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 9, 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 August 9, 2023, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended June 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 August 9, 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: August 9, 2023

MACROGENICS, INC.

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

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

- *Advancing enrollment of TAMARACK Phase 2 study in metastatic castration-resistant prostate cancer (mCRPC) under revised protocol*
- *Initiating lorigerlimab Phase 2 study in mCRPC patients*
- *Achieved $50 million milestone related to Sanofi's announcement of positive top-line data from TZIELD® (teplizumab-mzwv) type 1 diabetes study*
- *Conference call scheduled for today at 4:30 p.m. ET*

ROCKVILLE, MD., August 9, 2023 (GLOBE NEWSWIRE) — MacroGenics, Inc. (NASDAQ: MGNX), a biopharmaceutical company focused on developing 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, 2023.

"MacroGenics maintains its historical focus on developing innovative antibody-based therapeutics, and we are very excited about our continued progress in advancing our two Phase 2 programs in prostate cancer, which engage different yet potentially complementary mechanisms of action," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "Additionally, we've expanded our efforts to broaden our antibody-drug conjugate (ADC) portfolio through technology-enabling partnerships, internal discovery efforts on first-in-class targets, as well as our continued antibody engineering expertise. As we've indicated earlier, we intend to submit an investigational new drug (IND) application to the FDA by year-end for the first of potentially multiple new ADC molecules which incorporate a topoisomerase inhibitor payload."

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 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 began enrolling the TAMARACK Phase 2 study of vobra duo in patients with mCRPC under an amended protocol during the second quarter. This 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 100 patients. MacroGenics anticipates enrolling a majority of the study patients in 2023 and expects to provide a clinical update in 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 the dose expansion portion of the study by year-end 2023.

- ***Lorigerlimab*** is a bispecific, tetravalent PD-1 × CTLA-4 DART® molecule. Based on the encouraging lorigerlimab monotherapy clinical data in mCRPC previously presented at ASCO Genitourinary Cancers Symposium in February 2023, MacroGenics plans to commence enrollment of a randomized Phase 2 study of lorigerlimab in combination with docetaxel vs. docetaxel alone in second-line, chemotherapy-naïve mCRPC patients in the coming weeks. 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.
- ***Enoblituzumab*** is an Fc-optimized monoclonal antibody that targets B7-H3. Based on the recently published results from a Phase 2 investigator-sponsored study of enoblituzumab in men with prostate cancer, MacroGenics and collaborators at multiple academic institutions plan to initiate an investigator-sponsored randomized, translationally intense, neo-adjuvant prostate cancer study in a high-risk population by early 2024.

Other Corporate Updates

- ***$50 million TZIELD milestone***. On July 28, 2023, Sanofi S.A. (Sanofi) reported that the PROTECT placebo-controlled study investigating TZIELD in patients with newly diagnosed stage 3 Type 1 diabetes met its primary endpoint, having demonstrated preservation of beta cell function. This positive study outcome triggers payment of a $50 million milestone to MacroGenics by Sanofi, pursuant to a March 2023 agreement originally between MacroGenics and DRI Healthcare Acquisitions LP (DRI), the royalty interest and milestone payment obligations of which were sold by DRI to a subsidiary of Sanofi in April 2023.

  Under the MacroGenics agreement with DRI, since assumed by a Sanofi subsidiary, MacroGenics retains the right to receive a 50% share of the royalty on global net sales of TZIELD above a certain annual threshold. Under this agreement, the Company may also receive an additional $50 million milestone from Sanofi if TZIELD achieves a certain level of net sales. In addition, MacroGenics continues to be eligible to receive additional economics under the asset purchase agreement with Provention Bio, Inc.

Second Quarter 2023 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of June 30, 2023, were $240.3 million, compared to $154.3 million as of December 31, 2022. The

Company's cash balance as of June 30, 2023 did not include the $50 million milestone from Sanofi subsequently earned.

- **Revenue**: Total revenue was $13.1 million for the quarter ended June 30, 2023, compared to total revenue of $26.0 million for the quarter ended June 30, 2022.
- **R&D Expenses**: Research and development expenses were $43.2 million for the quarter ended June 30, 2023, compared to $51.7 million for the quarter ended June 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 and vobra duo.
- **SG&A Expenses**: Selling, general and administrative expenses were $13.7 million for each of the quarters ended June 30, 2023 and June 30, 2022.
- **Other Income**: Under GAAP guidelines and pursuant to Financial Accounting Standards Board's Accounting Standards Codification (ASC) 470, in March 2023, MacroGenics recorded the $100 million proceeds received from the sale of the Company's single-digit royalty interest on global net sales of TZIELD to DRI as a "Liability related to future royalties." This liability was to be amortized over the term of the arrangement using the effective interest rate method. In separate transactions, Sanofi subsequently acquired both Provention Bio, Inc. and the TZIELD royalty interest and milestone obligations from DRI on April 27, 2023, obviating the need for MacroGenics' involvement in the transfer of royalty payments to DRI. This resulted in a change to the arrangement, which was evaluated as a modification under the provisions of ASC 470. Accordingly, the Company recognized approximately $100 million as a component of other income on its financial statements for the quarter ended June 30, 2023.
- **Net Income (Loss)**: Net income was $57.5 million for the quarter ended June 30, 2023, compared to net loss of $41.3 million for the quarter ended June 30, 2022.
- **Shares Outstanding**: Shares of common stock outstanding as of June 30, 2023 were 61,938,493.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities balance of $240.3 million as of June 30, 2023, plus the $50 million milestone subsequently earned, 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 study of lorigerlimab in mCRPC 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)

	June 30, 2023	December 31, 2022
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 240,347	$ 154,346
Total assets	305,653	280,468
Deferred revenue	68,209	69,468
Total stockholders' equity	171,544	142,013

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Collaborative and other agreements	$ 6,021	$ 16,863	$ 22,708	$ 23,956
Product sales, net	5,062	4,672	8,552	8,252
Contract manufacturing	1,587	3,992	5,202	3,992
Royalty revenue	—	—	421	—
Government agreements	466	480	749	908
Total revenues	13,136	26,007	37,632	37,108
Costs and expenses:				
Cost of product sales	258	180	371	228
Cost of manufacturing services	919	2,222	4,329	2,222
Research and development	43,229	51,744	89,101	113,182
Selling, general and administrative	13,692	13,669	27,219	29,922
Total costs and expenses	58,098	67,815	121,020	145,554
Loss from operations	(44,962)	(41,808)	(83,388)	(108,446)
Gain on royalty monetization arrangement	100,930	—	100,930	—
Interest and other income	2,275	504	3,348	699
Interest expense	(774)	—	(1,430)	—
Net Income (loss)	57,469	(41,304)	19,460	(107,747)
Other comprehensive income (loss):				
Unrealized loss on investments	(80)	(43)	(67)	(265)
Comprehensive income (loss)	$ 57,389	$ (41,347)	$ 19,393	$ (108,012)
Net income (loss) per common share:				
Basic	$ 0.93	$ (0.67)	$ 0.31	$ (1.76)
Diluted	$ 0.92	$ (0.67)	$ 0.31	$ (1.76)
Weighted average common shares outstanding:				
Basic	61,880,096	61,384,943	61,845,151	61,354,721
Diluted	62,261,646	61,384,943	62,030,710	61,354,721

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 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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