August 20, 2024

IceCure Medical Reports 20% Growth in ProSense® System and Probe Sales for the First Half of 2024; Reflects Continued Adoption in the U.S. and Other Global Markets

Near-term regulatory and operating catalysts have potential to accelerate adoption of ProSense® for treatment of early-stage, low risk breast cancer

Conference call to be held today at 10:00 am Eastern Time

CAESAREA, Israel, Aug. 20, 2024 /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 reported financial results as of and for the six months ended June 30, 2024.

Significant Near and Short Term Value Enhancing Catalysts

- U.S. Food and Drug Administration ("FDA") Medical Device Advisory Committee expected Q4 2024. The purpose of the meeting is to obtain independent expert advice on scientific, technical, and policy matters related to the Company's De Novo Marketing Clearance Request for a minimally invasive alternative treatment for women diagnosed with early-stage, low risk breast cancer.
- The FDA will review and evaluate the recommendation of the Medical Device Advisory Committee and is expected to have a final decision regarding marketing clearance of ProSense® in early-stage, low risk breast cancer by early 2025.
- Data from interim results of the Company's ICESECRET, a prospective, multicenter, single-arm clinical trial of ProSense® in the treatment of kidney cancer, is expected to be presented by December 2024.

- The Company's partner in Japan, Terumo Corporation, is expected to file for regulatory approval of ProSense® for early-stage low risk breast cancer with endocrine therapy in Japan in the first quarter of 2025, with the aim of receiving clearance and making the Company's cryoablation system more commercially available to physicians and patients alike in Japan.
- With 15 ongoing independent studies being performed globally, the Company expects additional third-party data on ProSense® will be published in medical journals and presented at prestigious medical conferences.

"We have achieved all of our primary objectives for the first half of 2024, and we are now in the process of preparing for the FDA Medical Device Advisory Committee, which we expect to be scheduled for Q4," stated IceCure Medical's CEO, Eyal Shamir. "The data from the ICE3 study has been overwhelmingly positive, and with a reported 100% patient and physician satisfaction rate, our goal is to highlight these results and leverage the expert testimony to secure a favorable recommendation from the committee to treat women diagnosed with early-stage, low risk breast cancer, and to ensure we maintain the forward momentum through year-end and into 2025 upon potential clearance from the FDA.

"The U.S. is the largest healthcare market in the world and as a patient-centric company, we believe it's critically important to offer patients a safe and proven non-surgical procedure with a system that is cleared in 15 countries, including in the U.S. Moreover, we strongly believe that our first half 2024 system and probe sales growth of 20%, notwithstanding the revenue recognition from Terumo, is primarily due to women and their physicians making a conscious choice to use ProSense® and avoid a surgical procedure because it's a win-win scenario for patient, physician, health provider, and payor."

Second Quarter and Recent ProSense® Efficacy & Safety Data Reported by Independent Researchers

ProSense® Destroyed 100% of Breast Cancer Tumors in Independent Study of Patients Who Chose Cryoablation Instead of Surgery: The aim of the study titled "Acceptance and results of cryoablation for the treatment of early breast cancer in non-surgical patients" published in the *British Journal of Radiology* was to evaluate the acceptance of percutaneous cryoablation treatment by patients with early-stage breast cancer who choose not to have surgery. Of the 45 patients offered cryoablation with ProSense®, 43 patients, or 95.6% accepted. 36 of these, representing 39 malignant tumors (median size 24mm), proceeded to undergo cryoablation. The median age of patients treated with cryoablation was 87, with a range of 60-96. After a median follow-up of 16 months, the complete ablation rate in luminal A and B breast cancer with tumors ≤ 25mm was 100%. No major complications were seen.

Zero (0%) Breast Cancer Local Recurrence 5 Years Following Treatment in Japan with ProSense®: Data from a study performed in Japan was published in an article titled "Percutaneous ultrasound-guided cryoablation for early-stage primary breast cancer: a follow-up study in Japan," in the journal *Breast Cancer*. Eighteen early-stage breast cancer patients, with a mean age of 59.0 [±9.0 years], with a mean tumor size of 9.8 ±2.3 millimeters, who underwent treatment with ProSense® were followed for a mean of 44.3 months. No patients had local recurrence or distant metastasis in the 5-year follow-up. No serious adverse events were reported. Cosmetic outcomes were excellent and the overall patient satisfaction level and patient quality of life improved post-cryoablation.

European Study Provided More Evidence Supporting ProSense® Treatment for Metastatic and Recurrent Breast Cancer: Data published in the highly influential peer-reviewed journal, *Cancers*, concluded cryoablation with ProSense® is a safe, local treatment for breast cancer with a low complication rate, high complete ablation rate and satisfactory overall survival (OS), progression free survival (PFS) and local tumor control. The recurrence rate was 8.9% in a population of 45 patients who had previously received various therapies before cryoablation including surgery, radiation therapy, or chemotherapy with tumor sizes of up to 4 centimeters in diameter. Of those patients, 11 had recurrent tumors and 21 had metastatic disease. This higher-risk population contrasts with the early-stage breast cancer patient subjects in IceCure's U.S. ICE3 trial. The European study titled "CT-Guided Percutaneous Cryoablation of Breast Cancer: A Single-Center Experience" was conducted at Goethe University in Germany.

99.74% Recurrence Free Rate for Women with Breast Cancer Treated with ProSense® in Japan: From April 2014 through August 2020, 389 breast cancer patients with tumor lesions of less than 15 millimeters in diameter were treated with ProSense®. The ipsilateral breast tumor recurrence rate (IBTR) was 0.26%, resulting in a 99.74% recurrence free rate. These data were presented at 32nd Annual Meeting of the Japanese Breast Cancer Society, where the demand for minimally invasive breast cancer treatment was an overarching theme.

Financial Results for the Six Months Ended June 30, 2024

Sales of ProSense® systems and disposable probes for the six months ended June 30, 2024 grew by 20% to $1,654,000 compared to $1,373,000 for the six months ended June 30, 2023. The growth was primarily attributable to sales in Europe, the U.S., Japan and other territories in Asia which were partially offset by a decrease in sales in China. Total Revenue for the six months ended June 30, 2024, grew to $1,754,000 from $1,647,000 for the six months ended June 30, 2023 due to an increase in the sale of ProSense® systems and disposables, which was partially offset by a decrease in revenue recognition and other services in Japan of $100,000 and $274,000 in the first six months of 2024 and 2023, respectively.

Gross profit for the six months ended June 30, 2024 grew to $799,000 from $754,000 for the six months ended June 30, 2023. Gross margin for the six months ended June 30, 2024 and for the six months ended June 30, 2023 was 46%. Non-GAAP gross profit for the six months ended June 30, 2024 increased to $699,000 from $480,000 for the six months ended June 30, 2023, an increase of $219,000 or 46%. Non-GAAP gross margin for the six months ended June 30, 2024 grew to 42% from 35% for the six months ended June 30, 2023. The increase in non-GAAP gross profit and non-GAAP gross margin, which exclude revenue from the exclusive distribution agreements and other services in Japan, was attributable to the increase of 20% in revenue from sales of ProSense® systems. Non-GAAP gross profit and non-GAAP gross margin are financial measures that may be defined as "non-GAAP financial measures" by the U.S. Securities and Exchange Commission ("SEC"). For a reconciliation of these non-GAAP financial measures to the nearest comparable GAAP measure, see Appendix A to this press release.

Research and development expenses for the six months ended June 30, 2024 were $3,536,000 compared to $4,190,000 for the six months ended June 30, 2023. The decrease was primarily due to a reduction in development expenses for the XSense™

System, which received FDA clearance in June 2024, and a decrease in clinical and regulatory costs as the Company concluded the ICE3 study in March 2024 and submitted the application to the FDA in April 2024. Sales and marketing expenses for the six months ended June 30, 2024 were $2,296,000 compared to $2,253,000 million for the six months ended June 30, 2023. General and administrative expenses for the six months ended June 30, 2024, narrowed to $1,845,000 from $2,349,000 for the six months ended June 30, 2023.

Total operating expenses for the six months ended June 30, 2024 decreased to $7,677,000 from $8,792,000 for the six months ended June 30, 2023. The decrease in operating expenses was attributable to reductions in research and development, and general and administrative expenses, due to the Company's initiative to reduce non-critical operating expenses which were partially offset by an increase in sales and marketing expenses.

Net loss for the six months ended June 30, 2024 narrowed to $6,690,000 million, or $0.14 per share compared to a net loss of $7,657,000 million, or $0.17 per share, for the same period last year.

As of June 30, 2024, the Company had cash and cash equivalents, including short-term deposits, of approximately $10.5 million, compared to $11 million as of December 31, 2023. As of July 31, 2024, the Company had cash and cash equivalents of approximately $10.3 million. During the first half of 2024, the Company raised $4.7 million in net proceeds from the sale of 3,787,976 ordinary shares under its at-the-market ("ATM") offering facility.

Use of Non-U.S. GAAP Measures

In addition to disclosing financial results prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP), this press release contains certain financial measures which may be defined as "non-GAAP financial measures" by the SEC. The Company defines non-GAAP gross profit as gross profit less revenue from exclusive distribution agreements and other services. The Company has provided non-GAAP gross profit in this press release because it is a key measure used by management and the board of directors as an indication of our gross profit from sales of our systems and disposables and management believes that it is useful to investors' understanding and assessment of the Company's gross profit without the impact of revenue recorded from the Company's exclusive distribution agreements and other services. The Company has 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. The non-GAAP financial measures disclosed by the Company should not be considered in isolation or as a substitute for, or superior to, financial measures calculated in accordance with U.S. GAAP and the financial results calculated in accordance with U.S. GAAP and reconciliations to those financial results should be carefully evaluated.

Conference call & webcast info:

Tuesday, August 20, 2024, at 10:00 am EDT
US: 1-888-407-2553
Israel/International: +972-3-918-0696
A live webcast will be available at: https://Veidan.activetrail.biz/IcecureQ2-2024
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 advanced liquid-nitrogen-based cryoablation therapy systems 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 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: the pending FDA Medical Device Advisory Committee meeting to obtain independent expert advice on scientific, technical, and policy matters related to the Company's De Novo Marketing Clearance Request for a minimally invasive alternative treatment for women diagnosed with early-stage, low risk breast cancer; the schedule for the FDA marketing clearance decision for ProSense®; the expected timeline for presenting data from interim results of the Company's ICESECRET clinical trial of ProSense®; the expected filing for regulatory approval of ProSense for breast cancer in Japan in the first quarter of 2025; and expected additional third-party data on ProSense® to be published in medical journals and presented at medical conferences. 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 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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IR Contact:
Email: investors@icecure-medical.com
Michael Polyviou
Phone: 732-232-6914
Todd Kehrli
Phone: 310-625-4462

ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	As of June 30, 2024 (Unaudited)	As of December 31, 2023 (Audited)
	U.S. dollars in thousands	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	9,652	10,533
Short-term deposits	807	529
Trade receivables	325	103
Inventory	1,969	2,275
Prepaid expenses and other receivables	574	744
Total current assets	13,327	14,184
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	44	34
Right-of-use assets	608	679
Property and equipment, net	1,380	1,513
Total non-current assets	2,032	2,226
TOTAL ASSETS	15,359	16,410
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade payables	695	502
Lease liabilities	251	223
Employees and other current liabilities	3,534	3,146
Total current liabilities	4,480	3,871
NON-CURRENT LIABILITIES		
Long-term lease liabilities	269	376
Total non-current liabilities	269	376
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 49,517,660 shares and 45,729,684 shares as of June 30, 2024 and December 31, 2023, respectively		
Additional paid-in capital	107,361	102,224
Accumulated deficit	(96,751)	(90,061)
Total shareholders' equity	10,610	12,163
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	15,359	16,410

ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Six Months ended June 30,	
	2024	**2023**
	U.S. dollars in thousands (except per share data)	
Revenues	1,754	1,647
Cost of revenues	955	893
Gross profit	799	754
Research and development expenses	3,536	4,190
Sales and marketing expenses	2,296	2,253
General and administrative expenses	1,845	2,349
Operating loss	6,878	8,038
Finance income, net	(188)	(381)
Net loss and comprehensive loss	6,690	7,657
Basic and diluted net loss per share	0.14	0.17
Weighted average number of shares outstanding used in computing basic and diluted loss per share	47,850,703	45,623,434

ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Six Months ended June 30,	
	2024	**2023**
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(6,690)	(7,657)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	167	158
Share-based compensation	410	674
Exchange rate changes in cash and cash equivalents and short time deposits	79	98
Non-cash short-term deposits interest	(8)	(348)
Changes in assets and liabilities:		
Increase in trade receivables	(222)	(40)
Decrease in prepaid expenses and other receivables	170	651
Decrease in inventory	306	106
Decrease in right of use assets	135	62
Increase (decrease) in trade payables	193	(62)
Decrease in lease liabilities	(143)	(90)
Increase (decrease) in Employees and other current liabilities	388	(460)
Net cash used in operating activities	(5,215)	(6,908)
Cash flows from investing activities		
Investment in short-term deposits	(1,373)	(14.700)
Withdrawal of short-term deposits	1,065	1,400
Investment in restricted long-term deposits	(10)	-
Purchase of property and equipment	(34)	(322)
Net cash used in investing activities	(352)	(13,622)
Cash flows from financing activities:		
Issuance of ordinary shares, net of issuance costs	4,727	-
Net cash provided by financing activities	4,727	-
Decrease in cash and cash equivalents	(840)	(20,530)
Cash and cash equivalents at beginning of the year	10,533	23,659
Effect of exchange rate fluctuations on balances of cash and cash equivalents	(41)	(98)
Cash and cash equivalents at end of period	9,652	3,031
Non-cash activities		
Obtaining a right-of-use asset in exchange for a lease liability	64	100

APPENDIX A
NON-GAAP RECONCILIATIONS (Unaudited)

U.S. dollars in thousands	Six Months ended June 30, 2024	2023
GAAP gross profit	$ 799	$ 754
Revenue from Exclusive Distribution Agreement	(100)	(274)
Non-GAAP gross profit	$ 699	$ 480
Sales of systems and disposables	1,654	1,373
Non-GAAP gross profit	$ 699	$ 480
Non-GAAP gross margin %	42 %	35 %

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