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 3, 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 November 3, 2022, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended September 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 November 3, 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: November 3, 2022

MACROGENICS, INC.

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

MacroGenics Provides Corporate Update and Third Quarter 2022 Financial Results

- *Collaboration with Gilead to develop bispecific antibodies, including MGD024, announced*
- *Planned initiation of Phase 2 portion of MGC018 TAMARACK study in prostate cancer by year-end*
- *Anticipated update on lorigerlimab (PD-1 × CTLA-4 bispecific DART® molecule) monotherapy clinical data in first quarter of 2023*
- *Conference call scheduled for today at 4:30 p.m. ET*

ROCKVILLE, MD., November 3, 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 September 30, 2022.

“Over the past few months, we have strengthened our financial position by generating non-dilutive capital through our partnering efforts. We have achieved this through the receipt of $30 million in milestone payments from Incyte during the quarter and the subsequent receipt of a $60 million upfront payment from Gilead for our recently announced MGD024 collaboration. In addition, over the next few weeks, we await the U.S. Food and Drug Administration (FDA) decision regarding Provention Bio’s teplizumab biologics license application (BLA), which would generate an additional $60 million milestone payment obligation to MacroGenics, if approved,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “Moreover, we are focused on advancing our pipeline of clinical and preclinical product candidates. We look forward to initiating the MGC018 TAMARACK study later this year, continuing to enroll the MGC018 combination study with lorigerlimab and the MGD024 dose-escalation study, as well as reporting data from the lorigerlimab monotherapy expansion cohorts in early 2023.”

Updates on Proprietary Investigational Programs

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

- ***MGC018***, now also known as vobramitamab duocarmazine, 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 continues to expect to start the Phase 2 portion of the TAMARACK study of vobramitamab duocarmazine in patients with metastatic castration-

resistant prostate cancer (mCRPC) by year-end 2022. The Company believes that this should enable interim data from the Phase 2 portion of the study in 2024.

    - Patient recruitment continues in a Phase 1/2 dose escalation study of vobramitamab duocarmazine in combination with lorigerlimab in patients with various advanced solid tumors.

- ***Lorigerlimab*** is a bispecific, tetravalent PD-1 × CTLA-4 DART molecule. MacroGenics enrolled 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 (NSCLC) and expects to provide a data update from this study in the first quarter of 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 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.

Other Program Updates:

- ***Teplizumab*** is an investigational, anti-CD3 mAb acquired from MacroGenics by Provention Bio, Inc. under an asset purchase agreement in 2018. Provention Bio is developing teplizumab for the prevention and treatment of type 1 diabetes (T1D). The Prescription Drug User Fee Act (PDUFA) target date for action on the BLA for teplizumab for the prevention of T1D 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.

Gilead Collaboration

On October 14, 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 grants Gilead the option to license MGD024. As part of the agreement, Gilead paid MacroGenics an upfront payment of $60 million and MacroGenics will be eligible to receive up to $1.7 billion in target nomination, option fees, and development, regulatory and commercial milestones. MacroGenics will also be eligible to receive tiered, low double-digit royalties on worldwide net sales of MGD024 and a flat royalty on worldwide net sales of products resulting from the two additional research programs.

MacroGenics will be responsible for the ongoing Phase 1 study of MGD024 during which Gilead may elect to exercise its option to license the program at predefined decision points. The Phase

1 study includes a dose escalation segment and an expansion segment that is intended to evaluate MGD024 as monotherapy and in combination with other therapies across multiple indications.

Third Quarter 2022 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of September 30, 2022, were $123.6 million, compared to $243.6 million as of December 31, 2021. The September 30, 2022 balance did not include $60 million subsequently received from Gilead in October 2022.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $41.7 million for the quarter ended September 30, 2022, compared to total revenue of $15.7 million for the quarter ended September 30, 2021. Revenue for the quarter ended September 30, 2022 included MARGENZA net sales of $4.4 million, compared to $3.6 million for the quarter ended September 30, 2021.
- **R&D Expenses**: Research and development expenses were $48.2 million for the quarter ended September 30, 2022, compared to $49.8 million for the quarter ended September 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, 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 $15.4 million for the quarter ended September 30, 2022, compared to $17.2 million for the quarter ended September 30, 2021. The decrease was primarily related to decreased selling costs for MARGENZA as well as decreased consulting expenses.
- **Net Loss**: Net loss was $24.8 million for the quarter ended September 30, 2022, compared to net loss of $52.9 million for the quarter ended September 30, 2021.
- **Shares Outstanding**: Shares of common stock outstanding as of September 30, 2022 were 61,462,189.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities balance of $123.6 million as of September 30, 2022, $60 million subsequently received from Gilead, projected and anticipated future payments from partners and product revenues should extend its cash runway into mid-2024. This cash runway guidance reflects anticipated expenditures related to the planned Phase 2 portion of the TAMARACK study as well as MacroGenics' other ongoing 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, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 123,616	$ 243,616
Total assets	195,347	335,245
Deferred revenue	12,169	20,646
Total stockholders' equity	122,958	239,618

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,	
	2022	2021	2022	2021
Revenues:				
Collaborative and other agreements	$ 35,674	$ 11,986	$ 59,630	$ 54,338
Product sales, net	4,371	3,591	12,623	7,681
Contract manufacturing	1,142	—	5,134	—
Government agreements	547	85	1,455	1,281
Total revenues	41,734	15,662	78,842	63,300
Costs and expenses:				
Cost of product sales	3,007	1,665	3,235	1,704
Cost of manufacturing services	136	—	2,358	—
Research and development	48,191	49,823	161,373	158,724
Selling, general and administrative	15,355	17,161	45,277	47,431
Total costs and expenses	66,689	68,649	212,243	207,859
Loss from operations	(24,955)	(52,987)	(133,401)	(144,559)
Other income	142	101	841	466
Net loss	(24,813)	(52,886)	(132,560)	(144,093)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	213	(4)	(52)	4
Comprehensive income (loss)	$ (24,600)	$ (52,890)	$ (132,612)	$ (144,089)
Basic and diluted net loss per common share	$ (0.40)	$ (0.86)	$ (2.16)	$ (2.42)
Basic and diluted weighted average common shares outstanding	61,459,831	61,169,754	61,390,143	59,494,836

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.

###

CONTACTS:
Jim Karrels, Senior Vice President, CFO
1-301-251-5172
info@macrogenics.com