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: July 2024 (Report No. 5)

Commission File Number: 001-40753

ICECURE MEDICAL LTD. (Translation of registrant's name into English)

7 Ha'Eshel St., PO Box 3163 <u>Caesarea, 3079504 Israel</u> (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 July 22, 2024, IceCure Medical Ltd. (the "Company") issued a press release titled "99.74% Recurrence Free Rate for Women with Breast Cancer Treated with IceCure's ProSense® Cryoablation System: Key Findings Delivered at 32nd Annual Meeting of the Japanese Breast Cancer Society", a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.

The first, second, third and fourth 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. <u>333-26860</u> and <u>333-267272</u>) and Form S-8 (Registration Nos. <u>333-264578</u> and <u>333-262620</u>), 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a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 July 22, 2024, titled "99.74% Recurrence Free Rate for Women with Breast Cancer Treated with IceCure's ProSense® Cryoablation System: Key Findings Delivered at 32nd Annual Meeting of the Japanese Breast Cancer Society."

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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.

By: /s/ Eyal Shamir

Name Eyal Shamir Title: Chief Executive Officer

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Date: July 22, 2024

99.74% Recurrence Free Rate for Women with Breast Cancer Treated with IceCure's ProSense® Cryoablation System: Key Findings Delivered at 32nd Annual Meeting of the Japanese Breast Cancer Society

- Demand for minimally invasive breast cancer treatment was overarching theme of the conference
- In one independent study led by Professor Fukuma, 389 patients treated for up to 10 years had 99.74% recurrence free rate
- Another independent study led by Professor Kawamoto found 0% breast cancer local recurrence in five-year follow up
- ProSense® expected to gain further traction in Japan, as distribution partner Terumo Corporation plans to submit application to the Pharmaceuticals and Medical Devices Agency ("PMDA") for regulatory clearance for breast cancer in the first quarter of 2025

CAESAREA, Israel, July 22, 2024 – 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 that key findings from three clinical studies of ProSense® in the treatment of breast cancer were presented at the 32nd Annual Meeting of the Japanese Breast Cancer Society on July 12, 2024 in Miyagi, Japan.

During a symposium titled, "New techniques and strategies in breast surgery", chaired by Professor Takayuki Kinoshita, Division of Breast Surgery, NHO Tokyo Medical Center, data on breast cancer cryoablation with ProSense® were presented by Prof. Eisuke Fukuma, Breast Center, Kameda Medical Center, and Prof. Hisanori Kawamoto, Department of Breast Surgery, Breast and Imaging Center at St. Marianna University School of Medicine.

Demand for minimally invasive breast cancer treatment was an overarching theme of the Japanese Breast Cancer Society Annual Meeting and of high interest to the over 3,500 meeting attendees. The data on cryoablation was well received at the symposium. Symposium Chair Professor Kinoshita commented, "cryoablation for treating breast cancer has the potential to become an alternative to open surgery and other minimally invasive solutions in Japan. The data presented suggests excellent cosmetic results. As this procedure moves toward being incorporated into routine clinical practice after PMDA approval, we are pleased to have more data presented at this important annual meeting to leading breast cancer physicians in Japan."

Professor Fukuma, who has performed over 600 breast cryoablation procedures with ProSense®, presented a summary of IceCure's ICE3 study data as well the latest data from his ongoing research of ProSense® to treat breast cancer at Kameda Medical Center. From April 2014 through August 2020, 389 breast cancer patients with tumor lesions of less than 15 millimeters in diameter were treated with ProSense®. The ipsilateral breast tumor recurrence rate (IBTR) was 0.26%, resulting in a 99.74% recurrence free rate.

"The results with ProSense® continue to be excellent, and this is why cryoablation is becoming a common procedure here," Professor Fukuma stated. "Patients are becoming more interested. They are coming in and asking to learn more about it. In addition to great efficacy on treating tumors and favorable cosmetic results, there is evidence that cryoablation has potentially favorable impacts on the immune system, further improving longer term outcomes."

Professor Kawamoto presented data from an independent study he led which demonstrated zero (0%) breast cancer local recurrence or distant metastasis five years following treatment with ProSense®. These findings, which were published in the peer reviewed journal *Breast Cancer*, were previously announced by IceCure on May 7, 2024. 18 early-stage breast cancer patients with a mean tumor size of 9.8 ± 2.3 mm who underwent treatment with ProSense® were followed for a mean of 44.3 months. No serious adverse events were reported. Cosmetic outcomes were excellent and the overall patient satisfaction level and patient quality of life improved post-cryoablation.

"Japan is a very important market for ProSense® since we are partnered with Terumo Corporation, the largest medical device company in the country, and a growing number of doctors who are using ProSense® as part of their clinical studies are publishing compelling results," stated IceCure CEO Eyal Shamir. "We expect Terumo Corporation will file for regulatory approval of ProSense® for breast cancer in Japan in the first quarter of 2025, with the aim of making our cryoablation system more commercially available to doctors and patients alike in Japan."

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 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 that cryoablation for treating breast cancer has the potential to become an alternative to open surgery and other minimally invasive solutions in Japan, the potential of the impending Pharmaceuticals and Medical Devices Agency approval of the procedure and its potential to become routine practice, that cryoablation has potentially favorable impacts on the immune system, further improving longer term outcomes, and the expectation that Terumo Corporation will file for regulatory approval of ProSense® for breast cancer in Japan in the first quarter of 2025, with the aim of making IceCure's cryoablation system more commercially available to doctors and patients in Japan. 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 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

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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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