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: June 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 June 4, 2024, IceCure Medical Ltd. (the "Company") issued a press release titled "FDA to Convene Advisory Panel for Review of IceCure's De Novo Marketing Clearance Request for ProSense®, Decision Expected Early 2025; Aligns with Commercial Readiness Plan", 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 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a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 June 4, 2024, titled "FDA to Convene Advisory Panel for Review of IceCure's De Novo Marketing Clearance Request for ProSense®, Decision Expected Early 2025; Aligns with Commercial Readiness Plan."

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: June 4, 2024

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

FDA to Convene Advisory Panel for Review of IceCure's De Novo Marketing Clearance Request for ProSense®, Decision Expected Early 2025; Aligns with Commercial Readiness Plan

- ***Demonstrates public health importance of assessing ProSense®'s potential to offer optimal treatment that benefits women with early-stage breast cancer***
- ***Patients, patient advocacy groups, doctors, and the general public will be welcome to participate and comment in the open public hearing***
- ***IceCure welcomes a transparent public forum to share ICE3 study results and show how ProSense® cryoablation could potentially offer a minimally invasive alternative treatment to women diagnosed with early-stage breast cancer estimated at 65,000 in the U.S. annually***
- ***ProSense® is already approved for the treatment of early-stage breast cancer in numerous European countries, as well as Brazil, India, and China***

CAESAREA, Israel, June 4, 2024 – IceCure Medical Ltd. (Nasdaq: ICCM) ("IceCure", "IceCure Medical" 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") will convene a Medical Device Advisory Committee for a panel meeting (the "Advisory Panel") to obtain independent expert advice on scientific, technical, and policy matters related to ProSense® to help the FDA make a sound decision.

"We believe the opportunity to have a public, transparent, and open forum about this important women's health issue, led by outside, independent experts including physicians and researchers, will be highly beneficial to all stakeholders," stated IceCure's CEO, Eyal Shamir. "We applaud the FDA's decision to convene the Advisory Panel and for acknowledging the public health importance of being able to offer a minimally invasive alternative to lumpectomy. The ICE3 data for ProSense®, which has been consistently positive throughout IceCure's ICE3 study, will be shared with the Advisory Panel, highlighting its clinical and economic benefits and why women who have undergone a ProSense® cryoablation procedure have reported a 100% satisfaction rate. As we continue to engage with the FDA leading up to the Advisory Panel, we believe increased awareness of ProSense® as a result of the Advisory Panel may enable our U.S. commercial team to further support our commercial efforts upon potential regulatory approval in the U.S."

The Advisory Panel is expected to convene in the fourth quarter of 2024, with an FDA decision on whether to approve ProSense® expected by early 2025. The FDA is expected to provide the exact date for the Advisory Panel in the coming weeks, which the Company will also make known to its shareholders. The FDA generally makes Advisory Panel meeting materials and the live webcast link available to the public no later than two business days before any meeting. The Advisory Panel will review the vast body of data available on ProSense® as a treatment for early-stage breast cancer, including results from the 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 hormone therapy, were estimated to be free from local recurrence. 100% patient and physician satisfaction was reported.

As part of its De Novo Classification Request for Marketing Authorization, IceCure submitted data, including its final ICE3 study results, to the FDA, as part of its request for clearance for ProSense® for the indication of treating patients with early stage T1 invasive breast cancer with cryoablation and adjuvant hormone therapy.

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 (Sullivan)

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 impending submission of materials and data for and expected timeline and procedure of the Advisory Panel that is expected to take place in the last quarter of 2024, the belief that increased awareness of ProSense® as a result of the Advisory Panel will further the Company's commercial efforts upon potential regulatory approval, and that the decision on whether to approve 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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