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): March 15, 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 March 15, 2023, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the year ended December 31, 2022. 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 March 15, 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: March 15, 2023

MACROGENICS, INC.

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

MacroGenics Provides Corporate Update and 2022 Financial Results

- *Cash runway extended through 2025 with $250 million in non-dilutive funding over past eight months*
- *TAMARACK study design modified with objective of accelerating data readout*
- *Encouraging lorigerlimab (PD-1 × CTLA-4 bispecific DART® molecule) monotherapy clinical data presented at ASCO-GU*
- *Conference call scheduled for today at 4:30 p.m. ET*

ROCKVILLE, MD., March 15, 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 year ended December 31, 2022.

“Our recent presentation of encouraging, preliminary lorigerlimab data in patients with metastatic castration-resistant prostate cancer (mCRPC) at the ASCO Genitourinary Cancers Symposium, together with data we previously shared regarding vobramitamab duocarmazine in mCRPC patients, supports continued development of our two potential new treatment options for men with prostate cancer,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “I am very pleased that we were able to add $250 million in non-dilutive funding over the past eight months, including $150 million during the second half of 2022 and another $100 million to date in 2023 to develop these as well as our other product candidates. Also, I believe the modifications we are making to the TAMARACK study of vobramitamab duocarmazine will lead to more rapid dose selection and benefit the molecule’s overall product profile. Finally, beyond our clinical pipeline, we continue to develop multiple pre-clinical molecules and plan to submit an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for a new antibody-drug conjugate (ADC) later this year.”

Updates on Proprietary Investigational Programs

Recent progress and anticipated events related to MacroGenics’ investigational product candidates are highlighted below.

- ***Vobramitamab duocarmazine (vobra duo)***, formerly known as MGC018, is an 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 100 patients across two experimental arms in which they receive vobra duo at either

2.0 mg/kg or 2.7 mg/kg Q4W. This study initially included a control arm in which patients received a second androgen receptor axis-targeted (ARAT) agent. The treatment landscape for patients with mCRPC has evolved with declining acceptability regarding the use of a second ARAT agent in patients who progress on earlier therapies and the approval of a radiopharmaceutical medication. Given MacroGenics' objective to enroll TAMARACK and determine an optimal dose expeditiously, the Company has modified the trial by removing the ARAT control arm and the Phase 3 portion of the study, with regulatory approval for the modified protocol obtained to date in several countries. MacroGenics believes that removal of the control arm should allow the Company to provide a clinical update in 2024 potentially in support of a subsequent Phase 3 study in mCRPC.

    - MacroGenics continues to pursue 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.
    - MacroGenics presented preliminary clinical results from a dose expansion, single arm study of lorigerlimab in patients with advanced solid tumors in a poster session at the 2023 ASCO Genitourinary Cancers Symposium in February 2023. Among the data presented, 12 of 42 patients (28.6%) with mCRPC achieved ≥ 50% prostate-specific antigen (PSA) reduction (PSA50), including nine (21.4%) who achieved ≥ 90% PSA reduction (PSA90). Nine of 35 patients (25.7%) who had measurable mCRPC achieved confirmed partial responses. The overall safety profile observed across 127 patients from multiple solid tumor expansion cohorts was manageable.
    - MacroGenics plans to initiate 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.
    - As previously announced in October 2022, MacroGenics and Gilead Sciences, Inc. entered into an exclusive option and collaboration agreement to develop MGD024 and up to two additional bispecific research programs. The agreement granted Gilead the option to license MGD024 at predefined decision points during the Phase 1 study.

Other Corporate Updates

- ***TZIELD™ (teplizumab-mzwv) approval.*** As previously announced in November 2022, the FDA approved TZIELD to delay the onset of Stage 3 type 1 diabetes (T1D) in adult and pediatric patients aged 8 years and older with Stage 2 T1D. Teplizumab was acquired from MacroGenics by Provention Bio (Provention) in 2018, pursuant to an asset purchase agreement, as amended, with specific provisions that include:
    - Provention is obligated to pay MacroGenics a $60 million milestone for this first approval, which was split into four $15 million payments. The first two payments were received in November 2022 and March 2023 and the two remaining payments are due June 1, 2023 and September 1, 2023.
    - MacroGenics is eligible to receive additional contingent payments from Provention.
- ***Sale of TZIELD Royalty Interest for up to $200 Million***. As announced last week, MacroGenics sold its royalty interest in TZIELD to a wholly-owned subsidiary of DRI Healthcare Trust (DRI). MacroGenics retains its other economic interests related to TZIELD, including future potential regulatory and commercial milestones. The Company received a $100 million upfront payment from DRI for the sale of its single-digit royalty on global net sales of TZIELD. The Company retains the right to receive a 50% share of the royalty on global net sales above a certain annual threshold. In addition, MacroGenics is eligible to receive up to $50 million from DRI upon the occurrence of pre-specified events tied to the advancement of TZIELD for the treatment of newly diagnosed T1D and may also receive an additional $50 million if TZIELD achieves a certain level of net sales.
- ***Expanded ADC Collaboration with Synaffix***. In March 2023, MacroGenics expanded its technology agreement with Synaffix, which will allow MacroGenics to gain access to Synaffix's proprietary linker-payload platform to support up to four additional ADC molecules.
- ***New Board Members.*** As previously announced in January 2023, Dr. Margaret A. Liu and Meenu Chhabra Karson were appointed to MacroGenics' Board of Directors. Dr. Liu serves as a member of MacroGenics' Science and Technology Committee and Ms. Karson serves as a member of the Company's Audit Committee. Biographical information for both new Board members can be found on the Company's website.

2022 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of December 31, 2022, were $154.3 million, compared to $243.6 million as of December 31, 2021. This cash balance did not include the $45 million receivable due from Provention or the recent $100 million payment from DRI.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $151.9 million for the year ended December 31, 2022, compared to total revenue of $77.4 million for the year ended December 31, 2021.

- **R&D Expenses**: Research and development expenses were $207.0 million for the year ended December 31, 2022, compared to $214.6 million for the year ended December 31, 2021. The decrease was primarily related to decreased retifanlimab manufacturing costs for Incyte, and decreased costs related to discontinued studies. These decreases were partially offset by increased development, manufacturing and clinical trial costs related to vobramitamab duocarmazine, increased expenses related to discovery projects and preclinical molecules, and increased clinical expenses related to lorigerlimab and MGD024.
- **SG&A Expenses**: Selling, general and administrative expenses were $58.9 million for the year ended December 31, 2022, compared to $63.0 million for the year ended December 31, 2021. The decrease was primarily related to decreased selling costs for MARGENZA as well as decreased legal, consulting and stock-based compensation expenses.
- **Net Loss**: Net loss was $119.8 million for the year ended December 31, 2022, compared to net loss of $202.1 million for the year ended December 31, 2021.
- **Shares Outstanding**: Shares of common stock outstanding as of December 31, 2022 were 61,701,467.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities balance of $154.3 million as of December 31, 2022, plus the $100 million proceeds received from DRI related to the sale of the Company's TZIELD royalty interest, 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 clinical and preclinical studies currently ongoing.

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)

	December 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 154,346	$ 243,616
Total assets	280,468	335,245
Deferred revenue	69,468	20,646
Total stockholders' equity	142,013	239,618

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

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

	2022	2021	2020
Revenues:			
Collaborative and other agreements	$ 119,303	$ 63,294	$ 97,764
Product sales, net	16,727	12,349	—
Contract manufacturing	13,988	—	—
Government agreements	1,923	1,804	7,119
Total revenues	151,941	77,447	104,883
Costs and expenses:			
Cost of product sales	3,351	2,651	—
Cost of manufacturing services	4,033	—	—
Research and development	207,026	214,577	193,201
Selling, general and administrative	58,949	63,014	42,742
Total costs and expenses	273,359	280,242	235,943
Loss from operations	(121,418)	(202,795)	(131,060)
Other income	1,660	680	1,321
Net loss	(119,758)	(202,115)	(129,739)
Other comprehensive income (loss):			
Unrealized gain (loss) on investments	56	(54)	(23)
Comprehensive loss	$ (119,702)	$ (202,169)	$ (129,762)
Basic and diluted net loss per common share	$ (1.95)	$ (3.37)	$ (2.47)
Basic and diluted weighted average common shares outstanding	61,433,124	$ 59,944,717	52,442,389

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, 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, MARGENZA or any other product candidate’s revenue, expenses and costs may not be as expected, risks relating to TZIELD, vobramitamab duocarmazine, lorigerlimab, 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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