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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 2026 (Report No. 3)

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

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**CONTENTS**

On March 11, 2026, the Company issued a press release titled "U.S. FDA Approves IceCure's Post-Marketing "ChoICE" Study for ProSense® Cryoablation in the Local Treatment of Low-Risk Breast Cancer," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.

This Report of Foreign Private Issuer on Form 6-K (excluding the fourth, fifth and sixth paragraph of the press release included as Exhibit 99.1 hereto) is incorporated by reference into the Company's Registration Statements on Form F-3 (File Nos. [333-290046](#), [333-267272](#) and [333-258660](#)) and Form S-8 (File 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a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

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**EXHIBIT INDEX**

Exhibit No.	
99.1	<a href="#">Press release dated March 11, 2026 titled "U.S. FDA Approves IceCure's Post-Marketing "ChoICE" Study for ProSense® Cryoablation in the Local Treatment of Low-Risk Breast Cancer".</a>

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**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: March 11, 2026

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

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## U.S. FDA Approves IceCure's Post-Marketing "ChoICE" Study for ProSense® Cryoablation in the Local Treatment of Low-Risk Breast Cancer

*IceCure is engaged with leading medical institutions throughout the U.S. looking to participate in the post-market study with the FDA-cleared ProSense®*

*Clinical study sites may offer ProSense® cryoablation to additional patients not enrolled in the study, supporting its potential broader commercial adoption*

*Post-market study will be conducted using cryoprobe sold exclusively by IceCure and facilities will be able to use CPT Category III reimbursement code*

**CAESAREA, Israel**, March 11, 2026 – IceCure Medical Ltd. (Nasdaq: ICCM) ("IceCure", "IceCure Medical" or the "Company"), developer of minimally-invasive cryoablation technology that destroys tumors by freezing as an option to surgical tumor removal, today announced that the U.S. Food and Drug Administration ("FDA") has approved the study design for the "ChoICE Trial Post-Market Study," the Company's post-marketing study for ProSense® in the treatment of low-risk breast cancer (the "Study"). Patient enrollment is expected to commence in the second half of 2026, with at least 80 patients expected to be enrolled in the first year of the Study.

The FDA previously granted marketing authorization in October 2025 for ProSense® for the treatment of patients aged 70 years and older with biologically low-risk tumors ≤1.5 cm in size who are treated with adjuvant endocrine therapy. In connection with its grant of marketing authorization, the FDA requested that IceCure conduct a post-market surveillance study to generate additional real-world data regarding the use of ProSense® in this indication.

The Study is expected to enroll and treat approximately 400 patients across 30 clinical sites in the U.S. within 36 months. IceCure has already received interest and engagement from leading medical institutions across the country seeking to participate in the Study. Under the approved study design, participating sites will treat enrolled patients while also serving as active commercial sites, providing cryoablation to patients outside of the study, thereby supporting the Company's commercial expansion. The Study will be conducted using cryoprobes sold exclusively by IceCure and facilities will be able to use an established CPT Category III reimbursement code.

"We believe the combination of FDA marketing authorization, this FDA-approved post-market study with 30 clinical sites across the country, supportive American Society of Breast Surgeons ("ASBrS") guidelines, an established reimbursement code, and strong physician engagement positions us to meaningfully expand access to ProSense® as a minimally invasive treatment option for eligible breast cancer patients across the U.S.," stated Eyal Shamir, Chief Executive Officer of IceCure. "We are also very pleased to work with two leading thought leaders in breast cancer treatment, Dr. Robert Ward and Dr. Nathalie Johnson, who will be Co-Principal Investigators of the Study."

Robert C. Ward, M.D., is a specialist in women's imaging and breast tumor cryoablation. Dr. Ward is an experienced clinical investigator who has authored and co-authored several publications on breast cancer cryoablation and is a skilled ProSense® user. He is Assistant Professor of Diagnostic Imaging and Program Director for the Breast Imaging Fellowship at the Warren Alpert Medical School at Brown University, and Associate Chief of Diagnostic Imaging at Women & Infants Hospital of Rhode Island.

Nathalie McDowell Johnson, M.D., FACS, is Senior Medical Director of the Legacy Health Systems Cancer Institute and Legacy Breast Health Centers in Portland, Oregon. Dr. Johnson is the former President of the ASBrS and is an avid supporter of expanding minimally invasive treatment options for breast cancer patients.

Study procedures are eligible for reimbursement under the established Centers for Medicaid and Medicare Services CPT Category III code, which provides approximately \$4,000 for the facility fee alone. IceCure believes the existing reimbursement framework may support reimbursement claims for study procedures, and that additional reimbursement pathways may develop over time, particularly in light of the recent FDA marketing authorization and inclusion of cryoablation for breast cancer in the updated ASBrS resource guide.

### About ProSense®

The ProSense® Cryoablation System is the first and only medical device to receive FDA marketing authorization for the local treatment of low-risk breast cancer with adjuvant endocrine therapy for women aged 70 and above, including patients who are not suitable for surgical alternatives for breast cancer treatment. A full list of benefits and risks can be found on the Company's website.

ProSense® 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 in the 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 the 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 option to 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 Statement

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 commencement of patient enrollment in the Study in the second half of 2026; the anticipated enrollment of at least 80 patients in the first year of the study and approximately 400 patients across 30 clinical sites within 36 months; the belief that the combination of FDA marketing authorization, the post-market study, ASBrS guidelines, established reimbursement codes, and physician engagement may support broader access to ProSense® as a minimally invasive treatment option for eligible breast cancer patients; the expectation that participating clinical sites will serve as active commercial sites supporting the Company's commercial expansion; the belief that the existing CPT Category III reimbursement framework may support reimbursement claims for study procedures; and the expectation that additional reimbursement pathways may develop over time in light of the FDA marketing authorization and updated ASBrS resource guide. 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, 2024 filed with the SEC on March 27, 2025, 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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