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): July 29, 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 July 29, 2021, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended June 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 July 29, 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: July 29, 2021

MACROGENICS, INC.

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

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

- *Upcoming MGC018 and margetuximab MAHOGANY clinical data presentations at European Society for Medical Oncology (ESMO) Meeting*
- *Conference call scheduled for today at 4:30 p.m. ET.*

ROCKVILLE, MD., July 29, 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 June 30, 2021.

“In June, we presented encouraging data from a Phase 1 study of MGC018 at ASCO. We look forward to providing further updates on this compound and margetuximab in gastric cancer at ESMO in September. Beyond these two programs, we continue to progress our growing pipeline of investigational therapeutics for the potential treatment of cancer as well as to execute on the recent launch and commercialization of MARGENZA® with our partner, EVERSANA,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “Also in June, we announced our broad strategic collaboration with Zai Lab to develop and commercialize preclinical bispecific antibodies in oncology. We’re very pleased to have entered this second collaboration with Zai Lab.”

Key Updates on Proprietary Programs

Recent progress and anticipated events in 2021 related to MacroGenics’ approved product, MARGENZA, and its investigational product candidates in clinical development are highlighted below.

- ***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 (margetuximab-cmkb) 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. Based on the accrued overall survival (OS) events in the SOPHIA metastatic breast cancer Phase 3 study, the Company expects to complete and share top-line results from the final analysis of OS data, based on 385 OS events by the end of the third quarter of 2021.

- *Phase 2/3 MAHOGANY study in advanced gastric and gastroesophageal junction cancer.* All 40 patients have been enrolled in the first part of Module A of the MAHOGANY study, which is evaluating margetuximab in combination with retifanlimab, an anti-PD-1 molecule the Company licensed to Incyte Corporation in 2017. The Company plans to report interim safety and efficacy data on these patients at ESMO in September 2021.

- ***Flotetuzumab*** is a bispecific CD123 × CD3 DART® molecule being evaluated in patients with primary induction failure (PIF) and early relapsed (less than six months, or ER6) acute myeloid leukemia (AML). MacroGenics is conducting a single-arm, registration-enabling clinical study to evaluate flotetuzumab in up to 200 patients with PIF/ER6 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 late 2021.

- ***MGC018*** is an antibody-drug conjugate (ADC) that targets B7-H3. In June 2021, MacroGenics presented updated clinical data at the American Society of Clinical Oncology (ASCO) Annual Meeting demonstrating anti-tumor activity in patients with melanoma and metastatic castration-resistant prostate cancer (mCRPC). Preliminary results in the mCRPC cohort expansion showed 11 of 22 patients (50%) had a PSA reduction of 50% or greater, with anti-tumor activity observed in four of seven patients with measurable disease who had their first 9-week imaging results available, including one unconfirmed partial response. Anti-tumor activity was also reported in all three melanoma patients who received 4 mg/kg in dose escalation, with one patient achieving a confirmed partial response. MGC018 trial cohorts are ongoing for mCRPC, melanoma, non-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck (SCCHN) and triple negative breast cancer (TNBC). MacroGenics will provide an update of clinical data at ESMO in September.

- ***Enoblituzumab*** is an Fc-engineered, anti-B7-H3 mAb. MacroGenics continues to recruit 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. The Company has recently activated clinical trial sites in Europe to advance enrollment of the study.

- ***Tebotelimab*** is a bispecific, tetravalent DART molecule targeting PD-1 and LAG-3. MacroGenics is evaluating the molecule in patients as both monotherapy as well as in combination with other agents. The Company's partner in Greater China, Zai Lab, is evaluating tebotelimab as monotherapy in patients with hepatocellular carcinoma and melanoma as well as in combination with niraparib in a variety of advanced or metastatic solid tumors. MacroGenics expects to provide an update on the next stage of development for tebotelimab later this year.

- ***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.

- ***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 patients with select cancers and have indicated they anticipate disclosing initial data in early 2022.
- ***MGD024*** is a next-generation, bispecific CD123 × CD3 DART molecule in preclinical development. The molecule incorporates a CD3 component designed to minimize cytokine-release syndrome, while maintaining anti-tumor cytolytic activity, along with an Fc domain to permit intermittent dosing through a longer half-life. The Company expects to submit an Investigational New Drug (IND) application to the FDA in the fourth quarter of 2021.

Second Quarter 2021 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of June 30, 2021, were $297.3 million, compared to $272.5 million as of December 31, 2020. This does not include $55 million in consideration (consisting of a $25 million upfront payment and a $30 million equity investment) received from Zai Lab in July 2021, which related to the execution of the collaboration agreement that was announced on June 16, 2021.
- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $30.8 million for the quarter ended June 30, 2021, including $3.2 million net sales of MARGENZA, compared to total revenue of $20.3 million for the quarter ended June 30, 2020. This increase was primarily due to the recognition of $14.4 million of revenue from Zai Lab related to the recent June 2021 collaboration announcement and recognition of a $5 million milestone from Incyte Corporation.
- **R&D Expenses**: Research and development expenses were $55.8 million for the quarter ended June 30, 2021, compared to $57.4 million for the quarter ended June 30, 2020.
- **SG&A Expenses**: Selling, general and administrative expenses were $15.2 million for the quarter ended June 30, 2021, compared to $10.2 million for the quarter ended June 30, 2020. This increase was primarily related to MARGENZA launch costs.
- **Net Loss**: Net loss was $39.9 million for the quarter ended June 30, 2021, compared to net loss of $46.9 million for the quarter ended June 30, 2020.
- **Shares Outstanding**: Shares outstanding as of June 30, 2021 were 60,133,447, which excluded 958,467 shares issued to Zai Lab in early July as part of the recently announced collaboration.
- **Cash Runway Guidance**: MacroGenics anticipates that its cash, cash equivalents and marketable securities as of June 30, 2021, plus consideration received from Zai Lab in July 2021, as well as 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 June 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: 7983402.

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)

	June 30, 2021 (unaudited)	December 31, 2020
Cash, cash equivalents and marketable securities	$ 297,316	$ 272,531
Total assets	425,911	378,743
Deferred revenue	30,041	11,382
Total stockholders' equity	319,045	295,884

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,	
	2021	2020	2021	2020
Revenues:				
Revenue from collaborative and other agreements	$ 27,168	$ 15,636	$ 42,352	$ 28,603
Product revenue, net	3,203	—	4,090	—
Revenue from government agreements	386	4,621	1,196	5,336
Total revenues	30,757	20,257	47,638	33,939
Costs and expenses:				
Cost of product sales	22	—	39	—
Research and development	55,780	57,351	108,901	106,245
Selling, general and administrative	15,234	10,216	30,270	20,449
Total costs and expenses	71,036	67,567	139,210	126,694
Loss from operations	(40,279)	(47,310)	(91,572)	(92,755)
Other income	344	425	365	1,146
Net loss	(39,935)	(46,885)	(91,207)	(91,609)
Other comprehensive income:				
Unrealized gain (loss) on investments	(10)	(55)	8	1
Comprehensive loss	$ (39,945)	$ (46,940)	$ (91,199)	$ (91,608)
Basic and diluted net loss per common share	$ (0.66)	$ (0.94)	$ (1.56)	$ (1.85)
Basic and diluted weighted average common shares outstanding	60,068,315	50,018,462	58,643,496	49,515,562

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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