
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: February 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 February 26, 2024, IceCure Medical Ltd. (the "Company") issued a press release titled "Study Using IceCure's ProSense® Treatment Results in 100% Tumor Reduction in 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 and third 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and Exchange Commission, to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 February 26, 2024, titled "Study Using IceCure's ProSense® Treatment Results in 100% Tumor Reduction in Early-Stage Breast Cancer."](#)

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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: February 26, 2024

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

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Study Using IceCure's ProSense® Treatment Results in 100% Tumor Reduction in Early-Stage Breast Cancer

Independent study in women deemed inoperable for breast cancer reports median tumor reduction of 100% at 6 and 12 months following cryoablation

CAESAREA, Israel, February 26, 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 new data from a preliminary, independent breast cancer study conducted by Principal Investigator and ProSense® user, Dr. Federica. di Naro, of Azienda Ospedaliero-Universitaria Careggi, Diagnostic Senology Unit in Florence, Italy. IceCure previously announced interim results from this study on October 5, 2023. ProSense® is approved in Italy for numerous indications, including breast cancer.

In the single-site study conducted between January 2022 and January 2024, ultrasound-guided cryoablation using ProSense® was performed on 39 women aged 60-92, who had biopsy-proven malignant lesions, and were deemed inoperable due to advanced age and comorbidities, or who refused surgery. Patients were monitored at 1, 3, 6 and 12 months post-procedure, at which time the tumor size reduction rate was evaluated by ultrasound. Also at 12 months post-procedure, the effectiveness of the procedure was further evaluated by core needle biopsy on the post-procedural scar (inside the breast at the site of the tumor) and contrast enhanced mammography (“CEM”) to determine the presence or absence of residual tumoral cells and effectiveness of cryoablation.

The median breast cancer tumor size reduction rates reported in the study were as follows:

1 month:	27.8%
3 months:	60.9%
6 months:	100.0%
12 months:	100.0%

“These are phenomenal results of 100% median tumor size reduction in as little as 6 months and its effectiveness demonstrated by correlation between CEM outcomes versus biopsy at 12 months after our minimally invasive procedure that takes up to 40 minutes. We are so pleased that women in this study, who were deemed inoperable, benefitted from cryoablation,” stated IceCure CEO Eyal Shamir. “We are working hard to get ProSense® approved, available and affordable for as many women as possible in a number of countries around the world. This independent study is further validation of our mission, and we thank Dr. di Naro for her initiative in leading the study and giving patients options that save and prolong lives.”

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 statement in this press release when it discusses its endeavors to get ProSense® approved, available and affordable for as many women as possible in a number of countries around the world. 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.

IR Contact:

Email: investors@icecure-medical.com

Michael Polyviou

Phone: 732-232-6914

Todd Kehrli

Phone: 310-625-4462