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: October 2025

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

CONTENTS

On October 3, 2025, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure Receives FDA Marketing Authorization for ProSense® Cryoablation for the Treatment of Low-Risk Breast Cancer in Women Aged 70 and Above," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.

On October 3, 2025, the Company also issued a press release titled "IceCure Medical's ProSense® Cryoablation Granted FDA Marketing Authorization for Treatment of Low-Risk Breast Cancer in Women Aged 70 and Above: Significant Development in Giving Women with Breast Cancer Minimally Invasive Care," a copy of which is furnished as Exhibit 99.2 with this Report of Foreign Private Issuer on Form 6-K.

The press release attached herewith as Exhibit 99.1 (excluding the second, third, sixth and eighth paragraphs thereof) and the press release attached herewith as Exhibit 99.2 (excluding the second, seventh and fifteenth paragraphs thereof) are incorporated by reference into the Company's Registration Statements on Form F-3 (Registration Nos. 333-258660, 333-267272 and 333-290046) 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a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 October 3, 2025 titled "IceCure Receives FDA Marketing Authorization for ProSense® Cryoablation for the Treatment of Low-Risk Breast Cancer in Women Aged 70 and Above"
99.2	Press release dated October 3, 2025 titled "IceCure Medical's ProSense® Cryoablation Granted FDA Marketing Authorization for Treatment of Low-Risk Breast Cancer in Women Aged 70 and Above: Significant Development in Giving Women with Breast Cancer Minimally Invasive Care"

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: October 3, 2025

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

Exhibit 99.1

IceCure Receives FDA Marketing Authorization for ProSense® Cryoablation for the Treatment of Low-Risk Breast Cancer in Women Aged 70 and Above

- ***ProSense® is the first and only medical device to be granted FDA marketing authorization for the local treatment of breast cancer***
- ***Major advancement and new paradigm in breast cancer care as a simple, minimally invasive out-patient procedure***
- ***Initial reimbursement under the CPT III code which covers $3,800 of facility costs, with additional reimbursement coverage expected***
- ***U.S. sales and distribution team ready to drive sales of ProSense® systems and disposable probes—supporting medical community and patients looking for a new minimally invasive option to lumpectomy***
- ***Enthusiastic response from top U.S. breast surgeons and radiologists***
- ***Conference call to be held Monday, October 6 at 8:30AM Eastern Time***

CAESAREA, Israel, October 3, 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 option to surgical tumor removal, today announced that the U.S. Food and Drug Administration ("FDA") has granted marketing authorization to IceCure's De Novo application for the ProSense® cryoablation system for the local treatment of breast cancer in patients ≥70 years of age with biologically low-risk tumors ≤1.5 cm in size and treated with adjuvant endocrine therapy, representing approximately 46,000 women annually in the U.S. The authorized indication includes patients that are not suitable for surgery for breast cancer treatment.

Potentially Setting a New Standard of Care for the Defined Indication

"ProSense® offers the first new innovation in the treatment of women aged 70 and above with low-risk early-stage breast cancer in decades. We are proud to deliver a significant advancement and enhancement to women's cancer care and quality of life," stated IceCure's Chief Executive Officer, Eyal Shamir.

"We expect that the FDA's marketing authorization, the very enthusiastic response from physicians who have had clinical experience with ProSense®, and the existing reimbursement code, will all combine to drive strong demand for our cryoablation procedure in breast cancer. American women aged 70 and above diagnosed with low-risk, early-stage breast cancer now have access to a minimally invasive procedure that offers safe and effective treatment similar to standard of care lumpectomy, with excellent cosmetic results and patient satisfaction," Shamir added.

Post-Market Study to Support Commercial Roll Out

In granting marketing authorization, the FDA requested that IceCure conduct a post-market surveillance study with the aim of producing additional data in this indication. The post-market study is expected to include approximately 400 patients at 30 sites, and the established reimbursement code may be used to support claims and reimbursement for the study procedures. These sites, while treating study participants, will also be active commercial sites where any appropriate patient seeking treatment with ProSense® cryoablation may be treated.

The FDA's marketing authorization also establishes that any other company wishing to file for 510(k) marketing authorization for a different cryoablation system to treat breast cancer will be required to submit 5 years of follow-up data. To IceCure's knowledge, no other company is currently conducting a breast cryoablation clinical study in the U.S.

“Our U.S. team has been diligently preparing for the FDA authorization, and we are ready to seize the opportunity to expand our U.S. customer base,” stated VP of Sales North America, Mr. Shad Good. “While we expect the post-market study will support our product roll out through the initial 30 clinical sites, we are authorized to immediately commence ProSense® sales and procedures, independent of the post-market study.”

The FDA’s marketing authorization was based on an abundance of data including IceCure’s ICE3 trial, the largest multi-center clinical trial ever completed for liquid-nitrogen (LN2) based cryoablation for patients with low-risk, early-stage breast cancer without surgically removing the breast tumor.

ICE3 Investigator Richard Fine, MD, FACS, stated, “As proven in the ICE3 study, cryoablation with ProSense® is a safe, minimally invasive ablative procedure with results similar to that of lumpectomy patients who took endocrine therapy, with the benefit of being an office-based, non-surgical treatment. data coming out of the post-market study should continue to support and confirm that cryoablation with ProSense® is a successful alternative to surgical excision in appropriately selected patients.”

Reimbursement Code Established, ProSense® Minimizes Cost of Treatment for Payors

ProSense® enhances patient, provider, and payor value by accelerating recovery, minimizing pain, surgical risks, and complications, all while minimizing the cost of treatment relative to standard of care lumpectomy. With its easy, transportable design and LN2 utilization, ProSense® opens the door to fast and convenient out-patient procedures for breast tumors.

ProSense® has access to reimbursement under the CPT III code which covers $3,800 of facility costs. IceCure expects additional reimbursement coverage in the future based on the FDA’s marketing authorization and other factors including the post market activity and recommendations from professional medical associations.

Full Indication for ProSense® in the Treatment of Breast Cancer

ProSense® is authorized by the FDA for the local treatment of breast cancer in patients ≥70 years of age with biologically low-risk tumors ≤1.5 cm in size and treated with adjuvant endocrine therapy. Biologically low-risk breast cancer is defined as unifocal tumor, size ≤1.5cm, ER+, PR+, HER2-, Ki-67<15% and/or genomic testing indicative of low-risk breast cancer, infiltrating ductal carcinoma (excluding lobular carcinoma, extensive intraductal component, or evidence of lymphovascular invasion), and clinically negative lymph node (N0). The authorized indication includes patients that are not suitable for surgery for breast cancer treatment. For a complete discussion of the benefits and risks of ProSense Cryoablation System for the local treatment of breast cancer, please visit our website.

Company Webcast Information:

Monday, October 6, 2025 at 8:30 AM EDT
A live webcast will be available at: https://www.veidan-conferencing.com/icecure-investors
A recording of the webcast will be available at: https://www.ir.icecure-medical.com

About ProSense®

The ProSense® Cryoablation System is the first and only medical device to receive FDA marketing authorization for the local treatment of early-stage, low-risk breast cancer with adjuvant endocrine therapy for women aged 70 and above, including patients who are not suitable for surgical alternatives for breast cancer treatment. A full list of benefits and risks can be found on our website.

ProSense® 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 in the 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 the 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 option to 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 Asia.

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 the FDA's approval of ProSense® sets a new paradigm in breast cancer care and potentially sets a new standard of care; that the FDA's marketing authorization, the very enthusiastic response from physicians who have had clinical experience with ProSense®, and the existing reimbursement code, will all combine to drive strong demand for the Company' cryoablation procedure in breast cancer; that additional reimbursement coverage is expected; the details regarding the post-market study, including the number of expected patients and sites; that the post-market study sites will also be active commercial sites where any appropriate patient seeking treatment with ProSense® cryoablation may be treated; the expectation that the post-market study will support the Company's product roll out through the initial clinical sites; and that further data coming out of the post-market study should continue to support and confirm that cryoablation with ProSense® is a successful alternative to surgical excision in appropriately selected patients. 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, 2024 filed with the SEC on April 3, 2025, 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. Information on, or accessible through, the websites mentioned above does not form part of this press release.

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Michael Polyviou

Phone: 732-232-6914

IceCure Medical's ProSense® Cryoablation Granted FDA Marketing Authorization for Treatment of Low-Risk Breast Cancer in Women Aged 70 and Above: Significant Development in Giving Women with Breast Cancer Minimally Invasive Care

- ***ProSense® cryoablation offers the choice of a minimally invasive outpatient procedure that destroys tumors by freezing without surgical removal of breast tissue***
- ***First new innovation in the local treatment of early-stage, low-risk breast cancer in decades and only medical device to be granted FDA marketing authorization for breast cancer treatment***
- ***Offers efficacy and safety similar to standard of care lumpectomy, with excellent cosmetic results and patient satisfaction***
- ***Company conference call to be held at Monday, October 6 at 8:30 AM Eastern Time***

CAESAREA, Israel, October 3, 2025 – The U.S. Food and Drug Administration ("FDA") has granted marketing authorization for ProSense®, a minimally invasive cryoablation treatment for patients with early-stage low risk breast cancer when combined with adjuvant endocrine therapy for women aged 70 and over, an estimated population of 46,000 women annually in the U.S. The announcement was made on October 3, 2025, by IceCure Medical Ltd. (Nasdaq: ICCM) ("IceCure", "IceCure Medical" or the "Company"), the developer of minimally invasive cryoablation technology that destroys tumors by freezing as an option to surgical tumor removal.

"We are excited to add a minimally invasive choice around breast cancer treatments and to offer patients an effective, outpatient procedure," said Eyal Shamir, Chief Executive Officer, IceCure. "With the ProSense® Cryoablation System, we are giving women with low-risk, early-stage breast cancer the choice to freeze their cancer, not their lives, through an effective treatment that minimizes recovery time, and minimal cosmetic changes to the breast."

ProSense® is the first and only medical device to be granted FDA marketing authorization for the local treatment of breast cancer.

ProSense® is authorized by the FDA for the local treatment of breast cancer in patients ≥70 years of age with biologically low-risk tumors ≤1.5 cm in size and treated with adjuvant endocrine therapy. Biologically low-risk breast cancer is defined as unifocal tumor, size ≤1.5cm, ER+, PR+, HER2-, Ki-67<15% and/or genomic testing indicative of low-risk breast cancer, infiltrating ductal carcinoma (excluding lobular carcinoma, extensive intraductal component, or evidence of lymphovascular invasion), and clinically negative lymph node (N0). The authorized indication includes patients that are not suitable for surgery for breast cancer treatment. For a complete discussion of the benefits and risks of ProSense Cryoablation System for the local treatment of breast cancer, please visit our website.

In granting marketing authorization, the FDA requested that IceCure conduct a post-market surveillance study with the aim of producing additional data in this indication. The post-market study is expected to include approximately 400 patients at 30 sites.

Breast cancer cryoablation with ProSense®, is a simple, quick, out-patient procedure that can have a notably positive impact on the patient experience and can be beneficial for patients seeking more choices.

“You don’t need any kind of cosmetic follow-up, you don’t have a scar, and you don’t have the feeling of having lost part of your breast, because it’s all still there,” said breast cancer patient and ICE3 trial participant, Pam Dixon, when describing her experience with the ProSense® cryoablation procedure. “There was no pain. It was one of the easiest things I’ve ever done. I don’t remember any limitations on my activity.”

During the ProSense® cryoablation procedure, a doctor injects local anesthesia and uses ultrasound imaging to guide a small cryoprobe, a thin hollow needle, into the breast tumor. Once the cryoprobe is placed, liquid nitrogen creates extremely cold temperatures (-170C°) which destroys the breast tumor by creating an ice ball around the targeted tissue. Key advantages of ProSense® cryoablation procedure include:

Maintain breast shape: No tissue is removed and there is minimal scarring from the insertion of the cryoprobe. No breast reconstruction is needed.

Short, out-patient procedure with local anesthesia: Average cryoablation procedure time is approximately 30 - 45 minutes with no hospital waiting or overnight stay. Numbing agents (local anesthesia) are injected only into the area being treated and the ice formed during the procedure has a numbing effect.

Reduced recovery time: Patients typically return to normal activity within 24-hours. Median recovery time is one day with a range of 0 – 8 days.

The procedure is monitored in real-time by ultrasound to ensure the ice ball is growing sufficiently around the tumor, and to avoid damage to the skin or muscle. The doctor may use hydro-dissection to protect the skin or muscle during a procedure depending on the location of the tumor. The tissue destroyed by the ice ball is naturally reabsorbed by the body over time and adjacent tissue is left unharmed.

The FDA’s marketing authorization was based on an abundance of data including IceCure’s ICE3 trial which was published in the Annals of Surgical Oncology. With 194 patients, ICE3 is the largest multi-center clinical trial ever completed for liquid-nitrogen (LN2) based cryoablation for patients aged ≥60 with low-risk, early-stage breast cancer without surgically removing the breast tumor. Only 3.1% of patients with hormone receptor-positive and HER2-breast cancer treated locally with cryoablation and endocrine therapy (also known as hormone or hormonal therapy), experienced local recurrence of breast cancer within 5 years after treatment, based on the study results.

The majority of the cryoablation procedure-related adverse events besides breast cancer recurrence were edema (swelling), bruising, hematoma (bleeding into tissues), skin burn, and postoperative pain. These were mild in severity and all of these events resolved without any permanent effect.

ICE3 study lead author, Richard Fine, MD, FACS, of the West Cancer Center & Research Institute in Germantown, TN and past President of the American Society of Breast Surgeons emphasizes that, "The ICE3 study has proven that cryoablation with ProSense® is a safe, minimally invasive ablative procedure with results similar to that of lumpectomy patients who took endocrine therapy, and has the benefit of being an office-based, non-surgical treatment. data coming out of the post-market study should continue to support that cryoablation with ProSense® is a successful option in the de-escalation of breast cancer care in appropriately selected patients."

Conference webcast info:

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