

**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): April 9, 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 April 9, 2025, Microbot Medical Inc. (the “Company”) issued a press release announcing that it presented for the first time the data from its ACCESS-PVI pivotal trial at the Society of Interventional Radiology (SIR) annual meeting.

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 data presented by the Company from its ACCESS-PVI pivotal trial at the Society of Interventional Radiology (SIR) annual meeting, concluded that robotic endovascular procedures using LIBERTY[®] are feasible and significantly minimize radiation exposure. Highlights of the study include:

- Successful robotic navigation was achieved in every case (N=20), yielding a success rate of 100%, meeting the primary endpoint of the study.
- No Adverse Device Events (ADE=0%) were reported through the duration of follow-up.
- Mean difference in radiation exposure between operator and control was (-)29.8 μ S, resulting in a mean 92% relative reduction in radiation exposure.
- Median robotic navigation time to target was 3 minutes.
- Participating physicians reported LIBERTY[®] performed as planned with a 100% satisfaction rate.

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

Exhibit Number	Description
99.1	Press Release
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: April 9, 2025



Microbot Medical[®] Shares Results from Its Pivotal Clinical Trial, Achieving 100% Robotic Navigation Success for the LIBERTY[®] Endovascular Robotic System

Successful robotic navigation was achieved in every case and met the primary endpoint of the study

LIBERTY[®] showed a 92% reduction in radiation exposure with no adverse events reported

HINGHAM, Mass., April 9, 2025 — Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative LIBERTY[®] Endovascular Robotic System, presented for the first time the data from its ACCESS-PVI pivotal trial at the Society of Interventional Radiology (SIR) annual meeting. The study was performed at three leading medical centers in the U.S.; Memorial Sloan Kettering Cancer Center (New York, NY), Baptist Hospital of Miami (Miami, FL) and Brigham and Women's Hospital (Boston, MA). The late-breaking podium presentation was given by Francois Cornelis, M.D., PhD, Director of the Neuro Vascular Interventional Radiology Program at Memorial Sloan Kettering Cancer Center.

The data presented concluded that robotic endovascular procedures using LIBERTY[®] are feasible and significantly minimize radiation exposure.

Significant Highlights of the ACCESS-PVI Study:

- Successful robotic navigation was achieved in every case (N=20), yielding a success rate of 100%, meeting the primary endpoint of the study.
- No Adverse Device Events (ADE=0%) were reported through the duration of follow-up.
- Mean difference in radiation exposure between operator and control was (-)29.8 μ S, resulting in a mean 92% relative reduction in radiation exposure.
- Median robotic navigation time to target was 3 minutes.
- Participating physicians reported LIBERTY[®] performed as planned with a 100% satisfaction rate.

“The ACCESS-PVI data and the performance of the system throughout the study reflect the hard work that the team has put into LIBERTY[®] over the past few years,” commented Harel Gadot, Chairman, CEO and President. “We are extremely pleased with the results in all aspects. As we shift focus to building our commercial capabilities and preparing for launch, we are confident that LIBERTY[®] will be well received in the market.”

“We are very satisfied with the clinical data, as well as with the investigators’ feedback in terms of the short learning curve and intuitive operation of the device,” commented Dr. Juan Diaz-Cartelle, the Company’s Chief Medical Officer. “We are looking forward to working with interventional physicians and staff upon FDA’s clearance.”

LIBERTY[®] is an investigational device pending FDA 510(k) clearance, and is currently not available for sale in the U.S.

About Microbot Medical[®]

Microbot Medical Inc. (NASDAQ: MBOT) is a pre-commercial stage medical technology company with a vision to redefine endovascular robotics and 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[®] Endovascular Robotic System, uncertainty in the results of regulatory pathways and regulatory approvals, including whether the FDA will timely grant 510(k) clearance to commercially market the LIBERTY[®] Endovascular Robotic System in the United States if at all, uncertainty resulting from political, social and geopolitical conditions, particularly any changes in personnel or processes or procedures at the FDA and the recent announcement of tariffs on imports into the U.S., 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[®] 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.

Investor Contact: IR@microbotmedical.com
