
**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: February 2025 (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 February 24, 2025, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure Submits Filing for Regulatory Approval of its Next-Generation XSense™ Cryoablation System in Israel," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.

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part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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

| <u>Exhibit No.</u> | |
|--------------------|--|
| 99.1 | Press release dated February 24, 2025 titled "IceCure Submits Filing for Regulatory Approval of its Next-Generation XSense™ Cryoablation System in Israel" |

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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: February 24, 2025

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

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IceCure Submits Filing for Regulatory Approval of its Next-Generation XSense™ Cryoablation System in Israel

Application covering a wide range of indications is in line with trends in de-escalation of surgery and growth in minimally invasive cryoablation procedures, pointing to strong potential for increasing demand

CAESAREA, Israel, February 24, 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 filed for regulatory approval with the Medical Device Division (“AMAR”) of Israel’s Ministry of Health for its next-generation single cryoprobe cryoablation system, the XSense™ System and CryoProbes.

The filing contains a request for approval of all indications for which ProSense® has already received approval in Israel, including general surgery, dermatology, neurology, including cryoanalgesia, thoracic surgery, ENT (ear, nose, throat), gynecology, oncology (including benign and malignant breast tumors), proctology and urology. The Company has already received marketing authorization from the United States Food and Drug Administration (the “FDA”) for the XSense™ System and its cryoprobes.

“As a leader in liquid-nitrogen based cryoablation technologies, we continue to innovate and bring to market healthcare advancements that support the global move toward de-escalation of surgery and the substantial increase in minimally invasive surgery procedures,” stated IceCure’s Chief Executive Officer, Eyal Shamir. “While de-escalation of surgery is a trend specific to the treatment of breast cancer, we see growing opportunities for our cryoablation systems to offer minimally invasive solutions in a wide range and expanding number of indications. We are optimistic about receiving regulatory clearance for XSense™ in Israel in the coming months.”

The global minimally invasive surgery market is forecast to grow by a CAGR of 17% between 2022 and 2029 to reach \$174 billion by 2029.

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 Company’s view that opportunities for its cryoablation systems are growing in a wide range and expanding number of indications; the impending decision on regulatory clearance for XSense™ in Israel by AMAR; and the growth forecast of the global minimally invasive surgery market, pointing to strong potential for increasing demand. 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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