

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): November 5, 2024

MACROGENICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36112
(Commission
File Number)

06-1591613
(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 November 5, 2024, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended September 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 November 5, 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: November 5, 2024

MACROGENICS, INC.

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



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

- *Strengthened financial position resulting from recently announced MARGENZA[®] transaction and previously announced receipt of milestone payment from Incyte related to advancement of ZYNYZ[®]*
- *ADAM9-directed ADC (MGC028) Investigational New Drug (IND) application submitted to FDA*
- *Conference call scheduled for today at 4:30 p.m. ET*

ROCKVILLE, MD., Nov 5, 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 September 30, 2024.

“The pending MARGENZA transaction as well as the recently received milestone payment from Incyte further solidify our financial position, enabling us to remain focused on advancing our pipeline of innovative product candidates. In that regard, we are pleased to have submitted the IND for MGC028, our next topoisomerase I inhibitor-based ADC, and look forward to commencing the dose escalation study in the coming months,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “The advancement of our expanding clinical portfolio continues to create data read-out opportunities in the near future.”

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.

- The TAMARACK Phase 2 study of vobra duo is being conducted in patients with metastatic castration-resistant prostate cancer (mCRPC). While study participants are no longer being dosed in the study, participants continue to be monitored for adverse events, disease progression and survival.
- The Company presented interim results from the TAMARACK study at the European Society for Medical Oncology (ESMO) Congress in September 2024 and expects to have mature median radiographic progression-free survival (rPFS) data in hand no later than early 2025.

- Assessment of future development alternatives for vobra duo will be based on several factors, including the final TAMARACK safety and efficacy data in mCRPC, a review of the competitive treatment landscape for mCRPC, resource allocation across the Company's clinical portfolio as well as potential partnering opportunities for vobra duo. Until MacroGenics completes its assessment of the monotherapy development opportunity for vobra duo in mCRPC, the Company has paused its other development efforts in alternative tumor types as well as the Phase 1/2 dose combination study of vobra duo plus lorigerlimab.

Emerging ADC Pipeline

- **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 and potentially different safety/efficacy profiles, 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.
- **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 submitted an IND application for MGC028 to the U.S. Food and Drug Administration (FDA) in October.

Lorigerlimab

- **Lorigerlimab** is a bispecific, tetravalent PD-1 × CTLA-4 DART® molecule. This bispecific checkpoint molecule is being evaluated in the ongoing LORIKEET trial, a randomized Phase 2 study of lorigerlimab in combination with docetaxel vs. docetaxel alone in second-line, chemotherapy-naïve mCRPC patients. The current trial design includes a primary study endpoint of rPFS. A total of 150 patients are planned to be treated in the 2:1 randomized study, with more than 100 study participants enrolled to date. The Company anticipates completing enrollment of the study in late 2024 or early 2025 and providing a clinical update on the study in the first half of 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. 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 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 in July 2024 and continues to conduct global studies of retifanlimab across multiple indications.

During the quarter ended September 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.

- **MARGENZA (*margetuximab-cmkb*)** global rights will be sold to TerSera Therapeutics LLC (TerSera), a privately-held biopharmaceutical company with a focus on oncology and non-opioid pain management, pursuant to an agreement previously announced. TerSera is expected to pay MacroGenics \$40.0 million at closing and MacroGenics may receive additional sales milestone payments of up to an aggregate of \$35.0 million. The transaction is expected to close in the fourth quarter of 2024, subject to customary closing conditions. MacroGenics expects to pay an \$8.0 million amendment fee to its current commercialization partner during the fourth quarter of 2024. MacroGenics will manufacture MARGENZA drug substance on behalf of TerSera going forward.

Third Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities balance as of September 30, 2024, was \$200.4 million, compared to \$229.8 million as of December 31, 2023. The September 30, 2024, balance did not include the \$40.0 million upfront payment anticipated from the closing of the MARGENZA transaction.
- **Revenue:** Total revenue was \$110.7 million for the quarter ended September 30, 2024, compared to total revenue of \$10.4 million for the quarter ended September 30, 2023. The increase was primarily due to \$100.0 million in milestones received under the Incyte License Agreement in August.
- **R&D Expenses:** Research and development expenses were \$40.5 million for the quarter ended September 30, 2024, compared to \$30.1 million for the quarter ended September 30, 2023. The increase was primarily due to increased research and development costs related to the Company's preclinical ADC pipeline, vobra duo and the TAMARACK clinical trial.
- **SG&A Expenses:** Selling, general and administrative expenses were \$14.1 million for the quarter ended September 30, 2024, compared to \$12.4 million for the quarter ended September 30, 2023. The increase was primarily due to increased stock-based compensation expense and professional fees.
- **Net Income:** Net income was \$56.3 million for the quarter ended September 30, 2024, compared to net income of \$17.6 million for the quarter ended September 30, 2023. Net income for the quarter ended September 30, 2024, included \$100.0 million in

milestones received from Incyte in August related to retifanlimab. Net income for the quarter ended September 30, 2023, included a \$50.0 million milestone payment from Sanofi S.A. related to the previously disclosed achievement of a primary endpoint in a TZIELD® clinical study, which was recorded in other income.

- **Shares Outstanding:** Shares of common stock outstanding as of September 30, 2024 were 62,763,120.
- **Cash Runway Guidance:** MacroGenics anticipates that its cash, cash equivalents and marketable securities balance of \$200.4 million as of September 30, 2024, plus the \$40.0 million upfront payment anticipated from TerSera related to the MARGENZA transaction, less an \$8.0 million amendment fee to be paid to the Company's current commercialization partner, in addition to projected and anticipated future payments from partners should support its cash runway into 2026. The Company's expected funding requirements reflect anticipated expenditures related to the completion of the Phase 2 TAMARACK and LORIKEET clinical trials, 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)

	September 30, 2024		December 31, 2023
	(unaudited)		
Cash, cash equivalents and marketable securities	\$	200,363	\$ 229,805
Total assets		264,492	298,418
Deferred revenue		78,811	80,894
Total stockholders' equity		120,066	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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Collaborative and other agreements	\$ 101,408	\$ 895	\$ 105,180	\$ 24,024
Product sales, net	4,161	4,695	14,270	13,247
Contract manufacturing	4,573	4,462	9,742	9,664
Government agreements	566	345	1,417	1,094
Total revenues	110,708	10,397	130,609	48,029
Costs and expenses:				
Cost of product sales	168	85	614	456
Cost of manufacturing services	1,702	3,274	6,195	7,603
Research and development	40,543	30,131	138,304	119,232
Selling, general and administrative	14,104	12,409	43,237	39,628
Total costs and expenses	56,517	45,899	188,350	166,919
Loss from operations	54,191	(35,502)	(57,741)	(118,890)
Gain on royalty monetization arrangement	—	50,000	—	150,930
Interest and other income	2,118	3,056	7,335	6,404
Interest and other expense	—	—	(1,139)	(1,430)
Net income (loss)	56,309	17,554	(51,545)	37,014
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	38	38	20	(30)
Comprehensive income (loss)	\$ 56,347	\$ 17,592	\$ (51,525)	\$ 36,984
Net income (loss) per common share:				
Basic	\$ 0.90	\$ 0.28	\$ (0.82)	\$ 0.60
Diluted	\$ 0.90	\$ 0.28	\$ (0.82)	\$ 0.60
Weighted average common shares outstanding:				
Basic	62,744,005	61,980,680	62,566,723	61,890,824
Diluted	62,865,841	62,244,602	62,566,723	62,090,343

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, expected timing of the release of final safety and efficacy data, including mature median rPFS 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 timing and results of mature median radiographic progression-free survival, other efficacy and safety data 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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