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 8, 2022

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 8, 2022, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended June 30, 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 August 8, 2022
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 8, 2022

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress and Second Quarter 2022 Financial Results

- *First patient dosed in Phase 1 study of MGD024 in CD123-positive hematologic malignancies*
- *Plan to initiate MGC018 Phase 2/3 study in prostate cancer by year-end*
- *Initiates cost-saving measures through corporate restructuring with focus on key clinical programs, extending cash runway into 2024 with goal of delivering value-creating data milestones*
- *$30 million milestone payments received in July from Incyte as part of collaboration agreement*
- *Conference call scheduled for today at 4:30 p.m. ET.*

ROCKVILLE, MD., August 8, 2022 (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, 2022.

“We made important progress in the second quarter, during which we completed enrollment in a Phase 1/2 dose expansion study of lorigerlimab, a PD-1 × CTLA-4 DART® molecule. In addition, we recently dosed the first patient in a Phase 1 study of MGD024, our next-generation CD123 × CD3 DART molecule, in patients with CD123-positive hematologic malignancies,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “We are also pleased with continued progress made to operationalize TAMARACK, our Phase 2/3 study of MGC018, a B7-H3-directed antibody-drug conjugate (ADC), in patients with metastatic castration-resistant prostate cancer (mCRPC). We expect to start this study by year-end.”

Updates on Proprietary Investigational Programs

Recent progress and anticipated events in 2022 related to MacroGenics’ investigational product candidates in clinical development are highlighted below.

- ***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.
  - Following constructive interactions with the U.S. Food and Drug Administration (FDA) and European Medicines Agency, MacroGenics expects to start the TAMARACK Phase 2/3 study of MGC018 in patients with mCRPC by year-end. The Company believes that this should enable the delivery of interim data from the Phase 2 portion of the study by the end of 2024.
  - Patient recruitment continues in a Phase 1/2 dose escalation study of MGC018 in combination with lorigerlimab in patients with various advanced solid tumors.

- ***Lorigerlimab*** is a bispecific, tetravalent PD-1 × CTLA-4 DART molecule. MacroGenics completed enrollment of a Phase 1/2 dose expansion study with lorigerlimab as monotherapy in cohorts of patients with microsatellite stable colorectal cancer, mCRPC, melanoma and checkpoint-naïve non-small cell lung cancer. The Company expects to provide a data update from this study by early 2023.
- ***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 recently dosed the first patient in a Phase 1 study of MGD024 in patients with CD123-positive neoplasms, including acute myeloid leukemia and myelodysplastic syndromes.
- ***Enoblituzumab*** is an Fc-engineered, monoclonal antibody (mAb) that targets B7-H3.
    - As previously announced in July 2022, MacroGenics closed the Phase 2 study evaluating enoblituzumab in combination with either retifanlimab (anti-PD-1 mAb) or tebotelimab (PD-1 × LAG-3 bispecific antibody), each an investigational agent, in the first-line treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). The decision to discontinue this study was based on an internal review of safety data and a risk benefit analysis in front-line SCCHN patients. The Company does not believe this decision has any impact on its other B7-H3-directed programs or its ability to potentially develop enoblituzumab in other indications.
    - At the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, investigators at Johns Hopkins University presented encouraging clinical and safety data from their ongoing, investigator-sponsored Phase 2 trial of enoblituzumab in patients with localized prostate cancer in the neoadjuvant setting. In the 32-patient, single-arm study, enoblituzumab showed a favorable safety profile and encouraging activity with 66% of patients having PSA 0 at one-year post-surgical resection, which correlated with peripheral expansion of tumor associated T-cell clones. This published data from the ongoing investigator-sponsored trial to date provide rationale for further evaluation of enoblituzumab in prostate cancer.

Other Program Updates:

- ***Teplizumab*** is an investigational, anti-CD3 mAb acquired from MacroGenics by Provention Bio, Inc. (Provention) under an asset purchase agreement in 2018. Provention is developing teplizumab for the treatment of type 1 diabetes. On June 30, 2022, Provention announced that the FDA had extended its review period by three months for the biologics license application (BLA) for teplizumab. The extended Prescription Drug User Fee Act (PDUFA) target date is November 17, 2022. MacroGenics is eligible to receive royalties on net sales of teplizumab, if approved, in addition to milestone payments, including $60 million upon approval of a BLA in the United States.
- ***Retifanlimab*** is an investigational anti-PD-1 mAb that has been exclusively licensed to Incyte Corporation. MacroGenics is eligible to receive royalties on net sales of retifanlimab, if approved, in addition to milestone payments. In July 2022, MacroGenics received $30 million in milestone payments from Incyte as part of its collaboration

agreement. Retifanlimab is currently being studied as monotherapy or in combination with other agents across multiple studies.

Corporate Restructuring

MacroGenics today initiated cost-saving measures to focus on key clinical programs and to extend its cash runway with the goal of delivering value-creating data with its existing and anticipated financial resources. These planned measures include an approximate 15% workforce reduction in employees and closure of two of its satellite facilities, including a Brisbane, California-based research site and a smaller-scale, non-commercial GMP manufacturing site in Rockville, Maryland. The Company believes these measures will provide resources to advance its pipeline of innovative product candidates.

The reduction in workforce announced today will be implemented immediately in some areas and completed over time as certain projects are wound down and sites are closed. MacroGenics expects to incur additional costs as the Company recognizes one-time employee termination-related charges.

“In an effort to prioritize our pipeline of product candidates and reduce our spending, we have previously announced the termination of multiple studies. Today, we are taking additional decisive action to extend our cash runway and put MacroGenics in a stronger position to execute on our prioritized programs. The decision to reduce our workforce and close two sites was not taken lightly, and we are grateful to every MacroGenics employee who has helped advance our Company,” said Scott Koenig, M.D., Ph.D. “With these actions, we believe our updated cash runway should enable the delivery of interim data from the Phase 2 portion of the TAMARACK study of MGC018 by the end of 2024, data from the Phase 1 dose expansion of lorigerlimab by early 2023 and data from the dose escalation of MGD024 in AML patients, as well as execution of the Company’s other ongoing clinical and preclinical studies.”

Second Quarter 2022 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of June 30, 2022, were $133.7 million, compared to $243.6 million as of December 31, 2021. The June 30, 2022 balance did not include $34.5 million in payments subsequently received from collaboration partners in July 2022.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $26.0 million for the quarter ended June 30, 2022, compared to total revenue of $30.8 million for the quarter ended June 30, 2021. Revenue for the quarter ended June 30, 2022 included MARGENZA net sales of $4.7 million, compared to $3.2 million for the quarter ended June 30, 2021.
- **R&D Expenses**: Research and development expenses were $51.7 million for the quarter ended June 30, 2022, compared to $55.8 million for the quarter ended June 30, 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 of discovery projects and preclinical

molecules, increased clinical expenses related to lorigerlimab, and increased costs related to MGC018.

- **SG&A Expenses**: Selling, general and administrative expenses were $13.7 million for the quarter ended June 30, 2022, compared to $15.2 million for the quarter ended June 30, 2021. The was primarily related to decreased selling costs for MARGENZA, which launched in March 2021, as well as decreased consulting expenses.
- **Net Loss**: Net loss was $41.3 million for the quarter ended June 30, 2022, compared to net loss of $39.9 million for the quarter ended June 30, 2021.
- **Shares Outstanding**: Shares of common stock outstanding as of June 30, 2022 were 61,458,790.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities balance of $133.7 million as of June 30, 2022, combined with $34.5 million in payments subsequently received from collaboration partners, anticipated and potential collaboration payments, product revenues and savings from the execution of the Company's restructuring plan should extend its cash runway into 2024. This cash runway guidance reflects anticipated expenditures related to the planned Phase 2 portion of the MGC018 TAMARACK study as well as continuation of MacroGenics' other ongoing preclinical and clinical 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, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 133,740	$ 243,616
Total assets	218,043	335,245
Deferred revenue	17,728	20,646
Total stockholders' equity	142,481	239,618

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,	
	2022	2021	2022	2021
Revenues:				
Collaborative and other agreements	$ 16,863	$ 27,168	$ 23,956	$ 42,352
Product sales, net	4,672	3,203	8,252	4,090
Contract manufacturing	3,992	—	3,992	—
Government agreements	480	386	908	1,196
Total revenues	26,007	30,757	37,108	47,638
Costs and expenses:				
Cost of product sales	180	22	228	39
Cost of manufacturing services	2,222	—	2,222	—
Research and development	51,744	55,780	113,182	108,901
Selling, general and administrative	13,669	15,234	29,922	30,270
Total costs and expenses	67,815	71,036	145,554	139,210
Loss from operations	(41,808)	(40,279)	(108,446)	(91,572)
Other income	504	344	699	365
Net loss	(41,304)	(39,935)	(107,747)	(91,207)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	(43)	(10)	(265)	8
Comprehensive income (loss)	$ (41,347)	$ (39,945)	$ (108,012)	$ (91,199)
Basic and diluted net loss per common share	$ (0.67)	$ (0.66)	$ (1.76)	$ (1.56)
Basic and diluted weighted average common shares outstanding	61,384,943	60,068,315	61,354,721	58,643,496

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, 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 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 MGC018, MARGENZA or any other product candidate’s revenue, expenses and costs may not be as expected, risks relating to MGC018, MARGENZA or any other product candidate’s market acceptance, competition, reimbursement and regulatory actions, the uncertainties inherent in the initiation and enrollment of future clinical trials, the availability of financing to fund the 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, or 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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