# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

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# 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): October 17, 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**<br>**Rockville, Maryland**<br>(Address of Principal Executive Offices) | **20850**<br>(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 1.01 Entry into a Material Definitive Agreement.**

On October 14, 2022, MacroGenics, Inc. (the "Company") and Gilead Sciences, Inc. ("Gilead") entered into exclusive option and collaboration agreement (the "Agreement") to develop MGD024, an investigational, bispecific antibody that binds CD123 and CD3 using the Company's DART® platform, and two additional bispecific research programs. The agreement grants Gilead the option to license MGD024, a potential treatment for certain blood cancers, including acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS).

As part of the Agreement, Gilead will pay the Company an upfront payment of $60 million and the Company will be eligible to receive up to $1.7 billion in target nomination, option fees, and development, regulatory and commercial milestones. The Company 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 two research programs.

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

The Agreement will continue in full force and effect on a product-by-product and country-by-country basis until expiration of the last royalty term for a product in such country. No sooner than 18 months after the effective date of the Agreement, Gilead may terminate the Agreement for convenience either in its entirety, or on a product-by-product basis, with specified notice requirements which vary depending on whether said termination for convenience is before or after the option exercise. In addition, Gilead may terminate the Agreement on a product-by-product basis for safety reasons and for other specified reasons with certain notice and other requirements. Either party may terminate the Agreement upon a material breach by the other party that remains uncured or upon certain bankruptcy events or for a force majeure event.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which will be filed in redacted form as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2022.

**Item 7.01 Regulation FD Disclosure.**

On October 17, 2022, the Company and Gilead issued a joint press release announcing the Agreement (the "Press Release"). The full text of the Press Release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this item of this report.

*Forward-Looking Statements*

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. These include statements about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development of its therapeutic candidates, milestone, target nomination, option or royalty payments from the Company's collaborators, the Company's anticipated milestones and future expectations and plans and prospects for the Company. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. In addition, the forward-looking statements included in this Current Report on Form 8-K 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.

**Item 9.01** **Financial Statements and Exhibits**

**(d) Exhibits.**

| **Exhibit Number** | **Description of Exhibit** |
|---|---|
| 99.1 | Press Release dated October 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: October 17, 2022

MACROGENICS, INC.

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

**Gilead Contacts:** **MacroGenics Contact:**

Jacquie Ross, Investors Jim Karrels, Senior Vice President, CFO
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**GILEAD AND MACROGENICS ANNOUNCE ONCOLOGY COLLABORATION TO DEVELOP BISPECIFIC ANTIBODIES**

***– Gilead Granted Exclusive Option to License MGD024, a Phase 1 CD123×CD3 DART® Molecule with Potential to Treat Various Hematologic Malignancies –***

***– Potential for Companies to Collaborate on Two Additional Future Research Programs –***

**Foster City, Calif., and Rockville, Md. October 17, 2022 –** Gilead Sciences, Inc. (Nasdaq: GILD) and MacroGenics (NASDAQ: MGNX) today announced an exclusive option and collaboration agreement to develop MGD024, an investigational, bispecific antibody that binds CD123 and CD3 using MacroGenics' DART® platform, and two additional bispecific research programs. The collaboration agreement grants Gilead the option to license MGD024, a potential treatment for certain blood cancers, including acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS).

A leader in the bispecific antibody space, MacroGenics has extensive experience applying its proprietary DART platform to develop novel therapeutics. MGD024 is a next-generation, bispecific that incorporates a CD3 component that is designed to minimize cytokine-release syndrome (CRS), a potentially life-threatening toxicity, while increasing the magnitude of antitumor activity with a longer half-life to permit intermittent dosing.

"MacroGenics' bispecific expertise naturally complements Gilead's portfolio strengths in immuno-oncology and our growing hematology franchise," said Bill Grossman, MD, PhD, Senior Vice President, Oncology Clinical Development, Gilead Sciences. "We believe MGD024, with its potential to reduce CRS and permit intermittent dosing through a longer half-life, could translate to more patient-friendly dosing and enhanced clinical outcomes for people living with AML and MDS. This partnership is the latest in our efforts to develop and advance transformative new cancer therapies as we deepen our portfolio across oncology indications."

Scott Koenig, MD, PhD, President, and CEO, MacroGenics said, "Rapid advances over the last decade have made CD123 a very promising target in oncology research. Advancing our bispecific DART molecule, MGD024, through a strategic collaboration with the team at Gilead will accelerate our ability to drive further development of MGD024 to the potential benefit of people living with blood cancers."

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

**Financial Considerations**

As part of the agreement, Gilead will pay 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, double-digit royalties on worldwide net sales of MGD024 and a flat royalty on worldwide net sales of products under the two research programs.

Beginning in the first quarter of 2022, consistent with recent industry communications from the U.S. Securities and Exchange Commission (SEC), Gilead no longer excludes acquired IPR&D expenses from its non-GAAP financial measures and expects the transaction with MacroGenics to reduce Gilead's GAAP and non-GAAP 2022 EPS by approximately $0.04.

**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, and DART are trademarks or registered trademarks of MacroGenics, Inc.

**About Gilead Sciences**

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis, and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

**Gilead Forward-Looking Statements**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties, and other factors, including the ability of the parties to complete the transaction in a timely manner or at all; the possibility that various closing conditions for the transaction may not be satisfied or waived, including the possibility that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the transaction; the risk that Gilead may not realize the potential benefits of this collaboration with MacroGenics or its other investments in oncology; difficulties or unanticipated expenses in connection with the collaboration and the potential effects on Gilead's revenues and earnings; Gilead's ability to

achieve its anticipated full year 2022 financial results; the ability of the parties to initiate, progress or complete clinical trials within currently anticipated timelines or at all, and the possibility of unfavorable results from ongoing or additional trials, including those involving MGD024 or future research programs; the ability of the parties to file applications for regulatory approval or receive regulatory approvals in a timely manner or at all, including those involving MGD024 or future research programs, and the risk that any such approvals may be subject to significant limitations on use; the possibility that the parties may make a strategic decision to terminate the collaborations, including the development of MGD024 or future research programs, at any time; and any assumptions underlying any of the foregoing. These and other risks, uncertainties and other factors are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation and disclaims any intent to update any such forward-looking statements.

**MacroGenics Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for MacroGenics, including statements about the MacroGenics' strategy, future operations, clinical development of MGD024, including initiation and enrollment in clinical trials for MGD024, the consummation of the transactions discussed in this press release, milestone or option payments from Gilead 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 constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: risks that MGD024 may not provide a significant clinical benefit to patients with certain blood cancers; the uncertainties inherent in the initiation and enrollment of clinical trials; the availability of financing to fund the development of MGD024 and MacroGenics' other product candidates; availability and timing of data from ongoing clinical trials; expectations for developing further programs under the collaboration agreement with Gilead; the possibility that the parties may make a strategic decision to terminate the collaborations, including the development of MGD024 or future research programs, at any time; expectations for the timing and steps required in the regulatory review process for MGD024; expectations for regulatory approvals; expectations of milestone payments; the impact of competitive products; economic or political disruptions due to catastrophes or other events, including natural disasters, terrorist attacks, civil unrest and actual or threatened armed conflict; public health crises such as the COVID-19 pandemic; and other risks described in the MacroGenics' filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent MacroGenics' views only as of the date hereof. MacroGenics anticipates that subsequent events and developments will cause MacroGenics' views to change. However, while MacroGenics may elect to update these forward-looking statements at some point in the future, MacroGenics 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 MacroGenics' views as of any date subsequent to the date hereof.

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*For more information about Gilead, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000*