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, 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 May 9, 2023, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended March 31, 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 May 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: May 9, 2023

MACROGENICS, INC.

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

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

- *ZYNYZ™ is third product approved in U.S. that originated from MacroGenics' pipeline*
- *Multiple Phase 2 programs advancing in metastatic castration-resistant prostate cancer (mCRPC)*
- *Cash runway through 2025 with $270 million in non-dilutive funding achieved over past nine months*
- *Conference call scheduled for today at 4:30 p.m. ET*

ROCKVILLE, MD., May 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 March 31, 2023.

“The recent U.S. Food and Drug Administration (FDA) approval of Incyte’s ZYNYZ (retifanlimab-dlwr) represents the third U.S. marketing clearance of a product originating from MacroGenics’ pipeline of proprietary or partnered product candidates. We are delighted that the approval of ZYNYZ provides an additional option for treating patients with Merkel cell carcinoma (MCC), a rare and aggressive type of skin cancer,” said Scott Koenig, M.D., Ph.D., President and Chief Executive Officer of MacroGenics. “With the approval of both ZYNYZ and TZIELD™ (teplizumab-mzwv) by our partners, MacroGenics remains eligible to receive more than $1 billion in milestone payments related to the continued advancement and successful commercialization of these two products. Over the past nine months, these and other programs have allowed us to generate $270 million in non-dilutive capital, extending our cash runway through 2025.”

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 tumor types and a member of the B7 family of molecules involved in immune regulation.
  - MacroGenics initiated the Phase 2 portion of the TAMARACK study of vobra duo in patients with mCRPC in late 2022. This study is designed to evaluate vobra duo at two different doses, 2.0 mg/kg or 2.7 mg/kg every four weeks, in two experimental arms comprising a total of 100 patients. Regulatory approval of a modified protocol, primarily reflecting removal of a control arm, has been obtained in the U.S. and all countries targeted for study enrollment in the E.U. MacroGenics anticipates commencement of enrollment under the revised protocol beginning in the second quarter of 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.

- ***Lorigerlimab*** is a bispecific, tetravalent PD-1 × CTLA-4 DART® molecule. The Company presented encouraging preliminary clinical results from a single arm, dose-expansion study of lorigerlimab in patients with advanced solid tumors in a poster session at the ASCO Genitourinary Cancers Symposium in February 2023. Based on the strength of the mCRPC data presented, MacroGenics plans to commence enrollment of a randomized Phase 2 study of lorigerlimab in combination with docetaxel vs. docetaxel in second-line, chemotherapy-naïve mCRPC patients in the second half of 2023. A total of 150 patients are planned to be randomized 2:1. The current study 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. In April 2023, results from a Phase 2 investigator-sponsored study at the Johns Hopkins Kimmel Cancer Center was published in *Nature Medicine*. In the clinical study, 32 men with high-risk or very high-risk prostate cancer who were scheduled for prostate cancer surgery were treated with six weekly infusions of enoblituzumab prior to surgery and were followed for an average of 30 months thereafter. Twenty-one patients (66%) had an undetectable prostate-specific antigen (PSA) level 12 months following surgery, suggesting to the authors that there was no sign of residual disease. Additionally, the investigators reported the drug was well-tolerated overall; no patients had any surgical delays or medical complications during or after the operation.

Other Corporate Updates

- ***Sale of TZIELD royalty interest.*** As announced in March 2023, MacroGenics received a $100 million upfront payment from a wholly-owned subsidiary of DRI Healthcare Trust (DRI) for the sale to DRI of its single-digit royalty on global net sales of TZIELD, while retaining the right to receive a 50% share of the royalty on global net sales above a certain annual threshold. Sanofi, S.A. (Sanofi)'s acquisitions of both Provention Bio and DRI's royalty interest in TZIELD in April 2023 have not changed MacroGenics' economic interests, and MacroGenics is eligible to receive from Sanofi a total of up to $430 million in milestone payments, including $105 million upon the achievement of certain regulatory approval milestones, $225 million upon the achievement of certain sales milestones and $100 million in potential payments that Sanofi assumed from DRI.
- ***ZYNYZ approval*****.** As announced in March 2023, the FDA approved ZYNYZ, a humanized monoclonal antibody targeting PD-1, for the treatment of adults with metastatic or recurrent locally advanced MCC. Incyte continues to conduct global registrational studies of retifanlimab across multiple indications, including lung, anal and endometrial cancer. This molecule was initially developed by MacroGenics and licensed by Incyte in October 2017, pursuant to an exclusive global collaboration and license agreement that includes the following provisions:

- MacroGenics received a $15 million milestone payment from Incyte based on the approval of ZYNYZ in MCC and is eligible to receive up to a total of $320 million in potential remaining development and regulatory milestones and up to $330 million in potential commercial milestones from Incyte.
- MacroGenics is eligible to receive tiered royalties of 15% to 24% from Incyte on any global net sales of the product.
- MacroGenics will manufacture a portion of Incyte's global commercial supply of retifanlimab.

First Quarter 2023 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of March 31, 2023, were $241.7 million, compared to $154.3 million as of December 31, 2022. This cash balance did not include a $30 million payment received after March 31, 2023 related to the TZIELD approval milestone.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $24.5 million for the quarter ended March 31, 2023, compared to total revenue of $11.1 million for the quarter ended March 31, 2022.
- **R&D Expenses**: Research and development expenses were $45.9 million for the quarter ended March 31, 2023, compared to $61.4 million for the quarter ended March 31, 2022. The decrease was primarily related to decreased vobramitamab duocarmazine development costs and decreased costs related to discontinued studies. These decreases were partially offset by increased expenses related to discovery projects and preclinical molecules, and increased clinical expenses related to lorigerlimab.
- **SG&A Expenses**: Selling, general and administrative expenses were $13.5 million for the quarter ended March 31, 2023, compared to $16.3 million for the quarter ended March 31, 2022. The decrease was primarily related to decreased legal and consulting expenses.
- **Net Loss**: Net loss was $38.0 million for the quarter ended March 31, 2023, compared to net loss of $66.4 million for the quarter ended March 31, 2022.
- **Shares Outstanding**: Shares of common stock outstanding as of March 31, 2023 were 61,838,565.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities balance of $241.7 million as of March 31, 2023, plus projected and anticipated future payments from partners and product revenues should extend its cash runway through 2025. The Company's expected funding requirements reflect anticipated expenditures related to the Phase 2 TAMARACK clinical trial, the planned 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)

	March 31, 2023	December 31, 2022
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 241,656	$ 154,346
Total assets	343,498	280,468
Deferred revenue	67,255	69,468
Total stockholders' equity	109,268	142,013

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

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

	Three Months Ended March 31,	
	2023	**2022**
Revenues:		
Collaborative and other agreements	$ 16,686	$ 7,093
Product sales, net	3,490	3,580
Contract manufacturing	3,615	—
Royalty revenue	422	—
Government agreements	283	428
Total revenues	24,496	11,101
Costs and expenses:		
Cost of product sales	113	48
Cost of manufacturing services	3,410	—
Research and development	45,872	61,438
Selling, general and administrative	13,527	16,253
Total costs and expenses	62,922	77,739
Loss from operations	(38,426)	(66,638)
Interest and other income	1,073	195
Interest expense	(656)	—
Net loss	(38,009)	(66,443)
Other comprehensive income (loss):		
Unrealized gain (loss) on investments	13	(222)
Comprehensive loss	$ (37,996)	$ (66,665)
Basic and diluted net loss per common share	$ (0.61)	$ (1.08)
Basic and diluted weighted average common shares outstanding	61,809,817	61,324,163

About MacroGenics, Inc.
MacroGenics (the Company) is a biopharmaceutical company focused on developing 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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