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 6, 2023

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 November 6, 2023, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended September 30, 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 November 6, 2023
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 6, 2023

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress and Third Quarter 2023 Financial Results

- *Completed enrollment of TAMARACK Phase 2 study of vobra duo ahead of schedule*
- *Initiated LORIKEET Phase 2 study of lorigerlimab*
- *Submitted IND for MGC026, a topoisomerase inhibitor-based ADC*
- *Conference call scheduled for today at 4:30 p.m. ET*

ROCKVILLE, MD., Nov 6, 2023 (GLOBE NEWSWIRE) — MacroGenics, Inc. (NASDAQ: MGNX), a biopharmaceutical company focused on 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, 2023.

“Since mid-2022, we have received $335 million in non-dilutive capital from our collaboration partners and reduced our quarterly cash burn, enabling us to extend our cash runway into 2026. Over the next two years, we anticipate having multiple data read-outs, the first of which we expect during the first half of 2024 related to the now fully-enrolled TAMARACK study of vobra duo in metastatic castration-resistant prostate cancer,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “During this two-year period, we also expect data from the LORIKEET Phase 2 study of lorigerlimab in prostate cancer, results from the dose escalation study of MGD024 and results from a planned vobra duo plus lorigerlimab dose expansion cohort. Also during this time, we anticipate advancing multiple new ADC molecules from our preclinical portfolio, the first of which (MGC026) recently progressed to IND submission.”

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 recently completed enrollment of the TAMARACK Phase 2 study of vobra duo ahead of schedule. This study 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, across a total of approximately 100 patients. MacroGenics anticipates providing a clinical update in the first half of 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 2024.

- ***Lorigerlimab*** is a bispecific, tetravalent PD-1 × CTLA-4 DART® molecule. MacroGenics commenced enrollment of 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).

- ***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 an ADC with a topoisomerase inhibitor-based cytotoxic mechanism directed against an undisclosed solid tumor target. The Company recently submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration and, assuming acceptance, anticipates commencing a Phase 1 dose escalation study beginning in the first quarter of 2024. More details on this program will be provided in early 2024.

- ***Enoblituzumab*** is an Fc-optimized monoclonal antibody that targets B7-H3. MacroGenics' academic collaborators plan to initiate the HEAT study, an investigator-sponsored, randomized Phase 2 clinical trial. This study is expected to commence enrollment in early 2024 and will evaluate the activity of neoadjuvant enoblituzumab given prior to radical prostatectomy in men with high-risk localized prostate cancer.

Other Corporate Updates

- ***$15.7 Million Milestone Related to Gilead's Nomination of a Bispecific Research Program*.** On September 5, 2023, MacroGenics announced that its partner, Gilead Sciences, Inc., nominated the first of two potential research programs, leveraging MacroGenics' DART and TRIDENT® platforms for generating bispecific antibodies. This nomination grants Gilead an exclusive option, upon achievement of a pre-defined preclinical milestone, to license worldwide rights to the research program. MacroGenics received $15.7 million related to this nomination subsequent to September 30, 2023.

Third Quarter 2023 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities balance as of September 30, 2023, was $256.4 million, compared to $154.3 million as of December 31, 2022. The Company's cash balance as of September 30, 2023, did not include the $15.7 million milestone from Gilead subsequently received.

- **Revenue**: Total revenue was $10.4 million for the quarter ended September 30, 2023, compared to total revenue of $41.7 million for the quarter ended September 30, 2022.
- **R&D Expenses**: Research and development expenses were $30.1 million for the quarter ended September 30, 2023, compared to $48.2 million for the quarter ended September 30, 2022. The decrease was primarily related to decreased costs related to discontinued studies, partially offset by increased expenses related to preclinical ADC molecules and increased clinical expenses related to lorigerlimab.
- **SG&A Expenses**: Selling, general and administrative expenses were $12.4 million for the quarter ended September 30, 2023, compared to $15.4 million for the quarter ended September 30, 2022. The decrease was primarily related to decreased selling costs for MARGENZA.
- **Other Income**: During the quarter ended September 30, 2023, MacroGenics received 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. The accounting treatment for this milestone is consistent with that for the $100.0 million proceeds received from the sale of the Company's single-digit royalty interest on global net sales of TZIELD to DRI Healthcare Acquisitions LP in March 2023. Accordingly, $50.0 million was included in Other Income (as Gain on Royalty Monetization Arrangement) for the quarter ended September 30, 2023.
- **Net Income (Loss)**: Net income was $17.6 million for the quarter ended September 30, 2023, compared to net loss of $24.8 million for the quarter ended September 30, 2022.
- **Shares Outstanding**: Shares of common stock outstanding as of September 30, 2023 were 62,028,904.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities balance of $256.4 million as of September 30, 2023, plus the $15.7 million milestone subsequently received, 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)

	September 30, 2023	December 31, 2022
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 256,432	$ 154,346
Total assets	339,972	280,468
Deferred revenue	82,844	69,468
Total stockholders' equity	193,980	142,013

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Collaborative and other agreements	$ 885	$ 35,674	$ 23,593	$ 59,630
Product sales, net	4,695	4,371	13,247	12,623
Contract manufacturing	4,462	1,142	9,664	5,134
Royalty revenue	10	—	431	—
Government agreements	345	547	1,094	1,455
Total revenues	10,397	41,734	48,029	78,842
Costs and expenses:				
Cost of product sales	85	3,007	456	3,235
Cost of manufacturing services	3,274	136	7,603	2,358
Research and development	30,131	48,191	119,232	161,372
Selling, general and administrative	12,409	15,355	39,628	45,277
Total costs and expenses	45,899	66,689	166,919	212,243
Loss from operations	(35,502)	(24,955)	(118,890)	(133,401)
Gain on royalty monetization arrangement	50,000	—	150,930	—
Interest and other income	3,056	142	6,404	841
Interest expense	—	—	(1,430)	—
Net Income (loss)	17,554	(24,813)	37,014	(132,560)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	38	213	(30)	(52)
Comprehensive income (loss)	$ 17,592	$ (24,600)	$ 36,984	$ (132,612)
Net income (loss) per common share:				
Basic	$ 0.28	$ (0.40)	$ 0.60	$ (2.16)
Diluted	$ 0.28	$ (0.40)	$ 0.60	$ (2.16)
Weighted average common shares outstanding:				
Basic	61,980,680	61,459,831	61,890,824	61,390,143
Diluted	62,244,602	61,459,831	62,090,343	61,390,143

About MacroGenics, Inc.

MacroGenics (the Company) is a biopharmaceutical company focused on 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, DART and TRIDENT 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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