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: November 2024

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 November 8, 2024, IceCure Medical Ltd. (the "Company") issued a press release titled "FDA Advisory Panel Votes in Favor of IceCure's ProSense® Cryoablation Benefit-Risk Profile in Early-Stage 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.

The first, third and fourth paragraphs and the section titled "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a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 November 8, 2024 titled "FDA Advisory Panel Votes in Favor of IceCure's ProSense® Cryoablation Benefit-Risk Profile in Early-Stage Low Risk Breast Cancer"

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: November 8, 2024

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

Exhibit 99.1

FDA Advisory Panel Votes in Favor of IceCure's ProSense®
Cryoablation Benefit-Risk Profile in Early-Stage Low Risk Breast Cancer

FDA decision on marketing authorization expected in the first quarter of 2025

CAESAREA, Israel, November 8, 2024 – 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, announced the U.S. Food and Drug Administration's ("FDA") Medical Device Advisory Committee Panel's (the "Advisory Panel") favorable recommendation with 9 panelists voting in favor and 5 voting against the benefit-risk profile of IceCure's ProSense®. The majority of panelists voted that the benefits of IceCure's ProSense® System outweigh the risks when used according to the proposed indications for the treatment of patients with early-stage low risk invasive breast cancer with cryoablation and adjuvant endocrine therapy. Among those that voted "no", there were three who stated that if the FDA applied adequate special controls, this would have swayed their opinion in favor.

"This is a significant milestone on the path towards the marketing authorization of ProSense® cryoablation in the U.S. for early-stage low risk breast cancer and I believe a critically important development for women seeking an alternative to lumpectomy," stated IceCure's Chief Executive Officer, Eyal Shamir. "We expect the FDA's decision, based on the Advisory Panel's recommendation, in the first quarter of 2025. Our U.S. sales and distribution team is ready to support doctors and patients in the event of a successful marketing authorization for ProSense® in breast cancer."

The Advisory Panel's favorable vote was based on the comprehensive body of data available on ProSense® as a treatment for early-stage low risk breast cancer, including results from the Company's ICE3 study compared with data from the current standard of care, lumpectomy, as well as testimonies and input from a broad range of key stakeholders, including women with breast cancer and their family members, patient advocacy groups, doctors, nurses and researchers.

The purpose of the Advisory Panel was for the FDA 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 invasive breast cancer with cryoablation and adjuvant endocrine therapy. The Advisory Panel included breast surgeons, interventional radiologists, breast oncologists, and representatives from the patient, consumer, and regulatory communities.

About ProSense®

The ProSense® Cryoablation System provides a minimally invasive treatment 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 procedure for breast tumors.

About IceCure Medical

IceCure Medical (Nasdaq: ICCM) develops and markets advanced liquid-nitrogen-based cryoablation therapy systems for the treatment 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, India, Brazil and China.

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: that this is a significant milestone on the path towards the approval of ProSense® cryoablation in the U.S. for early-stage low risk breast cancer; the belief that this approval is critically important development for women seeking an alternative to lumpectomy; that the Company expects to receive news of the FDA's decision in the first quarter of 2025; and that the Company's U.S. sales and distribution team is ready to support doctors and patients in the event of successful marketing authorization for ProSense® in breast cancer. 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.

IR Contact:

Email: investors@icecure-medical.com
Michael Polyviou
Phone: 732-232-6914
Todd Kehrli
Phone: 310-625-4462
