

May 28, 2024



IceCure Medical Maintains Positive Momentum and Reports Sales Growth for Cryoablation System in First Quarter of 2024

- ***30% sales growth reflects continued adoption of ProSense® in the U.S. and other global markets***
- ***Major milestones achieved:***
 - ***Completion of landmark ICE3 trial for breast cancer***
 - ***Positive final ICE3 trial data***
- ***Awaiting FDA Decision***
- ***Independent studies performed globally continue to demonstrate ProSense®'s efficacy and safety across numerous indications***
- ***Conference call to be held today at 11:00 am Eastern Time***

CAESAREA, Israel, May 28, 2024 /PRNewswire/ -- [IceCure Medical Ltd.](#) (Nasdaq: ICCM) ("IceCure," "IceCure Medical" 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 financial results as of and for the three months ended March 31, 2024. During the quarter, the Company completed its landmark ICE3 trial and recently achieved several objectives, including: publishing and submitting the full data set of its ICE3 trial results to the U.S. Food and Drug Administration ("FDA"); and requesting marketing authorization for ProSense® for the indication of treating patients with early stage T1 invasive breast cancer with cryoablation and adjuvant hormone therapy.



"Having completed ICE3, the largest study of its kind in cryoablation in the U.S., we are now

awaiting the FDA's marketing clearance decision," stated IceCure's CEO, Eyal Shamir. "ProSense® is already cleared and is being used to treat early-stage breast cancer in numerous countries with great results. Since the U.S. is one of the largest markets in the world, we believe that delivering alternative surgery-free options to women in the U.S., while establishing ProSense® as a gold-standard globally, will have a significant impact on treating patients with breast cancer."

"During the first quarter, we also continued to experience an upward trend in sales in the U.S. We successfully managed to lower our operating expenses in non-revenue generating activities by exercising prudent cash management."

First Quarter 2024 and Recent Significant Operating, Clinical, Regulatory & Commercial Highlights:

Reported and Submitted Full ICE3 Breast Cancer Study Data to FDA: IceCure completed the largest controlled multicenter clinical trial ever performed for liquid nitrogen (LN2) based cryoablation of early-stage malignant breast tumors. Per the analysis, at the 5-year follow-up evaluation, 96.3% of the subgroup of patients treated with ProSense® cryoablation, followed by hormone therapy, were estimated to be free from local recurrence. 100% patient and physician satisfaction was reported. IceCure submitted the final ICE3 data, along with other analyses and data, to the FDA requesting marketing authorization of ProSense® for the indication of treating patients with early stage T1 invasive breast cancer with cryoablation and adjuvant hormone therapy. Full ICE3 study results were presented at the American Society of Breast Surgeons' ("ASBrS") annual meeting by ICE3 investigators, including Dr. Richard Fine who delivered an oral presentation titled "Cryoablation Without Excision for Early-Stage Breast Cancer; ICE3 Trial 5-year follow-up on Ipsilateral Breast Tumor Recurrence," which won the ABSrS Scientific Impact Award.

Zero (0%) Breast Cancer Local Recurrence 5 Years After Treatment with ProSense®: An independent 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*. In addition to no cancer recurrence 5 years following treatment with ProSense®, researchers also reported excellent cosmetic outcomes, a high degree of patient satisfaction, and improved quality of life post-cryoablation.

Treatment with ProSense® Resulted in 100% Tumor Reduction in Early-Stage Breast Cancer: An independent study in women deemed inoperable for breast cancer reported median tumor reduction of 100% at 6 and 12 months following cryoablation. The study was conducted by ProSense® user, Dr. Federica di Naro, of Azienda Ospedaliero-Universitaria Careggi in Florence, Italy.

ProSense® Found to be Promising Alternative Treatment for Extra-Pelvis Endometriosis: An investigator-initiated single-site study of women with endometriosis in the abdominal wall and para-diaphragmatic areas found that treatment with ProSense® for about 30 minutes resulted in the disappearance of hemorrhagic signals and development of necrotic changes, as well as pain reduction from a median of 7 on a scale of 0 - 10 to a median of 1, with some patients reporting 0. The independent study was conducted at University Hospital, Nîmes, France, and data were shared at the European Congress of Radiology 2024 in Vienna, Austria in a presentation titled "BEYOND PAIN: Cryoablation of

endometriotic nodules using liquid nitrogen."

ProSense® Boosts Immune Response Against Cancer by Enhancing CD8+ T Cell

Response: An independent study, conducted at Case Western Reserve University in Cleveland, Ohio and published in *Oncolmunology*, demonstrated that ProSense® can activate the body's natural immune response by enhancing CD8+ T cells, which are an important arm of immune response. The data support previous studies and suggest ProSense® may produce anti-cancer benefits in humans beyond tumor destruction during a cryoablation procedure.

Commercial and Medical Community Interest Continues to Grow with ProSense®

Featured at Conferences in the U.S., India and Japan: In the U.S., in addition to ICE3 data being presented at ASBrS, cryoablation gained prominence at the Society of Interventional Oncology (SIO) Annual Scientific Meeting where the technology was featured in the first breast cryoablation master class at SIO. ICE3 trial data were cited prominently in the master class given by several ProSense® users, including Dr. Kenneth Tomkovich, ICE3's co-principal investigator, and Dr. Fine. In India, ProSense® users and key opinion leaders highlighted the benefits of cryoablation at the Indian Society of Vascular and Interventional Radiology Conference and the Fourth Breast Imaging & Interventional Techniques conference. ProSense® was featured in a number of sessions, including one titled "Minimal access imaging guided therapies: cryoablative therapies in breast pathologies". Underscoring global adoption and use of ProSense®, Dr. Eisuke Fukuma, PhD, who has performed over 600 breast cryoablation procedures with ProSense®, hosted two events in Japan at the 30th Japan Breast Disease Society and the 8th International Oncoplastic Breast Surgery Symposium.

Received Patent Allowance in Japan for a Novel Cryogen Flow Control to Optimize

Patient Outcomes: IceCure received a Notice of Allowance from the Japan Patent Office for its patent application titled "Cryogen Flow Control" for a technology that enhances the efficacy and precision of cryoablation procedures.

Submitted Application for FDA Clearance of Next-Generation XSense™ System and

Cryoprobes: Demonstrating its global leadership in minimally invasive cryoablation technologies, IceCure submitted a 510(k) filing for its single probe XSense™ system and cryoprobes to the FDA for regulatory clearance in all the indications for which ProSense® has already received the requisite FDA clearance.

Financial Results for the Three Months Ended March 31, 2024

Revenues for the three months ended March 31, 2024 were \$743,000 compared to \$710,000 for the three months ended March 31, 2023, an increase of 5%, due to an increase in the sales, which was offset by the end of revenue recognition from the exclusive distribution rights agreement with Terumo Corporation in Japan for which no revenue was recognized in the three months ended March 31, 2024. For the three months ended March 31, 2024, the Company reported ProSense® systems and disposable probes sales of \$743,000 compared to \$573,000 for the three months ended March 31, 2023, an increase of 30%, driven primarily by higher sales in the U.S. and Japan.

Gross profit for the three months ended March 31, 2024 was \$269,000 compared to \$320,000 for the three months ended March 31, 2023. Gross margin for the three months

ended March 31, 2024 was 36%, compared to 45% for the three months ended March 31, 2023. Non-GAAP gross profit for the three months ended March 31, 2024 was \$269,000, compared to \$183,000 for the three months ended March 31, 2023, an increase of \$86,000 or 47%. Non-GAAP gross margin for the three months ended March 31, 2024 was 36% compared to 32% for the three months ended March 31, 2023. The increase in non-GAAP gross profit and non-GAAP gross margin, which exclude revenue from the exclusive distribution agreements, was attributable to the increase of 30% in revenue from sales of ProSense® systems and probes while the increase in cost of revenues was 22%. 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 three months ended March 31, 2024, were \$1,951,000 compared to \$2,111,000 for the three months ended March 31, 2023. The decrease was primarily due to a reduction in development expenses for the XSense™ System, and a decrease in clinical and regulatory costs.

Sales and marketing expenses for the three months ended March 31, 2024 were \$1,038,000, compared to \$1,075,000 for the three months ended March 31, 2023. General and administrative expenses for the three months ended March 31, 2024 were \$930,000, compared to \$1,091,000 for the three months ended March 31, 2023. The decrease was due, in part, to a decrease in directors and officers insurance costs and the depreciation of NIS against USD on NIS-denominated expenses such as payroll and related benefits.

Total operating expenses for the three months ended March 31, 2024 were \$3,919,000, compared to \$4,277,000 for the three months ended March 31, 2023. The decrease in operating expenses was attributable to reductions in research and development, general and administrative expenses, and sales and marketing expenses.

Net loss for the three months ended March 31, 2024 was \$3,609,000, or \$0.08 per share, compared to a net loss of \$3,768,000, or \$0.08 per share, for the same period last year.

As of March 31, 2024, the Company had cash and cash equivalents, including short-term deposits, of approximately \$11 million, compared to \$11 million as of December 31, 2023. As of May 28, 2024, the Company had cash and cash equivalents of approximately \$10.8 million.

During the first quarter of 2024, the Company raised \$2.98 million in net proceeds from the sale of 2,210,057 ordinary shares under its at-the-market ("ATM") offering facility, and the compensation paid by the Company with respect to sales of the ordinary shares pursuant to this ATM facility was \$76,000.

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 as an indication of our gross profit from sales of our systems and disposables. 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. The Company defines non-GAAP gross margin as a percentage of non-GAAP gross profit from sales of our systems and disposables. The Company has provided non-GAAP gross margin in this press release because it is a key measure used by management and the board of directors as an indication of the Company's profitability without the impact of revenue from the Company's exclusive distribution agreements. 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. 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, May 28, 2024, at 11:00 am EDT

US: 1-888-407-2553

Israel/International: +972-3-9180696

A live webcast will be available at: <https://veidan.activetrail.biz/IcecureQ1-2024>

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 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: the pending FDA marketing clearance decision for ProSense®, the belief that delivering alternative surgery-free options to women in the U.S., while establishing ProSense® as a gold standard globally, will have a significant impact, and the pending FDA 510(k) regulatory clearance application for the single probe XSense™ system and cryoprobes. 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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ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	As of March 31, 2024 (Unaudited)	As of December 31, 2023 (Audited)
	U.S. dollars in thousands	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	10,966	10,533
Deposits	-	529
Trade accounts receivables	157	103
Inventory	2,111	2,275
Prepaid expenses and other receivables	692	744
Total current assets	13,926	14,184
<u>NON-CURRENT ASSETS</u>		
Prepaid expenses and other long-term assets	44	34
Right-of-use assets	627	679
Property and equipment, net	1,456	1,513
Total non-current assets	2,127	2,226
TOTAL ASSETS	16,053	16,410
<u>LIABILITIES AND SHAREHOLDERS' EQUITY</u>		
<u>CURRENT LIABILITIES</u>		
Trade accounts payable	658	502
Lease liabilities	237	223
Other current liabilities	3,210	3,146
Total current liabilities	4,105	3,871
<u>NON-CURRENT LIABILITIES</u>		
Long-term lease liabilities	312	376
Total non-current liabilities	312	376
<u>SHAREHOLDERS' EQUITY</u>		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 47,939,194 shares and 45,729,684 shares as of March 31, 2024 and December 31, 2023, respectively		
Additional paid-in capital	105,306	102,224
Accumulated deficit	(93,670)	(90,061)
Total shareholders' equity	11,636	12,163
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	16,053	16,410

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

	Three months ended March 31,	
	2024	2023
	U.S. dollars in thousands (except per share data)	
Revenues	743	710
Cost of revenues	474	390
Gross profit	269	320
Research and development expenses	1,951	2,111
Sales and marketing expenses	1,038	1,075
General and administrative expenses	930	1,091
Operating loss	3,650	3,957
Finance expenses (income), net	(41)	(189)
Net loss and comprehensive loss	3,609	3,768
Basic and diluted net loss per share	0.08	0.08
Weighted average number of shares outstanding used in computing basic and diluted loss per share	46,736,034	45,623,434

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

	Three months ended March 31,	
	2024	2023
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(3,609)	(3,768)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	85	79
Share-based compensation	245	356
Exchange rate changes in cash and cash equivalents and short time deposits	43	8
Changes in assets and liabilities:		
Decrease (increase) in trade accounts receivables	(54)	(65)
Decrease in prepaid expenses and other receivables	52	374
Decrease (increase) in inventory	164	(71)
Decrease in right of use assets	75	48
Increase (decrease) in trade accounts payable	156	(29)
Decrease in lease liabilities	(73)	(57)
Increase in other current liabilities	64	188
Net cash used in operating activities	<u>(2,852)</u>	<u>(2,937)</u>
Cash flows from investing activities		
Withdrawal of (investment in) short-term deposits	529	(14,870)
Investment in restricted long term deposits	(10)	-
Purchase of property and equipment	(28)	(250)
Net cash provided by (used in) investing activities	<u>491</u>	<u>(15,120)</u>
Cash flows from financing activities:		
Issuance of ordinary shares, net of issuance costs	2,837	-
Net cash provided by financing activities	<u>2,837</u>	<u>-</u>
Increase (decrease) in cash and cash equivalents	476	(18,057)
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	(43)	(8)
Cash and cash equivalents at end of period	<u><u>10,966</u></u>	<u><u>5,594</u></u>
Non-cash activities		
Obtaining a right-of-use asset in exchange for a lease liability	<u>23</u>	<u>-</u>

APPENDIX A
NON-GAAP RECONCILIATIONS (Unaudited)

U.S. dollars in thousands	Three Months ended March 31,	
	2024	2023
GAAP gross profit	\$ 269	\$ 320
Revenue from Exclusive Distribution Agreement	-	(137)
Non-GAAP gross profit	\$ 269	\$ 183
GAAP gross margin %	36 %	45 %
 Sales of systems and disposables	 743	 543
Non-GAAP gross profit	\$ 269	\$ 183
Non-GAAP gross margin %	36 %	32 %

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SOURCE IceCure Medical