**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 2023 (Report No.2)

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 20, 2023, IceCure Medical Ltd. (the "Company") issued a press release titled: "IceCure Medical Receives FDA Response to De Novo Classification Request for Breast Cancer," 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, 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. 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and Exchange Commission, to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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.** | |
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| 99.1 | Press release titled: "IceCure Medical Receives FDA Response to De Novo Classification Request for Breast Cancer." |



## 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 20, 2023

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

**IceCure Medical Receives FDA Response to De Novo Classification Request for Breast Cancer**

**CAESAREA, Israel,** September 20, 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 that the U.S. Food and Drug Administration ("FDA") has at this time denied the Company's De Novo Classification request for breast cancer which was submitted based on interim analysis from its ICE3 study. The FDA's position on the De Novo Classification request for breast cancer has no effect on ProSense's FDA cleared authorization for other indications in the U.S. and patients in the U.S. continue to have access to ProSense for those treatments. The Company is pursuing all avenues to address the FDA's response as global adoption of ProSense outside of the United States continues to build. IceCure filed the De Novo request with the FDA in October 2022 based on interim data from its ICE3 breast cancer study for the Breakthrough Indication of early-stage (Luminal A T1 invasive) low-risk breast cancer patients who are at high risk to surgery (not suitable for surgical alternatives). IceCure continues its ICE3 clinical study, the largest clinical trial of its kind, which is expected to complete during the first quarter of 2024.

"The positive expected five-year results based on the interim analysis of the ICE3 trial, which demonstrated a survival-based estimate for the 5-year ipsilateral breast tumor recurrence (IBTR) of 4.3%*, allowed us a rare and unique opportunity to submit a De Novo Classification request and make our minimally-invasive ProSense cryoablation procedure available to women sooner for this important and underserved indication," commented Eyal Shamir, Chief Executive Officer. "We, along with our regulatory consultants, believe the FDA's response to the De Novo Classification request is largely due to the FDA's need for additional scientific literature as a comparator rate of recurrence in patients treated with lumpectomy. We are committed to working with the FDA to address its comments by using the broadly available published scientific literature on recurrence outcomes in patients treated with lumpectomy. ProSense remains available in the U.S. under prior FDA clearances and we will continue to execute our plan and progress towards achieving our primary objective of completing the 5-year follow ups with our last patients in the ICE3 study by the first quarter of 2024, while we simultaneously evaluate all strategies to efficiently and effectively address the FDA's comments."

The Company's ProSense system was given a Breakthrough Device Designation by the FDA in March 2021, and previously received clearance in the U.S. for general minimally invasive cryoablation applications, including kidney, liver and benign breast tumors. ProSense is approved for the treatment of malignant breast tumors in other jurisdictions, including Europe, China, and Brazil.

ICE3 is the largest controlled multi-location clinical trial ever performed for liquid nitrogen (LN2)–based cryoablation of small, low-risk, early-stage malignant breast tumors without subsequently removing them. The trial began in 2014 and has 194 eligible patients) in 19 hospitals and medical centers across the U.S., including Columbia University Medical Center and Mount Sinai Beth Israel. The expected survival-based estimate for the 5-year IBTR was 4.3%* for patients who received ProSense system cryoablation treatment are free of recurrence, with one-third of patients reaching 5 years post treatment. Additionally, to date, there have been no significant device-related adverse events reported with no scarring or change in shape and size of the breasts, while 100% of doctors and 100% of patients reported satisfaction with the cosmetic results.

*Based on the last interim results release on October 19, 2022, there have been 6 cases of ipsilateral breast tumor recurrence ("IBTR") out of 194 patients, or 3.09%. The survival-based estimate for the 5-year IBTR is 4.3% with a one-sided 95% confidence level, upper bound of 8.4% for the entire study.

**About ProSense**

ProSense cryoablation is a minimally invasive, non-surgical, outpatient 40-minute procedure that 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. Cryoablation costs less than the current standard of care breast cancer surgery of lumpectomy or partial mastectomy which requires general anesthesia and has cosmetic consequences.

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**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 plan and progress towards completion of the follow-up on the ICE3 clinical study in February 2024; evaluating all strategies to efficiently and effectively address the FDA's comments; and the expected 5-year results passed on the interim analysis of the ICE3 trial. 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. 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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