

**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): September 8, 2025

**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.)

175 Derby St., Bld. 27  
Hingham, MA 02043  
(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 September 8, 2025, Microbot Medical Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration (“FDA”) has granted 510(k) clearance for the Company’s LIBERTY<sup>®</sup> Endovascular Robotic System, the first FDA cleared single-use, remotely operated robotic system for peripheral endovascular procedures.

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.

In addition, the Company announced that it will attend the H.C. Wainwright Annual Investor Conference held in New York, New York, from September 8-10, 2025. Mr. Harel Gadot, the Company’s President, CEO and Chairman, will present live on Tuesday, September 9, 2025 at 9:00 am ET, and a live webcast may be accessed via the ‘Events’ section of the Company’s website at [www.microbotmedical.com](http://www.microbotmedical.com). Interested parties should reach out to their H.C. Wainwright sales representatives or contact [mpolyviou@evcgroup.com](mailto:mpolyviou@evcgroup.com) to schedule a one-on-one meeting with Microbot Medical’s management team.

## Item 8.01 Other Events.

The FDA has granted 510(k) clearance for the Company’s LIBERTY<sup>®</sup> Endovascular Robotic System, the first FDA cleared single-use, remotely operated robotic system for peripheral endovascular procedures. The FDA clearance positions the Company to commercialize LIBERTY<sup>®</sup> 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.

With FDA clearance, the Company expects to complete the final commercial activities that were contingent on marketing clearance, positioning the Company to commence commercialization, penetrate the approximately 2.5 million annual U.S. peripheral vascular procedures, and pursue entry into global markets.

### *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<br/>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: September 8, 2025

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**Microbot Medical<sup>®</sup> Receives FDA 510(k) Clearance for Its LIBERTY<sup>®</sup> Endovascular Robotic System**

*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., September 08, 2025** — Microbot Medical Inc. (Nasdaq: MBOT), developer and manufacturer of the innovative LIBERTY<sup>®</sup> Endovascular Robotic System, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for the LIBERTY<sup>®</sup> System, the first FDA cleared single-use, remotely operated robotic system for peripheral endovascular procedures. The FDA clearance positions the Company to commercialize LIBERTY<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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](http://www.microbotmedical.com). Investors should reach out to their H.C. Wainwright sales representatives or contact [mpolyviou@evcgroup.com](mailto:mpolyviou@evcgroup.com) to schedule a one-on-one meeting with Microbot Medical’s management team.

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## 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<sup>®</sup> 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](http://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<sup>®</sup> 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<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.

## Contacts:

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