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: April 2024 (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

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On April 15, 2024, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure Medical Reports Final ICE3 Breast Cancer Cryoablation Trial Results of 100% Patient and Physician Satisfaction and 96.3% Recurrence Free Rate: Data Submitted to FDA for Marketing Authorization to Treat 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, second, third and fourth paragraphs, the first paragraph under the section titled "Topline Data Presented at the ASBrS 2024 Annual Meeting", the section titled "Healthcare Economics", 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a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 April 15, 2024, titled "IceCure Medical Reports Final ICE3 Breast Cancer Cryoablation Trial Results of 100% Patient and Physician Satisfaction and 96.3% Recurrence Free Rate: Data Submitted to FDA for Marketing Authorization to Treat 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: April 15, 2024

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

Exhibit 99.1

IceCure Medical Reports Final ICE3 Breast Cancer Cryoablation Trial Results of 100% Patient and Physician Satisfaction and 96.3% Recurrence Free Rate: Data Submitted to FDA Requesting Marketing Authorization to Treat Early-Stage Breast Cancer

- ***Data presentation at highly influential American Society of Breast Surgeons ("ASBrS") Annual Meeting by Dr. Richard Fine wins Scientific Impact Award as voted by breast surgeons***
- ***President-Elect of the ASBrS, Dr. Michael Berry, presents data and states "cryoablation is ready for prime time"***
- ***Company seeks indication for treating women with early stage T1 invasive breast cancer with adjuvant hormone therapy***
- ***Available reimbursement code for facility expense expected to enhance usage upon receiving marketing authorization***
- ***Minimally-invasive ProSense® cryoablation offers highly favorable healthcare economics***

CAESAREA, Israel, April 15, 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, announced today that it has submitted final data to the U.S. Food and Drug Administration ("FDA") requesting marketing authorization for ProSense® for the indication of treating patients with early stage T1 invasive breast cancer with cryoablation and adjuvant hormone therapy. ProSense®, which received the FDA's Breakthrough Designation, is already cleared for use in the U.S. for several other indications, including treating benign tumors of the breast, and tumors in the kidney and liver.

The Company provided the following requested data to the FDA:

- ICE3 5-year follow up full data-set;
- sub-analysis of the ICE3 results compared with data from the "LUMINA" study (a study sponsored by Canada's Ontario Clinical Oncology Group, which evaluated the risk of recurrence in patients with low-risk Luminal A breast cancer who were treated with lumpectomy surgery and who had received adjuvant hormone therapy);
- analysis of the ICE3 data compared to an updated PRISMA meta-analysis; and
- real-world data from the use of ProSense® globally, including post-market commercial use as well as data from independent third-party studies.

The ICE3 study was the largest controlled multicenter clinical trial ever performed for liquid nitrogen (LN2) based cryoablation of low-risk, early-stage malignant breast tumors. The 5-year recurrence-free rates from this groundbreaking study, which evaluated IceCure's minimally invasive 20-to-40-minute outpatient cryoablation procedure, were in line with expectations and show similar outcomes to lumpectomy, the current standard of care for early-stage breast cancer patients.

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. A comparison of this result, from the ICE3 study, shows similar outcomes in 5-year recurrence rates compared to patients who were treated with lumpectomy followed by hormone therapy in the LUMINA study, which reported a 97.7% recurrence free rate at 5-year follow up and the PRISMA meta-study, which included Lumina, reporting a 97.19% recurrence free rate at 5-year follow up. ICE3 results are also in line with data from real-world use of ProSense® by third parties in territories where IceCure's cryoablation system is used to treat early-stage breast cancer. In the final ICE3 analysis, no significant device related adverse events or complications were reported, and all patients and physicians reported satisfaction with the ProSense® procedure.

"We believe ICE3 is a ground-breaking study and are excited to report that the efficacy data of our minimally invasive ProSense® cryoablation procedure show similar outcomes in recurrence compared to more invasive breast surgery, the current standard of care for early-stage breast cancer," stated IceCure CEO, Eyal Shamir.

"I, along with our marketing and clinical team, were at the ASBrS Annual Meeting where we witnessed an overwhelmingly positive response from breast surgeons who voted on Dr. Fine's presentation to win the Scientific Impact Award, demonstrating how impactful our cryoablation technology is expected to be for women with early-stage breast cancer. Further demonstrating its potential, ASBrS's President-Elect Dr. Berry deemed cryoablation is ready for prime time."

"Initial reimbursement codes are already in place and our U.S. marketing and commercial team is ready, as we await the FDA's response. Driven by favorable healthcare economics combined with patient satisfaction and demand, we expect rapid adoption pending FDA granting the DeNovo Classification Request for Marketing Approval."

Topline Data Presented at the ASBrS 2024 Annual Meeting

Final data from ICE3 were presented to leading breast surgeons from across the U.S. at the ASBrS 25th Annual Meeting by ICE3 Investigators Dr. Richard Fine and Dr. Michael Berry. Dr. Fine gave an oral presentation titled "Cryoablation Without Excision for Early-Stage Breast Cancer; ICE3 Trial 5 year follow up on Ipsilateral Breast Tumor Recurrence." Dr. Berry, President-Elect of the ASBrS, gave an oral presentation titled "Cryoablation: Is It Ready for Primetime?"

Dr. Berry stated, "In my opinion, cryoablation is 'primetime' as an alternative to surgical resection in a highly selected patient population based on data that show it is safe and aligned with what we are seeing in standard of care."

Dr. Fine commented, "Cryoablation is a safe, minimally invasive ablative procedure with acceptably low 5-year same breast recurrence similar to that of lumpectomy for similar patient populations, with the benefit of being an office-based, nonsurgical treatment. Further study within a clinical trial or registry is needed to confirm cryoablation as a viable alternative to surgical excision in the appropriately selected patients."

Healthcare Economics

As a minimally invasive outpatient procedure with no need for general anesthesia, cryoablation costs less than standard of care lumpectomy. It also reduces risk of re-excision (follow up surgery) as compared to a re-excision rate of 14-21% in lumpectomy.

IceCure's application to the U.S. Centers for Medicare & Medicaid Services (CMS) is the first and only Medicare coverage approval of a cryoablation procedure for breast cancer. CMS assigned CPT Category III code 0581T to ambulatory payment classification 5091, Level 1 Breast/Lymphatic Surgery and Related payment assignment by the CMS at approximately $3,400 for the facility fee alone. Additional coverage, including payment for the physician, is expected upon establishment of the permanent CPT Category I code, which is conditioned on factors including the Company's receipt of FDA marketing authorization of ProSense® for breast cancer.

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: that the Company expects rapid adoption if regulatory clearance from the FDA is granted; how impactful cryoablation technology is expected to be for women with early-stage breast cancer; Dr. Berry's assertion that cryoablation is 'primetime' as an alternative to surgical resection; and Dr. Fine's assertion that further study is needed to confirm cryoablation as a viable alternative to surgical excision. 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 U.S. Securities and Exchange Commission (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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