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 25, 2020

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 25, 2020, the Company announced financial and operating results as of and for the year ended December 31, 2019. 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 25, 2020

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 25, 2020

MACROGENICS, INC.

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

Exhibit 99.1

MacroGenics Provides Update on Corporate Progress and 2019 Financial Results

– *Margetuximab: BLA for metastatic HER2-positive breast cancer accepted for review by the FDA; Phase 2/3 MAHOGANY study ongoing in front-line advanced HER2-positive gastric cancer*

– *First clinical data from Phase 1/2 studies of MGD013, MGC018 and MGD019 anticipated in 2020*

– *Conference call scheduled for today at 4:30 p.m. ET.*

ROCKVILLE, MD, February 25, 2020 – 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 recent corporate progress and reported financial results for the year ended December 31, 2019.

“2019 was an important year for MacroGenics, with the submission of our BLA for margetuximab for HER2-positive breast cancer. We also initiated a registration directed clinical study with margetuximab in combination with checkpoint blockade in advanced HER2-positive gastric cancer,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “During 2020, we anticipate additional key events. Following promising data presented at ASH in 2019, we plan to define a registration path for flotetuzumab in refractory AML, pending further discussions with FDA. We also look forward to presenting initial clinical data from several of our programs currently in Phase 1, potentially including our two bispecific DART molecules that provide dual checkpoint blockade, MGD013 and MGD019, as well as MGC018, our ADC targeting B7-H3. We look forward to a productive year for MacroGenics in 2020.”

Key Pipeline Updates

Recent progress and anticipated events in 2020 related to MacroGenics’ investigational product candidates in clinical development are highlighted below.

Margetuximab is an Fc-engineered, anti-HER2 monoclonal antibody being evaluated for the treatment of patients with advanced HER2-positive cancers.

- *Metastatic Breast Cancer*. In December 2019, MacroGenics submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for margetuximab for the treatment of patients with metastatic HER2-positive breast cancer in combination with chemotherapy. The safety and efficacy results provided in the BLA are primarily from the pivotal Phase 3 SOPHIA study, which is evaluating margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in patients with HER2-positive metastatic breast cancer who have received prior anti-HER2 therapies. Updated results from the study were presented at the San Antonio Breast Cancer Symposium in December 2019. In February 2020, the BLA was accepted for review by the FDA. MacroGenics expects that there will be a Standard Review process and we anticipate a Prescription Drug User Fee Act (PDUFA) date by the end of 2020. In addition, the Company believes that the FDA will require an Oncologic Drugs Advisory Committee (ODAC) meeting in the second half of 2020.

  Separately, in February 2020, MacroGenics' regional partner in Greater China, Zai Lab Limited (Zai Lab), announced the initiation of a registrational bridging study of margetuximab plus chemotherapy

for the treatment of patients with metastatic HER2-positive breast cancer who have received prior anti-HER2 therapies.

- *Advanced Gastric and Gastroesophageal Junction Cancer.* In October 2019, MacroGenics announced the initiation of the Phase 2/3 MAHOGANY study designed to evaluate the combination of margetuximab with anti-PD-1-based therapies as a front-line treatment. Initial safety and efficacy data are expected in the second half of 2020 from Module A of this study, which is evaluating a chemotherapy-free regimen. Module A has been designed to support a potential accelerated approval in the U.S. based on evaluation of objective response rate in a single-arm study.

Flotetuzumab is a bispecific CD123 x CD3 DART® molecule being evaluated for the treatment of patients with relapsed or refractory acute myeloid leukemia (AML). At the American Society of Hematology (ASH) annual meeting in December 2019, MacroGenics presented updated results from patients with AML who are refractory to induction treatment (primary induction failure) in a Phase 1/2 dose expansion study. The Company intends to define a potential registration path in the U.S. for the treatment of patients with primary induction failure AML in the first half of 2020, pending continued discussions with the FDA.

In October 2019, MacroGenics initiated a Phase 1/2 study outside of the U.S. combining flotetuzumab with MGA012, an anti-PD-1 antibody, based on preclinical and translational data that indicate the combination may enhance CD123-directed T cell killing.

MGA012 (INCMGA0012) is an anti-PD-1 monoclonal antibody that has been exclusively licensed to Incyte Corporation. There are currently six registration-directed clinical studies ongoing or planned in 2020 across a broad range of tumor types.

MGD013 is a first-in-class, bispecific PD-1 x LAG-3 DART molecule being evaluated in a Phase 1 dose expansion study. MacroGenics is selecting one or more indications for further development and has submitted data from select cohorts in the ongoing study for presentation at a scientific conference in the first half of 2020. Separately, in February 2020, MacroGenics' regional partner in Greater China, Zai Lab, announced the initiation of a Phase 1 study of MGD013 in combination with niraparib, a PARP (poly [ADP-ribose] polymerase) inhibitor, for the treatment of patients with advanced gastric or gastroesophageal junction cancer.

Enoblituzumab is an Fc-engineered, anti-B7-H3 monoclonal antibody. In 2020, MacroGenics plans to evaluate the activity of both enoblituzumab plus MGA012 and enoblituzumab plus MGD013 as chemotherapy-free regimens in front-line patients with recurrent and metastatic squamous cell carcinoma of the head and neck (SCCHN) as a lead-in module before proceeding with one of these combinations in a Phase 2/3 study.

MGC018 is an antibody-drug conjugate (ADC) targeting B7-H3 and ***MGD019*** is a bispecific PD-1 x CTLA-4 DART molecule. The Company expects to complete dose escalation for each of these molecules in 2020 and then initiate focused dose expansion studies in select tumor types. In addition, MacroGenics expects to submit data from the dose escalation cohorts for presentation at scientific conferences in 2020.

2019 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of December 31, 2019 were $215.8 million, compared to $232.9 million as of December 31, 2018.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $64.2 million for the year ended December 31, 2019, compared to $60.1 million for the year ended December 31, 2018. This increase was primarily due to the timing of revenue recognition under our collaborative agreements.

- **R&D Expenses**: Research and development expenses were $195.3 million for the year ended December 31, 2019, compared to $190.8 million for the year ended December 31, 2018. This increase was primarily due to continued enrollment in multiple ongoing clinical trials.
- **G&A Expenses**: General and administrative expenses were $46.1 million for the year ended December 31, 2019, compared to $40.5 million for the year ended December 31, 2018. This increase was primarily due to an increase in consulting costs related to market research and other commercial preparation activities.
- **Net Loss**: Net loss was $151.8 million for the year ended December 31, 2019, compared to net loss of $171.5 million for the year ended December 31, 2018.
- **Shares Outstanding**: Shares outstanding as of December 31, 2019 were 48,958,763.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities as of December 31, 2019, combined with anticipated and potential collaboration payments, will enable it to fund its operations into 2021, assuming the Company's programs and collaborations advance as currently contemplated. Through the prioritization of programs and ongoing realignment of its resources, MacroGenics is focused on extending its cash runway into 2022.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (ET) to discuss financial results for the year ended December 31, 2019 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: 5581596.

The 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,	
	2019	**2018**
Cash, cash equivalents and marketable securities	$ 215,756	$ 232,863
Total assets	312,501	332,130
Deferred revenue	19,853	40,722
Total stockholders' equity	230,628	242,877

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,		
	2019	2018	2017
Revenues:			
Revenue from collaborative and other agreements	$ 62,024	$ 58,644	$ 155,516
Revenue from government agreements	2,164	1,477	2,226
Total revenues	64,188	60,121	157,742
Costs and expenses:			
Research and development	195,309	190,827	147,232
General and administrative	46,064	40,500	32,653
Total costs and expenses	241,373	231,327	179,885
Loss from operations	(177,185)	(171,206)	(22,143)
Other income (expense)	25,374	(247)	2,517
Net loss	(151,811)	(171,453)	(19,626)
Other comprehensive loss:			
Unrealized gain on investments	19	58	21
Comprehensive loss	$ (151,792)	$ (171,395)	$ (19,605)
Basic and diluted net loss per common share	$ (3.16)	$ (4.19)	$ (0.54)
Basic and diluted weighted average number of common shares	48,082,728	40,925,318	36,095,080

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 the timing and steps required in the regulatory review process, expectations for regulatory approvals, the impact of competitive products, our ability to enter into agreements with strategic partners and 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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