
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: January 2025 (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
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 January 27, 2025, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure Files for Regulatory Approval of ProSense® Cryoablation System in China," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.

The first two paragraphs and the section titled "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a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 INDEX

Exhibit No. _____

99.1 [Press release dated January 27, 2025 titled "IceCure Files for Regulatory Approval of ProSense® Cryoablation System in China"](#)

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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: January 27, 2025

By: /s/ Eyal Shamir

Name: Eyal Shamir

Title: Chief Executive Officer

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IceCure Files for Regulatory Approval of ProSense® Cryoablation System in China*Seeks to expand regulatory approval in China where IceSense3 has already been approved*

CAESAREA, Israel, January 27, 2025 – 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 it has submitted a regulatory filing with China’s National Medical Products Administration (“NMPA”) for the approval of its ProSense® Cryoablation System. IceCure’s IceSense3, its predecessor cryoablation system, already has regulatory approval in China.

The indicated use for ProSense® in China, per the Company’s regulatory filing application, is as a cryosurgical tool in the fields of general surgery including breast tissue, dermatology, thoracic surgery including lung tissue, gynecology, oncology, proctology, and urology including kidney tissue. The ProSense® application with the NMPA expands upon the current IceSense3 clearance to include a total of five different cryoprobes of varying length, diameter, and ice ball shape, as well as the use of introducers, which provide increased accessibility to the targeted tissue in certain indications.

“China is potentially a very large market for cryoablation and we are moving forward with an expanded line of available products, as well as securing reimbursement, so that IceCure can be ideally positioned to serve this important geography,” stated IceCure CEO, Eyal Shamir.

About ProSense®

The ProSense® Cryoablation System is a minimally invasive cryosurgical tool that provides the 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 procedures for breast tumors.

About IceCure Medical

IceCure Medical (Nasdaq: ICCM) develops and markets advanced liquid-nitrogen-based cryoablation therapy systems for the destruction 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 China is potentially a very large market for cryoablation and that the Company is moving forward with an expanded product line of available products, as well as securing reimbursement, so that IceCure can be ideally positioned to the Chinese market. 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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