March 29, 2023

IceCure Medical Reports 2022 Full Year Financial Results & Recent Corporate Developments; Milestone Achievements Expected to Drive Revenue Growth in 2023

- ***Rising Utilization of ProSense in the U.S. Market Generates Year-over-Year Consumable Revenue Growth***
- ***Physician Adoption Continues to Grow Ahead of the FDA's Response to the Company's Application for Marketing Approval in Breast Cancer Indication***
- ***Regulatory Approval Received in China for Commercial Use of IceSense3 Disposable Cryoprobes, to be Used in Combination with its IceSense3 Cryoablation System Console, Which was Previously Approved in China***
- ***Cryoablation System and Cryoprobes to be Sold in China Through Exclusive Distribution Partnership***
- ***Conference Call to be Held Today at 10:00 am Eastern Time***

CAESAREA, Israel, March 29, 2023 /PRNewswire/ -- IceCure Medical Ltd. (Nasdaq: ICCM) (TASE: ICCM) developer of the ProSense System of minimally-invasive cryoablation technology that destroys tumors by freezing, today reported audited financial results as of and for the twelve months ended December 31, 2022.

"Our success throughout 2022 and the trends we are currently experiencing position us to make significant commercial advances in key markets, including in the U.S., for the ProSense platform for early-stage breast cancer and in China where our cryoprobes recently received approval for commercial use in combination with our cryoablation system console, which was previously approved. Commercialization in China is driven by our exclusive

distribution agreement with Shanghai Medtronic Zhikang Medical Devices Co. Ltd., an affiliate of Medtronic ("Shanghai Medtronic Zhikang"), the world's largest medical device company, which includes minimum purchase targets," stated Eyal Shamir, IceCure's Chief Executive Officer. "We believe that our achievements in 2022, which included regulatory, reimbursement, clinical, and commercial milestones, provide us with a solid foundation to execute our growth strategy to drive revenues in the years to come.

"Our rising confidence is bolstered by accelerated sales of our disposable cryoprobes in the U.S., demonstrating that the previously installed ProSense systems are increasingly being utilized by physicians. We also believe our strengthened balance sheet, which includes the $14.5 million we raised in December 2022, allows us to expand our global marketing footprint. The capital resources we have will enable us to execute on our commercialization plans throughout 2023 and beyond while ensuring we can also invest in future generations of our novel technology."

Significant Operating, Clinical, Regulatory & Commercial Highlights

- **Rising Awareness and Utilization of ProSense System:** System and disposables sales in the U.S. represented 20% of 2022 revenues, up from 11% in 2021, as increased utilization of systems generated a 28% year-over-year increase in U.S. sales. Worldwide, disposable sales accounted for 43% of 2022 revenue, up from 29% in 2021.
- **Filed for FDA Marketing Authorization of ProSense for Breast Cancer:** The Company submitted a De Novo Classification Request regulatory filing with the U.S. Food and Drug Administration ("FDA") for marketing authorization based on ICE3 clinical trial ("ICE3") interim analysis for the indication of early-stage (Luminal A T1 invasive) low-risk breast cancer in patients who are at high risk to surgery (not suitable for surgical alternatives). This indication alone represents approximately 43,000 women in the U.S. annually.
- **Initial Medicare Reimbursement Code for ProSense Established:** The Centers for Medicare & Medicaid Services ("CMS") assigned ProSense breast cancer cryoablation procedures with a CPT Category III reimbursement code setting the facility fee at $3,400 per procedure. Additional reimbursement coverage, including payment for the physician, is expected upon CMS establishing the permanent CPT Category I code, which is conditioned on several factors, particularly the Company's receipt of FDA marketing authorization of ProSense for breast cancer.
- **Received Regulatory Approval in China for Commercial Use of Cryoprobes in 2023:** The National Medical Products Administration ("NMPA") of China approved the IceSense3 (ProSense's brand name in China) disposable cryoprobes for commercial use, to be used in combination with the Company's IceSense3 system console, which was previously approved by the NMPA.
- **Signed China Distribution Agreement with Shanghai Medtronic Zhikang Medical Devices Co. Ltd.:** IceCure's wholly-owned subsidiary, IceCure (Shanghai) MedTech Co., Ltd. ("IceCure Shanghai"), signed an exclusive distribution agreement for IceSense3 cryoablation systems with Shanghai Medtronic Zhikang and Beijing Turing Medical Technology Co. Ltd. ("Turing"), to be the exclusive distributors of the IceSense3 and its disposable probes in mainland China for an initial period of three years, with minimum purchase targets of $3.5 million for this period.
- **Patents Granted in U.S. and Japan:** IceCure received patents in the U.S. and Japan

for its novel cryogenic pump, potentially broadening the clinical indications addressed by the Company's platform technology.

- **Achieved Regulatory Milestones in Major Global Markets—Additional Responses Expected in 2023:** ProSense cryoprobes and introducers received regulatory approval in Brazil for several indications, including breast and other cancers, benign tumors, and palliative intervention. Approval for the ProSense system is currently pending in Brazil, and a response from the Brazilian Health Regulatory Agency ("ANVISA") is expected in 2023. Applications for regulatory approval of ProSense and its accessories were filed in Canada and Vietnam.
- **Presented Interim Study Results Showing ProSense is Safe and Effective in Treating Kidney Tumors with 89.5% Recurrence-Free Rate:** At the Urological Association Conference in Israel, the Company presented interim findings from its ICESECRET study for the treatment of patients with small renal masses ("SRM") who cannot be offered kidney-preserving surgery. ProSense was found to be a safe and effective treatment method for renal lesions smaller than 5 cm in patients not suitable for kidney-preserving surgery. In a subgroup of patients with no previous history of kidney cancer on the same kidney and a lesion ≤3 cm, an 89.5% recurrence-free rate was observed at a mean follow-up time of 22.2 months when the procedure protocol was followed. ProSense is approved for the treatment of benign and malignant kidney tumors in the U.S., Europe, and numerous other countries.

Strengthened Balance Sheet

As of December 31, 2022, the Company had cash and cash equivalents including short-term deposits of approximately $23.7 million, compared to approximately $25.6 million as of December 31, 2021. The Company will use its resources to execute its global business strategy and continue to raise awareness of the clinical and economic benefits of its ProSense system.

Financial Results for the Twelve Months Ended December 31, 2022

For the twelve months ended December 31, 2022, the Company reported revenue of $3.1 million compared to revenue of $4.1 million for the twelve months ended December 31, 2021. As previously disclosed on February 9, 2023, the year-over-year decline was due to lower revenue recognition of approximately $0.6 million from the distribution agreements with Terumo Corporation and a decrease in sales of new systems, mostly in Thailand. This was partially offset by higher revenue from sales of the Company's disposable probes, as previously sold and installed systems were utilized for procedures in clinical settings, as well as higher sales in the U.S. compared to the prior year period.

Gross profit was approximately $1.4 million for the twelve months ended December 31, 2022, compared to approximately $2.1 million for the twelve months ended December 31, 2021. Gross margin was approximately 47% for the twelve months ended December 31, 2022, compared to approximately 53% for the twelve months ended December 31, 2021. The decrease in gross margin compared to the same period last year was attributable to the decrease in revenue recognition from the Terumo distribution agreements.

Research and development expenses for the twelve months ended December 31, 2022, were approximately $9.1 million compared to approximately $5.9 million for the twelve months ended December 31, 2021. The increase was primarily due to the development of

IceCure's next-generation single-probe system, along with increased clinical and regulatory activities, including the FDA and NMPA submissions.

Sales and marketing expenses for the twelve months ended December 31, 2022 were approximately $3.2 million, compared to approximately $1.9 million for the twelve months ended December 31, 2021. The increase was attributed to the Company's expanding commercialization efforts in the U.S. and other territories.

General and administrative expenses for the twelve months ended December 31, 2022 were approximately $5.9 million, compared to approximately $4.1 million for the twelve months ended December 31, 2021. The increase was attributed to the Company's increased Nasdaq listing-related expenses.

Total operating expenses for the twelve months ended December 31, 2022 were approximately $18.2 million, compared to approximately $11.9 million for the twelve months ended December 31, 2021. The increase in operating expenses was primarily attributable to increased development, commercialization, and Nasdaq listing-related activities. As a result of lower revenue and increased operating activities, net loss reported for the twelve months ended December 31, 2022 increased to approximately $17.0 million, or $0.46 per share, compared with a net loss of approximately $9.9 million, or $0.35 per share, for the same period last year.

Conference call information:

The Company will discuss its results today via teleconference at 10:00 a.m. Eastern Time. To access the live call, dial 1-888-642-5032 (U.S. toll-free) or +972-3-9180609 (International) and ask to join the IceCure earnings call. An archived recording of the call will also be accessible on the "Investors" section of our website at www.icecure-medical.com.

About IceCure Medical

IceCure Medical (Nasdaq: ICCM) (TASE: 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 to-date by the FDA and approved in Europe with the CE Mark.

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 and Israeli 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 positioning to make significant commercial advances in key markets, its ability to execute its growth strategy and drive revenues, expected financial results and continued growth, the belief that the Company's

achievements provide it with a solid foundation to execute its growth strategy to drive revenues in the years to come, its ability to expand its global marketing footprint and execute its commercialization plans, anticipating the FDA's response to regulatory requests for approvals, the continued commercial rollout and commercial growth of its products, pursuit of and timing for regulatory approvals in various jurisdictions, its strategic plans, and expansion of clinical applications and potential market adoption of its minimally-invasive cryoablation technology. Because such statements deal with future events and are based on IceCure's current expectations, they are subject to various risks and uncertainties and actual results, performance, or achievements of IceCure could differ materially from those described in or implied by the statements in this press release. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, many of which are beyond the control of the Company, including those 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 April 1, 2022, 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, 2022	As of December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	23,659	25,621
Restricted deposit	296	-
Trade accounts receivable	78	456
Inventory	2,857	1,955
Prepaid expenses and other receivables	1,240	2,290
Total current assets	28,130	30,322
NON-CURRENT ASSETS		
Right of use assets	668	913
Property and equipment, net	1,356	713
Prepaid expenses and other long-term assets	34	333
Total non-current assets	2,058	1,959
TOTAL ASSETS	30,188	32,281
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade accounts payable	714	881
Lease liabilities	167	224
Other current liabilities	3,455	2,915
Total current liabilities	4,336	4,020
NON-CURRENT LIABILITIES		
Long term lease liabilities	430	685
Other long-term liabilities	-	618
Total non-current liabilities	430	1,303
Commitments and contingencies		
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 45,623,434 shares and 35,780,335 shares as of December 31, 2022 and December 31, 2021, respectively	-	-
Pre-funded warrants to ordinary shares, Issued and outstanding: zero Pre-funded warrants and 1,034,000 Pre-funded warrants as of December 31, 2022 and December 31, 2021, respectively	-	-
Additional paid-in capital	100,831	85,389
Accumulated deficit	(75,409)	(58,431)
Total shareholders' equity	25,422	26,958
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	30,188	32,281

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

	Year ended December 31, 2022	Year ended December 31, 2021
Revenues	3,085	4,138
Cost of revenues	1,640	1,943
Gross profit	1,445	2,195
Research and development expenses	9,123	5,877
Sales and marketing expenses	3,204	1,917
General and administrative expenses	5,857	4,125
Operating loss	16,739	9,724
Financial expenses (income), net	239	171
Net loss and comprehensive loss	16,978	9,895
Basic and diluted net loss per share	0.46	0.35
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	37,016,631	28,548,676

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

	Year ended December 31, 2022	Year ended December 31, 2021
Cash flows from operating activities:		
Net loss	(16,978)	(9,895)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	248	127
Share-based compensation	1,865	316
Exchange rate changes in cash and cash equivalents and deposit	359	5
Changes in assets and liabilities:		
Decrease (increase) in trade accounts receivable	378	(362)
Increase in inventory	(902)	(891)
Decrease (increase) in prepaid expenses and other receivables	1,050	(2,030)
Decrease in prepaid expenses ~ and other long- term assets	-	-
Decrease (increase) in right of use assets	245	(607)
Increase (decrease) in trade accounts payable	(167)	236
Increase (decrease) in lease liabilities	(312)	577
Increase (decrease) in other current liabilities	540	60
Increase (decrease) in other long-term liabilities	(618)	(141)
Net cash used in operating activities	(14,292)	(12,605)
Cash flows from investing activities:		
Realization of (Investment in) deposits	-	4,621
Investment of restricted deposits	-	(296)
Purchase of property and equipment	(891)	(533)
Net cash provided by (used in) investing activities	(891)	3,792
Cash flows from financing activities:		
Issuance of ordinary shares, net of issuance costs	13,569	14,586
Issuance of restricted ordinary shares	6	-
Issuance of ordinary shares and pre- funded warrants, net of issuance costs	-	15,966
Exercise of pre- funded warrants	1	-
Exercise of options to ordinary shares	1	337
Net cash provided by financing activities	13,577	30,889
Increase (decrease) in cash and cash equivalents	(1,606)	22,076
Cash and cash equivalents beginning of the year	25,621	3,502
Effect of foreign exchange rate on cash and cash equivalents	(356)	43
Cash and cash equivalents end of the year	23,659	25,621

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