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): October 15, 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 October 15, 2024, Microbot Medical Inc. (the "Company") issued a press release announcing that it has successfully completed enrollment and follow up for all patients in its ACCESS-PVI human clinical trial. The Company remains on track to file its 510(k) submission with the U.S. Food and Drug Administration (FDA) by of the end of 2024.

The Company also announced that it is accelerating its go-to-market strategy. It expects to begin building out the commercial infrastructure, including the hiring of a seasoned healthcare executive to lead its sales efforts, upon the FDA clearance, which is expected during the second quarter of 2025.

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 successfully completed enrollment and follow up for all patients in its ACCESS-PVI human clinical trial. The Company remains on track to file its 510(k) submission with the U.S. Food and Drug Administration (FDA) by of the end of 2024.

The Company also is accelerating its go-to-market strategy. It expects to begin building out the commercial infrastructure, including the hiring of a seasoned healthcare executive to lead its sales efforts, upon the FDA clearance, which is expected during the second quarter of 2025.

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: October 15, 2024

Exhibit 99.1

Microbot Medical Announces the Successful Completion of its Pivotal Human Clinical Trial; Accelerates Go-to-Market Strategy to Prepare for Commercial Launch of LIBERTY® during 2Q 2025

U.S. Food and Drug Administration (FDA) Submission Expected by end of 2024

Clinical Data to be Presented at Medical Conference in Early 2025

BRAINTREE, Mass., October 15, 2024 — Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative LIBERTY® Endovascular Robotic Surgical System, today announced that it has successfully completed enrollment and follow up for all patients in its ACCESS-PVI human clinical trial. The Company remains on track to file its 510(k) submission with the U.S. Food and Drug Administration (FDA) by of the end of 2024.

The Company also announced that it is accelerating its go-to-market strategy. It expects to begin building out the commercial infrastructure, including the hiring of a seasoned healthcare executive to lead its sales efforts, upon the FDA clearance, which is expected during 2Q 2025.

“We are very pleased with the performance of LIBERTY® throughout the study,” commented Juan Diaz-Cartelle, MD, Chief Medical Officer. “We want to thank all our investigators for their enthusiastic commitment to the trial. We expect to share the results of the clinical trial with the medical community and the public at a conference in early 2025.”

“This is a monumental moment and a significant achievement for Microbot Medical,” commented Harel Gadot, Chairman, CEO and President. The conclusion of the trial and physician feedback is an encouraging development, and our immediate task is to prepare and finalize the FDA 510(k) submission package so we can file it by the end of the year. Concurrently, we will deploy our go-to-market strategy and begin to build out a commercial infrastructure to ensure we are fully prepared to launch LIBERTY® upon the FDA’s clearance, which we expect during 2Q 2025.

ACCESS-PVI is a prospective, multi-center, single-arm, trial to evaluate the performance and safety of LIBERTY® in human subjects undergoing Peripheral Vascular Interventions. The trial will support the 510(k) submission to the FDA and subsequent commercialization. The Company wants to thank the patients, physicians and clinical sites for their participation in the trial.

About Microbot Medical

Microbot Medical Inc. (NASDAQ: MBOT) is a clinical- stage medical device company that specializes in transformational micro-robotic technologies, with the goals of improving clinical outcomes for patients and increasing accessibility through the natural and artificial lumens within the human body.

The Investigational LIBERTY® Endovascular Robotic Surgical System aims to improve the way surgical robotics are being used in endovascular procedures today, by eliminating the need for large, cumbersome, and expensive capital equipment, while reducing radiation exposure and physician strain. The Company believes the LIBERTY® Endovascular Robotic Surgical System's remote operation has the potential to be the first system to democratize endovascular interventional procedures.

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, 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, market conditions, risks inherent in the development and/or commercialization of the LIBERTY® Endovascular Robotic Surgical System, the outcome of its studies to evaluate the LIBERTY® Endovascular Robotic Surgical System, uncertainty in the results of pre-clinical and clinical trials or regulatory pathways and regulatory approvals, including whether the Company's pivotal study in humans is successful, 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, need and ability to obtain future capital, 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