January 13, 2025

IceCure Medical CEO Issues Letter to Shareholders & Reports Increase of 42% in ProSense® Sales for 2024 in North America

- ***Increase in sales of ProSense®, based on preliminary unaudited results, demonstrate growing adoption of ProSense® cryoablation for breast tumors.***
- ***FDA decision on market authorization of ProSense® for early-stage breast cancer is expected in the first quarter of 2025.***
- ***FDA Advisory Panel voted in favor of ProSense®'s benefit-risk profilefor early-stage low risk breast cancer.***
- ***Positive ProSense® results reported through 10 peer-reviewed journals and 23 presentations at medical conferences.***

CAESAREA, Israel, Jan. 13, 2025 /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 alternative to surgical tumor removal, today issued the following letter to shareholders from its Chief Executive Officer, Eyal Shamir.

Dear shareholders,

In 2024, we observed a number of rising trends that we believe clearly demonstrate ProSense®'s potential for widescale adoption across numerous indications in multiple markets. De-escalation of surgery, which has become an increasing focus of discussion in the medical field, is being evaluated in studies and emerging as a growing trend in practice. As a minimally invasive option, cryoablation with ProSense® offers an excellent choice for de-escalation of surgery with results that parallel invasive surgery - and doctors and their patients are taking notice. The continued growth in our ProSense® console and disposable

probe sales is in line with this trend.

2024 was truly a pivotal year for IceCure during which we completed our 10-year long ICE3 study with excellent results. We had a highly productive public meeting with the U.S. Food and Drug Administration ('FDA') Medical Device Advisory Committee Panel ('Advisory Panel') that led to a positive vote. We are currently in ongoing discussions with the FDA, which is expected to make its decision on marketing authorization for early-stage breast cancer in the first quarter of 2025. We look forward to executing on substantial market opportunities in 2025.

As we enter the new year, we have expanded our Board of Directors to include Vic Lee (Li Haixiang), our controlling shareholder who truly understands IceCure's potential to set a new standard for minimally-invasive procedures. Mr. Lee is the Chairman of VI Asset Management, where he invests in new medical technologies and robotics. We are honored to welcome him to our Board of Directors.

2024 Key Achievements

Growth in ProSense® System and Probe Sales Demonstrates Global Adoption Across Numerous Indications: Based on our expected preliminary unaudited 2024 results, ProSense® system and disposable probe sales increased to $3.19 million for the year ended December 31, 2024, compared to $2.96 million in 2023. Revenues for the year ended December 31, 2024, grew to $3.29 million compared to $3.23 million in 2023. Most notably, the North American market demonstrated significant growth, with a 42% increase in sales compared to 2023. An increase in system and probe sales was partially offset by a decrease in revenue recognition from our distribution agreement with Terumo Corporation. Our cash and cash equivalents balance as of December 31, 2024, was approximately $7.5 million.

FDA Advisory Panel Voted in Favor of ProSense®'s Benefit-Risk Profilefor Early-Stage Low Risk Breast Cancer: Following a public day-long forum, the FDA's Advisory Panel delivered a favorable recommendation based on the ICE3 study's final results, with nine panelists voting in favor and five voting against ProSense®'s benefit-risk profile. The majority of panelists voted that ProSense®'s benefits outweigh the risks when used according to the proposed indications for the treatment of patients with early-stage low risk invasive breast cancer with cryoablation and adjuvant endocrine therapy. Among those that voted 'no', there were three panelists who stated that if the FDA applied adequate special controls, this would have swayed their opinion in favor of ProSense®'s benefit-risk profile.

Final ICE3 Results Reported with 100% Patient and Physician Satisfaction and 96.3% Recurrence Free Rate: The ICE3 study was the largest controlled multi-center clinical trial ever performed for liquid nitrogen-based cryoablation of low-risk, early-stage malignant breast tumors. The five-year recurrence-free rates from this groundbreaking study, which evaluated IceCure's minimally invasive 20-to-40-minute outpatient cryoablation procedure, were in line with expectations and show similar outcomes to lumpectomy, which is the current standard of care for early-stage breast cancer patients. The results were published in the prestigious peer-reviewed journal, *Annals of Surgical Oncology,* in an article titled, "Cryoablation Without Excision for Early–Stage Breast Cancer: ICE3 Trial 5–Year Follow–Up on Ipsilateral Breast Tumor Recurrence." The lead author of the study is Dr. Richard Fine, an ICE3 Investigator, who co-authored the publication with co-primary investigator, Dr. Kenneth Tomkovich, and 24 other doctors who are ProSense® users.

ICESECRET Kidney Cancer Study Interim Results Demonstrate 88.7% Recurrence-Free Rate: Interim results from our study of ProSense® in the treatment of kidney cancer reported an impressive 88.7% recurrence-free rate. Results were presented at the Israeli Urological Association Conference in December 2024. Kidney cancer is a largely unmet need, particularly in patients who are ineligible for kidney-preserving surgery. The interim results are highly relevant as ProSense® is approved as a cryosurgical tool in the destruction of malignant and benign tumors of the kidney in key markets.

Positive ProSense® Results Reported Through 33 Peer-Reviewed Journals and Medical Conferences: A number of prestigious medical conferences around the world and peer-reviewed journals reported on and published data regarding ProSense®'s efficacy and safety in breast, kidney, lung, bone, and soft tissue cancers. Several presentations won awards at prestigious medical conferences, including the Scientific Impact Award at the American Society of Breast Surgeons' Annual Meeting. The vast majority of the published data involved independent studies in breast cancer, and a large number of independent studies are currently ongoing.

Fortified Intellectual Property with More Patents Granted and Allowed: IceCure was granted and allowed four new patents in the U.S., Japan, and Europe covering our latest innovations, including its next-generation multi-probe cryoablation system, cryogenic pump, and cryogenic flow control technology.

FDA Granted Regulatory Clearance for XSense™ Cryoablation System with CryoProbes: The next-generation XSense™ system is cleared for the same indications that our flagship ProSense® system is currently approved for, and we believe it has future potential to address other indications in the U.S. for significant indications with unmet needs.

2025 Objectives

- We are hopeful that the FDA will grant market authorization for ProSense®for early-stage breast cancer in the first quarter of 2025 following the FDA Advisory Panel's positive vote in November 2024. Authorization, if granted, is expected to increase direct sales of ProSense® systems and disposable probes in the U.S, which is currently led by our VP of Sales North America, Mr. Shad Good, and our U.S. team.
- Greater market traction is expected in the other markets for ProSense® in breast cancer based on the positive final ICE3 data and the FDA Advisory Panel's positive vote in favor of ProSense®'s benefit-risk profile. Market authorization in the U.S., if granted, is expected to further propel regulatory approvals and global adoption.
- Terumo, our distributor in Japan, is expected to submit a request for breast cancer clearance to Japan's Pharmaceuticals and Medical Devices Agency.
- More peer-reviewed publications are expected from ongoing independent studies of ProSense® worldwide. Nine abstracts have already been accepted for publication in the first quarter of 2025 alone.
- In China, IceCure Shanghai is expected to submit ProSense® and its cryoprobes for regulatory approval to the National Medical Products Administration ('NMPA') in early 2025. IceSense3 and its disposable probes have already been approved by the NMPA.
- We continue to explore opportunities for strategic cooperation and partnership, driven by our recent advancements and innovations.

We wish you all a peaceful, healthy, and prosperous 2025.

Sincerely,
Eyal Shamir, CEO

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 its expected preliminary results for the financial year ended December 31, 2024; its objectives for 2025, its strategy; that the FDA's decision whether to grant market authorization to ProSense® for early-stage breast cancer is expected in the first quarter of 2025, and the effects of a positive decision on sales and regulatory approvals, its belief that the growing number of published studies will have a direct and favorable impact on the Company; that 2025 will be a pivotal year for the Company with continued penetration in the U.S. and global markets; its belief that the increased adoption of ProSense® by physicians is attributable to the cost-effective nature and its successful marketing efforts; that the ICESECRET interim results will lead to an increased adoption of ProSense®; its impending expansion of the global commercial rollout of ProSense® and disposable probes; the impending result, expected by the end of January 2025, of its appeal with regards to its ICE3 study; its focus on increasing sales of its systems across the globe through current and new distribution partner; Terumo Corporation's upcoming submission for clearance for ProSense® with the Pharmaceuticals and Medical Devices Agency in Japan in early 2025; its belief that its increased patent portfolio across different markets will increase adoption of the Company's technologies; that the FDA's regulatory clearance for XSense™ cryoablation system with cryoprobes will result in adoption by physicians for significant indications with unmet needs; and when it discusses

exploring strategic alternatives and seeking to establish cooperation with potential strategic partners. 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.

IR Contact:
Email: investors@icecure-medical.com
Michael Polyviou
Phone: 732-232-6914
Todd Kehrli
Phone: 310-625-4462

Logo: https://mma.prnewswire.com/media/2319310/IceCure_Medical_Logo.jpg

View original content:https://www.prnewswire.com/news-releases/icecure-medical-ceo-issues-letter-to-shareholders--reports-increase-of-42-in-prosense-sales-for-2024-in-north-america-302349202.html

SOURCE IceCure Medical