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 9, 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** (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 9, 2024, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended March 31, 2024. 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 9, 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: May 9, 2024

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress, First Quarter 2024 Financial Results and Interim TAMARACK Phase 2 Study Data

- *Presentation of interim TAMARACK Phase 2 study data: updated safety and preliminary efficacy of vobra duo in mCRPC patients*
- *Conference call scheduled for today at 4:30 p.m. ET*

ROCKVILLE, MD., May 9, 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 quarter ended March 31, 2024.

“We are very encouraged by the interim updated safety and preliminary efficacy data from the TAMARACK study of vobra duo in metastatic castration-resistant prostate cancer," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “We believe this interim data set helps validate our previously stated hypothesis that improved tolerability coupled with compelling biological activity could be achieved through dose reductions and a longer dosing interval. We believe vobra duo’s biological activity shown to date aligns well with the parameters we outlined at the outset of the study. Based on our evaluation of the interim data to date, we have initiated planning activities for a potential Phase 3 study that could commence next year. We anticipate sharing final safety, efficacy and durability data, including radiographic progression-free survival data, which is the primary endpoint of the study, in the second half of 2024. Furthermore, having preliminarily identified suitable vobra duo doses in mCRPC in the TAMARACK study, we have greater confidence in the molecule’s potential to help patients with a broad range of B7-H3-expressing cancers.”

“The interim safety and anti-tumor activity observed to date in the TAMARACK study look very promising for patients with metastatic castration-resistant prostate cancer,” said Johann DeBono, Regius Professor of Cancer Research and Professor in Experimental Cancer Medicine at The Institute of Cancer Research, London and The Royal Marsden NHS Foundation Trust. “With the limited treatment options currently available to these patients, this novel ADC molecule could potentially become the first therapy targeting B7-H3 in patients with prostate cancer and would represent an important new treatment for this population.”

Updates on Proprietary Investigational Programs

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

B7-H3-Directed Therapies

- ***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. 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).
  - A new presentation of TAMARACK interim data, consisting of updated safety and preliminary efficacy data, all based on a data cut-off date of April 12, 2024, is available under "Events & Presentations" in the Investor Relations section of MacroGenics' website or directly via this link. Below is a high-level summary of this interim data, which is subject to further updates:

	Vobra Duo 2.0 mg/kg q4W	Vobra Duo 2.7 mg/kg q4W
Patients Enrolled	n=91	n=90
PSA Reduction Summary:		
PSA Evaluable Patients	n=82	n=71
Any PSA Reduction ≥50%	41 (50.0%)	36 (50.7%)
Confirmed PSA Reduction ≥50%	36 (43.9%)	26 (36.6%)
Tumor Response Summary:		
RECIST Evaluable Patients with Measurable Disease at Baseline	n=45	n=32
Disease Control Rate (CR+PR+SD)	41 (91.1%)	28 (87.5%)
Overall Response Rate (CR+PR, confirmed only)	8 (17.8%)	8 (25.0%)
Overall Response Rate (CR+PR, including unconfirmed)	11 (24.4%)	14 (43.8%)
Safety Summary:		
Safety Population	n=90	n=86
Treatment-Emergent Adverse Events All Grade	89 (98.9%)	86 (100.0%)
Treatment- Emergent Adverse Events Grade ≥3	49 (54.4%)	44 (51.2%)
TEAE Leading to Study Drug Discontinuation	10 (11.1%)	13 (15.1%)
TEAE Leading to Study Drug Dose Reduction	39 (43.3%)	44 (51.2%)
TEAE Leading to Study Drug Dose Interruption	38 (42.2%)	48 (55.8%)
Five Most Common TEAE All Grade	Asthenia (46.7%) Nausea (35.6%) Oedema peripheral (32.2%) Decreased appetite (28.9%) Fatigue (25.6%)	Asthenia (58.1%) Decreased appetite (37.2%) Oedema peripheral (36.0%) Nausea (30.2%) Pleural effusion (29.1%)
Pleural Effusions	Grade 1=8.9% Grade 2=8.9% No Grade ≥ 3 event	Grade 1=14.0% Grade 2=14.0% Grade 3=1.2%
Palmar-plantar Erythrodysaesthesia Syndrome	Grade 1=11.1% Grade 2=4.4% No Grade ≥ 3 event	Grade 1=12.8% Grade 2=9.3% Grade 3=1.2%

    - The median number of cycles of vobra duo administered was five (range of 1-10).

- A total of five events with fatal outcome occurred as follows: one Grade 5 event in the 2.0 mg/kg dosing cohort: acute myocardial infarction (considered unrelated to study drug by the investigator); three Grade 5 events in the 2.7 mg/kg dosing cohort: one cardiac arrest (considered unrelated to study drug by the investigator) and two events of pneumonitis. In addition, a patient in the 2.7 mg/kg dosing cohort had a Grade 3 pleural effusion that is recorded as having a fatal outcome. The latter three deaths are being investigated, as follow-up is incomplete on this ongoing trial.
- Additional data is provided in the presentation on the Company's website and as filed with the Securities and Exchange Commission.
- Based on a current evaluation of this interim data, the Company is undertaking the initial steps necessary to prepare for the potential initiation of a Phase 3 study in mCRPC in 2025. The final decision to pursue such a Phase 3 study will be based on an analysis of the final data set, including rPFS, when available.

- The Company intends to share final safety, efficacy, and durability data, including the primary endpoint of radiographic progression-free survival, from the TAMARACK trial in the second half of 2024.
- MacroGenics plans 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.

- ***MGC026*** is a clinical B7-H3-targeting ADC that is site-specifically conjugated to exatecan, a topoisomerase I inhibitor 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. A Phase 1 dose escalation study of MGC026 in patients with advanced solid tumors is ongoing.

  MGC026 preclinical data was presented recently at the American Association for Cancer Research (AACR) Annual Meeting. In preclinical studies, MGC026 was shown to have greater potency than B7-H3-directed antibodies conjugated to deruxtecan, or DXd, a topoisomerase-based payload utilized in other ADCs. In addition, the MGC026 payload has been shown to be less susceptible to multi-drug resistance (MDR) mechanisms than DXd and SN-38.

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

Lorigerlimab

- ***Lorigerlimab*** is a bispecific, tetravalent PD-1 × CTLA-4 DART® molecule. In addition to the ongoing study of lorigerlimab in combination with vobra duo mentioned above, 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 completing enrollment of the study in 2024 and providing a clinical update in the first half of 2025.

Emerging ADC Pipeline

- ***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. The Company currently anticipates submitting an investigational new drug (IND) application for MGC028 by the end of 2024.

  MGC028 preclinical data was presented recently at the AACR Annual Meeting. In preclinical studies, MGC028 demonstrated specific antitumor activity in *in vivo* models representing gastric, lung, pancreatic, colorectal cancer, SCCHN and cholangiocarcinoma. In addition, in a non-human primate study, MGC028 was well tolerated at high dose levels, with mild, reversible side effects and no ocular toxicity, which is often a concern with tubulin-inhibitor-based ADCs. These promising preclinical results support the continued investigation of MGC028 as a therapeutic option for treating ADAM9-expressing solid cancers.

Partnered Program

- ***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. 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. Under an October 2022 exclusive option and collaboration agreement, Gilead Sciences, Inc. has the option to license MGD024 at predefined decision points during the Phase 1 study.

First Quarter 2024 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities balance as of March 31, 2024, was $184.2 million, compared to $229.8 million as of December 31, 2023.
- **Revenue**: Total revenue was $9.1 million for the quarter ended March 31, 2024, compared to total revenue of $24.5 million for the quarter ended March 31, 2023. The decrease was primarily due to a decrease in revenue from collaborative and other agreements, including a $15.0 million milestone received from Incyte in the quarter ended March 31, 2023.

- **R&D Expenses**: Research and development expenses were $46.0 million for the quarter ended March 31, 2024, compared to $45.9 million for the quarter ended March 31, 2023.
- **SG&A Expenses**: Selling, general and administrative expenses were $14.7 million for the quarter ended March 31, 2024, compared to $13.5 million for the quarter ended March 31, 2023. The increase was primarily related to increased stock-based compensation expense and other professional fees.
- **Net Loss**: Net loss was $52.2 million for the quarter ended March 31, 2024, compared to net loss of $38.0 million for the quarter ended March 31, 2023.
- **Shares Outstanding**: Shares of common stock outstanding as of March 31, 2024 were 62,560,502.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities balance of $184.2 million as of March 31, 2024, 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)

	March 31, 2024	December 31, 2023
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 184,237	$ 229,805
Total assets	248,285	298,418
Deferred revenue	79,019	80,894
Total stockholders' equity	106,154	152,613

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

	Three Months Ended March 31,	
	2024	**2023**
Revenues:		
Collaborative and other agreements	$ 1,449	$ 16,686
Product sales, net	4,861	3,490
Contract manufacturing	2,276	3,615
Royalty revenue	160	422
Government agreements	358	283
Total revenues	9,104	24,496
Costs and expenses:		
Cost of product sales	270	113
Cost of manufacturing services	1,846	3,410
Research and development	46,029	45,872
Selling, general and administrative	14,709	13,527
Total costs and expenses	62,854	62,922
Loss from operations	(53,750)	(38,426)
Interest and other income	2,693	1,073
Interest and other expense	(1,133)	(656)
Net loss	(52,190)	(38,009)
Other comprehensive income (loss):		
Unrealized gain (loss) on investments	(29)	13
Comprehensive loss	$ (52,219)	$ (37,996)
Basic and diluted net loss per common share	$ (0.84)	$ (0.61)
Basic and diluted weighted average common shares outstanding	62,290,538	61,809,817

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; future data updates, especially with respect to vobramitamab duocarmazine; 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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CONTACTS:
Jim Karrels, Senior Vice President, CFO
1-301-251-5172

info@macrogenics.com