



Microbot Medical® Receives FDA 510(k) Clearance for Its LIBERTY® Endovascular Robotic System

September 8, 2025

Accelerated Launch Readiness Plans Position Company for Commercialization during Q4 2025

The Company's Initial Addressable Market Includes Approximately 2.5 Million Peripheral Endovascular Procedures in the U.S. Annually

CEO, President & Chairman to Present Live Webcast at the H.C. Wainwright Annual Investor Conference on September 9, 2025, at 9 AM ET.

HINGHAM, Mass., Sept. 08, 2025 (GLOBE NEWSWIRE) -- Microbot Medical Inc. (Nasdaq: MBOT), developer and manufacturer of the innovative LIBERTY® Endovascular Robotic System, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for the LIBERTY® System, the first FDA cleared single-use, remotely operated robotic system for peripheral endovascular procedures. The FDA clearance positions the Company to commercialize LIBERTY® in the U.S., with the goal of transforming the field to enable accessibility to advanced robotics without the traditional constraints of capital equipment and a dedicated infrastructure.

"Obtaining FDA 510(k) clearance for LIBERTY® marks a defining moment for Microbot Medical and, we believe, for the future of endovascular robotics. This achievement validates our mission to expand access to advanced robotic technologies while addressing critical unmet needs and supporting cost-effective healthcare," commented Harel Gadot, Chairman, CEO & President. "With our commercial readiness strategy being developed and executed since Q2 this year, we believe we are well positioned to accelerate market entry. With FDA clearance, we can now complete the final commercial activities that were contingent on marketing clearance, positioning us to commence commercialization, penetrate the approximately 2.5 million annual U.S. peripheral vascular procedures, and pursue entry into global markets."

The LIBERTY® pivotal study showed 100% success in the robotic navigation to target, and zero device related adverse events. The study also showed a 92% relative reduction in radiation exposure for physicians. Its remote design is expected to improve ergonomics, which would aid in reducing the physical strain on healthcare providers. The Company believes that LIBERTY® has the potential to enhance procedure efficiency, lower procedure costs, and improve the overall quality of care. The Company plans to continue clinical data collection for LIBERTY® during the commercial launch.

The Company will attend the H.C. Wainwright Annual Investor Conference held in NYC from September 8-10, 2025. Mr. Gadot will present live on Tuesday, September 9th at 9:00am ET, and a live webcast may be accessed via the 'Events' section of the Company's website at www.microbotmedical.com. Investors should reach out to their H.C. Wainwright sales representatives or contact mpolyviou@evcgroup.com to schedule a one-on-one meeting with Microbot Medical's management team.

About Microbot Medical

Microbot Medical Inc. (NASDAQ: MBOT) is a breakthrough medical device company focused on transforming endovascular procedures through advanced robotic technology. Microbot's LIBERTY® Endovascular Robotic System is the first single-use, remotely operated robotic solution designed for precision, efficiency and provider safety. Backed by a strong intellectual property portfolio and a commitment to innovation, Microbot is driving the future of endovascular care.

Learn more at www.microbotmedical.com and connect on [LinkedIn](#) and [X](#).

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 "contemplates," "continues," "could," "forecasts," "intends," "may," "might," "possible," "potential," "predicts," "projects," "should," "would," "will," "believes," "plans," "anticipates," "expects," "estimates" and similar expressions) should also be considered to be forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. 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 commercialization of the LIBERTY® Endovascular Robotic System, and in the development of future versions of or applications for the system, uncertainty in the results of regulatory pathways and regulatory approvals, uncertainty resulting from political, social and geopolitical conditions, particularly any changes in personnel or processes or procedures at the FDA and announcements of tariffs on imports into the U.S., disruptions resulting from new and ongoing hostilities between Israel and the Palestinians, Iran 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.

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A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/c01cb38f-28e3-4704-93bf-42dde06458f2>

A video accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/6731e329-813d-4c29-b1d1-c1c860a8ea31>



Source: Microbot Medical Inc.

LIBERTY Endovascular Robotic System



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