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): April 29, 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 April 29, 2021, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended March 31, 2021. 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 April 29, 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.

Date: April 29, 2021

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress and First Quarter 2021 Financial Results

- *MARGENZA™ launched in mid-March*
- *Upcoming poster presentation of MGC018 initial Phase 1 clinical data at ASCO*
- *Conference call scheduled for today at 4:30 p.m. ET.*

ROCKVILLE, MD., April 29, 2021 (GLOBE NEWSWIRE) -- MacroGenics, Inc. (NASDAQ: MGNX), a biopharmaceutical 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 quarter ended March 31, 2021.

“With the recent launch and commercialization of MARGENZA, we are delivering on our vision to provide potentially life-changing therapeutics to patients with cancer. We are well positioned to advance this mission as the growing body of data emerges from our deep pipeline of clinical and pre-clinical product candidates," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics, “and we look forward to sharing additional data with you as the year progresses.”

Key Updates on Proprietary Programs

Recent progress and anticipated events in 2021 related to MacroGenics’ approved and investigational product candidates in clinical development 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) commercial launch.* In mid-March 2021, MacroGenics and its commercial partner, EVERSANA, launched MARGENZA for the treatment of adult patients with metastatic HER2-positive breast cancer, in combination with chemotherapy, who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. Also during the quarter, results from the SOPHIA metastatic breast cancer Phase 3 study of MARGENZA were published in the *Journal of the American Medical Association (JAMA*) *Oncology*. Finally, based on the current accrual rate of overall survival (OS) events in the ongoing SOPHIA trial that supported approval by the FDA, the Company now anticipates completing the final analysis of OS data, based on accrual of the 385th OS event, by the end of the third quarter.
    - *Phase 2/3 MAHOGANY study in advanced gastric and gastroesophageal junction 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. All 40 patients have been enrolled in the first part of Module A, which is evaluating margetuximab in combination with retifanlimab (an anti-PD-1 therapy). The Company expects to report safety and efficacy data in the third quarter 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 MacroGenics' 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) acute myeloid leukemia (AML). 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 late 2021 and completing full enrollment of this study in 2022.
- ***MGC018*** is an antibody-drug conjugate (ADC) that targets B7-H3. In April 2021, MacroGenics presented pre-clinical data at the American Association for Cancer Research (AACR) Annual Meeting demonstrating that at clinically relevant dose levels, MGC018 potentiated antitumor activity in vivo in mouse patient-derived xenograft (PDX) models of squamous cell carcinoma of the head and neck (SCCHN). MacroGenics recently expanded its Phase 1 clinical study to include SCCHN and melanoma; the Company continues to enroll patients with metastatic castration-resistant prostate cancer (mCRPC), triple negative breast cancer (TNBC) and non-small cell lung cancer (NSCLC). MacroGenics will provide a clinical data update via poster presentation at the upcoming American Society of Clinical Oncology (ASCO) 2021 Annual Meeting, June 4-8, 2021.
- ***Enoblituzumab*** is an Fc-engineered, anti-B7-H3 mAb. During the first quarter, MacroGenics initiated a Phase 2 study of enoblituzumab in a chemotherapy-free regimen in combination with retifanlimab in front-line patients with 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. MacroGenics expects to provide updates on the next-stage of development for tebotelimab later this year.
- ***MGD019*** is a bispecific, tetravalent DART molecule targeting PD-1 and CTLA-4. The Company is conducting Phase 1 dose expansion cohorts at the recommended Phase 2 dose in patients with microsatellite stable colorectal cancer (MSS CRC) and checkpoint-naïve NSCLC and recently added cohorts of patients with mCRPC and melanoma.
- ***IMGC936*** is an ADC that targets ADAM9, a cell surface protein over-expressed in several solid tumor types, and is being developed jointly under a 50/50 collaboration with ImmunoGen, Inc. Pre-clinical data recently presented at the AACR Annual Meeting showed that IMGC936 had activity against multiple solid tumor types in in vivo mouse PDX models. Under the collaboration, ImmunoGen is leading clinical development of IMGC936 in a Phase 1 clinical trial evaluating safety and pharmacokinetics in patients with select cancers and have indicated they anticipate disclosing initial data by early 2022.
- ***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.

First Quarter 2021 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of March 31, 2021, were $343.2 million, compared to $272.5 million as of December 31, 2020. During the quarter ended March 31, 2021, $98.2 million in net proceeds were received from the sale of 3,622,186 shares of the Company's common stock pursuant to its at-the-market (ATM) offering.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $16.9 million for the quarter ended March 31, 2021, including $0.9 million net sales of MARGENZA, which was launched in mid-March, compared to $13.7 million for the quarter ended March 31, 2020. This increase was primarily due to the recognition of a $10 million milestone from Incyte, partially offset by a decrease of approximately $5.8 million recognized under a clinical supply agreement with Incyte.
- **R&D Expenses**: Research and development expenses were $53.1 million for the quarter ended March 31, 2021, compared to $48.9 million for the quarter ended March 31, 2020. This increase was primarily due to higher expenses related to flotetuzumab, MGC018, MGD019 and preclinical projects, partially offset by a decrease in development and manufacturing costs for retifanlimab.
- **SG&A Expenses**: Selling, general and administrative expenses were $15.0 million for the quarter ended March 31, 2021, compared to $10.2 million for the quarter ended March 31, 2020. This increase was primarily due to MARGENZA pre-launch and launch costs.
- **Net Loss**: Net loss was $51.3 million for the quarter ended March 31, 2021, compared to net loss of $44.7 million for the quarter ended March 31, 2020.
- **Shares Outstanding**: Shares outstanding as of March 31, 2021 were 60,011,206.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities as of March 31, 2021, as well as anticipated and potential collaboration payments, should enable it to fund its operations through 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 p.m. (ET) to discuss financial results for the quarter ended March 31, 2021 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: 5257004.

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)

	March 31, 2021 (unaudited)	December 31, 2020
Cash, cash equivalents and marketable securities	$ 343,177	$ 272,531
Total assets	435,445	378,743
Deferred revenue	10,780	11,382
Total stockholders' equity	350,531	295,884

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

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

	Three Months Ended March 31,	
	2021	2020
Revenues:		
Revenue from collaborative and other agreements	$ 15,184	$ 12,967
Product revenue, net	887	—
Revenue from government agreements	810	715
Total revenues	16,881	13,682
Costs and expenses:		
Cost of product sales	17	—
Research and development	53,121	48,894
Selling, general and administrative	15,036	10,233
Total costs and expenses	68,174	59,127
Loss from operations	(51,293)	(45,445)
Other income	21	721
Net loss	(51,272)	(44,724)
Other comprehensive income:		
Unrealized gain on investments	18	56
Comprehensive loss	$ (51,254)	$ (44,668)
Basic and diluted net loss per common share	$ (0.90)	$ (0.91)
Basic and diluted weighted average common shares outstanding	57,202,846	49,012,663

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