
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 November 2022

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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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On November 8, 2022, IceCure Medical Ltd. (the "Company") issued a press release titled: "IceCure's ProSense® Achieves Significant Milestone in Medicare Coverage of Breast Cancer Procedures," 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, second, third and sixth paragraphs and the section titled "Forward Looking Statements" in the press release are incorporated by reference into the Company's Registration Statements on Form F-3 (Registration No. [333-258660](#) and Registration No. [333-267272](#)) and Form S-8 (Registration No. [333-262620](#) and Registration No. [333-264578](#)), 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and Exchange Commission, to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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: "IceCure's ProSense® Achieves Significant Milestone in Medicare Coverage of Breast Cancer Procedures."](#)

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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: November 8, 2022

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



IceCure's ProSense® Achieves Significant Milestone in Medicare Coverage of Breast Cancer Procedures

- *Receives assignment to a Medicare Payment Group for hospital outpatient payment*
- *Marks CMS's first payment assignment for cryoablation of breast cancer*
- *Code and preliminary payment amount for facility fee will be effective January 1, 2023, which together may lead to a coverage policy subject to receipt of FDA marketing authorization*
- *Filed De Novo Classification with FDA for breast cancer marketing authorization in October 2022*

CAESAREA, Israel, November 8, 2022 -- IceCure Medical Ltd. (NASDAQ: ICCM) (TASE: ICCM) ("IceCure" or the "Company"), developer of minimally-invasive cryoablation technology, the ProSense® System that destroys tumors by freezing, today announced the Centers for Medicare & Medicaid Services ("CMS") assigned its ProSense breast cancer cryoablation procedures with CPT Category III code 0581T to ambulatory payment classification 5091, Level 1 Breast/Lymphatic Surgery and Related Procedures. This payment assignment for the procedure will go into effect on January 1, 2023, opening the potential for facilities to be paid, on a case-by-case basis, for these procedures subject to the Company's receipt of U.S. Food and Drug Administration ("FDA") marketing authorization of ProSense for breast cancer. A De Novo Classification Request for breast cancer marketing authorization was filed with the FDA for the initial breakthrough indication of early-stage low-risk breast cancer patients at high risk to surgery in October 2022.

Backed by its ICE3 clinical trial interim analysis data of ProSense, IceCure's application is the first and only Medicare coverage approval of cryoablation procedure for breast cancer.

Backed by its ICE3 clinical trial interim analysis data of ProSense IceCure's application to the CMS, is the first and only payment group assignment for cryoablation of breast cancer

As a minimally invasive procedure that destroys early-stage breast cancer tumors, ProSense significantly reduces the cost burden of treatment as compared to current standard of care lumpectomy procedures. Under the temporary CPT Category III code, IceCure's procedure is priced for coverage by the CMS at approximately \$3,400 for the facility fee alone. Additional coverage, including payment for the physician, is expected upon establishment of the permanent CPT Category I code, which is conditioned on several factors including the Company's receipt of FDA marketing authorization of ProSense for breast cancer.

"We believe IceCure is the only company that has the clinical data needed to move cryoablation forward on both the regulatory and reimbursement front and to provide women facing breast cancer what they deserve—a state-of-the-art optimized, minimally invasive technology that destroys tumors, so they can simply walk out of the procedure room and return to a cancer-free life," stated IceCure CEO Eyal Shamir.

"This Medicare Payment Group assignment is a significant milestone that will support our commercialization of ProSense for early-stage breast cancer if we receive FDA marketing authorization. We believe private insurers will be similarly open to covering the procedure based on the CMS's position, the robust data on favorable patient outcomes, and the corresponding improved healthcare economics. It is our mission to make the procedure widely available and affordable," Shamir added.



Factors contributing to ProSense's improved healthcare economics include:

- A ProSense cryoablation procedure costs less—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 and walk out following the in-office procedure—as compared to the current standard of care breast cancer surgery of lumpectomy or partial mastectomy which requires general anesthesia and has cosmetic consequences.
- Data suggests the use of ProSense cryoablation in breast procedures eliminates the risk of re-excision (a second surgery) as compared to breast cancer surgeries, 14% - 20% of which result in re-excision which is associated with greater morbidity, patient anxiety, poorer cosmetic outcomes, and increased cost.

About IceCure Medical Ltd.

IceCure Medical Ltd. (NASDAQ: ICCM) (TASE: 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 to-date by the FDA and approved in Europe with the CE Mark.

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, other Federal securities laws and the Israeli securities law. 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 effective date for payment assignment for ProSense breast cancer cryoablation procedures with the CPT Category III code; IceCure's belief that FDA approval of its De Novo Classification Request may lead to a coverage policy; additional coverage, including payment for the physician, is expected upon establishment of the permanent CPT Category I code; and that private insurers will be open to covering the procedure based on the CMS's position, data on patient outcomes and improved healthcare economics. 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, 2021 filed with the Securities Exchange Commission (the "SEC") on April 1, 2022, as amended, which is 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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