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): August 6, 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 August 6, 2024, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended June 30, 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 August 6, 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: August 6, 2024

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress, Second Quarter 2024 Financial Results

- *Upcoming poster presentation of protocol-defined TAMARACK Phase 2 mCRPC study data at ESMO in September*
- *Received $100.0 million in milestones related to Incyte's advancement of ZYNYZ® (retifanlimab-dlwr) subsequent to quarter-end*
- *Confirming cash runway guidance into 2026*

ROCKVILLE, MD., Aug 6, 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 June 30, 2024.

"We are pleased to have the opportunity to present updated safety and efficacy data from our Phase 2 TAMARACK trial of vobra duo at the upcoming European Society for Medical Oncology (ESMO) Congress in September," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "In addition, we recently solidified our cash position with the receipt of $100.0 million in milestones, following the positive Phase 3 top-line results from Incyte's registrational studies of retifanlimab in both anal and lung cancer."

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.
    - The TAMARACK Phase 2 study of vobra duo 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). MacroGenics completed enrollment of the TAMARACK study in the fourth quarter of 2023, and the study has reached its landmark primary endpoint of 6-month radiographic progression-free survival (rPFS) rate. While mCRPC study participants are no longer being dosed in the study, participants continue to be monitored for adverse events, disease progression and survival.

- Updated TAMARACK safety and efficacy data, including the study's primary endpoint, will be presented in a poster session at the ESMO Congress in September 2024. This data will be based on a data cut-off date of July 9, 2024. The abstract submitted to ESMO in May was based on an April 12 data cut off. MacroGenics expects to have the mature efficacy findings, including median rPFS, in the second half of 2024 and plans to present the data at a subsequent medical conference.
- Following the ESMO poster presentation, the Company plans to host a conference call with investors to discuss the TAMARACK data and potential next steps for vobra duo.
- 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 later this year.

- ***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.

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 rPFS. The Company anticipates completing enrollment of the study in 2024 or early 2025 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 continues to anticipate submitting an investigational new drug (IND) application for MGC028 by the end of 2024 and initiating a Phase 1 clinical study in 2025.

Partnered Programs

- ***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. (Gilead) has the option to license MGD024 at predefined decision points during the Phase 1 study.

- ***ZYNYZ® (retifanlimab-dlwr)*** is a humanized monoclonal antibody targeting PD-1 that the Company licensed to Incyte Corporation (Incyte) in 2017. Incyte recently announced positive Phase 3 top-line results for its registrational studies of retifanlimab in squamous cell carcinoma of the anal canal and non-small cell lung cancer and continues to conduct global studies of retifanlimab across multiple indications.

  Subsequent to June 30, 2024, MacroGenics announced the achievement of $100.0 million in milestones from Incyte related to development progress of retifanlimab, following an agreement on July 24, 2024, pursuant to which certain milestones were deemed to have been met. MacroGenics is further eligible to receive up to a total of $210.0 million in remaining development and regulatory milestones and up to $330.0 million in potential commercial milestones from Incyte. MacroGenics receives tiered royalties of 15% to 24% from Incyte on any global net sales of the product and manufactures a portion of Incyte's global commercial supply of retifanlimab.

Second Quarter 2024 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities balance as of June 30, 2024, was $140.4 million, compared to $229.8 million as of December 31, 2023. The June 30, 2024 balance did not include the $100.0 million in milestones subsequently received from Incyte.
- **Revenue**: Total revenue was $10.8 million for the quarter ended June 30, 2024, compared to total revenue of $13.1 million for the quarter ended June 30, 2023. The decrease was primarily due to less revenue recognized under the Provention Asset Purchase Agreement and was partially offset by increased revenue from the Company's collaboration with Gilead and increased contract manufacturing revenue.
- **R&D Expenses**: Research and development expenses were $51.7 million for the quarter ended June 30, 2024, compared to $43.2 million for the quarter ended June 30, 2023. The increase was primarily due to manufacturing and IND-enabling costs related to MGC028.
- **SG&A Expenses**: Selling, general and administrative expenses were $14.4 million for the quarter ended June 30, 2024, compared to $13.7 million for the quarter ended June 30, 2023.
- **Net Income (Loss)**: Net loss was $55.7 million for the quarter ended June 30, 2024, compared to net income of $57.5 million for the quarter ended June 30, 2023. Net income for the quarter ended June 30, 2023 included approximately $100.0 million as a component of Other Income related to the sale of the Company's single-digit royalty interest on global net sales of TZIELD® (teplizumab-mzwv) to DRI Healthcare Acquisitions LP in March 2023.

- **Shares Outstanding**: Shares of common stock outstanding as of June 30, 2024 were 62,720,969.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities balance of $140.4 million as of June 30, 2024, plus the $100.0 million in milestones subsequently received from Incyte, in addition to projected and anticipated future payments from partners and product revenues should support 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.

No Conference Call

Given the embargoed TAMARACK data being presented at the upcoming ESMO presentation, the Company's management has entered a quiet period and will not be hosting a conference call to discuss its financial results or corporate progress for the quarter ended June 30, 2024. The Company intends to resume its quarterly results conference calls in the future.

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

	June 30, 2024	December 31, 2023
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 140,372	$ 229,805
Total assets	201,137	298,418
Deferred revenue	79,321	80,894
Total stockholders' equity	57,819	152,613

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Collaborative and other agreements	$ 2,065	$ 6,021	$ 3,514	$ 22,708
Product sales, net	5,248	5,062	10,109	8,552
Contract manufacturing	2,893	1,587	5,169	5,202
Royalty revenue	98	—	258	421
Government agreements	493	466	851	749
Total revenues	10,797	13,136	19,901	37,632
Costs and expenses:				
Cost of product sales	176	258	446	371
Cost of manufacturing services	2,647	919	4,493	4,329
Research and development	51,732	43,229	97,760	89,101
Selling, general and administrative	14,423	13,692	29,133	27,219
Total costs and expenses	68,978	58,098	131,832	121,020
Loss from operations	(58,181)	(44,962)	(111,931)	(83,388)
Gain on royalty monetization arrangement	—	100,930	—	100,930
Interest and other income	2,523	2,275	5,216	3,348
Interest and other expense	(6)	(774)	(1,139)	(1,430)
Net income (loss)	(55,664)	57,469	(107,854)	19,460
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	11	(80)	(18)	(67)
Comprehensive income (loss)	$ (55,653)	$ 57,389	$ (107,872)	$ 19,393
Net income (loss) per common share:				
Basic	$ (0.89)	$ 0.93	$ (1.73)	$ 0.31
Diluted	$ (0.89)	$ 0.92	$ (1.73)	$ 0.31
Weighted average common shares outstanding:				
Basic	62,663,677	61,880,096	62,477,108	61,845,151
Diluted	62,663,677	62,261,646	62,477,108	62,030,710

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 and regulatory plans for the Company’s therapeutic candidates, including trial design, initiation and enrollment in clinical trials, expected timing of results from clinical trials, discussions with regulatory agencies, commercial prospects of or product revenues from the Company’s products and 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), the Company’s current cash resources supporting our planned operating expenses and capital requirements into 2026 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; costs of litigation and the failure to successfully defend lawsuits and other claims against us; 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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