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: January 2024 (Report No. 4)

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 January 30, 2024, IceCure Medical Ltd. (the "Company") issued a press release titled "U.S. FDA Grants IceCure Medical's Appeal: Reopens De Novo Classification Request for Marketing Authorization of ProSense® for Early-Stage 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 five paragraphs and the section titled "Forward Looking Statements" in the press release furnished herewith 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, and 333-262620), filed with the Securities and Exchange Commission, to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit No.	
99.1	Press release dated January 30, 2024, titled "U.S. FDA Grants IceCure Medical's Appeal: Reopens De Novo Classification Request for Marketing Authorization of ProSense® for Early-Stage 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: January 30, 2024

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

Exhibit 99.1

U.S. FDA Grants IceCure Medical's Appeal: Reopens De Novo Classification Request for Marketing Authorization of ProSense® for Early-Stage Breast Cancer

IceCure to submit full 5-year dataset from entire ICE3 study population to the FDA this spring, ahead of previous expectation

CAESAREA, Israel, January 30, 2024 – IceCure Medical Ltd. (Nasdaq: ICCM) ("IceCure" or the "Company"), developer of the ProSense® System, a 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 ("FDA") has responded affirmatively to the Company's request for supervisory review ("Appeal") under 21 CFR 10.75 regarding the FDA's prior denial of IceCure's De Novo Classification Request for treating patients with early-stage, low risk breast cancer.

The FDA determined there is sufficient basis to reopen the De Novo file and requested IceCure submit the full 5-year dataset from the Company's ICE3 trial. The final ICE3 study patient is expected to complete her 5-year follow up examination by the end of February 2024. IceCure plans to expedite data monitoring and analysis to submit the final 5-year dataset to the FDA by April 2024, which is several months ahead of the Company's prior submission timeline.

In its initial De Novo classification request in October 2022, IceCure submitted interim results from its ICE3 study, the largest controlled multi-location clinical trial ever performed for liquid-nitrogen (LN2)-based cryoablation of small, low-risk, early-stage malignant breast tumors. The ICE3 study will provide 5-year recurrence outcomes on a patient population which represents approximately 65,000 people in the U.S. alone annually.

Additionally, the FDA requested that IceCure submit an analysis of the ICE3 results compared with data from the LUMINA study. LUMINA, a study sponsored by the Ontario Clinical Oncology Group (Canada) evaluated the risk of recurrence in patients with low-risk Luminal A breast cancer who were treated with lumpectomy surgery with adjuvant hormone therapy. A full peer-reviewed article on LUMINA results was published in August 2023, while FDA review of IceCure's De Novo request was underway.

IceCure was invited by the FDA to submit real-world data from the use of ProSense® globally, including post-market commercial use in territories where ProSense® is approved for breast cancer, as well as data from independent third-party studies.

"The FDA has set a very clear path to clearance for ProSense® in early-stage breast cancer, which may lead to women having a new, minimally invasive, safe, and effective treatment option," stated IceCure CEO Eyal Shamir. "We remain hopeful that final ICE3 data will be in line with our interim results and are confident that we can deliver the dataset, comparable analysis, and real-world data to the FDA in the next few months."

About ProSense®

The ProSense® Cyroablation 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 statement in this press release when it discusses: expediting data monitoring and analysis to submit the final ICE3 dataset and other real-world data to the FDA by April 2024; that the reopening of the Company's De Novo Classification Request may lead to women having a new, minimally invasive, safe and effective treatment option; and that the Company is hopeful that the final ICE3 data will be in line with interim results. 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, 2022 filed with the SEC on March 29, 2023, 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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