



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

December 30, 2024

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

BRAINTREE, Mass., Dec. 30, 2024 (GLOBE NEWSWIRE) -- 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).

#### **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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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](http://www.sec.gov). Microbot Medical<sup>®</sup> disclaims any intent or obligation to update these forward-looking statements, except as required by law.

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