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 2, 2021

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 2, 2021, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended September 30, 2021. 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 2, 2021
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 2, 2021

MACROGENICS, INC.

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

MacroGenics Provides Update on Corporate Progress and Third Quarter 2021 Financial Results

- *Investigational New Drug (IND) application submitted for MGD024, a next generation DART® molecule targeting CD123 and CD3 for AML*
- *U.S. Food & Drug Administration (FDA) approves MacroGenics' GMP manufacturing facility to produce MARGENZA® drug substance*
- *Discontinuing enrollment of Cohort A of Phase 2/3 MAHOGANY study of margetuximab*
- *Conference call scheduled for today at 4:30 p.m. ET.*

ROCKVILLE, MD., November 2, 2021 (GLOBE NEWSWIRE) -- MacroGenics, Inc. (NASDAQ: MGNX), a biopharmaceutical company focused on developing and commercializing innovative monoclonal 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, 2021.

"In September, we were pleased to present encouraging preliminary results from our ongoing Phase 1 cohort expansion study of MGC018 at the European Society for Medical Oncology (ESMO) Annual Meeting. We look forward to providing additional clinical data updates on this study next year as well as sharing our future development plans for this molecule in the first quarter of next year, after continued engagement with Key Opinion Leaders and regulatory agencies," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "Beyond MGC018, we continue to advance our growing pipeline of investigational product candidates for the potential treatment of cancer. Finally, the recent FDA approval to manufacture MARGENZA drug substance at our GMP manufacturing facility is an important achievement for the Company."

Updates on Proprietary Programs

The recent progress and key events related to MacroGenics' investigational product candidates in clinical development and its approved product, MARGENZA, are highlighted below:

- ***MGC018*** is an antibody-drug conjugate (ADC) that targets B7-H3. At ESMO, MacroGenics presented encouraging preliminary clinical results from the ongoing Phase 1 study of MGC018 in patients with solid tumors. The Phase 1 study cohort expansions are ongoing for metastatic castrate-resistant prostate cancer (mCRPC), non-small cell lung cancer (NSCLC), melanoma, squamous cell carcinoma of the head and neck (SCCHN) and triple negative breast cancer (TNBC). The Company expects to present additional data from the ongoing Phase 1 study of MGC018 in the first half of next year. In addition, MacroGenics intends to provide details regarding further development plans in mCRPC in the first quarter of 2022. The Company also intends to initiate a study combining

MGC018 with one of its proprietary checkpoint inhibitor molecules in the first half of next year.

- ***Enoblituzumab*** is an Fc-engineered, monoclonal antibody that targets B7-H3. MacroGenics continues to recruit patients into its Phase 2 study of enoblituzumab in a chemotherapy-free regimen in combination with retifanlimab in front-line patients with SCCHN who are PD-L1 positive and with tebotelimab in SCCHN patients who are PD-L1 negative. In September, I-Mab Biopharma announced that an IND to initiate a Phase 2 trial of enoblituzumab in combination with pembrolizumab in patients with select solid tumors was accepted in China, triggering a net $4.5 million milestone payment to MacroGenics. I-Mab has development and commercial rights to enoblituzumab in Greater China.

- **Bispecific CD123 × CD3 DART molecules**:

    - ***Flotetuzumab*** is a bispecific CD123 × CD3 DART molecule being evaluated in patients with refractory acute myeloid leukemia (AML). MacroGenics is conducting a single-arm clinical study to evaluate flotetuzumab in up to 200 patients with refractory AML, with complete remission (CR) and CR with partial hematological recovery (CRh) as the composite primary endpoint. The Company anticipates providing further updates on the clinical development of flotetuzumab in 2022.

    - ***MGD024*** is a next-generation, bispecific CD123 × CD3 DART molecule designed to minimize cytokine-release syndrome, while maintaining anti-tumor cytolytic activity, and has an Fc domain to permit intermittent dosing through a longer half-life. MacroGenics submitted an IND application for MGD024 to the FDA in October. The Company intends to present preclinical MGD024 data at the American Society of Hematology (ASH) Annual Meeting in December.

- ***Tebotelimab*** is a bispecific, tetravalent DART molecule targeting PD-1 and LAG-3. MacroGenics is evaluating the molecule in patients as monotherapy as well as in combination with other agents. The Company's partner for this molecule in Greater China, Zai Lab, expanded its Phase 1b/2 study of tebotelimab in combination with the PARP inhibitor niraparib into new indications, including gastric cancer, TNBC and biliary tract cancer. In addition, Zai Lab enrolled the first patient in an endometrial cancer cohort in October 2021.

- ***MGD019*** is a bispecific, tetravalent DART molecule targeting PD-1 and CTLA-4. The Company is conducting a Phase 1 dose expansion study in cohorts of patients with microsatellite stable colorectal cancer (MSS CRC), checkpoint-naïve NSCLC, mCRPC and melanoma. The Company anticipates sharing data from its ongoing Phase 1 dose expansion study next year.

- ***IMGC936*** is an ADC that targets ADAM9, a cell surface protein over-expressed in several solid tumor types, and is being developed jointly under a 50/50 collaboration with ImmunoGen, Inc. Under the collaboration, ImmunoGen is leading clinical development

of IMGC936 in a Phase 1 clinical trial evaluating safety and pharmacokinetics in multiple solid tumors and has indicated they anticipate disclosing initial data in 2022.

- ***Margetuximab*** is an Fc-engineered, monoclonal antibody (mAb) that targets the HER2 oncoprotein, which is expressed by certain breast, gastroesophageal and other solid tumor cells.

    - *MARGENZA Commercial Launch*. In March 2021, MacroGenics and its commercial partner, EVERSANA, launched MARGENZA for the treatment of adult patients with metastatic HER2-positive breast cancer, in combination with chemotherapy, who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. As previously reported, the median overall survival (OS) in the intent-to-treat population was not statistically different between the two arms. A prespecified, non-alpha allocating, exploratory analysis of OS by CD16A genotype in the SOPHIA trial showed a numerical OS advantage in favor of margetuximab in F homozygous patients and a numerical OS advantage in favor of trastuzumab in V homozygous patients. Finally, MacroGenics recently received U.S. FDA approval to manufacture MARGENZA drug substance at its GMP manufacturing facility in Rockville, MD.

    - *MAHOGANY Study*. At ESMO, MacroGenics presented results from Cohort A Part 1 of the Phase 2/3 MAHOGANY study of margetuximab in combination with retifanlimab, an anti-PD-1 molecule the Company licensed to Incyte Corporation, in patients with advanced gastric and gastroesophageal junction cancer. Although the number of confirmed responses by independent review (twenty one of 40 (53%) patients) exceeded the prespecified futility boundary for this chemotherapy-free regimen, MacroGenics has decided to discontinue enrollment of Cohort A based on a number of factors, including the prioritization of its other product candidates given the competition in this indication, and the accelerated approval of combination therapy with pembrolizumab. MacroGenics' partner for margetuximab in Greater China, Zai Lab, continues to enroll patients in Cohort B.

    - *Zai Lab's Bridging Study*. In October 2021, Zai Lab announced that the bridging study of margetuximab plus chemotherapy in advanced, previously treated HER2-positive breast cancer met its primary endpoint with acceptable safety and tolerability. The study showed that efficacy of the combination in Chinese patients was consistent with that seen in the global population in MacroGenics' SOPHIA Phase 3 trial. Zai Lab has indicated that it anticipates submitting a BLA in China for pretreated metastatic HER2-positive breast cancer by approximately year-end 2021.

Updates on Partnered Program

- ***Retifanlimab*** is an investigational anti-PD-1 antibody that MacroGenics licensed to Incyte. Incyte will present clinical results in poster presentations from both a Phase 2 study of retifanlimab in patients with advanced or metastatic Merkel cell carcinoma and

a tumor specific expansion cohort study in patients with recurrent MSI-H or deficient mismatch repair (dMMR) recurrent endometrial cancer at the 2021 Society for Immunotherapy of Cancer (or SITC) Virtual Meeting taking place November 10 - 14, 2021.

Third Quarter 2021 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of September 30, 2021, were $298.9 million, compared to $272.5 million as of December 31, 2020. .
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $15.7 million for the quarter ended September 30, 2021, compared to total revenue of $18.3 million for the quarter ended September 30, 2020. Revenue for the quarter ended September 30, 2021 included $3.6 million net sales of MARGENZA.
- **R&D Expenses**: Research and development expenses were $49.8 million for the quarter ended September 30, 2021, compared to $44.7 million for the quarter ended September 30, 2020. The increase was primarily related to increased clinical trial and development costs related to the Company's product candidates, as well as research costs related to preclinical molecules, partially offset by decreased clinical costs and BLA support for margetuximab and decreased development and manufacturing costs related to flotetuzumab.
- **SG&A Expenses**: Selling, general and administrative expenses were $17.2 million for the quarter ended September 30, 2021, compared to $9.7 million for the quarter ended September 30, 2020. The increase was primarily related to MARGENZA launch, as well as labor-related costs and legal expenses.
- **Net Loss**: Net loss was $52.9 million for the quarter ended September 30, 2021, compared to net loss of $36.0 million for the quarter ended September 30, 2020.
- **Shares Outstanding**: Shares outstanding as of September 30, 2021 were 61,254,693.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities as of September 30, 2021, plus anticipated and potential collaboration payments, should enable it to fund its operations through 2023, assuming the Company's programs and collaborations advance as currently contemplated.

Conference Call Information

MacroGenics will host a conference call today at 4:30 p.m. (ET) to discuss financial results for the quarter ended September 30, 2021 and provide a corporate update. To participate in the conference call, please dial (877) 303-6253 (domestic) or (973) 409-9610 (international) five minutes prior to the start of the call and provide the Conference ID: 6063045.

The listen-only webcast of the conference call can be accessed under "Events & Presentations" in the Investor Relations section of the Company's website at http://ir.macrogenics.com/events.cfm. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company's website for 30 days following the call.

MACROGENICS, INC.
SELECTED CONSOLIDATED BALANCE SHEET DATA
(Amounts in thousands)

	September 30, 2021 (unaudited)	December 31, 2020
Cash, cash equivalents and marketable securities	$ 298,898	$ 272,531
Total assets	392,160	378,743
Deferred revenue	25,889	11,382
Total stockholders' equity	291,438	295,884

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,	
	2021	2020	2021	2020
Revenues:				
Revenue from collaborative and other agreements	$ 11,986	$ 17,415	$ 54,338	$ 46,018
Product revenue, net	3,591	—	7,681	—
Revenue from government agreements	85	838	1,281	6,174
Total revenues	15,662	18,253	63,300	52,192
Costs and expenses:				
Cost of product sales	1,665	—	1,704	—
Research and development	49,823	44,656	158,724	150,901
Selling, general and administrative	17,161	9,732	47,431	30,181
Total costs and expenses	68,649	54,388	207,859	181,082
Loss from operations	(52,987)	(36,135)	(144,559)	(128,890)
Other income	101	92	466	1,238
Net loss	(52,886)	(36,043)	(144,093)	(127,652)
Other comprehensive income:				
Unrealized gain (loss) on investments	(4)	(15)	4	(14)
Comprehensive loss	$ (52,890)	$ (36,058)	$ (144,089)	$ (127,666)
Basic and diluted net loss per common share	$ (0.86)	$ (0.66)	$ (2.42)	$ (2.49)
Basic and diluted weighted average common shares outstanding	61,169,754	54,463,412	59,494,836	51,176,884

About MacroGenics, Inc.
MacroGenics 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 the Company, including statements about the Company's strategy, future operations, clinical development of the Company's therapeutic candidates, commercial prospects of or product

revenues from MARGENZA, milestone or opt-in payments from the Company's collaborators, the Company's anticipated milestones and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "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 MARGENZA revenue, expenses and costs may not be as expected, risks relating to MARGENZA's market acceptance, competition, reimbursement and regulatory actions, the uncertainties inherent in the initiation and enrollment of future clinical trials, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company's product candidates 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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CONTACTS:
Chris James, M.D., Vice President, Investor Relations & Corporate Communications
Jim Karrels, Senior Vice President, CFO
1-301-251-5172
info@macrogenics.com