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): December 10, 2024

MICROBOT MEDICAL INC.
(Exact name of registrant as specified in its charter)

Delaware	**000-19871**	**94-3078125**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

288 Grove Street, Suite 388
Braintree, MA 02184
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (781) 875-3605

(Former Name or Former Address, if Changed Since Last Report)

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:

☐ 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))

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, $0.01 par value	MBOT	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 7.01 Regulation FD Disclosure.

On December 10, 2024, Microbot Medical Inc. (the "Company") issued a press release announcing that it has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for its LIBERTY® Endovascular Robotic System. The 510(k) submission follows the successful completion of its multi-center, single-arm, trial to evaluate the performance and safety of LIBERTY® in human subjects undergoing Peripheral Vascular Interventions.

The Company anticipates FDA marketing clearance during the second quarter of 2025, with U.S. commercialization activities expected to commence after the clearance.

The press release, which is furnished as Exhibit 99.1 to this Current Report on Form 8-K, is incorporated herein by reference. The information in this Item 7.01 and Exhibit 99.1 is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. This report will not be deemed an admission as to the materiality of any information in this Item 7.01 or Exhibit 99.1.

Item 8.01 Other Events.

The Company has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for its LIBERTY® Endovascular Robotic System. The 510(k) submission follows the successful completion of its multi-center, single-arm, trial to evaluate the performance and safety of LIBERTY® in human subjects undergoing Peripheral Vascular Interventions.

The Company anticipates FDA marketing clearance during the second quarter of 2025, with U.S. commercialization activities expected to commence after the clearance.

Forward Looking Statements

This Item 8.01 of this Current Report on Form 8-K may contain "forward-looking statements." Such statements which are not purely historical (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "intends," "would," "could" and "estimates") are forward-looking statements and include any statements regarding beliefs, plans, expectations or intentions regarding the future, including but not limited to, regulatory milestones.

Actual results could differ from those projected in any forward-looking statements due to numerous factors. These forward-looking statements are made as of the date of this Form 8-K, and the Company assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Although the Company believes that the beliefs, plans, expectations and intentions contained in this Form 8-K are reasonable, there can be no assurance that such beliefs, plans, expectations or intentions will prove to be accurate. Investors should consult all of the information set forth herein and should also refer to the risk factors disclosure outlined in the Company's reports and statements filed from time-to-time with the Securities and Exchange Commission.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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 thereunto duly authorized.

MICROBOT MEDICAL INC.

By: */s/ Harel Gadot*
Name: Harel Gadot
Title: Chief Executive Officer, President and Chairman

Date: December 10, 2024

Exhibit 99.1

Microbot Medical® Announces FDA Submission for the Commercialization of the LIBERTY® Endovascular Robotic System

FDA 510(k) Submission Follows the Successful Completion of the Pivotal Human Clinical Trial

FDA 510(k) Clearance Anticipated During the Second Quarter of 2025

Company Preparing to Commence Commercialization Following FDA 510(k) Clearance

BRAINTREE, Mass., December 10, 2024 — Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative single use LIBERTY® Endovascular Robotic System, today announced that it has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for LIBERTY®. LIBERTY® is the world's first single-use, fully disposable robotic system for endovascular procedures. The 510(k) submission follows the successful completion of its multi-center, single-arm, trial to evaluate the performance and safety of LIBERTY® in human subjects undergoing Peripheral Vascular Interventions.

The Company anticipates FDA marketing clearance during the second quarter of 2025, with U.S. commercialization activities expected to commence after the clearance.

"This is a pivotal milestone for our Company, as the 510(k) submission reflects the commencement of our transition to a commercially focused company," commented Harel Gadot, Chairman, CEO and President. "We are excited to transition our focus towards preparing for our expected U.S. launch in the second quarter of 2025 and targeting the more than 2 million peripheral vascular procedures performed in the U.S. each year. We believe, based on feedback from physicians and the medical community, that LIBERTY® is positioned to redefine the peripheral endovascular space with the introduction of the world's first commercially available single-use robotic system."

As the world's first single-use, fully disposable endovascular robotic system, LIBERTY® eliminates the need for large and expensive capital equipment and streamlines customers' access to robotics. With its remote control, LIBERTY® is designed to significantly reduce radiation exposure to physicians and staff, and improve ergonomics, which has the potential to reduce the physical strain on healthcare providers. The Company also believes that LIBERTY® has the potential to lower procedure costs, increase procedure efficiency and improve the overall quality of care.

About Microbot Medical®

Microbot Medical Inc. (NASDAQ: MBOT) is a pre-commercial stage medical technology company with a vision to improve the quality of care for millions of patients and providers globally. The Company has developed the world's first single-use, fully disposable endovascular robotic system, which aims to eliminate traditional barriers to accessing advanced robotic systems.

Further information about Microbot Medical® is available at http://www.microbotmedical.com.

Safe Harbor

Statements to future financial and/or operating results, future growth in research, technology, clinical development, commercialization and potential opportunities for Microbot Medical Inc. and its subsidiaries, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and the Federal securities laws. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects" and "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, the Company's need for and ability to obtain additional working capital to continue its transition to a commercially focused company, market conditions, risks inherent in the development and/or commercialization of the LIBERTY® Endovascular Robotic Surgical System, uncertainty in the results of regulatory pathways and regulatory approvals, including whether the FDA will grant 510(k) clearance to commercially market the LIBERTY® Endovascular Robotic Surgical System in the United States, disruptions resulting from new and ongoing hostilities between Israel and the Palestinians and other neighboring countries, and maintenance of intellectual property rights. Additional information on risks facing Microbot Medical® can be found under the heading "Risk Factors" in Microbot Medical's periodic reports filed with the Securities and Exchange Commission (SEC), which are available on the SEC's web site at www.sec.gov. Microbot Medical® disclaims any intent or obligation to update these forward-looking statements, except as required by law.

Investor Contact: IR@microbotmedical.com