
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: March 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 March 19, 2024, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure Medical Reports Positive Topline Results From ICE3 Cryoablation Breast Cancer Study: Achievement of 96.39% Recurrence Free Rate Brings Company One Step Closer to Providing Women a Non-Surgical Alternative to Lumpectomy," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.

The first two 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a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 March 19, 2024, titled "IceCure Medical Reports Positive Topline Results From ICE3 Cryoablation Breast Cancer Study: Achievement of 96.39% Recurrence Free Rate Brings Company One Step Closer to Providing Women a Non-Surgical Alternative to Lumpectomy."
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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: March 19, 2024

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

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IceCure Medical Reports Positive Topline Results From ICE3 Cryoablation Breast Cancer Study: Achievement of 96.39% Recurrence Free Rate Brings Company One Step Closer to Providing Women a Non-Surgical Alternative to Lumpectomy

- *Expects to submit full dataset to the FDA in April for marketing authorization of ProSense® for minimally invasive treatment of early-stage breast cancer*
- *Study represents largest cryoablation study of its kind in the U.S. for early-stage low-risk malignant breast tumors*

CAESAREA, Israel, March 19, 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 positive topline results from the Company’s ICE3 study, the largest controlled multicenter clinical trial ever performed for liquid nitrogen (LN2) based cryoablation of low-risk, early-stage malignant breast tumors, following the 5-year follow-up evaluation of the ICE3 study’s last patient. In the ICE3 study, 96.39% of patients (187 out of 194 patients) were local recurrence-free with no significant device-related adverse events or complications reported.

Based on the strength of the topline results, ProSense has the potential to be a safe and effective alternative to lumpectomy for early-stage breast cancer. The Company plans to complete the analysis and evaluation of the full data set and expects to submit the results to the U.S. Food and Drug Administration (the “FDA”) in April 2024, as previously requested by the FDA with respect to IceCure’s De Novo Classification Request for Marketing Authorization of ProSense® for the treatment of early-stage low-risk breast cancer.

“We are very pleased with this topline outcome and believe these results demonstrate a highly favorable safety and efficacy profile that positions ProSense® as a desirable alternative to lumpectomy for early-stage breast cancer. Having completed the study on schedule, we are now compiling the full data set which we plan to submit to the FDA next month for marketing clearance,” stated Eyal Shamir, Chief Executive Officer of IceCure. “While the FDA evaluates the data, we are optimistic their upcoming decision will give women in the U.S. the same access as those who are already benefitting from ProSense® in other countries.”

“On behalf of the entire IceCure team, I thank the patients, their families, the sites and the clinicians for taking part in this landmark study. This has been a rigorous and thoroughly performed, ten-year long trial with positive data at each interval that is validated by recent independent studies performed globally by leading physicians .”

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 anticipates that it will submit the results of the ICE3 study in April 2024; that the Company believes ProSense®’s potential to offer a safe and effective alternative to lumpectomy for early-stage breast cancer; that the ICE3 topline outcome positions ProSense® as a desirable alternative to lumpectomy for early-stage breast cancer; and that the Company is optimistic regarding the upcoming decision by the FDA regarding the Company’s De Novo Classification Request for Marketing Authorization of ProSense® for the treatment of early-stage 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, 2022 filed with the U.S. Securities and Exchange Commission (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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