# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of: March 2025 (Report No. 4)

Commission File Number: 001-40753

ICECURE MEDICAL LTD. (Translation of registrant's name into English)

7 Ha'Eshel St., PO Box 3163
<u>Caesarea, 3079504 Israel</u>
(Address of principal executive office)

(Address of principal executive office)	
Indicate by check mark whether the registrant files or will file annual reports under cover of	of Form 20-F or Form 40-F:
⊠ Form 20-F	□ Form 40-F
CONTE	NTS
On March 20, 2025, IceCure Medical Ltd. (the "Company") issued a press rel Marketing Authorization for ProSense® in Early-Stage Breast Cancer," a copy of which is	lease titled "IceCure Reports Updated Timeline and Progress with FDA Regarding furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.
The first and fourth paragraphs and the section titled "Forward-Looking State reference into the Company's Registration Statements on Form F-3 (Registration Nos. 333-333-262620 and 333-281587), filed with the Securities and Exchange Commission, to be a K is submitted, to the extent not superseded by documents or reports subsequently filed or	a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-
EXHIBIT I	NDEX
Exhibit No.	
99.1 Press release dated March 20, 2025 titled "IceCure Reports Updated Ti Early-Stage Breast Cancer"	imeline and Progress with FDA Regarding Marketing Authorization for ProSense® in
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SIGNATU	IDES
	nt has duly caused this report to be signed on its behalf by the undersigned, thereunto
duly authorized.	in his dary caused and report to be signed on its behalf by the undersigned, increasing
	ICECURE MEDICAL LTD.
Date: March 20, 2025	By: /s/ Eyal Shamir Name: Eyal Shamir Title: Chief Executive Officer
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#### IceCure Reports Updated Timeline and Progress with FDA Regarding Marketing Authorization for ProSense® Cryoablation in Early-Stage Breast Cancer

## IceCure working in close collaboration with FDA towards De Novo decision

CAESAREA, Israel, March 20, 2025 – IceCure Medical Ltd. (Nasdaq: ICCM) ("IceCure", "IceCure Medical" or the "Company"), developer of minimally-invasive cryoablation technology that destroys tumors by freezing as an alternative to surgical tumor removal, today announced it is in continued discussions with the U.S. Food and Drug Administration ("FDA") regarding its De Novo marketing authorization request for ProSense® in early-stage low risk breast cancer with endocrine therapy. The Company now expects the FDA's marketing authorization decision to be reached after the first quarter of 2025.

"Given the novelty of our product and the importance of breast cancer in public health, the FDA has included many stakeholders in the discussion of the De Novo marketing clearance for ProSense® for the treatment of early-stage, low-risk breast cancer with endocrine therapy" stated IceCure's Chief Executive Officer, Eyal Shamir.

"We appreciate the attention of many at the FDA despite the evolving situation at the agency as we work productively together towards a decision on marketing authorization," Shamir added.

Due to the public health importance of breast cancer, the FDA convened a Medical Device Advisory Committee Panel ("Advisory Panel") in November 2024 to obtain independent non-binding expert advice on scientific, technical and policy matters related to the potential granting of marketing authorization of ProSense® for treating patients with early-stage low risk breast cancer with endocrine therapy. The Advisory Panel, which included breast surgeons, interventional radiologists, breast oncologists, and representatives from the patient, consumer, and regulatory communities, voted in favor of ProSense®'s benefit-risk profile in early-stage low risk breast cancer.

#### **About IceCure Medical**

IceCure Medical (Nasdaq: ICCM) develops and markets advanced liquid-nitrogen-based cryoablation therapy systems for the destruction of tumors (benign and cancerous) by freezing, with the primary focus areas being breast, kidney, bone and lung cancer. Its minimally invasive technology is a safe and effective alternative to hospital surgical tumor removal that is easily performed in a relatively short procedure. The Company's flagship ProSense® system is marketed and sold worldwide for the indications cleared and approved to date including in the U.S., Europe and Asia.

## Forward Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements. For example, IceCure is using forward looking statements in this press release when it discusses the expected timing of the FDA's marketing authorization decision. Historical results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials will suggest identical or even similar conclusions. Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among others: the Company's planned level of revenues and capital expenditures; the Company's available cash and its ability to obtain additional funding; the Company's ability to market and sell its products; legal and regulatory developments in the United States and other countries; the Company's ability to maintain its relationships with suppliers, distributors and other partners; the Company's ability to maintain or protect the validity of its patents and other intellectual property; the Company's ability to expose and educate medical professionals about its products; political, economic and military instability in the Middle East, specifically in Israel; as well as those factors set forth in the Risk Factors section of the Company's Annual Report on Form 20-F for the year ended December 31, 2023 filed with the SEC on April 3, 2024, and other documents filed with or furnished to the SEC which are available on the SEC's website, www.sec.gov. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.

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