January 10, 2024

IceCure Medical CEO Issues Letter to Shareholders & Reports Increase in Sales in Preliminary Unaudited 2023 Results

- ***U.S. sales continue to increase with 25% jump in ProSense® system and disposable probe sales in 2023 over prior year***
- ***ICE3 study is set for completion and final data read out***

CAESAREA, Israel, Jan. 10, 2024 /PRNewswire/ -- IceCure Medical Ltd. (Nasdaq: ICCM) ("IceCure" or the "Company"), developer of the ProSense® System, a minimally-invasive cryoablation technology that destroys tumors by freezing as an alternative to surgical tumor removal, today issued the following letter to its shareholders from its Chief Executive Officer, Eyal Shamir.

Dear shareholders,

2023 was a year of strong growth for IceCure. Cryoablation became increasingly recognized as a highly favorable minimally invasive alternative to open surgery and ProSense® achieved an expanded global rollout with regulatory clearances received in significantly large markets such as Brazil, Canada, and China. Furthermore, the trend toward performing cryoablation procedures is increasing amongst breast surgeons and breast radiologists. We believe that the growing abundance of peer-reviewed journals publishing ProSense® and cryoablation studies will have a direct and favorable impact on IceCure as we continue to expand our global distribution footprint. We are very optimistic about 2024 and believe it will be a pivotal year marked by the completion of our ICE3 breast cancer study and continued penetration in the U.S. and global markets.

2023 Key Achievements

Increased Revenues, System, and Probe Sales: Based on our expected preliminary unaudited 2023 results, ProSense® system and disposable probe sales increased by 26% globally over 2022. Product sales in the U.S. were up 25% in 2023 over 2022 levels. On a preliminary unaudited basis, total revenues increased for the financial year ended December 31, 2023 to $3.2 million, as compared to $3.1 million in 2022. An increase in system and probe sales was partially offset by a decrease in revenue recognition from our distribution agreement with Terumo Corporation. On a preliminary unaudited basis, as of December 31, 2023, we had cash and cash equivalents, including short-term deposits, of $11 million. During the fourth quarter of 2023 we implemented an expense reduction plan to reduce our non-revenue generating and clinical development costs, lowering monthly cash utilization, to help ensure that we meet our primary goals in 2024.

The above information reflects preliminary unaudited estimates with respect to certain results of IceCure for the full year ended December 31, 2023, based on currently available information. Because the audit for 2023 is not yet complete, the Company's final results may vary from the preliminary estimates provided herein.

Growing Adoption Among World's Leading Physicians as Evidenced by 17 Ongoing Independent Studies Across Several Indications: Our expected 2023 revenue momentum and the growing number of independent, non-sponsored studies of ProSense® point to an increased adoption of ProSense® around the world across several indications. Twelve non-sponsored studies that demonstrate ProSense®'s safety and efficacy, in line with results reported in our own studies, have been published in peer reviewed journals and presented at scientific conferences to date. Our two studies, ICE3 for breast cancer and ICESECRET for kidney cancer, and 17 independent, non-sponsored studies are ongoing. Thirteen of the published and ongoing studies are for breast cancer with the remaining studies focused on fibroadenomas, endometriosis, and malignant or benign tumors of the lung, kidney, and musculoskeletal system. The increased adoption by physicians of ProSense® is attributable to a clear need in the market for a safe, effective, and more cost-efficient alternative to open surgery, combined with IceCure's well-executed awareness and marketing efforts at world leading medical conferences for breast care and interventional radiology. 2023 marked a key year for cryoablation in the U.S. as the American Society of Breast Surgeons (ASBrS) 2023 Annual Meeting featured a first-of-its-kind continuing medical education (CME) course for cryotherapy that used the ProSense® system in its demonstration. The ASBrS also presented its plan for a proposed ASBrS breast cancer cryoablation trial during the cryotherapy CME course.

Completing ICE3 Breast Cancer Study in the U.S.: Only 10 patients remain who need to undergo their five-year follow-up examinations in our ICE3 study, the largest of its kind in the U.S. We expect that the last patient will return for her final follow-up examination in the first quarter of 2024.

ICESECRET Kidney Cancer Study Continues: Interim results from our study of ProSense® in the treatment of kidney cancer had reported an impressive 89.5% recurrence-free rate based on interim results at the end of 2022. We expect ICESECRET's five-year patient follow-up to be completed in 2026.

Regulatory Approvals Received in Key Global Markets: Further expanding and

supporting the global commercial rollout of ProSense®, our cryoablation system, and disposable probes now have regulatory approval in 15 countries, including countries where approval was granted in 2023 such as China, Canada, and Brazil.

Seeking to Expand Approvals in the U.S. to Include Breast Cancer: ProSense® is currently approved by the U.S. Food and Drug Administration (FDA) in general minimally invasive cryoablation procedures including kidney, liver, neurology, and fibroadenoma. We are focused on attaining FDA clearance to market ProSense® to address a significant unmet need for a minimally invasive option to treat early-stage breast cancer. In 2022, we had filed a De Novo Classification request with the FDA for regulatory approval of ProSense® for the indication of early-stage low-risk breast cancer in patients who are at high risk for surgery, based on interim data from ICE3. We received a denial from the FDA on our De Novo request in September 2023 and subsequently filed an appeal. The FDA's decision has no bearing on patients in the U.S. for indications already cleared by the FDA. Our appeal with the FDA focused on the FDA's choice of comparator group for our ICE3 interim study data. We believe that an appropriate comparator group agreement with the FDA and subsequent analysis of the data may lead to marketing clearance for ProSense® in this indication. We anticipate a response to the appeal from the FDA by the end of January 2024. Our continued commitment to the U.S. market, which represents more than 300,000 breast cancer patients diagnosed annually, was further demonstrated this past year when we appointed Shad Good as our Vice President of Sales for North America. Mr. Good brings nearly 20 years of medical device sales and leadership experience, including as a global leader in minimally invasive breast diagnostic and therapeutic systems. He is focused on potential targeted users of ProSense® throughout the U.S. and Canada and continuing to accelerate sales momentum.

Increased Distributors and Global Installations: In 2023, we entered a non-exclusive distribution agreement with Medicinália Cormédica – MC Medical, Lda., the largest distributor of third-party medical devices in Portugal, further expanding the distribution of ProSense® in Europe where the system has the European Union's CE mark of regulatory approval. In India, ProSense® was used to perform the country's first breast cryoablation procedure at a hospital where our system was installed earlier in the year. Having received regulatory approval in Brazil, sales are expected through our $6.6 million, 5-year distribution agreement with Ktrfios Importa*ção* e Exporta*ção* LTDA.

2024 Objectives

- Driven by growing awareness of ProSense®'s safety and efficacy in breast cancer and numerous other indications, as demonstrated through the 17 independent and two IceCure studies, we are focused on increasing sales of our systems and disposable probes with corresponding revenues across the globe through current and new distribution partners.
- Broadening ProSense®'s adoption as a breast cancer treatment, IceCure's Japanese partner, Terumo Corporation is expected to submit the request for clearance under a breast cancer indication with the Pharmaceuticals and Medical Devices Agency in Japan in the second half of 2024.
- The ICE3 study is expected to be completed by the end of the first quarter of 2024.
- Top-line results from ICE3 are expected in the second quarter of 2024. We believe these data, if favorable and in line with the interim results that demonstrated an

estimated 95.7% five-year recurrence free rate, may lead to additional regulatory approvals and increased sales in territories where ProSense® is already approved for breast cancer.
- We anticipate a response from the FDA to our appeal by the end of January 2024 and are hopeful for a positive response as we continue to work closely with the FDA towards an outcome that would make ProSense® available to women in the U.S. who seek a non-surgical, minimally invasive option for early-stage breast cancer.
- Our next-generation single-probe cryoablation system is expected to be introduced in 2024.

We start 2024 with hope and wishes for a peaceful, healthy, and prosperous year for all.

Sincerely,

Eyal Shamir, CEO
IceCure Medical

About ProSense®

The ProSense® Cyroablation System provides a minimally invasive treatment 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 procedure for breast tumors.

About IceCure Medical

IceCure Medical (Nasdaq: ICCM) develops and markets ProSense®, an advanced liquid-nitrogen-based cryoablation therapy for the treatment 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 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 statement in this press release when it discusses its expected preliminary results for the financial year ended December 31, 2023, the Company's strategy, the belief that the growing number of published studies will have a direct and favorable impact on the Company, that 2024 will be a pivotal year with the completion of the ICE3 study and continued penetration in the U.S.

and global markets, that the implementation of its expense reduction plan will help ensure the Company meets its primary goals in 2024, its belief that the increased adoption of ProSense® by physicians is attributable to the cost-effective nature and its successful marketing efforts, its upcoming follow-up examinations in the ICE3 study in the first quarter of 2024 that would mark the study's completion and about which its top-line results are expected in the second quarter of 2024, that the ICESECRET five-year patient follow-up is to be completed in 2026, its impending expansion of the global commercial rollout of ProSense® and disposable probes, the impending result, expected by the end of January 2024, of the Company's appeal with regards to its ICE3 study, the Company's 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 the second half of 2024, and that the Company's next-generation single-probe cryoablation system is expected to be introduced in 2024. 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, 2022 filed with the SEC on March 29, 2023, 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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