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): May 3, 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 May 3, 2022, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended March 31, 2022. 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 May 3, 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: May 3, 2022

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress and First Quarter 2022 Financial Results

- *Plan to start Phase 2/3 prostate cancer study with MGC018 by year-end*
- *Initiated Phase 1 study of MGC018 in combination with lorigerlimab in advanced solid tumors*
- *Targeting mid-2022 start of Phase 1 study of MGD024 in hematologic malignancies*
- *Conference call scheduled for today at 4:30 p.m. ET.*

ROCKVILLE, MD., May 3, 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 quarter ended March 31, 2022.

“We are very pleased by the progress made during the first quarter. Our recent end of Phase 1 meeting with the U.S. Food and Drug Administration (FDA) regarding MGC018, our B7-H3-directed antibody-drug conjugate (ADC), marks a significant milestone for the Company. Our current Phase 2/3 clinical plan for MGC018 reflects our productive dialogue with the FDA and feedback received on key elements of the program. We are targeting commencement of enrollment of the Phase 2/3 study by year-end,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “Other exciting developments include the initiation of a Phase 1 dose escalation study of MGC018 in combination with lorigerlimab in advanced solid tumors and FDA clearance of the IND for MGD024, our investigational next-generation CD123 × CD3 DART® molecule, enabling MacroGenics to proceed with the planned initiation of a clinical trial in CD123-positive neoplasms, including acute myeloid leukemia (AML) in mid-2022.”

Updates on Proprietary Investigational Programs

B7-H3 Programs: MacroGenics is developing two 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 ADC that targets B7-H3.
  - Following a constructive FDA meeting in March 2022, MacroGenics finalized the Phase 2/3 study design of MGC018 in patients with metastatic castration-resistant prostate cancer (mCRPC). The Phase 2/3 study is designed to enroll patients with mCRPC who have had prior exposure to a taxane and at least one androgen receptor axis-targeted, or ARAT, agent (including abiraterone, enzalutamide or apalutimide), and a PARP (poly adenosine diphosphate-ribose polymerase) inhibitor, if appropriate. During the Phase 2 portion of the study, approximately 150 patients are expected to be randomized 1:1:1 to receive

either 2.0 mg/kg or 2.7 mg/kg of MGC018 every four weeks in the experimental groups or physician's choice of an ARAT agent not previously received in the control group. These lower doses compare to the starting dose of 3.0 mg/kg every three weeks (and any subsequent dose reductions) evaluated in the Phase 1 dose expansion study and are based on modelling and simulation of patient pharmacokinetic and safety data generated across dose expansion cohorts to date. The Company anticipates that the lower doses will decrease both the frequency and severity of adverse events and potentially improve efficacy by allowing patients to stay on therapy longer. The Company expects analysis of the data to be performed upon completion of the Phase 2 portion of the study. In the Phase 3 portion, MacroGenics plans to randomize additional patients 1:1 to receive either MGC018 at the recommended dose or an ARAT agent for the control group. The inclusion of the Phase 2 interim analysis to evaluate the two MGC018 dose levels will allow the Company to further assess safety, tolerability and futility before proceeding to the Phase 3 portion of the study. The primary endpoint of the study will be radiographic progression-free survival (rPFS) and key secondary endpoints include objective response rate (ORR) and overall survival (OS). The Company expects to begin enrollment by year-end 2022.

    - MacroGenics' Phase 1/2 expansion study of MGC018 is 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 squamous cell carcinoma of the head and neck (SCCHN) cohort. The Company is encouraged by initial clinical activity observed in patients with melanoma and plans to recruit 20 additional melanoma patients in its ongoing dose expansion study, evaluating a dose of 2.7 mg/kg administered every four weeks. As for the other tumor types enrolled in the expansion study, the Company is evaluating possible next steps for enrolling additional patients with NSCLC. MacroGenics does not plan to proceed with advancing the study in patients with TNBC at this time. The Company intends to provide an update on clinical data from patients in the Phase 1/2 dose expansion study in the second half of 2022.
    - MacroGenics recently dosed the first patient in a Phase 1 dose escalation study of MGC018 in combination with lorigerlimab in patients with various advanced solid tumors.
    - Finally, in April, MacroGenics presented a poster titled "Targeting B7-H3 in Prostate Cancer: Preclinical Proof-of-Concept with MGC018, an Investigational Anti-B7-H3 Antibody-Drug Conjugate," at the American Association for Cancer Research (AACR) Annual meeting. MGC018 demonstrated anti-tumor effects toward prostate cancer cell lines and enhanced activity in some lines when combined with PARP or androgen-receptor inhibitors.

- ***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 front-line patients with SCCHN, in which PD-L1 positive patients receive combination therapy with retifanlimab (anti-PD-1 antibody) and PD-L1 negative patients receive combination therapy with tebotelimab (PD-1 x

LAG-3 DART molecule). 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.

- Updated study results from an earlier Phase 1 study of the combination of enoblituzumab and pembrolizumab in advanced B7-H3-expressing solid tumors was published in the *Journal for ImmunoTherapy of Cancer* in April (data cut-off: March 14, 2019). This combination was well tolerated and demonstrated objective responses in 6 of 18 patients (33.3%) with SCCHN who were checkpoint-naïve and had previously progressed after receiving first-line platinum-based chemotherapy. The updated published data showed a median OS of 17.4 months (95% CI: 9.2 to NR) in patients with SCCHN. These encouraging findings helped guide our current development strategy for enoblituzumab.

DART Molecules for Immune Checkpoint Blockade: MacroGenics is studying multiple 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 for one of these molecules include:

- ***Lorigerlimab*** is a bispecific, tetravalent DART molecule targeting PD-1 and CTLA-4. During the first quarter of 2022, the Company initiated a combination study of MGC018 with lorigerlimab in patients with various solid tumors. MacroGenics is also conducting a Phase 1/2 dose expansion study with lorigerlimab as monotherapy in cohorts of patients with microsatellite stable colorectal cancer (MSS CRC), mCRPC, melanoma and checkpoint-naïve NSCLC. MacroGenics anticipates sharing data from this ongoing study in the second half of 2022.

Bispecific CD123 × CD3 DART molecule: MacroGenics is developing an investigational, next-generation CD123 × CD3 DART molecule. Recent updates 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 April, MacroGenics' IND application for MGD024 was cleared by the FDA for evaluation in patients with hematologic malignancies. The Company expects to begin enrollment in a Phase 1 study of MGD024 in patients with CD123-positive neoplasms, including acute myeloid leukemia (AML) in mid-2022.

Other Program Updates:

- ***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 March 21, 2022, Provention announced that the FDA had accepted the Biologics License Application (BLA) for teplizumab for the delay of clinical T1D in at-risk

individuals. The FDA assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 17, 2022.

First Quarter 2022 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of March 31, 2022, were $184.0 million, compared to $243.6 million as of December 31, 2021.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $11.1 million for the quarter ended March 31, 2022, compared to total revenue of $16.9 million for the quarter ended March 31, 2021. Revenue for the quarter ended March 31, 2022 included $3.6 million net sales of MARGENZA. The Company continues to have modest expectations for MARGENZA sales.
- **R&D Expenses**: Research and development expenses were $61.4 million for the quarter ended March 31, 2022, compared to $53.1 million for the quarter ended March 31, 2021. The increase was primarily related to development, manufacturing and clinical trial costs related to MGC018, development of discovery projects and preclinical molecules, and increased clinical expenses related to lorigerlimab. These increases were partially offset by decreased development, manufacturing and clinical trial costs related to flotetuzumab (which development has been discontinued), decreased margetuximab manufacturing costs related to the Zai Lab agreement, and decreased retifanlimab manufacturing costs for Incyte.
- **SG&A Expenses**: Selling, general and administrative expenses were $16.3 million for the quarter ended March 31, 2022, compared to $15.0 million for the quarter ended March 31, 2021. The increase was primarily related to MARGENZA selling costs, as well as stock-based compensation and consulting expenses.
- **Net Loss**: Net loss was $66.4 million for the quarter ended March 31, 2022, compared to net loss of $51.3 million for the quarter ended March 31, 2021.
- **Shares Outstanding**: Shares outstanding as of March 31, 2022 were 61,333,074.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities as of March 31, 2022, plus anticipated and potential collaboration payments, and product revenues should enable it to fund its operations through 2023. The Company's expected funding requirements do not reflect anticipated expenditures related to the full Phase 2/3 development of MGC018 in mCRPC anticipated to begin by year-end 2022, or further expansion of other studies currently ongoing. However, the Company believes that it can reasonably obtain funding for the planned Phase 2 portion of the MGC018 study through a combination of existing financial resources, a variety of external funding or potential revenue sources, and project prioritization.

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, 2022, 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: 6791448.

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, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 183,986	$ 243,616
Total assets	271,445	335,245
Deferred revenue	31,926	20,646
Total stockholders' equity	178,214	239,618

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

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

	Three Months Ended March 31,	
	2022	**2021**
Revenues:		
Revenue from collaborative and other agreements	$ 7,093	$ 15,184
Product revenue, net	3,580	887
Revenue from government agreements	428	810
Total revenues	11,101	16,881
Costs and expenses:		
Cost of product sales	48	17
Research and development	61,438	53,121
Selling, general and administrative	16,253	15,036
Total costs and expenses	77,739	68,174
Loss from operations	(66,638)	(51,293)
Other income	195	21
Net loss	(66,443)	(51,272)
Other comprehensive income (loss):		
Unrealized gain (loss) on investments	(222)	18
Comprehensive income (loss)	$ (66,665)	$ (51,254)
Basic and diluted net loss per common share	$ (1.08)	$ (0.90)
Basic and diluted weighted average common shares outstanding	61,324,163	57,202,846

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 MacroGenics (“Company”), including statements about the Company’s strategy, future

operations, clinical development of the Company’s therapeutic candidates, including initiation and enrollment in clinical trials, expected timing of results from clinical trials, discussions with regulatory agencies, commercial prospects of or product revenues from MARGENZA and the Company’s product candidates, if approved, 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”, “potential,” “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 MGC018, MARGENZA or any other product candidate’s revenue, expenses and costs may not be as expected, risks relating to MGC018, MARGENZA or any other product candidate’s market acceptance, competition, reimbursement and regulatory actions, the uncertainties inherent in the initiation and enrollment of future clinical trials, the availability of financing to fund the development of our product candidates, 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, business, or economic or political disruptions due to catastrophes or other events, including natural disasters, terrorist attacks, civil unrest and actual or threatened armed conflict, or public health crises such as the novel coronavirus (referred to as COVID-19 pandemic), 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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