

**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 30, 2024

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

Delaware
(State or other jurisdiction
of incorporation)

000-19871
(Commission
File Number)

94-3078125
(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 30, 2024, Microbot Medical Inc. issued a press release summarizing the achievement of its 2024 key milestones, as it shifts focus to prepare for commercial launch of the LIBERTY[®] Endovascular Robotic Surgical System as it enters 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 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 30, 2024



Microbot Medical® Concludes 2024 by Achieving Key Milestones Culminating in FDA Submission for the Commercialization of LIBERTY®

Company Shifts Focus to Preparing for Commercial Launch as it Enters 2025

BRAINTREE, Mass., December 30, 2024 — Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative LIBERTY® Endovascular Robotic System, concludes 2024 with the achievement of several key milestones, including the recent FDA 510(k) submission for FDA commercial approval of LIBERTY®, which the company believes will position the Company for continued success in 2025.

“As we entered 2024, the Company had three primary goals in our quest to ensure we are ready for the successful commercial launch of LIBERTY in 2025: 1) complete FDA 510(k) submission, 2) establish pre-commercial infrastructures, and 3) execute strategic initiatives to support future growth,” commented Harel Gadot, Chairman and Chief Executive Officer. “Thanks to the efforts of our team, coupled with a close collaboration with our internal and external stakeholders, I am very pleased with the progress we made throughout the year toward achieving these goals. I have a high level of confidence we will be positioned to meet our commercial objectives moving forward.”

The following are the key milestones the Company has reported achieving during the past 12 months:

Complete FDA 510(k) submission

- Received Investigational Drug Exemption (IDE) approval from the FDA to initiate the ACCESS-PVI pivotal human clinical trial.
- Successfully completed the ACCESS-PVI pivotal human clinical trial in three leading medical centers in the USA: Miami Baptist (Miami, FL), Memorial Sloan Kettering (NYC, NY) and Brigham & Women’s (Boston, MA).
- Successfully completed the substantial R&D testing required for FDA’s 510(k) submission, including biocompatibility, transportation validation, and usability testing, among others.
- Submitted 510(k) file to FDA for the commercialization of the LIBERTY® Endovascular Robotic System.

Establish pre-commercial infrastructures

- Received ISO 13485 certification for our quality management system to support commercialization.
 - Initiated inventory build-up while improving operational infrastructure.
 - Submitted the ACCESS-PVI pivotal human clinical trial results to conferences in anticipation of sharing them publicly by leveraging these professional channels.
 - Attended several endovascular medical conferences, including the Society of Interventional Radiology (SIR) and Cardiovascular and Interventional Radiological Society of Europe (CIRSE).
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Execute strategic initiatives to support future growth

- Completed Phase 1 and Phase 2 of the telesurgery collaboration with Corewell Health, culminating in a simulated procedure between two facilities located 5 miles apart.
- Entered into an agreement with Emory University to collaborate on the development of autonomous robotics.

Based on these achievements, the Company believes it has laid the necessary groundwork to support its commercial objectives in 2025. The Company is anticipating the launch of LIBERTY in Q2 2025 in the U.S. and continuing its efforts to receive additional regulatory approval outside the U.S. to support future growth.

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
