
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 December 2023

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 December 13, 2023, IceCure Medical Ltd. (the "Company") issued a press release titled: "Study Using IceCure's ProSense® Finds: "Cryoablation Allows the Ultimate De-escalation of Surgical Therapy for Select Breast Cancer Patients," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K (the "Report").

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and Exchange Commission, to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 titled: "Study Using IceCure's ProSense® Finds: "Cryoablation Allows the Ultimate De-escalation of Surgical Therapy for Select Breast Cancer Patients."
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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: December 13, 2023

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

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Study Using IceCure’s ProSense® Finds: “Cryoablation Allows the Ultimate De-escalation of Surgical Therapy for Select Breast Cancer Patients”

- *Independent study published in *Annals of Surgical Oncology* concludes cryoablation is an oncologically safe and feasible minimally invasive procedure option in lieu of surgery for patients with early-stage, low-risk breast cancer*
- *Study’s authors suggest the widespread use of screening mammography allows for earlier detection - and therefore increased customization of treatment, less aggressive management, reduced treatment burden, improved quality of life - and examines cryoablation as the “next step in the surgical de-escalation of breast cancer”*
- *Study suggests that cryoablation provides a significantly superior alternative when it comes to financial implications, as compared to surgical resection*

CAESAREA, Israel, December 13, 2023 – IceCure Medical Ltd. (Nasdaq: ICCM), 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 publication of a study titled “Cryoablation Allows the Ultimate De-escalation of Surgical Therapy for Select Breast Cancer Patients” in the peer-reviewed journal *Annals of Surgical Oncology*.

The independent study, in which ProSense® was one of two cryoablation systems analyzed, was overseen and conducted at the Breast Center of Excellence and the Department of Surgery, School of Medicine at Texas Tech University Health Sciences Center by Sonia Y. Khan MD, Jaclyn Cole MD, Zaina Habrawi MD, Michael W. Melkus PhD, and Rakhshanda Layeequr Rahman MD.

A total of 32 early-stage breast cancer patients with a median age of 70 (range of 50-91) were treated with cryoablation. Six of the 32 patients (18.5%) received adjuvant radiation, and 31 of 32 patients (97%) received adjuvant endocrine therapy. The mean follow-up was 15 months, with 20 patients (62.5%) completing two years, and 12 patients (37.5%) completing more than three years.

All patients were disease-free at the last follow-up visit, and no major complications from the procedure were reported. One patient had regional disease at 18 months. She did not have sentinel node biopsy and did not take endocrine therapy. She had delayed axillary dissection, started endocrine therapy, and remains disease-free after 5 years of follow-up evaluation. One patient died one year after cryoablation due to unrelated causes. The patient population in this study is similar to the population in IceCure’s ongoing ICE3 study, the largest controlled multi-center clinical trial ever performed in the U.S. for liquid nitrogen-based cryoablation of small, low-risk, early-stage malignant breast tumors as an alternative to surgery.

Highlights from the article include:

- **Regarding cost of care**, the article states: “Clinical trials have determined not only that cryoablation is just as effective as surgical resection for early-stage, low-risk tumors, but that cryoablation also provides a superior alternative when it comes to financial implications.”
- **Citing ICE3 as a leading study** that makes the case for surgical de-escalation, the article states: “The ablative therapies were first entertained as options for women who might not be good surgical candidates or refuse surgery. However, two large multi-institutional studies on cryoablation (Simmons et al. (ACOSOG Z-1072), and Fine et al. (ICE3) have led the way to the use of ablation as a means for further surgical de-escalation for small early-stage, low-risk breast cancers.”

“Cryoablation is an excellent option for select patients to avoid general anesthesia, and enjoy a potential cure without surgery through an outpatient procedure with minimal disruption of life.” Stated study co-author, Dr. Rakhshanda Layeequr Rahman



“This independent study is quite compelling in that it goes beyond providing data. It presents the case that due to widespread screening with mammography, early-stage tumors can be treated with new, safe, and effective treatments that minimize the impact on patients and the healthcare system in general,” stated IceCure’s Chief Executive Officer, Eyal Shamir. “We are grateful, as always, to the growing number of medical professionals who are using ProSense® to improve patient outcomes and going above and beyond to publish their results for the advancement of innovative new treatments that improve care.”

About ProSense®

ProSense® cryoablation is a minimally invasive, non-surgical, outpatient 40-minute treatment option that destroys tumors by freezing them. The procedure only requires a local 1% lidocaine injection (similar to its use by dentists when performing certain dental procedures) enabling the patient to remain alert during the procedure and then walk out of the doctor’s office to resume their day. ProSense® has been investigated and proven effective in various clinical applications, including breast tumors, kidney cancer, lung cancer, and in palliative care. Independent and company-sponsored clinical studies of ProSense® have shown strong results, with high rates of tumor destruction, and patient and physician satisfaction.

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 and Israeli 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 that early-stage tumors can be treated effectively due to screening mammography. 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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