

---

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 October 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

---

**CONTENTS**

On October 2, 2023, IceCure Medical Ltd. (the "Company") issued a press release titled: "Independent Study Validates IceCure's ProSense Cryoablation is Safe & Effective Outpatient Procedure for Breast Cancer with 96.8% Success Rate," 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 four 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and Exchange Commission, to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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	<a href="#">Press release titled: "Independent Study Validates IceCure's ProSense Cryoablation is Safe &amp; Effective Outpatient Procedure for Breast Cancer with 96.8% Success Rate."</a>
------	---

1

---

**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: October 2, 2023

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

2

---



**Independent Study Validates IceCure's ProSense Cryoablation is Safe & Effective Outpatient Procedure for Breast Cancer with 96.8% Success Rate**

- *Study was conducted in Spain with women who declined standard of care surgery*
- *ProSense is approved for the treatment of breast cancer throughout the European Union*

**CAESAREA, Israel**, October 2, 2023 -- 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 that new data was presented at the European Society of Breast Imaging ("EUSOBI") Scientific Meeting in Valencia, Spain by Lucía Graña-López, MD, PhD, principal investigator of the independent, non-sponsored study.

In a poster titled "Cryoablation for the treatment of early-stage breast cancer in patients who decline surgery" Dr. Graña-López presented the findings of her study conducted at University Hospital Lucus Augusti in Lugo, Spain which used ProSense for cryoablation treatment of 31 patients with early-stage breast cancer who declined surgery, the standard of care. Dr. Graña-López, a radiologist who specializes in breast and women's imaging, is Head of the Breast Unit at University Hospital Lucus Augusti.

All patients were diagnosed with biopsy-proven early breast cancer (cT1-2cN0-1cM0) with a median tumor size of 24 mm, ranging between 6 to 45 mm. Patients were followed by mammography and ultrasound every 6 months for 2 years and annually thereafter. The median follow-up was 10 months, with a range of 0 to 40 months. Cancer progression was observed in 1 patient (1/31, 3.2%). No major complications were seen and the procedure was well tolerated by all patients.

The study concluded that cryoablation could be an alternative treatment to surgery for breast cancer in patients who reject surgery. Underscoring the need for such an alternative, the poster presented that breast cancer is the most commonly diagnosed malignant neoplasm worldwide and that while surgery is the standard of care for early-stage breast cancer, some patients, most of them elderly, decline standard of care surgery and prefer a less invasive option.

Dr. Graña-López commented, "I've been effectively using ProSense for cryoablation in women who decline surgery with very good results. I think that soon, cryoablation will be a real alternative to surgery in early-stage breast cancer in post-menopausal women. Beyond breast cancer, I believe ProSense can have an impact on the way cancers of the kidney, lung, and thyroid gland are treated."

"Doctors around the world are using ProSense with women who want an alternative to surgery for early-stage breast cancer, and it's highly encouraging to see these physicians publish and share their results with the medical community," stated IceCure's CEO, Eyal Shamir. "These data are very much in line with the interim results of our ICE3 study, the largest of its kind in the U.S., which is expected to conclude in the first quarter of 2024."

#### **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: the expected conclusion of its ICE3 study in the first quarter of 2024; and that, according to Dr. Graña-López, soon cryoablation will be a real alternative to surgery in early-stage breast cancer in post-menopausal women. Historic 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. Because such statements deal with future events and are based on IceCure's current expectations, they are subject to various risks and uncertainties and actual results, performance, or achievements of IceCure could differ materially from those described in or implied by the statements in this press release. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, many of which are beyond the control of the Company, including those 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](http://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](mailto:investors@icecure-medical.com)  
 Michael Polyviou  
 Phone: 732-232-6914  
 Todd Kehrli  
 Phone: 310-625-4462