

**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 17, 2022

MACROGENICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
*(State or Other Jurisdiction
of Incorporation)*

001-36112
*(Commission
File Number)*

06-1591613
*(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 8.01 Other Events

On November 17, 2022, MacroGenics, Inc. (the “Company”) issued a press release in which it announced the U.S. Food and Drug Administration (the “FDA”) has approved the Biologics License Application (“BLA”) for teplizumab, an anti-CD3 monoclonal antibody that was previously developed by the Company and was acquired by Provention Bio, Inc. (“Provention”) in May 2018. Pursuant to the terms of the asset purchase agreement, the approval of teplizumab triggers a \$60 million milestone obligation to the Company from Provention for the FDA approval of teplizumab’s first indication in the United States. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description of Exhibit
99.1	Press Release dated November 17, 2022
104	Cover Page Interactive Data File (formatted as Inline XBRL).

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 17, 2022

MACROGENICS, INC.

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



MacroGenics Earns \$60 Million Milestone with U.S. FDA Approval of Teplizumab

ROCKVILLE, MD., November 17, 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 reported that the U.S. Food and Drug Administration announced the approval of the Biologics License Application (BLA) for teplizumab, an anti-CD3 monoclonal antibody that was previously developed by MacroGenics. Teplizumab was acquired by Provention Bio, Inc. in May 2018 pursuant to an asset purchase agreement.

“We are very pleased to see the culmination of years of effort by Provention, MacroGenics, and tireless champions in academia and government, with the achievement of the approval of teplizumab,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “We applaud this outcome, which represents an advancement for individuals and their families dealing with the risks and consequences of type 1 diabetes.”

Under the agreement, Provention is obligated to pay MacroGenics contingent milestone payments totaling \$170 million upon the achievement of certain regulatory approval milestones, including \$60 million for the approval of a BLA for a first indication in the United States. In addition, Provention is obligated to make contingent milestone payments to MacroGenics totaling \$225 million upon the achievement of certain sales milestones as well as a single-digit royalty on net sales of the product.

Based on MacroGenics’ cash, cash equivalents and marketable securities balance as of September 30, 2022, plus projected and anticipated payments from partners, including timely receipt of the milestone payment from Provention, MacroGenics currently anticipates having a cash runway into late 2024.

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 and the MacroGenics logo 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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