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 24, 2022

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 24, 2022, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the year ended December 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 February 24, 2022
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: February 24, 2022

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress and 2021 Financial Results

- *Initiating Phase 1 dose escalation study of MGC018 in combination with lorigerlimab (formerly MGD019) in coming weeks*
- *Prioritizing MGD024 as lead CD3-based DART® molecule targeting CD123 and discontinuing development of flotetuzumab*
- *Presented encouraging preclinical combinatorial anti-tumor activity with MGD024 at ASH in December*
- *Conference call scheduled for today at 4:30 p.m. ET.*

ROCKVILLE, MD., February 24, 2022 (GLOBE NEWSWIRE) --MacroGenics, Inc. (NASDAQ: MGNX), a biopharmaceutical company focused on developing and commercializing innovative 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, 2021.

“We are excited about our 2022 plans for our B7-H3-directed programs for the potential treatment of multiple solid tumors. We believe we are well-positioned to be a leader in this promising field and are prioritizing our efforts around B7-H3. First, I am pleased to share that later this quarter, we plan to meet with the U.S. Food and Drug Administration (FDA) to discuss the design of a potential registration-directed study of MGC018 in patients with metastatic castration-resistant prostate cancer (mCRPC). Second, we expect to initiate a study of MGC018 in combination with lorigerlimab, our bispecific DART molecule targeting PD-1 and CTLA-4, in the coming weeks. And third, during the second half of this year, we intend to provide an update from a study of our second B7-H3 targeted molecule, enoblituzumab, being evaluated in combination with two of our checkpoint molecules in front-line squamous cell carcinoma of the head and neck (SCCHN). Beyond these B7-H3 programs, we are advancing several of our other clinical-stage molecules and have a variety of ongoing preclinical activities intended to expand our pipeline of differentiated investigational product candidates for the potential treatment of cancer,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics.

Updates on Proprietary Programs

B7-H3 Programs: MacroGenics is developing two investigational, clinical product candidates that target B7-H3, an antigen with broad expression across multiple solid tumor types and a member of the B7 family of molecules involved in immune regulation. Recent highlights for these two molecules include:

- ***MGC018*** is an antibody-drug conjugate (ADC) that targets B7-H3. MacroGenics presented encouraging preliminary clinical results from an ongoing Phase 1/2 study of MGC018 in patients with solid tumors at the American Society of Clinical Oncology (ASCO) and European Society for Medical Oncology (ESMO) meetings in 2021. The Phase

1/2 study expansion cohorts are fully enrolled for patients with mCRPC (n=40) and smaller cohorts of patients (n=approximately 20 each) with non-small cell lung cancer (NSCLC), melanoma and triple negative breast cancer (TNBC), while the Company continues to recruit patients for the SCCHN cohort. MacroGenics plans to meet with FDA later this quarter to discuss its development strategy in mCRPC. In addition, the Company intends to provide an update on clinical data from the dose expansion cohorts in the second half of 2022 as the data further mature. Finally, beyond monotherapy, the Company expects to initiate a combination study of MGC018 with lorigerlimab across multiple indications in the coming weeks.

- ***Enoblituzumab*** is an Fc-engineered, monoclonal antibody (mAb) that targets B7-H3. MacroGenics continues to recruit patients into its Phase 2 study of enoblituzumab in combination with retifanlimab, the Company's investigational, anti-PD-1 antibody that was licensed to Incyte, in front-line patients with SCCHN who are PD-L1 positive and with tebotelimab in SCCHN patients who are PD-L1 negative. The Company expects to complete enrollment of the PD-L1 positive patient cohort during the first half of this year and provide an update on this cohort during the second half of the year. I-Mab, MacroGenics' partner in Greater China, announced in December that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) approved its Investigational New Drug (IND) submission for the initiation of a Phase 2 trial in China for enoblituzumab in combination with pembrolizumab in patients with solid tumors, including NSCLC, urothelial carcinoma and other selected cancers.

DART Molecules for Immune Checkpoint Blockade: MacroGenics is studying multiple investigational, PD-1-directed programs to provide further differentiation from existing PD-1-based treatment options and enable combination opportunities across the Company's portfolio. Recent highlights include:

- ***Lorigerlimab (formerly MGD019)*** is a bispecific, tetravalent DART molecule targeting PD-1 and CTLA-4. MacroGenics is conducting a Phase 1/2 dose expansion study in cohorts of patients with microsatellite stable colorectal cancer (MSS CRC), mCRPC, melanoma and checkpoint-naïve NSCLC. The Company anticipates sharing data from this ongoing study in the second half of 2022. As described above, MacroGenics expects to initiate a dose escalation study of MGC018 in combination with lorigerlimab in the coming weeks.

- ***Tebotelimab*** is a bispecific, tetravalent DART molecule targeting PD-1 and LAG-3. Tebotelimab was evaluated in a Phase 1/2 dose expansion study in several tumor types and is currently being studied in combination with enoblituzumab in SCCHN. The Company expects to provide an update on potential future development plans for tebotelimab in the second half of 2022. MacroGenics' partner in Greater China, Zai lab, recently informed the Company that it has decided to discontinue development of tebotelimab for indications it was enrolling in its territory and is evaluating future development plans in other indications.

Bispecific CD123 × CD3 DART molecule: MacroGenics has prioritized the development of MGD024, its investigational, next-generation CD123 × CD3 DART molecule, and will discontinue the development of flotetuzumab. Recent updates of these DART molecules include:

- ***MGD024*** is a next-generation, humanized CD123 × CD3 DART molecule designed to minimize cytokine-release syndrome, while maintaining anti-tumor cytolytic activity, and permitting intermittent dosing through a longer half-life. In November, MacroGenics announced submission of an IND application for MGD024 to FDA. At the American Society of Hematology (ASH) Annual Meeting in December, MacroGenics presented preclinical data from the combination of MGD024 with standard-of-care agents used to treat CD123-positive hematological malignancies. The Company expects to initiate a Phase 1 dose escalation study of MGD024 in patients with CD123-positive neoplasms, including acute myeloid leukemia (AML), pending IND clearance by FDA.

- ***Flotetuzumab*** is the Company's first-generation, investigational, bispecific CD123 × CD3 DART molecule. An interim efficacy threshold from the single-arm study evaluating flotetuzumab in patients who were refractory to induction therapy was met with manageable safety. However, the Company has recently decided to prioritize the development of MGD024 and discontinue development of flotetuzumab, in view of the Company's belief that MGD024 may offer certain advantages over flotetuzumab, including easier dose administration and a more facile means to combine with other agents.

Margetuximab is an Fc-engineered mAb that targets the HER2 oncoprotein, which is expressed by certain breast, gastroesophageal and other solid tumor cells. **MARGENZA®** (margetuximab-cmkb) was launched in March 2021 by MacroGenics and its commercial partner, Eversana Life Science Services, LLC, 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. In January 2022, Zai Lab announced that the China NMPA accepted the New Drug Application (NDA) for margetuximab for the treatment of the same HER2-positive breast cancer indication.

Zai Lab recently informed MacroGenics that they have decided to discontinue enrollment of Module B of the MAHOGANY study in gastric cancer based on their review of both the clinical data and the changing treatment landscape. MacroGenics previously announced in November 2021 that the Company had decided to discontinue enrollment of Module A of the MAHOGANY study.

Selected Partnered Program Updates:

- ***IMGC936*** is an investigational 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. Under the collaboration, ImmunoGen is leading clinical development of IMGC936 in a Phase 1 clinical trial evaluating safety and pharmacokinetics in multiple solid tumors and has indicated they anticipate disclosing initial data in 2022.

- ***Teplizumab*** is an investigational, anti-CD3 monoclonal antibody acquired from MacroGenics by Provention Bio, Inc. under an asset purchase agreement in 2018 for which MacroGenics is entitled to receive future milestone payments and royalties on net sales. Provention is developing teplizumab for the treatment of type 1 diabetes (T1D). On February 22, 2022, Provention announced that it had resubmitted the Biologics License Application (BLA) for teplizumab for the delay of clinical T1D in at-risk individuals. The BLA resubmission followed Provention's Type B meeting with FDA earlier in the year.

2021 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of December 31, 2021, were $243.6 million, compared to $272.5 million as of December 31, 2020.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $77.4 million for the year ended December 31, 2021, compared to total revenue of $104.9 million for the year ended December 31, 2020. Revenue for the year ended December 31, 2021 included $12.3 million net sales of MARGENZA.
- **R&D Expenses**: Research and development expenses were $214.6 million for the year ended December 31, 2021, compared to $193.2 million for the year ended December 31, 2020. The increase was primarily related to development, manufacturing and clinical trial costs related to MGC018, as well as other preclinical molecules and increased clinical expenses related to enoblituzumab and lorigerlimab. These increases were partially offset by decreased development and manufacturing costs related to retifanlimab for Incyte and decreased clinical costs and BLA support for margetuximab.
- **SG&A Expenses**: Selling, general and administrative expenses were $63.0 million for the year ended December 31, 2021, compared to $42.7 million for the year ended December 31, 2020. The increase was primarily related to the MARGENZA launch, as well as labor-related costs and legal expenses.
- **Net Loss**: Net loss was $202.1 million for the year ended December 31, 2021, compared to net loss of $129.7 million for the year ended December 31, 2020.
- **Shares Outstanding**: Shares outstanding as of December 31, 2021 were 61,307,428.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities as of December 31, 2021, plus anticipated and potential collaboration payments, and product revenues should enable it to fund its operations through 2023. Such guidance does not reflect anticipated expenditures related to the potential late-stage development of MGC018 in mCRPC or further expansion of studies currently ongoing.

Conference Call Information

MacroGenics will host a conference call today at 4:30 p.m. (ET) to discuss financial results for the year ended December 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: 1067087.

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)

	December 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 243,616	$ 272,531
Total assets	335,245	378,743
Deferred revenue	20,646	11,382
Total stockholders' equity	239,618	295,884

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

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Revenues:			
Revenue from collaborative and other agreements	$ 63,294	$ 97,764	$ 62,024
Product revenue, net	12,349	—	—
Revenue from government agreements	1,804	7,119	2,164
Total revenues	77,447	104,883	64,188
Costs and expenses:			
Cost of product sales	2,651	—	—
Research and development	214,577	193,201	195,309
Selling, general and administrative	63,014	42,742	46,064
Total costs and expenses	280,242	235,943	241,373
Loss from operations	(202,795)	(131,060)	(177,185)
Other income	680	1,321	25,374
Net loss	(202,115)	(129,739)	(151,811)
Other comprehensive income:			
Unrealized gain (loss) on investments	(54)	(23)	19
Comprehensive loss	$ (202,169)	$ (129,762)	$ (151,792)
Basic and diluted net loss per common share	$ (3.37)	$ (2.47)	$ (3.16)
Basic and diluted weighted average common shares outstanding	59,944,717	52,442,389	48,082,728

About MacroGenics, Inc.

MacroGenics (the Company) 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, MARGENZA 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, expected timing of results from clinical trials, discussions with regulatory agencies, 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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