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: September 2025 (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

CONTENTS

On September 15, 2025, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure Receives Regulatory Approval in Israel for its Next-Generation XSense™ Cryoablation System for Breast Cancer and Other Indications," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.

The first, second and fifth paragraphs and the section titled "Forward Looking Statements" in the press release attached herewith as Exhibit 99.1 is incorporated by reference into the Company's Registration Statements on Form F-3 (Registration Nos. 333-258660, 333-267272 and 333-290046) 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a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 September 15, 2025 titled "IceCure Receives Regulatory Approval in Israel for its Next-Generation XSense™ Cryoablation System for Breast Cancer and Other Indications"

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: September 15, 2025

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

Exhibit 99.1

IceCure Receives Regulatory Approval in Israel for its Next-Generation XSense™ Cryoablation System for Breast Cancer and Other Indications

Approved for a broad range of indications including in gynecology, oncology and general surgery

CAESAREA, Israel, September 15, 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 option to surgical tumor removal, today announced it has received regulatory approval from the Medical Device Division of Israel's Ministry of Health ("AMAR") for its next-generation single cryoprobe cryoablation system, the XSense™ System and CryoProbes.

As of mid-2024, XSense™ and its cryoprobes have also received regulatory clearance in the United States from the U.S. Food and Drug Administration ("FDA") for all of the indications for which ProSense®, the Company's flagship cryoablation system, has already received from the FDA.

"We believe that this latest regulatory approval for our next-generation cryoablation system reaffirms IceCure's leadership position in liquid-nitrogen based cryoablation," stated IceCure's Chief Executive Officer, Eyal Shamir. "The minimally invasive cryoablation option that we offer across a broad range of indications can de-escalate cancer care, reduce treatment costs for payers, and accelerate recovery time for patients."

"We are particularly pleased with the breast cancer indication approval in Israel, as we believe the growing body of evidence on cryoablation as a minimally invasive option for breast cancer supports accelerated commercial adoption," Shamir added.

XSense™ is now approved in Israel for all indications for which ProSense® has already received approval in Israel, including general surgery, dermatology, neurology, including cryoanalgesia, thoracic surgery, ENT (ear, nose, throat), gynecology, oncology (including benign and malignant breast tumors), proctology and urology.

About IceCure's Cryoablation Systems

IceCure's platform technology, including the ProSense® Cryoablation System and XSense™ Cryoablation System and CryoProbes, provides a minimally invasive treatment option to destroy tumors by freezing them. The systems uniquely harness 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.

IceCure's cryoablation systems enhance patient and provider value by accelerating recovery, reducing pain, surgical risks and complications. With easy, transportable design and liquid nitrogen utilization, ProSense® and XSense™ open the door to fast and convenient office-based procedure 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 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 belief that the AMAR approval reaffirms IceCure's leadership position in liquid-nitrogen based cryoablation; the potential advantage of XSense; and the belief that the growing body of evidence on cryoablation as a minimally invasive option for breast cancer supports accelerated commercial adoption. 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.

IR Contact:

Email: investors@icecure-medical.com

Michael Polyviou

Phone: 732-232-6914
