7, 2018

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 7, 2018

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress and 3rd Quarter 2018 Financial Results

- **Margetuximab: Phase 3 SOPHIA study enrollment completed; topline results 1Q 2019**
- **PD-1 franchise: MGD013 cohort expansions initiated; $15 million in MGA012 milestones triggered; MGD019 IND cleared**
- **B7-H3 franchise: enoblituzumab oral presentation at SITC; MGC018 Phase 1 study initiating**
- **Flotetuzumab: two oral presentations at ASH**

ROCKVILLE, MD, November 7, 2018 – MacroGenics, Inc. (NASDAQ: MGNX), a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, today provided an update on its corporate progress and reported financial results for the quarter ended September 30, 2018.

"During the third quarter, MacroGenics made tremendous progress in advancing its portfolio of immuno-oncology product candidates towards multiple near-term data read-outs," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "Given the Company's substantial pipeline progress over the past several months, we believe that the next twelve months are poised to be transformative for MacroGenics, during which we expect to continue to advance our core mission of developing breakthrough biologics that may become life-changing medicines for patients."

Key Pipeline Updates

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

- **Fully Enrolled Phase 3 Metastatic Breast Cancer Study**. The Company has completed enrollment of 530 relapsed/refractory HER2-positive metastatic breast cancer patients in its pivotal SOPHIA study. MacroGenics anticipates disclosure of topline PFS data in the first quarter of 2019. In anticipation of a potential future product launch, MacroGenics is progressing its U.S. commercial planning and actively exploring ex-U.S. development and commercialization partnership opportunities.
- **Phase 2 Gastric Cancer Study Demonstrated Antitumor Activity**. At the 2018 European Society of Medical Oncology (ESMO) Congress in October, MacroGenics presented updated interim clinical data from a Phase 2 study of margetuximab plus an anti-PD-1 agent in patients with HER2-positive gastroesophageal adenocarcinoma. This chemotherapy-free combination, designed to coordinately engage innate and adaptive immunity, demonstrated antitumor activity in patients with advanced gastric cancer. The Company recently completed enrollment of 25 additional gastric cancer patients and expects to present data from this ongoing portion of the study in the first quarter of 2019.

PD-1 Franchise. MacroGenics is advancing multiple PD-1-directed programs to provide further differentiation from existing PD-1-based treatment options and enable a broad set of combination opportunities across the Company's portfolio. Recent program highlights include:

- **MGA012 Achieves Development Milestones**. This anti-PD-1 mAb, also known as INCMGA0012, was licensed to Incyte Corporation in 2017 under a global collaboration and license agreement. MacroGenics retains the rights to develop MGA012 in combination with its pipeline assets. MGA012 met certain clinical proof-of-concept criteria, triggering a total of $15 million in milestones from Incyte, $10 million of which has been recognized in the third quarter and $5 million of which is expected to be recognized in the fourth quarter. Incyte plans to present updated data from the cohort expansion portion of the Phase 1 study of MGA012 in a poster session at the upcoming Society for Immunotherapy for Cancer (SITC) Annual Meeting. Incyte has announced its intention to pursue monotherapy development of MGA012 in MSI-high endometrial cancer, Merkel cell carcinoma and anal cancer through registration-directed studies with initial data anticipated in 2020. In addition, across both Incyte and MacroGenics, multiple studies have been initiated which will feature various combination regimens with MGA012.
- **MGD013 Dose Expansion Initiated.** This first-in-class DART® molecule provides co-blockade of two immune checkpoint molecules expressed on T cells, PD-1 and LAG-3, for the potential treatment of a range of solid tumors and hematological malignancies. MacroGenics recently established the dose and schedule for MGD013 administration and has initiated dose expansion in up to nine tumor types in a Phase 1 study.
- **MGD019 IND Cleared.** This DART molecule is designed to provide co-blockade of both PD-1 and CTLA-4, two immune checkpoint inhibitors, on T cells. MacroGenics' Investigational New Drug (IND) application for MGD019 was cleared by the FDA and the Company is currently engaged in Phase 1 study startup.

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. Recent program highlights include:

- **Enoblituzumab Oral Presentation at SITC**: Clinical data from MacroGenics' study of this Fc-optimized mAb that targets B7-H3 combined with an anti-PD-1 mAb was selected for oral presentation at the upcoming SITC Annual Meeting. Like the combination of margetuximab and anti-PD-1, enoblituzumab and anti-PD-1 is designed to leverage Fc-optimization and checkpoint blockade to coordinately engage innate and adaptive immunity, the two major components of the immune response. As an update of the recently released abstract, the combination of enoblituzumab and anti-PD-1 demonstrated antitumor activity in checkpoint inhibitor-naïve patients who had squamous cell carcinoma of the head and neck (SCCHN) and in checkpoint inhibitor-naïve patients with non-small cell lung cancer (NSCLC) with tumor PD-L1 expression of <1%. In these two cohorts, objective responses occurred in 6/18 (33%) response-evaluable SCCHN patients and in 5/14 (36%) response-evaluable NSCLC patients. Additional details will be provided at SITC.
- **Orlotamab Studies Ongoing**: This DART molecule targeting B7-H3 and CD3 is being evaluated in a Phase 1 monotherapy study in multiple tumor types. In addition, a combination study of orlotamab and MGA012 is ongoing.
- **MGC018 Phase 1 Startup Initiated**: MacroGenics' IND submission for this anti-B7-H3 antibody-drug conjugate (ADC) was cleared by the FDA and the Company is initiating a Phase 1 study. This first-in-man study is designed to study MGC018 both as monotherapy and in combination with MGA012 in patients with solid tumors.

Flotetuzumab. Recent highlights of the Company's bispecific, humanized DART molecule that recognizes both CD123 and CD3, include:

- **Oral Presentations at ASH**. MacroGenics plans to present both updated clinical data as well as gene signature data from its completed acute myeloid leukemia (AML) dose expansion cohort in two oral presentations at the American Society of Hematology (ASH) Annual Meeting next month. The Company's collaborator, Servier, has development and commercialization rights outside North America, Japan, Korea and India for flotetuzumab, also known as S80880.

- **Combination Study with MGA012 Planned**. MacroGenics has previously presented data supporting the rationale for using checkpoint blockade as an approach to potentially enhance the anti-leukemic activity of flotetuzumab and plans to commence a combination study with MGA012.

Third Quarter 2018 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of September 30, 2018, were $260.1 million, compared to $305.1 million as of December 31, 2017.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $20.8 million for the quarter ended September 30, 2018, compared to $1.7 million for the quarter ended September 30, 2017. This increase was primarily due to revenue recognized under the Incyte MGA012 collaboration. Revenue from collaborative agreements 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 $46.2 million for the quarter ended September 30, 2018, compared to $41.0 million for the quarter ended September 30, 2017. This increase was primarily due to the initiation of combination studies of MGA012, continued enrollment in multiple ongoing studies, increased development/manufacturing costs related to MGA012, which were partially reimbursed by Incyte, and increased headcount to support expanded manufacturing and development activities.
- **G&A Expenses**: General and administrative expenses were $9.6 million for the quarter ended September 30, 2018, compared to $8.4 million for the quarter ended September 30, 2017. This increase was primarily due to increased patent-related expenses and consulting and other costs incurred related to the implementation of the Company’s new enterprise resource planning (ERP) system.
- **Net Loss**: Net loss was $34.0 million for the quarter ended September 30, 2018, compared to net loss of $47.0 million for the quarter ended September 30, 2017.
- **Shares Outstanding**: Shares outstanding as of September 30, 2018 were 42,248,075.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (ET) to discuss financial results for the quarter ended September 30, 2018 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: 6548008.

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, 2018 (unaudited)	December 31, 2017
Cash and cash equivalents	$ 260,143	$ 305,121
Total assets	355,356	373,883
Deferred revenue	21,511	20,839
Total stockholders' equity	282,644	299,238

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Revenue from collaborative agreements	$ 20,617	$ 1,076	$ 43,670	$ 3,435
Revenue from government agreement	181	587	657	1,948
Total revenues	20,798	1,663	44,327	5,383
Costs and expenses:				
Research and development	46,218	40,984	143,902	108,246
General and administrative	9,584	8,403	29,953	24,249
Total costs and expenses	55,802	49,387	173,855	132,495
Loss from operations	(35,004)	(47,724)	(129,528)	(127,112)
Other income	975	681	2,719	1,759
Net loss	(34,029)	(47,043)	(126,809)	(125,353)
Other comprehensive loss:				
Unrealized gain (loss) on investments	(18)	56	61	55
Comprehensive loss	$ (34,047)	$ (46,987)	$ (126,748)	$ (125,298)
Basic and diluted net loss per common share	$ (0.81)	$ (1.28)	$ (3.13)	$ (3.50)
Basic and diluted weighted average common shares outstanding	42,239,327	36,779,305	40,462,658	35,847,449

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. The Company generates its pipeline of product candidates primarily from its proprietary suite of next-generation antibody-based technology platforms, which have applicability across broad therapeutic domains. 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.

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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