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, 2021

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** (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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	MGNX	Nasdaq Global Select Market

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, 2021, the Company announced financial and operating results as of and for the year ended December 31, 2020. 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, 2021
104	Cover Page Interactive Data (embedded within the Inline XBRL document)

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.

MACROGENICS, INC.

Date: February 25, 2021

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

Exhibit 99.1

MacroGenics Provides Update on Corporate Progress and 2020 Financial Results

- *MARGENZA™ approved in December 2020; commercial launch expected March 2021*
- *July 2021 PDUFA target action dates for partnered products retifanlimab and teplizumab*
- *Multiple clinical updates across portfolio anticipated in 2021*
- *Conference call scheduled for today at 4:30 p.m. ET.*

ROCKVILLE, MD, February 25, 2021 (GLOBE NEWSWIRE) – MacroGenics, Inc. (NASDAQ: MGNX), a bbiopharmaceutical company focused on developing and commercializing 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, 2020.

“Following the approval in late 2020 of our first drug with the U.S. Food and Drug Administration (FDA), 2021 has the potential to be another transformative year for MacroGenics. We expect to launch MARGENZA in the coming weeks and will continue to advance our deep pipeline of promising product candidates in multiple clinical trials," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “We are particularly excited about our ongoing, potentially registration-enabling studies, including flotetuzumab in acute myeloid leukemia (AML) and margetuximab in gastric cancer, as well as two Prescription Drug User Fee Act (PDUFA) target action dates in July related to retifanlimab and teplizumab. And finally, we look forward to providing clinical updates on multiple, ongoing dose expansion studies this year.”

Key Updates on Proprietary Programs

Recent progress and anticipated events in 2021 related to MacroGenics’ approved and investigational product candidates in clinical development, as well as an advanced preclinical program, are highlighted below.

- ***Margetuximab*** is an Fc-engineered, monoclonal antibody (mAb) that targets the HER2 oncoprotein, which is expressed by certain breast, gastroesophageal and other solid tumor cells.
    - *MARGENZA (margetuximab-cmkb) approval and commercial launch.* In December 2020, the FDA approved MARGENZA in combination with chemotherapy for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. The launch, which is being coordinated with MacroGenics’ commercial partner, EVERSANA, is expected in March.
    - *Phase 2/3 MAHOGANY study in advanced gastric (GC) and gastroesophageal junction (GEJ) cancer.* The MAHOGANY clinical program contains two modules designed to evaluate margetuximab as an investigational agent in combination with a checkpoint inhibitor, with or without chemotherapy, as a potential first-line treatment for patients with advanced or metastatic HER2-positive GC/GEJ. Initial safety and efficacy data from among the first 40 patients enrolled in Module A, which is evaluating margetuximab in

combination with retifanlimab (an anti-PD-1 therapy), are expected in the first half of 2021. Enrollment in Module B, which is evaluating margetuximab plus MacroGenics' checkpoint inhibitor molecules in combination with chemotherapy compared to standard of care therapy of trastuzumab with chemotherapy in patients with HER2-positive tumors irrespective of PD-L1 expression, is currently ongoing in coordination with the Company's regional partner in Greater China, Zai Lab.

- ***Flotetuzumab*** is a bispecific CD123 **×** CD3 DART® molecule being evaluated in patients with primary induction failure (PIF) and early relapsed (less than six months, or ER6) AML. Six clinical and preclinical abstracts related to AML and flotetuzumab were presented at the American Society of Hematology (ASH) Annual Meeting & Exposition in December 2020. MacroGenics is conducting a single-arm, registration-enabling clinical study to evaluate flotetuzumab in up to 200 patients with PIF/ER6 AML, with complete remission (CR) and CR with partial hematological recovery (CRh) as the composite primary endpoint. The Company anticipates providing further updates on the clinical development of flotetuzumab in the second half of 2021, and completing full enrollment of this study in 2022.

- ***MGC018*** is an antibody-drug conjugate that targets B7-H3. MacroGenics continues to enroll patients with metastatic castration-resistant prostate cancer (mCRPC), triple negative breast cancer (TNBC) and non-small cell lung cancer (NSCLC) in the dose expansion portion of the Phase 1 clinical study. The Company expects to provide an update on this study in mid-2021.

- ***Enoblituzumab*** is an Fc-engineered, anti-B7-H3 mAb. In the coming weeks, MacroGenics expects to initiate a Phase 2 study of enoblituzumab in a chemo-free regimen in combination with retifanlimab in front-line patients with squamous cell carcinoma of the head and neck (SCCHN) who are PD-L1 positive and with tebotelimab in SCCHN patients who are PD-L1 negative.

- ***Tebotelimab*** is a bispecific, tetravalent DART molecule targeting PD-1 and LAG-3. Tebotelimab is being evaluated in a Phase 1 dose expansion study as monotherapy in several tumor types. An oral presentation of tebotelimab Phase 1 data in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) was made at ASH in December 2020. In addition, data from the combination study of tebotelimab and margetuximab in patients with advanced HER2+ neoplasms were presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2020. MacroGenics' regional partner in Greater China, Zai Lab, is also evaluating tebotelimab in Phase 1 combination studies with niraparib and brivanib for the study of advanced gastric cancer and hepatocellular carcinoma, respectively, as well as a monotherapy study in patients with melanoma. MacroGenics expects to provide clinical updates on tebotelimab in 2021, including future development plans.

- ***MGD019*** is a bispecific, tetravalent DART molecule targeting PD-1 and CTLA-4. The Company is enrolling Phase 1 dose expansion cohorts, initially in patients with microsatellite stable colorectal cancer (MSS CRC) and checkpoint-naïve NSCLC at the recommended Phase 2 dose. The Company expects to provide a clinical update on this study in mid-2021.

- ***IMGC936*** is an antibody-drug conjugate that targets ADAM9, a cell surface protein over-expressed in several solid tumor types. IMGC936 is being advanced under a co-development agreement with ImmunoGen, Inc. Under the 50/50 collaboration, ImmunoGen is leading clinical development and the Phase 1 dose escalation study is currently enrolling patients with select advanced solid tumors.

- ***MGD024*** is a next-generation, bispecific CD123 × CD3 DART molecule in preclinical development. The molecule incorporates a CD3 component designed to minimize cytokine-release syndrome, while maintaining anti-tumor cytolytic activity, along with an Fc domain to

permit intermittent dosing through a longer half-life. The Company anticipates submitting an Investigational New Drug (IND) application to the FDA by the end of 2021.

Key Partnered Programs Update

Recent progress and disclosed priorities for MacroGenics' partnerered investigational molecules are highlighted below.

- ***Retifanlimab*** is an anti-PD-1 mAb that has been exclusively licensed to Incyte Corporation. To date, MacroGenics has earned $65 million in milestones related to retifanlimab, triggered by advancement of the molecule through various clinical and regulatory activities. In January 2021, Incyte announced that the FDA had accepted for Priority Review its Biologics License Application (BLA) for retifanlimab as a potential treatment for adult patients with locally advanced or metastatic squamous cell carcinoma of the anal canal. The PDUFA target action date for retifanlimab is July 25, 2021. MacroGenics is eligible to receive up to a total of $685 million in potential remaining development, regulatory and commercial milestones. If retifanlimab is approved and commercialized, MacroGenics would be eligible to receive royalties, tiered from 15 to 24 percent, on future worldwide net sales of the drug.
- ***Teplizumab*** is a mAb being developed by Provention Bio, Inc. for the treatment of type 1 diabetes. In January 2021, Provention announced the FDA filing of a BLA and Priority Review for this molecule, with a PDUFA target action date of July 2, 2021. In 2018, MacroGenics sold its interest in teplizumab to Provention and is eligible to receive up to $170 million upon the achievement of certain regulatory approval milestones, including $60 million upon approval of a BLA in the U.S., additional milestone payments totaling $225 million upon the achievement of certain sales milestones and single-digit royalties on net sales of the molecule.

Corporate Updates

- **Janssen Collaboration.** In December 2020, MacroGenics announced a research collaboration and global license agreement to develop a preclinical bispecific molecule with Janssen Biotech, Inc. The research collaboration will incorporate MacroGenics' proprietary DART platform to enable simultaneous targeting of two undisclosed targets in a therapeutic area outside oncology. Under the terms of the agreement, Janssen paid MacroGenics an upfront payment of $20 million and will be responsible for funding all expenses. MacroGenics will also be eligible to receive up to $312 million in potential milestone payments and tiered royalties on worldwide product sales.
- **Ms. Federica O'Brien Added to Board.** MacroGenics recently announced the appointment of Federica "Freddi" O'Brien, a veteran executive with 25 years of financial and operational leadership in biopharmaceutical, medical device, and technology companies, to its Board of Directors.

2020 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of December 31, 2020 were $272.5 million, compared to $215.8 million as of December 31, 2019.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $104.9 million for the year ended December 31, 2020, compared to $64.2 million for the year ended December 31, 2019. This increase was primarily due to the recognition of milestones, partially offset by timing of revenue recognition under the Company's collaborative agreements.

- **R&D Expenses**: Research and development expenses were $193.2 million for the year ended December 31, 2020, compared to $195.3 million for the year ended December 31, 2019.
- **G&A Expenses**: General and administrative expenses were $42.7 million for the year ended December 31, 2020, compared to $46.1 million for the year ended December 31, 2019. This decrease was primarily due to a decrease in external costs, including consulting.
- **Net Loss**: Net loss was $129.7 million for the year ended December 31, 2020, compared to net loss of $151.8 million for the year ended December 31, 2019.
- **Shares Outstanding**: Shares outstanding as of December 31, 2020 were 56,244,771.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities as of December 31, 2020, as well as anticipated and potential collaboration payments, should enable it to fund its operations into 2023, assuming the Company's programs and collaborations advance as currently contemplated.

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, 2020 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: 6094343.

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,	
	2020	**2019**
Cash, cash equivalents and marketable securities	$ 272,531	$ 215,756
Total assets	378,743	312,501
Deferred revenue	11,382	19,853
Total stockholders' equity	295,884	230,628

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

	Year Ended December 31,		
	2020	2019	2018
Revenues:			
Revenue from collaborative and other agreements	$ 97,764	$ 62,024	$ 58,644
Revenue from government agreements	7,119	2,164	1,477
Total revenues	104,883	64,188	60,121
Costs and expenses:			
Research and development	193,201	195,309	190,827
General and administrative	42,742	46,064	40,500
Total costs and expenses	235,943	241,373	231,327
Loss from operations	(131,060)	(177,185)	(171,206)
Other income (expense)	1,321	25,374	(247)
Net loss	(129,739)	(151,811)	(171,453)
Other comprehensive loss:			
Unrealized gain (loss) on investments	(23)	19	58
Comprehensive loss	$ (129,762)	$ (151,792)	$ (171,395)
Basic and diluted net loss per common share	$ (2.47)	$ (3.16)	$ (4.19)
Basic and diluted weighted average number of common shares	52,442,389	48,082,728	40,925,318

IMPORTANT SAFETY INFORMATION - MARGENZA
BOXED WARNING: LEFT VENTRICULAR DYSFUNCTION AND EMBRYO-FETAL TOXICITY

- **Left Ventricular Dysfunction:** MARGENZA may lead to reductions in left ventricular ejection fraction (LVEF). Evaluate cardiac function prior to and during treatment. Discontinue MARGENZA treatment for a confirmed clinically significant decrease in left ventricular function.
- **Embryo-Fetal Toxicity:** Exposure to MARGENZA during pregnancy can cause embryo-fetal harm. Advise patients of the risk and need for effective contraception.

WARNINGS & PRECAUTIONS:

Left Ventricular Dysfunction

- Left ventricular cardiac dysfunction can occur with MARGENZA.
- MARGENZA has not been studied in patients with a pretreatment LVEF value of <50%, a prior history of myocardial infarction or unstable angina within 6 months, or congestive heart failure NYHA class II-IV.
- Withhold MARGENZA for ≥16% absolute decrease in LVEF from pre-treatment values or LVEF below institutional limits of normal (or 50% if no limits available) and ≥10% absolute decrease in LVEF from pretreatment values.
- Permanently discontinue MARGENZA if LVEF decline persists greater than 8 weeks, or dosing is interrupted more than 3 times due to LVEF decline.
- Evaluate cardiac function within 4 weeks prior to and every 3 months during and upon completion of treatment. Conduct thorough cardiac assessment, including history, physical examination, and determination of LVEF by echocardiogram or MUGA scan.
- Monitor cardiac function every 4 weeks if MARGENZA is withheld for significant left ventricular cardiac dysfunction.

Embryo-Fetal Toxicity

- Based on findings in animals and mechanism of action, MARGENZA can cause fetal harm when administered to a pregnant woman. Post-marketing studies of other HER-2 directed antibodies during pregnancy resulted in cases of oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death.
- Verify pregnancy status of women of reproductive potential prior to initiation of MARGENZA.
- Advise pregnant women and women of reproductive potential that exposure to MARGENZA during pregnancy or within 4 months prior to conception can result in fetal harm.
- Advise women of reproductive potential to use effective contraception during treatment and for 4 months following the last dose of MARGENZA.

Infusion-Related Reactions (IRRs)

- MARGENZA can cause IRRs. Symptoms may include fever, chills, arthralgia, cough, dizziness, fatigue, nausea, vomiting, headache, diaphoresis, tachycardia, hypotension, pruritus, rash, urticaria, and dyspnea.
- Monitor patients during and after MARGENZA infusion. Have medications and emergency equipment to treat IRRs available for immediate use.
- In patients experiencing mild or moderate IRRs, decrease rate of infusion and consider premedications, including antihistamines, corticosteroids, and antipyretics. Monitor patients until symptoms completely resolve.
- Interrupt MARGENZA infusion in patients experiencing dyspnea or clinically significant hypotension and intervene with supportive medical therapy as needed. Permanently discontinue MARGENZA in all patients with severe or life-threatening IRRs.

MOST COMMON ADVERSE REACTIONS:

The most common adverse drug reactions (≥10%) with MARGENZA in combination with chemotherapy are fatigue/asthenia, nausea, diarrhea, vomiting, constipation, headache, pyrexia, alopecia, abdominal pain, peripheral neuropathy, arthralgia/myalgia, cough, decreased appetite, dyspnea, infusion-related reactions, palmar-plantar erythrodysesthesia, and extremity pain.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch or to MacroGenics at (844)-MED-MGNX (844-633-6469).

Link to full Prescribing Information, including Boxed Warning

About MacroGenics, Inc.

MacroGenics is a biopharmaceutical company focused on developing and commercializing 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, commercial prospects of or product revenues from MARGENZA, milestone or opt-in payments from the Company's collaborators, the Company's anticipated milestones 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: risks that MARGENZA revenue, expenses and costs may not be as expected, risks relating to MARGENZA's market acceptance, competition, reimbursement and regulatory actions, 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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