

January 12, 2026



# **IceCure CEO Issues Letter to Shareholders: Reports Record Fourth Quarter and Full Year 2025 ProSense® Sales**

*Company experiencing strong demand in the U.S. following FDA marketing authorization of ProSense® as the only on-label minimally invasive solution for the local treatment of low-risk breast cancer, addressing a market opportunity of approximately 200,000 patients*

*Record European sales, driven by positive effects of U.S. clearance and continued growing adoption of ProSense® cryoablation for breast cancer in key markets*

*Record number of peer-reviewed publications and presentations at global conferences demonstrates growing clinical evidence for cryoablation of breast, musculoskeletal, and kidney cancers with ProSense®*

CAESAREA, Israel, Jan. 12, 2026 /PRNewswire/ -- [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 issued the following letter to shareholders from its Chief Executive Officer, Eyal Shamir.



Dear shareholders,

2025 was a pivotal year for IceCure – we were granted the U.S. Food and Drug Administration's ("FDA") marketing authorization for ProSense® cryoablation for the local treatment of low-risk breast cancer with endocrine therapy in women aged 70 and above, including those who are not candidates for breast cancer surgery. This achievement has

strengthened our belief that ProSense® can expand patient choice, enhance care, and offer improved healthcare economics through a minimally invasive approach. This milestone marks a meaningful step toward establishing cryoablation as a new standard of care for eligible women in the United States seeking effective care without surgical removal of breast tissue.

Following the FDA marketing authorization in October 2025, we have experienced and continue to experience an overwhelmingly positive response and interest in ProSense® consoles and disposable cryoprobes. This has contributed to record fourth quarter results in 2025 in North America. We are particularly enthused to see systems being placed at highly regarded institutions in the United States, which we believe can further accelerate broader adoption of ProSense®. Our sales team is engaged with leading hospitals, clinics, breast surgeons, and interventional radiologists currently evaluating ProSense® in the U.S.

Based on preliminary, unaudited estimates, IceCure delivered a record ProSense® sales of approximately \$3.4 million for the year ended December 31, 2025, driven by growing demand in the U.S. and record sales in Europe as we continue to execute our global commercial strategy. Our cash and cash equivalents balance as of December 31, 2025 was approximately \$8.9 million. This preliminary financial information has been prepared solely on the basis of information that is currently available to, and that is the responsibility of, management. This preliminary financial information is based upon our estimates and remains subject to, among other things, the completion of IceCure's financial closing procedures and final adjustments, which may impact the results and expectations set forth above.

We also saw continued advancement in the large body of data supporting ProSense® for other indications. In 2025, independent investigators produced a record number of peer-reviewed publications and presentations regarding the use of ProSense® for breast, musculoskeletal, and kidney cancers. We believe this expanding body of evidence is critical to long-term adoption and to supporting expanded clinical use around the world.

## **2025 Key Achievements**

**FDA Marketing Authorization for Low-Risk Breast Cancer in Women Aged 70 and Above:** The FDA granted marketing authorization for ProSense® for the local treatment of low-risk breast cancer in women aged 70 and above with endocrine therapy, establishing ProSense® as the first and only medical device to receive FDA marketing authorization for the local treatment of breast cancer.

**Significant Addressable U.S. Patient Population:** ProSense® addresses a U.S. patient population for breast cryoablation of approximately 200,000 women annually. This population includes approximately 46,400 early-stage, low-risk breast cancer patients aged 70 and over, 88,500 patients who are not candidates for breast cancer surgery, and 63,000 patients with fibroadenomas who opt for excision.

**Commercial Expansion Across North America:** ProSense® systems were sold and installed at new locations across North America, including at one of the most highly regarded medical institutions in the United States, reflecting strong clinical interest following the FDA marketing authorization.

**Record Scientific Visibility and Independent Validation:** IceCure achieved a record number of peer-reviewed publications and conference presentations by 16 principal investigators at 10 conferences across the globe including the U.S., Europe, and Asia, covering indications including breast, musculoskeletal and kidney cancer. These independent third-party studies continue to demonstrate ProSense® efficacy and safety in breast cancer and its potential for other indications.

**Clinical Validation in Lung Cancer and Endometriosis:** While a large body of evidence in ProSense®'s treatment of breast cancer continues to accumulate, independent studies demonstrated that IceCure's cryoablation system, combined with radiation therapy, successfully treated non-small cell lung cancer ("NSCLC"), demonstrating 92% disease-specific 5-year survival. Additional independent studies also demonstrated that ProSense® substantially reduced abdominal wall endometriosis pain with high procedural efficacy.

**Regulatory Achievements:** ProSense® received regulatory approval in Switzerland for indications including breast, lung, liver, and kidney cancer, while the next-generation XSense™ received regulatory approval in Israel.

**Intellectual Property Estate Continued to Grow:** IceCure was granted and allowed four new patents in the U.S. and China covering our latest innovations, including next-generation multi-probe cryoablation system, cryogenic pump, and cryogenic flow control technology.

## **2026 Objectives**

- We believe the commercial sales momentum in the U.S. and wider utilization in Europe is expected to generate higher ProSense® system and cryoprobe sales in 2026.
- We expect additional reimbursement coverage may potentially become available for ProSense® procedures in 2026 and beyond based on factors including the FDA's marketing authorization in low-risk breast cancer, post-market activity, and recommendations from professional medical associations. ProSense® currently has reimbursement under the CPT III code which increased to \$4,049 effective January 2026.
- Terumo, our distributor in Japan, is expected to submit a request for breast cancer clearance to Japan's Pharmaceuticals and Medical Devices Agency in the first half of 2026.
- More peer-reviewed publications are expected from ongoing independent studies of ProSense® worldwide.
- We expect continued progress toward regulatory approvals for ProSense® in additional global markets.
- We continue to explore opportunities for strategic cooperation and partnership, supported by recent clinical, regulatory, and commercial progress.

We wish you all a peaceful, healthy, and prosperous 2026.

Sincerely,  
Eyal Shamir, CEO

## **About ProSense®**

The ProSense® Cryoablation System is the first and only medical device to receive FDA

marketing authorization for the local treatment of 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 the Company's 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 Statement**

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: its preliminary unaudited estimates for certain 2025 financial performance, which are subject to, among other things, the completion of IceCure's financial closing procedures and final adjustments, which may impact the results and expectations set forth above; expectations that the FDA marketing authorization will accelerate broader adoption of ProSense® and support its establishment as a new standard of care in the United States; beliefs that commercial sales in the U.S. and increased utilization in Europe are expected to generate higher ProSense® system and cryoprobe sales in 2026; expectations that additional reimbursement coverage may potentially become available in 2026 and beyond; anticipated regulatory submissions and approvals in additional global markets, including a planned submission for breast cancer clearance in Japan; and expectations regarding future peer-reviewed publications, strategic collaborations, and continued clinical, regulatory, and commercial progress. 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 March 27, 2025, and other documents filed with or furnished to the SEC which are available on the SEC's website, [www.sec.gov](http://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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