**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: September 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 September 24, 2024, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure's ICE3 5-Year Trial Results Published in the Peer Reviewed Annals of Surgical Oncology Journal: ProSense® Cryoablation Without Excision for Early-Stage, Low-Risk Breast Cancer Demonstrates 96.3% Recurrence Free Rate," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.

The first paragraph and the sections titled "Key highlights and findings from the article include" and "Forward Looking Statements" in the press release attached herewith as Exhibit 99.1 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, 333-262620 and 333-281587), 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a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 September 24, 2024 titled "IceCure's ICE3 5-Year Trial Results Published in the Peer Reviewed Annals of Surgical Oncology Journal: ProSense® Cryoablation Without Excision for Early-Stage, Low-Risk Breast Cancer Demonstrates 96.3% Recurrence Free Rate." |



**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: September 24, 2024

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

**Exhibit 99.1**

**IceCure's ICE3 5-Year Trial Results Published in the Peer Reviewed Annals of Surgical Oncology Journal: ProSense® Cryoablation Without Excision for Early-Stage, Low-Risk Breast Cancer Demonstrates 96.3% Recurrence Free Rate**

- ***Publication comes ahead of the FDA Advisory Panel Meeting for Marketing Authorization of ProSense® in Early-Stage Low Risk Breast Cancer scheduled for November 7, 2024***
- ***96.3% recurrence free rate for women treated with ProSense® cryoablation and endocrine therapy; 100% of patients and treating physicians were satisfied with the cosmetic outcome***
- ***Lead study author, Dr. Richard E. Fine, is an ICE3 investigator and winner of the 2024 American Society of Breast Surgeons' Scientific Impact Award for his presentation of the ICE3 trial data***
- ***ProSense® offers women the choice of a quick minimally invasive in-office procedure under local anesthesia with minimal pain, minimal scarring and rapid recovery as compared to lumpectomy which involves full anesthesia and hours of surgery and recovery, followed by 1-2 weeks of limited movement***

**CAESAREA, Israel, Sept. 24, 2024 (GLOBE NEWSWIRE) --** IceCure Medical Ltd. (Nasdaq: ICCM) ("IceCure", "IceCure Medical" or the "Company"), developer of minimally-invasive cryoablation technology that destroys tumors by freezing as an alternative to surgical tumor removal, today announced the publication of an article titled "Cryoablation Without Excision for Early-Stage Breast Cancer: ICE3 Trial 5-Year Follow-Up on Ipsilateral Breast Tumor Recurrence" in the *Annals of Surgical Oncology*, the official journal of the Society of Surgical Oncology. The open access article, which is available HERE, presents the results of IceCure's ICE3 trial, the largest controlled multicenter clinical trial ever completed in the U.S. for liquid nitrogen ("$LN_2$") based cryoablation of small, low-risk, early-stage malignant breast tumors as an alternative to surgery. The lead author of the study is Dr. Richard Fine, an ICE3 Investigator, who co-authored the publication with 24 doctors who are ProSense® users including co-primary investigator, Dr. Kenneth Tomkovich.

"Publication of our final ICE3 results in this prestigious peer-reviewed surgical oncology journal is a very important milestone toward ProSense® being widely recognized as a safe and effective alternative to surgery for low-risk, early-stage breast cancer, and it is very well timed, as we look ahead to our U.S. Food and Drug Administration ("FDA") Advisory Panel meeting in November," stated IceCure's Chief Executive Officer, Eyal Shamir. "We believe the wealth of data presented in the article will support and accelerate the market adoption of ProSense®, should the FDA grant marketing clearance. Our thanks go out to Dr. Fine, his co-authors, and the entire team of doctors and patients who participated in ICE3, with the aim of bringing a minimally invasive and patient-friendly alternative to women with low-risk, early-stage breast cancer."

Dr. Fine commented, "Our analysis of the trial's primary outcome, ipsilateral breast tumor recurrence (IBTR) at 5 years, suggests that cryoablation with ProSense® is safe and effective for patients with early-stage low-risk breast cancer. At the 5-year follow-up, we observed local control similar to surgical standard of care. Cryoablation may be considered as an alternative to lumpectomy in this select population if followed by appropriate adjuvant treatment. Future study within a clinical trial or registry is encouraged to confirm cryoablation as a viable alternative to surgical excision."

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**Key highlights and findings from the article include:**

- 194 patients meeting eligibility received successful cryoablation treatment per protocol and were included in the final results for analysis
- The mean age was 74.9 years (55–94) with a mean tumor size of 7.4 mm transverse (2.8–14.0 mm) and 8.1 mm sagittal (2.5–14.9 mm)
- With a mean follow-up period of 54.16 months for the total population of the ICE3 trial, the IBTR rate at 5 years was 4.3% and breast cancer survival was 96.7%
- Of the 124 patients who received cryoablation and endocrine therapy, the IBTR was 3.7%, resulting in a recurrence-free rate of 96.3%
- No serious device-related adverse events were reported
- Quality-of-life score demonstrated statistically significant improvement ($p < 0.001$) in distress at 6 months as compared with baseline
- 100% of patients and treating physicians were satisfied with the cosmetic outcome
- ICE3 is a non-randomized trial that was conducted at 19 sites in the U.S.

**About IceCure Medical**

IceCure Medical (Nasdaq: ICCM) develops and markets advanced liquid-nitrogen-based cryoablation therapy systems 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 Company's flagship ProSense® 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 the belief that publication of the Company's final ICE3 results in the *Annals of Surgical Oncology* is an important milestone toward ProSense® being widely recognized as a safe and effective alternative to surgery for low-risk, early-stage breast cancer, and that it is well timed, in advance of the FDA Advisory Panel, the belief that the data presented in the article will support and accelerate the market adoption of ProSense®, should the FDA grant marketing clearance, and other clinical considerations in future studies. 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 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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