April 3, 2024

IceCure Medical Reports Full Year 2023 Financial Results: Global ProSense® and Disposables Sales Increase 26% as Company Continues Transition to Commercial Phase and Expects to Submit ICE3 Breast Cancer Study Data to FDA this Month for Marketing Clearance

Conference call to be held today at 10:00 am Eastern Time; Focus on U.S. market for ProSense® in breast cancer indication

CAESAREA, Israel, April 3, 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 reported sales as of and for the twelve months ended December 31, 2023 increased 26% compared to the twelve months ended December 31, 2022, as the Company continues to transition from a research and development and clinical phase company to a commercial phase company.

2023 Key Financial Highlights:

- Product sales globally rose 26%
- Product sales in the U.S. grew 24%
- Cash and cash equivalents of $11.1 million at December 31, 2023
- During the first quarter of 2024, the Company raised $3 million in gross proceeds from the sale of ordinary shares under its At-the-Market ("ATM") offering facility, ending the quarter with cash and cash equivalents of approximately $11 million, which the

Company believes provides the resources to execute its clinical, regulatory and commercial objectives for 2024.

"We have achieved what we believe is the most significant milestone in our company's history with the completion of the ICE3 breast cancer study and reporting of topline results," stated IceCure's CEO, Eyal Shamir. "In the next few weeks, we will be reporting full results and submitting them to the FDA for review. We believe the data from ICE3 and numerous independent studies of ProSense® in breast cancer support our thesis that ProSense® can have a very meaningful positive impact on the health and wellbeing of women with early-stage breast cancer. Our U.S. commercial team is ready to launch marketing and distribution of ProSense® for breast cancer as we await the U.S. Food and Drug Administration's ("FDA") decision. Should the FDA grant clearance, we believe this decision would further boost commercial demand in global markets where ProSense® already has approval for breast cancer."

"We are pleased that the ICE3 full data results will be presented at the highly influential American Society of Breast Surgeons ("ASBrS") 25th Annual Meeting by ICE3 Investigator Dr. Richard Fine and by Dr. Michael Berry. Breast surgeons considering ProSense® for their practice are eager to see the results, and we are hopeful that they will be impressed by the data."

"Physician initiated studies in many other indications continue to increase in Europe, the U.S., and Asia. The growing number of independent studies, we believe, is a very strong indicator of future adoption."

"As we increased our commercial activities through medical conferences and added more distributors, we had a corresponding growth in 2023 revenues, system, and probe sales. While total revenues in 2023 were up slightly to $3.2 million, compared to $3.1 million in 2022, a more meaningful increase of 26% or $0.6 million in ProSense® system and disposable probe sales demonstrates continued increasing demand."

2023 and Recent Significant Operating, Clinical, Regulatory & Commercial Highlights:

Completed ICE3 Breast Cancer Study and Reported Topline Results: IceCure successfully completed a 10-year long landmark study, the largest controlled multicenter clinical trial ever performed for liquid nitrogen (LN2) based cryoablation of low-risk, early-stage malignant breast tumors. In the ICE3 study, 96.39% of patients (187 out of 194 patients) were local recurrence-free with no significant device-related adverse events or complications reported. These results are in line with data from numerous third-party studies conducted by physicians currently using ProSense®.

Full ICE3 Data to be Submitted to FDA: The Company plans to complete the analysis and evaluation of the full data set and expects to submit the results to the FDA in April 2024. The FDA requested this data as part of IceCure's De Novo Classification Request for Marketing Authorization of ProSense® for the treatment of early-stage low-risk breast cancer.

ICE3 Full Results to be Presented at ASBrS's 25th Annual Meeting: Dr. Richard Fine, ICE3 Investigator, will present the full ICE3 study results at the ASBrS's annual meeting, the most prominent event in the U.S. for breast surgeons, in a presentation titled "Cryoablation Without Excision for Early-Stage Breast Cancer; ICE3 Trial 5 year follow up on Ipsilateral

Breast Tumor Recurrence". Additionally, ICE3 Investigator Dr. Michael Berry will present a session titled "Cryoablation: Is It Ready for Primetime?".

Regulatory Approval Received in Brazil, Canada, and China: ProSense® now has regulatory approvals in 15 countries for a broad range of indications.

Global Rollout Momentum with New Distribution and Installations in Portugal, India, and Brazil: IceCure entered a non-exclusive distribution agreement with Medicinália Cormédica – MC Medical, Lda., the largest distributor of third-party medical devices in Portugal. The first breast cryoablation procedure in India was performed in 2023 with ProSense® and there has been strong interest in the country at medical conferences where IceCure's cryoablation system was featured. In Brazil, where ProSense® received regulatory approval in 2023, IceCure's in-country distributor has launched commercial activities and procedures have commenced.

Independent Investigator Initiated Studies Build Data to Support Potential New Indications, Adoption, and Reimbursement: Numerous third-party studies have been initiated to evaluate ProSense® in various indications. Results from completed studies have been presented at medical conferences and published in peer-reviewed journals including studies from Spain and Italy that demonstrated ProSense®'s efficacy in early-stage breast cancer, with data similar to ICE3's topline results. Two endometriosis studies in France revealed ProSense®'s potential in treating a condition that afflicts 190 million women globally. With current treatments only aiming to control symptoms and no curative option available, endometriosis is an indication for which ProSense® may deliver significant benefits to patients and payors alike. Another study in France reported a 92% disease-free survival rate in kidney cancer patients treated with ProSense®. These data support further adoption and reimbursement, particularly in countries where ProSense® has already been approved for these indications. Elucidating ProSense®'s efficacy in cancer, a study at Case Western Reserve University in the U.S., demonstrated that ProSense® boosts immune response against caner by enhancing CD8+ T cell response.

IP Portfolio and Technology Pipeline Continue to Grow: IceCure added three more patents to its expanding cryoablation-focused IP portfolio. In March 2024, IceCure was issued a patent in Japan for a novel cryogen flow control system to optimize patient outcomes. The U.S. and Japan both issued patents to IceCure for a novel cryogenic pump for its next-generation cryoablation systems. In April 2024, the Company filed a 510(k) submission with the FDA for its next-generation single probe XSense™ System and cryoprobes for all the indications for which ProSense® has already received the requisite FDA clearance.

Financial Results for the Twelve Months Ended December 31, 2023

Revenues for the twelve months ended December 31, 2023 were $3.2 million compared to $3.1 million for the twelve months ended December 31, 2022. The minor increase is due to the increase in ProSense® systems and disposables sales which was offset by the decrease in revenue recognition from the exclusive distribution rights agreement with Terumo Corporation in Japan. For the twelve months ended December 31, 2023, the Company reported a 26% increase in ProSense® systems and disposable probes sales to $3 million, compared to $2.3 million for the twelve months ended December 31, 2022, driven by higher sales in the U.S. and other territories.

Gross profit was $1.3 million for the twelve months ended December 31, 2023 compared to $1.4 million for the twelve months ended December 31, 2022. Gross margin was 40% for the twelve months ended December 31, 2023, compared to 47% for the twelve months ended December 31, 2022. Non-GAAP gross profit and non-GAAP gross margin for the year ended December 31, 2023, increased by $0.3 million, or 47%, to $1 million, compared to $0.7 million for the year ended December 31, 2022. The increase in non-GAAP gross profit and non-GAAP gross margin, without taking into consideration revenue from the exclusive distribution agreements, is attributable to the increase of 26% in revenue from sales of ProSense® systems and probes while the increase in cost of revenues was 18%.

Research and development expenses for the twelve months ended December 31, 2023, were $8.3 million compared to $9.1 million for the twelve months ended December 31, 2022. The decrease was primarily due to the depreciation of NIS against the USD on NIS-denominated expenses such as payroll and related benefits, a reduction in our development expenses for the XSense™ System, and a decrease in clinical and regulatory costs.

In support of ongoing global commercial adoption and in anticipation of increasing U.S. commercial efforts, sales and marketing expenses for the twelve months ended December 31, 2023 were $4.4 million, compared to $3.2 million for the twelve months ended December 31, 2022. General and administrative expenses for the twelve months ended December 31, 2023 decreased by 30% to $4.2 million, compared to $5.9 million the twelve months ended December 31, 2022. A portion of the decrease was due to a decrease in director and officer insurance costs and the depreciation of NIS against USD on NIS denominated expenses such as payroll and related benefits.

Total operating expenses for the twelve months ended December 31, 2023 decreased to $16.9 million, compared to $18.2 million for the twelve months ended December 31, 2022. The decrease in operating expenses was attributable to reductions in research and development expenses and general and administrative expenses, which were partially offset by the increase in sales and marketing expenses.

Net loss for the twelve months ended December 31, 2023 decreased by 14% to $14.7 million, or $0.32 per share, compared with a net loss of $17.0 million, or $0.46 per share, for the same period last year.

As of December 31, 2023, the Company had cash and cash equivalents, including short-term deposits, of approximately $11.1 million, compared to $23.7 million as of December 31, 2022. As of March 31, 2024, the Company had cash and cash equivalents, including short-term deposits, of approximately $11 million. To ensure the Company is in a position to achieve its near-term objectives, IceCure has implemented an expense reduction plan that will reduce its non-revenue generating and clinical efforts costs, lowering the monthly cash utilization and ensuring it can meet its primary goals in 2024.

Use of Non-U.S. GAAP Measures

In addition to disclosing financial results prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP), this press release contains non-U.S. GAAP financial measures that the Company uses as measures of its performance.

These measures may be different from non-GAAP financial measures used by other companies. The Company calculates (i) non-GAAP gross profit as gross profit, less revenue

from exclusive distribution agreements, as an indication of our gross profit from sales of our systems and disposables; and (ii) non-GAAP gross margin is a percentage of non-GAAP gross profit from revenues from sales of systems and disposables which reflects the gross margins on our systems and disposables sales. These non-GAAP financial measures are included as a supplemental disclosure because they are performance measures used by our management and board of directors to determine the commercial performance of our business. These non-GAAP measures should be viewed as a supplement to and not a substitute for the Company's U.S. GAAP measures of performance and financial results in accordance with U.S. GAAP and reconciliations from these results should be carefully evaluated. We have provided a reconciliation below of non-GAAP gross profit and non-GAAP gross margin to the most directly comparable financial measure calculated and presented in accordance with U.S. GAAP.

Conference call & webcast info:

Wednesday, April 3, 2024, at 10:00 am EDT
US: 1-888-407-2553
Israel/International: +972-3-9180696
A live webcast will be available at: https://veidan.activetrail.biz/IcecureQ4-2023
A recording of the webcast will be available at: ir.icecure-medical.com/

About ProSense®

The ProSense® Cryoablation 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

statements in this press release when it discusses: that the Company will report and submit full results upon the completion of the ICE3 breast cancer study, that the Company believes the data from ICE3 and independent studies of ProSense® shows that ProSense® can have a very meaningful positive impact on the health and wellbeing of women with early-stage breast cancer, that prospective FDA clearance would boost commercial demand for ProSense® where it already has regulatory approval, and the belief that the growing number of independent studies is a strong indicator of future adoption. 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 U.S. Securities and Exchange Commission (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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CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share data and per share data)

	As of December 31, 2023	As of December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	10,533	23,659
Short-term deposit	529	-
Restricted deposit	-	296
Trade receivables	103	78
Inventory	2,275	2,857
Prepaid expenses and other receivables	744	1,240
Total current assets	14,184	28,130
NON-CURRENT ASSETS		
Right of use assets	679	668
Property and equipment, net	1,513	1,356
Prepaid expenses and other long-term assets	34	34
Total non-current assets	2,226	2,058
TOTAL ASSETS	16,410	30,188
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade payables	502	714
Lease liabilities	223	167
Other current liabilities	3,146	3,455
Total current liabilities	3,871	4,336
NON-CURRENT LIABILITIES		
Long term lease liabilities	376	430
Total non-current liabilities	376	430
Commitments and contingencies		
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 45,729,684 shares and 45,623,434 shares as of December 31, 2023 and December 31, 2022, respectively	-	-
	-	-
Additional paid-in capital	102,224	100,831
Accumulated deficit	(90,061)	(75,409)
Total shareholders' equity	12,163	25,422
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	16,410	30,188

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(U.S. dollars in thousands, except share data and per share data)

	Year ended December 31, 2023	Year ended December 31, 2022
Revenues	3,229	3,085
Cost of revenues	1,929	1,640
Gross profit	1,300	1,445
Research and development expenses	8,273	9,123
Sales and marketing expenses	4,437	3,204
General and administrative expenses	4,166	5,857
Operating loss	15,576	16,739
Financial expenses (income), net	(924)	239
Net loss and comprehensive loss	14,652	16,978
Basic and diluted net loss per share	0.32	0.46
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	45,638,030	37,016,631

CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands, except share data and per share data)

	Year ended December 31, 2023	Year ended December 31, 2022
Cash flows from operating activities:		
Net loss	(14,652)	(16,978)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	323	248
Share-based compensation	1,310	1,865
Exchange rate changes in cash and cash equivalents and deposit	(25)	359
Changes in assets and liabilities:		
Decrease (increase) in trade receivables	(25)	378
Decrease (increase) in inventory	582	(902)
Decrease (increase) in prepaid expenses and other receivables	496	1,050
Decrease (increase) in right of use assets	182	245
Increase (decrease) in trade payables	(212)	(167)
Increase (decrease) in lease liabilities	(191)	(312)
Increase (decrease) in other current liabilities	(309)	540
Increase (decrease) in other long-term liabilities	-	(618)
Net cash used in operating activities	(12,521)	(14,292)
Cash flows from investing activities:		
Realization of (Investment in) deposits	(529)	-
Realization of (investment in) restricted deposits	296	-
Purchase of property and equipment	(480)	(891)
Net cash provided by (used in) investing activities	(713)	(891)
Cash flows from financing activities:		
Issuance of ordinary shares, net of issuance costs	-	13,569
Issuance of restricted ordinary shares	-	6
Issuance of ordinary shares and pre- funded warrants, net of issuance costs	-	-
Exercise of pre- funded warrants	-	1
Exercise of options to ordinary shares	83	1
Net cash provided by financing activities	83	13,577
Increase (decrease) in cash and cash equivalents	(13,151)	(1,606)
Cash and cash equivalents beginning of the year	23,659	25,621
Effect of foreign exchange rate on cash and cash equivalents	25	(356)
Cash and cash equivalents end of the year	10,533	23,659
Non-cash activities		
Obtaining a right-of-use asset in exchange for a lease liability	193	-

RECONCILIATIONS OF US GAAP TO NON-US GAAP FINANCIAL MEASURES

U.S. dollars in thousands	Year Ended December 31, 2023		Year Ended December 31, 2022	
GAAP revenues	$ 3,229		$ 3,085	
GAAP gross profit	$ 1,300		$ 1,445	
GAAP gross margin %	40	%	47	%
Less:				
Revenue from exclusive distribution agreement	(274)		(747)	
Revenues from sales of systems and disposables	2,955		2,338	
Non-GAAP gross profit	1,026		698	
Non-GAAP gross margin %	35	%	30	%

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