

**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): August 13, 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 August 13, 2024, Microbot Medical Inc. (the “Company”) issued a press release announcing that it has received ISO 13485:2016 certification for its quality management system.

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 received ISO 13485:2016 certification for its quality management system, which is required to obtain CE mark approval for sales in the European Union. In addition, in view of the recent revision published by the U.S. Food & Drug Administration (FDA) regarding the QMSR (quality system management regulation) and its incorporation by reference of the ISO 13485 standard, the Company believes it will help streamline the Company’s transition into this revised FDA regulation.

***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***

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release</a>
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: August 13, 2024

---



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

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

**BRAINTREE, Mass., August 13, 2024** — Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative LIBERTY<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Endovascular Robotic Surgical System, the outcome of its studies to evaluate the LIBERTY<sup>®</sup> 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](http://www.sec.gov). Microbot Medical disclaims any intent or obligation to update these forward-looking statements, except as required by law.

### **Investor Contact:**

Michal Efraty

[IR@microbotmedical.com](mailto:IR@microbotmedical.com)

---