**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: February 2025

Commission File Number: 001-40753

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

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

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

☒ Form 20-F ☐ Form 40-F

## CONTENTS

On February 4, 2025, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure's ProSense® in the Spotlight at Society of Interventional Oncology (SIO) Annual Meeting: Award Winning Abstract and Hands-On Training for Breast Cryoablation as Medical Community Anticipates FDA's Market Authorization Decision," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.

The first three paragraphs and the sections titled "Highlights of the independent studies are the following" and "Forward Looking Statements" in the press release attached herewith as Exhibit 99.1 are incorporated by reference into the Company's Registration Statements on Form F-3 (Registration Nos. 333-258660 and 333-267272) and Form S-8 (Registration Nos. 333-270982, 333-264578, 333-262620 and 333-281587), filed with the Securities and Exchange Commission, to be a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.



## EXHIBIT INDEX

| Exhibit No. | |
|---|---|
| 99.1 | Press release dated February 4, 2025 titled "IceCure's ProSense® in the Spotlight at Society of Interventional Oncology (SIO) Annual Meeting: Award Winning Abstract and Hands-On Training for Breast Cryoablation as Medical Community Anticipates FDA's Market Authorization Decision" |



## 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.

**ICECURE MEDICAL LTD.**

Date: February 4, 2025

By: /s/ Eyal Shamir
Name: Eyal Shamir
Title: Chief Executive Officer

**IceCure's ProSense® in the Spotlight at Society of Interventional Oncology (SIO) Annual Meeting: Award Winning Abstract and Hands-On Training for Breast Cryoablation as Medical Community Anticipates FDA's Market Authorization Decision**

- ***Two independent studies of ProSense® cryoablation in breast cancer were presented, one of which won the Highest Scoring Abstract Award in its category***
- ***Hands-on ProSense® training featured during the SIO Mini Masterclass on Breast Cryoablation; the session was extremely well attended with presentations led by interventional oncology and breast cancer thought leaders***
- ***FDA's decision on ProSense® market authorization for early-stage breast cancer expected Q1 2025***

**CAESAREA, Israel,** February 4, 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 its participation as one of the sponsors of the Breast Cryoablation Mini Masterclass held during the 2025 Society of Interventional Oncology (SIO) Annual Meeting in Las Vegas, which took place January 29 to February 3, 2025.

Two independent studies demonstrating ProSense®'s safety and efficacy in breast cancer were shared in poster presentations. A study performed in the Netherlands titled "The Treatment of Breast Cancer with Percutaneous Thermal Ablation: Results of the THERMAC trial" was awarded "Highest Scoring Abstract" in the "Other Category". This study found that cryoablation was the only thermal ablative technique that satisfied the requirements to warrant a randomized Phase 3 trial comparing thermal ablation with surgery.

IceCure sponsored a Breast Cryoablation Mini Master Class on February 1, 2025. Participants in the half-day course received a comprehensive overview of ablative therapies including breast cancer therapies and patient selection for breast cryoablation. The course was led by experts in breast cryoablation in the fields of interventional oncology, breast radiology, and breast surgery, including Robert Ward, MD, Franco Orsi, MD, Richard Fine, MD, who was the lead author of the ICE3 trial on cryoablation of early-stage, low-risk breast cancer publication, and co-primary investigator of the ICE3 trial, Kenneth Tomkovich, MD.

"As the medical community and we look forward to the U.S. Food and Drug Administration's decision on market authorization of ProSense® in early-stage breast cancer, we are pleased to see a heightened level of interest in our cryoablation system from exactly those doctors who may be employing it upon approval in the U.S.," IceCure's Chief Executive Officer, Eyal Shamir commented. "We congratulate the doctors from the Netherlands and Romania whose cryoablation abstracts were presented and well received. Their research presented at SIO, a global medical conference with a high attendance by U.S. physicians, shows an increase in awareness of and eagerness to adopt ProSense®, especially for breast cryoablation."

**Highlights of the independent studies are the following:**

**Title**: "The Treatment of Breast Cancer with Percutaneous Thermal Ablation: Results of the THERMAC trial"

**Authors**: L. Riks, S.M. Wooldrik, E.M.F. van de Voort, G.M. Struik, A. Moelker, G.G.L. Yo, M.J.P.V. Macco, R.H.J.A. Sinke, S. Wilhelmus, M. Franckena, E. Birnie, T. van Dalen, C.Verhoef, T.M.A.L. Klem

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**Objective**: The objective of this study was to determine the efficacy rate in terms of complete ablation for the most promising techniques of thermal ablation: radiofrequency ablation (RFA), microwave ablation (MWA), and cryoablation (CA) for patients with early-stage breast cancer to warrant a randomized Phase 3 trial comparing thermal ablation with surgery.

**Conclusion**: Cryoablation was the only thermal ablative technique that met the minimum requirements and will therefore be selected for the Phase 3 trial. Complete ablation was reached in 72% in the MWA arm and in 94% in the CA arm. Treatment in the RFA arm was terminated prematurely due to reaching a protocol-defined stopping rule after 5 inclusions. Adverse events occurred in 44% and 0% of patients in the MWA and CA arms, respectively.

**Title**: "Initial experience in Romania - tumor reduction and safety outcomes of percutaneous cryoablation for benign and malignant breast lesions at a single-center"

**Authors**: Georgiana-Cristiana Camen, Michael Schenker

**Objective**: The study aimed to evaluate the safety and efficacy of a liquid nitrogen-based cryoablation system for treating breast lesions, representing the first experience at Saint Nectarie Oncology Center in Romania.

**Conclusion**: Cryoablation proved safe and effective for tumors ≤35 mm. Technical success was 100% with high physician and patient satisfaction and very good cosmetic results. Data collection is ongoing, with expectations high for long-term outcomes. With increased experience, Saint Nectarie Oncology Center aims to integrate cryoablation into its breast unit's protocol, enhancing the institution's approach to breast care.

**About ProSense®**

The ProSense® Cryoablation System is a minimally invasive cryosurgical tool that provides the option to destroy tumors by freezing them. The system uniquely harnesses the power of liquid nitrogen to create large lethal zones for maximum efficacy in tumor destruction in benign and cancerous lesions, including breast, kidney, lung, and liver.

ProSense® enhances patient and provider value by accelerating recovery, reducing pain, surgical risks, and complications. With its easy, transportable design and liquid nitrogen utilization, ProSense® opens that door to fast and convenient office-based procedures for breast tumors.

**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 China.



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**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 impending U.S. Food and Drug Administration decision on the market authorization of ProSense® in early-stage breast cancer and the belief that there is increased awareness of and eagerness to adopt ProSense®, especially for breast cryoablation. 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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