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): March 7, 2024

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)

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 March 7, 2024, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the year ended December 31, 2023. 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 March 7, 2024
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: March 7, 2024

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress and 2023 Financial Results

- *Presentation of preliminary data from TAMARACK Phase 2 study of vobra duo in mCRPC patients expected at ASCO 2024*
- *Initiation of Phase 1 study of MGC026, MacroGenics' first topoisomerase I inhibitor-based ADC*
- *Preclinical data on two topoisomerase I inhibitor-based ADC product candidates, MGC026 and MGC028, to be presented in posters at AACR*
- *Conference call scheduled for today at 4:30 p.m. ET*

ROCKVILLE, MD., Mar 7, 2024 (GLOBE NEWSWIRE) — MacroGenics, Inc. (NASDAQ: MGNX), a biopharmaceutical company focused on discovering, developing, manufacturing 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, 2023.

“We expect that 2024 will be an important year for MacroGenics, with multiple pipeline advancements anticipated," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “Late last year, we completed enrollment of 177 patients in the TAMARACK Phase 2 study of vobra duo, which was ahead of schedule. We plan to present the initial TAMARACK clinical data in the second quarter of this year. Later in the year, we expect to share updated clinical data from the trial. In addition, we continue to enroll the LORIKEET Phase 2 study of lorigerlimab in mCRPC and expect to start enrolling patients in the dose expansion portion of the combination study of vobra duo and lorigerlimab. Finally, we are excited about the potential of our topoisomerase I inhibitor-based ADCs, including MGC026, for which we recently began a Phase 1 study, and MGC028, for which we anticipate submitting an IND by year end.”

Updates on Proprietary Investigational Programs

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

- ***Vobramitamab duocarmazine (vobra duo***) is an antibody-drug conjugate (ADC) that targets B7-H3, an antigen with broad expression across multiple solid tumors and a member of the B7 family of molecules involved in immune regulation.
    - MacroGenics completed enrollment of the TAMARACK Phase 2 study of vobra duo in November 2023. A total of 177 patients have been dosed in the study, exceeding the study design goal of 100 participants. TAMARACK is being conducted in patients with metastatic castration-resistant prostate cancer (mCRPC) who were previously treated with one prior androgen receptor axis-targeted therapy (ARAT). Participants may have received up to one prior taxane-containing regimen, but no other chemotherapy agents. The TAMARACK study is designed to evaluate vobra duo at

two different doses: 2.0 mg/kg or 2.7 mg/kg every four weeks (q4W).

In late January 2024, the TAMARACK independent data safety monitoring committee (IDSMC) recommended continuing the study. Also, in early February, MacroGenics submitted an abstract to the American Society of Clinical Oncology Annual Meeting (ASCO) that included the safety data reviewed by the IDSMC, based on a January 2024 data cut-off. The Company anticipates presenting updated safety and preliminary efficacy data at ASCO.

- MacroGenics intends to expand the TAMARACK study of vobra duo by enrolling patients with non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), melanoma, squamous cell carcinoma of the head and neck (SCCHN) and anal cancer. The Company expects to initiate dosing in these additional cohorts in mid-2024.
- MacroGenics continues to enroll a Phase 1/2 dose escalation study of vobra duo in combination with lorigerlimab in patients with various advanced solid tumors. The Company anticipates commencing a dose expansion study of this combination in mCRPC and at least one additional indication in 2024.

- ***Lorigerlimab*** is a bispecific, tetravalent PD-1 × CTLA-4 DART® molecule. MacroGenics is enrolling LORIKEET, a randomized Phase 2 study of lorigerlimab in combination with docetaxel vs. docetaxel alone in second-line, chemotherapy-naïve mCRPC patients. A total of 150 patients are planned to be treated in the 2:1 randomized study. The current trial design includes a primary study endpoint of radiographic progression-free survival (rPFS). The Company anticipates providing a study update in the second half of 2024.
- ***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. MacroGenics continues to enroll patients in a Phase 1 dose-escalation study of MGD024 in patients with CD123-positive neoplasms, including acute myeloid leukemia and myelodysplastic syndromes.
- ***MGC026*** is a clinical ADC directed against B7-H3, incorporating a novel site-specific linker and topoisomerase I inhibitor-based cytotoxic payload developed by Synaffix (a Lonza company). With distinct mechanisms of action, vobra duo and MGC026 may address different cancers, tumor stages, or be used in combination with alternate agents — or potentially with one another — to enhance their clinical utility. The Company plans to present MGC026 preclinical data at the upcoming American Association for Cancer Research (AACR) Annual Meeting in April 2024. MacroGenics recently initiated a Phase 1 dose escalation study of MGC026 in patients with advanced solid tumors.
- ***MGC028*** is a preclinical ADC incorporating an ADAM9-targeting antibody and represents the second MacroGenics ADC molecule that incorporates Synaffix's novel site-specific linker and topoisomerase I inhibitor-based cytotoxic payload. ADAM9 (a disintegrin and metalloprotease domain 9) is a member of the ADAM family of multifunctional type 1 transmembrane proteins that play a role in tumorigenesis and cancer progression and is overexpressed in multiple cancers, making it an attractive target for cancer treatment. MacroGenics plans to present preclinical data for MGC028 at the upcoming AACR Annual Meeting in April and currently anticipates submitting an investigational new drug

(IND) application for MGC028 by the end of 2024.

MGC028 is the second ADAM9-targeted ADC that MacroGenics has pursued. The first was IMGC936, a molecule with a maytansinoid payload that was advanced under a co-development arrangement with ImmunoGen, Inc. (ImmunoGen, now part of AbbVie). Under the 50/50 collaboration, ImmunoGen led clinical development and completed initial Phase 1 dose escalation and dose expansion studies. Neither MacroGenics nor AbbVie intends to further pursue development of IMGC936 as the molecule did not achieve pre-established clinical safety and efficacy benchmarks. The Company believes ADAM9 remains a promising target for delivery of an alternative cytotoxic payload.

- ***Enoblituzumab*** is an Fc-optimized monoclonal antibody that targets B7-H3. MacroGenics' academic collaborators have initiated the HEAT study, an investigator-sponsored, randomized Phase 2 clinical trial. This study will evaluate the activity of neoadjuvant enoblituzumab given prior to radical prostatectomy in up to 219 men with high-risk localized prostate cancer.

2023 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities balance as of December 31, 2023, was $229.8 million, compared to $154.3 million as of December 31, 2022.
- **Revenue**: Total revenue was $58.7 million for the year ended December 31, 2023, compared to total revenue of $151.9 million for the year ended December 31, 2022. The decrease was primarily due to a decrease in revenue from collaborative and other agreements.
- **R&D Expenses**: Research and development expenses were $166.6 million for the year ended December 31, 2023, compared to $207.0 million for the year ended December 31, 2022. The decrease was primarily due to decreased manufacturing-related costs for vobra duo, decreased development and clinical trial costs related to margetuximab, and decreased costs related to discontinued studies, partially offset by increased expenses related to MGC026 and MGC028 development.
- **SG&A Expenses**: Selling, general and administrative expenses were $52.2 million for the year ended December 31, 2023, compared to $58.9 million for the year ended December 31, 2022. The decrease was primarily related to decreased selling costs for MARGENZA®.
- **Other Income**: During the year ended December 31, 2023, MacroGenics received $100.0 million proceeds from the sale of its single-digit royalty interest on global net sales of TZIELD® to DRI Healthcare Acquisitions LP. In addition, the Company received a $50.0 million milestone payment from Sanofi S.A. related to the achievement of a primary endpoint in a TZIELD clinical study. Under GAAP guidelines and pursuant to Financial Accounting Standards Board's Accounting Standards Codification 470, this combined $150.0 million was included in Other Income as a "Gain on royalty monetization arrangement" in 2023.

- **Net Loss**: Net loss was $9.1 million for the year ended December 31, 2023, compared to net loss of $119.8 million for the year ended December 31, 2022.
- **Shares Outstanding**: Shares of common stock outstanding as of December 31, 2023 were 62,070,627.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities balance of $229.8 million as of December 31, 2023, in addition to projected and anticipated future payments from partners and product revenues should extend its cash runway into 2026. The Company's expected funding requirements reflect anticipated expenditures related to the Phase 2 TAMARACK clinical trial, the Phase 2 LORIKEET study as well as MacroGenics' other ongoing clinical and preclinical studies.

Conference Call Information

To participate via telephone, please register in advance at this link. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call.

The listen-only webcast of the conference call can be accessed under "Events & Presentations" in the Investor Relations section of MacroGenics' website at http://ir.macrogenics.com/events.cfm. A recorded replay of the webcast will be available shortly after the conclusion of the call and archived on MacroGenics' website for 30 days following the call.

MACROGENICS, INC.
SELECTED CONSOLIDATED BALANCE SHEET DATA
(Amounts in thousands)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 229,805	$ 154,346
Total assets	298,418	280,468
Deferred revenue	80,893	69,468
Total stockholders' equity	152,613	142,013

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

	2023	2022	2021
Revenues:			
Collaborative and other agreements	$ 28,990	$ 119,303	$ 63,294
Product sales, net	17,939	16,727	12,349
Contract manufacturing	9,833	13,988	—
Royalty revenue	431	—	—
Government agreements	1,556	1,923	1,804
Total revenues	58,749	151,941	77,447
Costs and expenses:			
Cost of product sales	619	3,351	2,651
Cost of manufacturing services	7,603	4,033	—
Research and development	166,583	207,026	214,577
Selling, general and administrative	52,188	58,949	63,014
Total costs and expenses	226,993	273,359	280,242
Loss from operations	(168,244)	(121,418)	(202,795)
Gain on royalty monetization arrangement	150,930	—	—
Interest and other income	9,686	1,660	680
Interest expense	(1,430)	—	—
Net loss	(9,058)	(119,758)	(202,115)
Other comprehensive income (loss):			
Unrealized gain (loss) on investments	(1)	56	(54)
Comprehensive income (loss)	$ (9,059)	$ (119,702)	$ (202,169)
Basic and diluted net loss per common share	$ (0.15)	$ (1.95)	$ (3.37)
Basic and diluted weighted average common shares outstanding	61,929,198	61,433,124	59,944,717

About MacroGenics, Inc.

MacroGenics (the Company) is a biopharmaceutical company focused on discovering, developing, manufacturing 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, manufacturing services revenue, 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, as well as future global net sales of TZIELD and the Company’s ability to achieve the milestone payments set forth under the terms of the agreement with DRI (or its successors or assigns with respect to such agreement), 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 TZIELD, vobramitamab duocarmazine, lorigerlimab, ZYNYZ, MARGENZA or any other product candidate’s revenue, expenses and costs may not be as expected, risks relating to TZIELD, vobramitamab duocarmazine, lorigerlimab, ZYNYZ, MARGENZA or any other product candidate’s market acceptance, competition, reimbursement and regulatory actions; our ability to provide manufacturing services to our customers; the uncertainties inherent in the initiation and enrollment of future clinical trials; the availability of financing to fund the internal 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; expectations of future milestone payments; 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, 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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