Microbot Medical Receives Quality Certification to Support Future Regulatory Submissions and Commercialization

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The ISO 13485 certification is a validation of the Company's robust quality system

BRAINTREE, Mass., Aug. 13, 2024 (GLOBE NEWSWIRE) -- Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative LIBERTY® Endovascular Robotic Surgical System, today announces it has received ISO 13485:2016 certification for its quality management system. Receiving ISO 13485 certification indicates that a company has developed and implemented robust policies and procedures for the development and manufacture of regulated medical products.

The ISO 13485 standard was designed for the medical industry and requires a specific approach to risk assessment and the management of each process necessary for the development and realization of regulated medical products. Companies that comply with these quality requirements must prove that they consistently review and validate their product development and manufacturing processes, manage their operations with effective procedures, and maintain records for product traceability.

"I am extremely proud of the efforts by the entire Microbot team," said Noa Ofer, PhD, Sr. Director of Quality Assurance and Regulatory Affairs. "An ISO 13485 audit is a very extensive process, and our certification is a testament that we are building the right capabilities and infrastructure as we progress toward commercialization."

Compliance with ISO 13485 is often viewed as the initial step in ensuring adherence to European regulatory requirements under the new Medical Device Regulation (EU MDR) and is required to obtain CE mark approval for sales in the European Union. In addition, in view of the recent revision published by the FDA regarding the QMSR (quality system management regulation) and its incorporation by reference of the ISO 13485 standard, this certificate helps streamline Microbot's transition into this revised FDA regulation.

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, any failure or inability to recruit physicians and clinicians to serve as primary investigators to conduct regulatory studies which could adversely affect or delay such studies, disruptions resulting from new and ongoing hostilities between Israel and the Palestinians and other neighboring countries, any lingering uncertainty resulting from the COVID-19 pandemic, 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.

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