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 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

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On September 12, 2024, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure Announces FDA Advisory Panel Meeting Date for Marketing Authorization of ProSense® in Early-Stage Low Risk Breast Cancer Scheduled for November 7, 2024," 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a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 No.	
99.1	Press release dated September 12, 2024 titled "IceCure Announces FDA Advisory Panel Meeting Date for Marketing Authorization of ProSense® in Early-Stage Low Risk Breast Cancer Scheduled for November 7, 2024."

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 12, 2024

By: /s/ Ronen Tsimerman
Name: Ronen Tsimerman
Title: Chief Financial Officer

Exhibit 99.1

IceCure Announces FDA Advisory Panel Meeting Date for Marketing Authorization of ProSense® in Early-Stage Low Risk Breast Cancer Scheduled for November 7, 2024

- ***Public forum to evaluate ProSense® cryoablation as a minimally invasive alternative to lumpectomy for an estimated 70,000 women diagnosed in U.S. annually with early-stage low risk breast cancer***

- ***FDA decision regarding marketing authorization of ProSense® expected by early 2025***

CAESAREA, Israel, September 12, 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, today announced the U.S. Food and Drug Administration's ("FDA") Medical Device Advisory Committee Panel (the "Advisory Panel") is scheduled to take place on Thursday, November 7, 2024. The purpose of the Advisory Panel is for the FDA to obtain independent expert advice on scientific, technical and policy matters related to the De Novo Classification Request for marketing authorization of ProSense® for the indication of treating patients with early-stage low risk invasive breast cancer with cryoablation and adjuvant endocrine therapy.

"This public forum transparency ensures key stakeholders, including women with early-stage low risk breast cancer, their doctors and payors, can exchange views and data regarding the potential benefits of minimally invasive cryoablation with ProSense® as an alternative to surgery," stated IceCure's CEO, Eyal Shamir. "Following the Advisory Panel, we anticipate that the FDA will make a decision regarding marketing clearance of ProSense® by early 2025."

The Advisory Panel will include breast surgeons, interventional radiologists and industry representatives from the regulatory community. The vast body of data available on ProSense® as a treatment for early-stage low risk breast cancer will be reviewed by the Advisory Panel, including results from the Company's ICE3 study, the largest controlled multicenter clinical trial ever performed for liquid nitrogen-based cryoablation of early-stage malignant breast tumors. Per the analysis, at the 5-year follow-up evaluation, 96.3% of the subgroup of patients treated with ProSense® cryoablation, followed by adjuvant endocrine therapy, were estimated to be free from local recurrence. 100% patient and physician satisfaction was reported. The Advisory Panel is expected to make its recommendations at the conclusion of the meeting, at which time the FDA will commence its review process.

The FDA generally makes Advisory Panel meeting materials and the live webcast link available to the public no later than two business days before the meeting, at which time IceCure intends to share the link with shareholders via a press release.

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 ProSense®, an advanced liquid-nitrogen-based cryoablation therapy 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 system is marketed and sold worldwide for the indications cleared and approved to date including in the U.S., Europe, 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: the upcoming Advisory Panel; the benefits of the Advisory Panel to all stakeholders; the expected timeline and procedure of the Advisory Panel and FDA review process; and that the decision regarding marketing clearance of ProSense® is expected by early 2025. 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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