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): February 26, 2019

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 February 26, 2019, the Company announced financial and operating results as of and for the year ended December 31, 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 February 26, 2019

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: February 26, 2019

MACROGENICS, INC.

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

Exhibit 99.1

MacroGenics Provides Update on Corporate Progress and 2018 Financial Results

- **Margetuximab: Positive Phase 3 SOPHIA study with BLA submission planned for second half of 2019; Plans to initiate Phase 2/3 registration-directed, front-line gastric cancer study**
- **Enoblituzumab: Encouraging anti-PD-1 combo data supports Phase 2 study initiation in second half of 2019**
- **PD-1 franchise: MGA012 registration-directed studies underway at Incyte; MGD019 dosing initiated**

ROCKVILLE, MD, February 26, 2019 – 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 year ended December 31, 2018.

"If the positive progression-free survival (PFS) data from our Phase 3 SOPHIA trial supports approval of margetuximab, this would provide a new treatment option for patients with HER2+ metastatic breast cancer," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "We have designed an antibody that, through optimization of the molecule's Fc domain, performed better than HERCEPTIN in the SOPHIA study. This molecule was created using the same Fc Optimization technology that is used in the most advanced asset in our B7-H3 franchise, enoblituzumab. During the fourth quarter, we reported encouraging initial results in our trial of enoblituzumab plus anti-PD-1 in patients with either squamous cell carcinoma of the head and neck (SCCHN) or non-small cell lung carcinoma (NSCLC) and we intend to further pursue this signal starting later this year. Beyond these two molecules, we continue to advance our pipeline of promising immuno-oncology product candidates."

Key Pipeline Updates

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

- **Positive Phase 3 Metastatic Breast Cancer Study**: In February 2019, MacroGenics announced positive results from SOPHIA, the Phase 3 clinical trial of margetuximab in HER2-positive metastatic breast cancer patients. The SOPHIA clinical trial met the trial's first primary endpoint of prolongation of PFS in patients treated with the combination of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy. Results of the SOPHIA study have been submitted for presentation later this year at a major scientific conference. Follow-up for determination of the impact of therapy on the sequential second primary endpoint of overall survival (OS) is ongoing, as pre-specified in the study protocol. MacroGenics anticipates submitting a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for margetuximab on the basis of the PFS results in the second half of 2019.
- **Updated Phase 2 Gastric Cancer Study Data**: The Company is also evaluating margetuximab in a Phase 2 clinical trial in patients with HER2-positive gastric or gastroesophageal junction cancer in combination with an anti-PD-1 mAb. In January 2019, data demonstrating encouraging anti-tumor activity and acceptable safety and tolerability were presented at the ASCO Gastrointestinal Cancers Symposium. During the first quarter of 2019, MacroGenics discussed with the FDA its development plans for a proposed Phase 2/3 registration-directed study of margetuximab in combination with checkpoint inhibitor molecules, including MGA012 and MGD013. The Company expects to initiate the study in the second half of 2019.

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 2018 SITC**: MacroGenics' most advanced product candidate in its B7-H3 franchise, enoblituzumab, is a mAb that targets B7-H3 and has been enhanced using the same Fc domain modifications used in margetuximab. The Company believes that this technology could promote activation of both innate and adaptive immunity in the treatment of cancer. In November 2018, encouraging data from a clinical study of the combination of enoblituzumab and an anti-PD-1 mAb were presented at the Society for Immunotherapy of Cancer Annual Meeting. In the study, cohorts of patients who were naïve to anti-PD-1 therapy with either SCCHN or NSCLC had objective responses at rates that benchmarked favorably with data reported in prior studies in which patients were treated with anti-PD-1 monotherapy. The combination of enoblituzumab and an anti-PD-1 mAb demonstrated acceptable safety and tolerability in patients treated to date. Encouraged by these results, MacroGenics intends to commence a Phase 2 study of enoblituzumab in combination with MGA012 in patients with SCCHN beginning in the second half of 2019.
- **MGD009 Studies Ongoing**: MGD009 is a bispecific DART® molecule that is designed to target both B7-H3 expressed on tumor cells as well as CD3, which is expressed on normal T cells. MacroGenics is conducting a Phase 1 clinical trial with MGD009 as monotherapy and in a separate study that combines MGD009 and MGA012.
- **MGC018 Dose Escalation Initiated**: The Company's third B7-H3-directed molecule is MGC018, an antibody-drug conjugate (ADC) that is designed to target solid tumors expressing B7-H3. MacroGenics initiated a Phase 1 dose escalation study of MGC018 in the fourth quarter of 2018.

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 in Registration-directed Studies:** MGA012, also known as INCMGA0012, is an anti-PD-1 mAb licensed to Incyte Corporation in 2017, but for which MacroGenics retains the rights to develop in combination with its pipeline of product candidates. At the November 2018 SITC meeting, Incyte presented encouraging initial anti-tumor and safety and tolerability data in the following tumor cohorts: NSCLC, cervical cancer, endometrial cancer and soft tissue sarcoma. Incyte is pursuing development of MGA012 through three monotherapy registration-directed studies with initial data anticipated in 2020, in the case of MSI-high endometrial cancer and Merkel cell carcinoma, and in 2021, in the case of anal cancer. In addition, MacroGenics and Incyte are each studying MGA012 in combination with other agents.
- **MGD013 Dose Expansion Ongoing:** MGD013 is a first-in-class bispecific DART molecule that is designed 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 solid tumors and hematological malignancies. MacroGenics' Phase 1 dose expansion study in up to nine tumor types is ongoing and the Company expects to present data from this study in 2019.
- **MGD019 Dose Escalation Initiated:** MGD019 is a bispecific DART molecule designed to provide co-blockade of both PD-1 and CTLA-4, two immune checkpoint inhibitors, on T cells. The Company is currently evaluating MGD019 in a Phase 1 dose escalation study.

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

- **Oral Presentations at ASH**: In December 2018, MacroGenics presented 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 2018 American Society of Hematology Annual Meeting. In the study, flotetuzumab demonstrated anti-leukemic activity and acceptable tolerability in patients with relapsed/refractory AML, with a higher response rate observed in primary refractory patients, an extremely challenging population to treat. MacroGenics plans to enroll additional patients in this ongoing study and announce data in 2019. The Company's collaborator, Servier, has development and commercialization rights outside North America, Japan, Korea and India for flotetuzumab, also known as S80880.

Recent Corporate Developments

- **Collaboration with Zai Lab**: In November 2018, MacroGenics entered into an exclusive collaboration and license agreement with Zai Lab Limited (Zai Lab) pursuant to which it licensed to Zai Lab the right to develop and commercialize margetuximab, MGD013 and an undisclosed preclinical TRIDENT™ binding molecule in mainland China, Hong Kong, Macau and Taiwan. Zai Lab will lead clinical development in its territory by leveraging its regulatory and clinical development expertise and broad regional network of investigators. Under its agreement with Zai Lab, MacroGenics received an upfront cash payment of $25 million, less foreign withholding, in January 2019 and is eligible to receive up to $140 million in potential development and regulatory-based milestone payments. In addition, Zai Lab has agreed to pay the Company double-digit royalties on annual net sales of the assets, which may be subject to adjustment in specified circumstances.

- **Completed Follow-on Offering of Common Stock**: In February 2019, MacroGenics completed a public offering of 6,325,000 shares of its common stock, raising net proceeds to the Company of $118.5 million, net of underwriting discounts and commissions and estimated offering expenses. This included $15.5 million of additional net proceeds following the full exercise of the over-allotment option by the underwriters.

2018 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of December 31, 2018 were $232.9 million, compared to $305.1 million as of December 31, 2017. Cash, cash equivalents and marketable securities as of December 31, 2018 did not include the $25 million, less foreign withholding, upfront payment from Zai Lab or the $118.5 million net proceeds from the follow-on offering recently completed.

- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $60.1 million for the year ended December 31, 2018, compared to $157.7 million for the year ended December 31, 2017. This decrease was primarily due to the $150.0 million upfront payment recognized under the Incyte agreement in 2017, compared to $41.0 million recognized in 2018 under the Incyte agreements. 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 $190.8 million for the year ended December 31, 2018, compared to $147.2 million for the year ended December 31, 2017. This increase was primarily due to continued enrollment in multiple ongoing clinical trials, including the SOPHIA Phase 3 study of margetuximab, increased development/manufacturing costs related to MGA012 and increased headcount to support expanded manufacturing and development activities.

- **G&A Expenses**: General and administrative expenses were $40.5 million for the year ended December 31, 2018, compared to $32.7 million for the year ended December 31, 2017. This increase was primarily due to increased labor-related costs including stock-based compensation expense, patent-related expenses and information technology-related expenses.

- **Net Loss**: Net loss was $171.5 million for the year ended December 31, 2018, compared to net loss of $19.6 million for the year ended December 31, 2017.

- **Shares Outstanding**: Shares outstanding as of December 31, 2018 were 42,353,301.

- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities as of December 31, 2018, combined with the estimated net proceeds from its recently completed equity offering as well as proceeds from collaboration payments the Company anticipates receiving, will enable it to fund its operations into 2021, assuming all of the Company's programs and collaborations advance as currently contemplated.

Conference Call Information

Exhibit 99.1

MacroGenics will host a conference call today at 4:30 pm (ET) to discuss financial results for the year ended December 31, 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: 4399964.

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)

	As of December 31,	
	2018	**2017**
Cash, cash equivalents and marketable securities	$ 232,863	$ 305,121
Total assets	332,130	373,883
Deferred revenue	40,722	20,839
Total stockholders' equity	242,877	299,238

Exhibit 99.1

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

	Year Ended December 31,		
	2018	2017	2016
Revenues:			
Revenue from collaborative agreements	$ 58,644	$ 155,516	$ 86,582
Revenue from government agreements	1,477	2,226	5,298
Total revenues	60,121	157,742	91,880
Costs and expenses:			
Research and development	190,827	147,232	122,091
General and administrative	40,500	32,653	29,831
Total costs and expenses	231,327	179,885	151,922
Loss from operations	(171,206)	(22,143)	(60,042)
Other income (expense)	(247)	2,517	1,514
Net loss	(171,453)	(19,626)	(58,528)
Other comprehensive loss:			
Unrealized gain (loss) on investments	58	21	(77)
Comprehensive loss	$ (171,395)	$ (19,605)	$ (58,605)
Basic and diluted net loss per common share	$ (4.19)	$ (0.54)	$ (1.69)
Basic and diluted weighted average number of common shares	40,925,318	36,095,080	34,685,274

Exhibit 99.1

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, 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.

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