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 4, 2020

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 4, 2020, MacroGenics, Inc. (the "Company") announced financial and operating results as of and for the quarter ended September 30, 2020. 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 4, 2020
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 4, 2020

MACROGENICS, INC.
By: /s/ Jeffrey Peters
Name: Jeffrey Peters
Title: Vice President and General Counsel

MacroGenics Provides Update on Corporate Progress and Third Quarter 2020 Financial Results

– *Conference call scheduled for today at 4:30 p.m. ET.*

ROCKVILLE, MD., November 4, 2020 (GLOBE NEWSWIRE) -- MacroGenics, Inc. (NASDAQ: MGNX), a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, today provided an update on its corporate progress and reported financial results for the quarter ended September 30, 2020.

“MacroGenics continued the advancement of its portfolio of multiple clinical molecules during the third quarter of 2020, with three investigational programs currently in pivotal studies: margetuximab, flotetuzumab and retifanlimab. The PDUFA action date for margetuximab in breast cancer is December 18. Just prior, we look forward to our next presentation of flotetuzumab clinical data at ASH in December, following the publication of data in three separate journals this year highlighting the medical and scientific interest in this DART® molecule,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "At ESMO in September, we and our partner, Incyte, presented clinical data on MGD019 and retifanlimab, respectively. And on the heels of MGC018 data presented at ASCO, we recently commenced the enrollment of patients with mCRPC, TNBC and NSCLC. More near-term, we look forward to providing an update on tebotelimab plus margetuximab in HER2-positive patients at the upcoming SITC Annual Meeting this month. Finally, we look forward to updating you on continued progress through the rest of 2020 and into 2021.”

Key Highlights from Investigational Product Candidates in Pivotal Studies:

- **Margetuximab (Fc-engineered, anti-HER2 mAb):** A Biologics License Application (BLA) for margetuximab, in combination with chemotherapy as a treatment for patients with metastatic HER2-positive breast cancer, is being reviewed by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) target action date is December 18, 2020. Based on the current accrual rate of overall survival (OS) events in the Phase 3 SOPHIA study, MacroGenics now anticipates accrual of the 385th OS event, which triggers the final OS analysis, in the second half of 2021.

  Enrollment of the global Phase 2/3 MAHOGANY study of margetuximab plus checkpoint blockade, with or without chemotherapy, as a potential first-line treatment for patients in front-line gastric and gastroesophageal junction cancer is ongoing. MacroGenics’ partner in Greater China, Zai Lab, recently announced dosing of the first patient in that region. MacroGenics anticipates providing a clinical update on Module A of the study in the first half of 2021.

- **Flotetuzumab (bispecific CD123 × CD3 DART molecule):** During the third quarter, two manuscripts were published in *Blood* and *Blood Advances*, two publications of the American Society of Hematology (ASH). The first publication reported on clinical results as of November 2019, while the most recent publication reported on the potential role of flotetuzumab in the immunotherapy of

TP53-positive acute myeloid leukemia (AML). In addition, six flotetuzumab and AML abstracts were accepted for presentation at the upcoming ASH Annual Meeting.

MacroGenics continues to enroll the single-arm, registrational study to evaluate flotetuzumab in up to 200 AML patients with primary induction failure or early relapse (PIF/ER) AML, with complete remission (CR) and CR with partial hematological recovery (CRh) as the primary endpoint.

- **Retifanlimab (anti-PD-1 mAb previously known as MGA012 or INCMGA0012):** At the European Society for Medical Oncology (ESMO) Virtual Congress 2020 in September, data from potentially registration-enabling monotherapy studies in patients with squamous cell carcinoma of the anal canal and Merkel cell carcinoma were presented. Also in September, a $15 million milestone payment to MacroGenics was triggered under the Company's exclusive global collaboration and license agreement with Incyte Corporation. This milestone was triggered by Incyte's initiation of the Phase 3 clinical trial evaluating the efficacy and safety of retifanlimab with platinum-based chemotherapy in patients with metastatic squamous and non-squamous non-small cell lung cancer (NSCLC).

Key Highlights from Other Investigational Product Candidates:

- **MGC018 (B7-H3 antibody-drug conjugate):** Encouraged by the MGC018 interim clinical dose escalation data presented at the American Society of Clinical Oncology (ASCO) meeting in May, the Company recently commenced the enrollment of patients with metastatic castration-resistant prostate cancer (mCRPC), triple negative breast cancer (TNBC) and non-small cell lung cancer (NSCLC) in the dose expansion portion of the Phase 1 clinical study. The Company expects to provide an update on this study in the first half of 2021.

- **Enoblituzumab (Fc-engineered, anti-B7-H3 mAb):** In the first quarter of 2021, MacroGenics expects to initiate a Phase 2 study of enoblituzumab in a chemo-free regimen in combination with either retifanlimab in front-line patients with squamous cell carcinoma of the head and neck (SCCHN) who are PD-L1 positive or with tebotelimab in SCCHN patients who are PD-L1 negative.

- **Tebotelimab (also known as MGD013, a bispecific PD-1 × LAG-3 DART molecule):** The Company will present updated data via poster presentation from the ongoing Phase 1 dose expansion study of tebotelimab in combination with margetuximab in a cohort of patients with advanced HER2-positive tumors at the upcoming Society for Immunotherapy of Cancer (SITC) Annual Meeting.

- **MGD019 (bispecific PD-1 × CTLA-4 DART molecule):** In September, data from the Phase 1 dose escalation study of MGD019 was presented during an oral session at the ESMO Virtual Congress 2020. Based on the results presented, the Company has expanded the study initially in patients with microsatellite stable colorectal cancer (MSS CRC) and checkpoint-naïve NSCLC at the recommended Phase 2 dose of 6.0 mg/kg.

- **IMGC936 (ADAM9 antibody-drug conjugate):** IMGC936 is an ADC that targets ADAM9, a cell surface protein over-expressed in several solid tumor types. IMGC936 is being advanced under a co-development agreement with ImmunoGen, Inc. Under the 50/50 collaboration, ImmunoGen is leading clinical development and they are currently screening patients for the Phase 1 dose escalation study in patients with select advanced solid tumors.

Third Quarter 2020 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities as of September 30, 2020, were $280.7 million, compared to $215.8 million as of December 31, 2019. During the quarter ended September 30, 2020, $74.0 million in net proceeds were received from the sale of 2,552,333 shares

of the Company's common stock pursuant to its at-the-market (ATM) offering. The $15.0 million milestone payment from Incyte was received after September 30, 2020.

- **Revenue**: Total revenue, consisting primarily of revenue from collaborative agreements, was $18.2 million for the quarter ended September 30, 2020, compared to $18.7 million for the quarter ended September 30, 2019.
- **R&D Expenses**: Research and development expenses were $44.7 million for the quarter ended September 30, 2020, compared to $44.9 million for the quarter ended September 30, 2019.
- **G&A Expenses**: General and administrative expenses were $9.7 million for the quarter ended September 30, 2020, compared to $11.8 million for the quarter ended September 30, 2019. This decrease is primarily due to a decrease in external costs, including consulting.
- **Net Loss**: Net loss was $36.0 million for the quarter ended September 30, 2020, compared to net loss of $44.6 million for the quarter ended September 30, 2019.
- **Shares Outstanding**: Shares outstanding as of September 30, 2020 were 56,174,932.

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, 2020 and provide a corporate update. To participate in the conference call, please dial (877) 303-6253 (domestic) or (973) 409-9610 (international) ten minutes prior to the start of the call and provide the Conference ID: 5986584.

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, 2020 (unaudited)	December 31, 2019
Cash, cash equivalents and marketable securities	$ 280,659	$ 215,756
Total assets	374,380	312,501
Deferred revenue	15,037	19,853
Total stockholders' equity	291,585	230,628

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,	
	2020	2019	2020	2019
Revenues:				
Revenue from collaborative and other agreements	$ 17,415	$ 17,984	$ 46,018	$ 37,468
Revenue from government agreements	838	757	6,174	1,528
Total revenues	18,253	18,741	52,192	38,996
Costs and expenses:				
Research and development	44,656	44,852	150,901	143,352
General and administrative	9,732	11,833	30,181	34,174
Total costs and expenses	54,388	56,685	181,082	177,526
Loss from operations	(36,135)	(37,944)	(128,890)	(138,530)
Other income (expense)	92	(6,687)	1,238	17,115
Net loss	(36,043)	(44,631)	(127,652)	(121,415)
Other comprehensive loss:				
Unrealized gain (loss) on investments	(15)	(11)	(14)	26
Comprehensive loss	$ (36,058)	$ (44,642)	$ (127,666)	$ (121,389)
Basic and diluted net loss per common share	$ (0.66)	$ (0.91)	$ (2.49)	$ (2.54)
Basic and diluted weighted average common shares outstanding	54,463,412	48,902,766	51,176,884	47,796,957

About MacroGenics, Inc.

MacroGenics is a clinical-stage biopharmaceutical company focused on discovering and developing 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, 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, 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", "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: 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 the timing and steps required in the regulatory review process, expectations for regulatory approvals, 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 disruptions due to catastrophes or other events, including natural disasters or public health crises such as the novel coronavirus (referred to as COVID-19), 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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