

IceCure Medical Reports 2024 Financial Results: 42% Growth in ProSense® Cryoablation Sales in North America

Expecting FDA decision on marketing authorization for early-stage low risk breast cancer with endocrine therapy

Positive ProSense® results were reported through 33 peer-reviewed journals and medical conferences during 2024

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

CAESAREA, Israel, March 27, 2025 /PRNewswire/ -- <u>IceCure Medical Ltd.</u> (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 twelve months ended December 31, 2024.



IceCure continues to engage with the U.S. Food and Drug Administration ("FDA") regarding its De Novo marketing authorization request for ProSense® in early-stage low risk breast cancer with endocrine therapy. Should ProSense® receive marketing authorization in this indication, ProSense® would become a first-in-class minimally invasive alternative to standard of care lumpectomy.

"The sales momentum we have experienced in 2024 for ProSense® in North America, as well as in Europe and Japan, are encouraging signs that a positive marketing clearance outcome in the U.S. may lead to a higher adoption of ProSense®. Early interest in the U.S. for breast cancer cryoablation is evident following the favorable decision of the FDA Medical Device Advisory Panel ("Advisory Panel") in November 2024," stated IceCure Medical's CEO, Eyal Shamir.

"We continue to see adoption of ProSense® cryoablation in numerous indications across the globe. This traction is evident through 33 investigator-initiated studies presented and published during 2024," Shamir added.

Upcoming 2025 Catalysts

- The FDA's marketing authorization decision for ProSense® in early-stage low risk breast cancer with endocrine therapy is expected
- If market authorization is received in the U.S., this, combined with the final ICE3 trial data and the in-depth analysis of ProSense® during the public meeting of the Advisory Panel in November 2024, is expected to drive further sales momentum in global markets
- Terumo Corporation, IceCure's partner in Japan, is expected to file for regulatory approval of ProSense® for breast cancer in Japan
- Regulatory approval is expected for the next-generation XSense™ in Israel.
- Additional third-party data on ProSense® are expected to be published in medical journals and presented at prestigious medical conferences throughout 2025

Financial Results for the Twelve Months Ended December 31, 2024 Demonstrate Accelerating Growth of ProSense® Adoption and Utilization

Sales of ProSense® systems and disposable probes for the twelve months ended December 31, 2024 increased to \$3,191,000 compared to \$2,955,000 for the twelve months ended December 31, 2023. The growth was primarily attributable to sales in North America, as well as increases in Japan and other territories in Asia and Europe, partially offset by a decrease in sales in China and Latin America. Total revenue for the twelve months ended December 31, 2024 increased to \$3,291,000 from \$3,229,000 for the twelve months ended December 31, 2023, primarily due to an increase in product sales, which was partially offset by a decrease in revenue recognition and other services in Japan of \$100,000 and \$274,000 in the twelve months of 2024 and 2023, respectively.

Gross profit for the twelve months ended December 31, 2024 increased by 12% to \$1,451,000 from \$1,300,000 for the twelve months ended December 31, 2023. Gross margin increased to 44% in the twelve months ended December 31, 2024 compared to 40% in the twelve months ended December 31, 2023. The increase in gross profit and gross margin was attributable to an 8% increase in revenue from product sales. Non-GAAP gross profit for the twelve months ended December 31, 2024 increased to \$1,351,000 from \$1,026,000 for the twelve months ended December 31, 2023, an increase of \$325,000 or 32%. Non-GAAP gross margin for the twelve months ended December 31, 2024 increased to 42% from 35% for the twelve months ended December 31, 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 8% in revenue from product sales. 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 measure calculated in accordance with generally accepted accounting principles in the U.S. ("GAAP"), see Appendix A to this press release.

Research and development expenses for the twelve months ended December 31, 2024 decreased by 14% to \$7,096,000 compared to \$8,273,000 for the twelve months ended

December 31, 2023. The decrease was primarily due to a reduction in development expenses for the XSense™ System, which received FDA authorization in June 2024, and a decrease in clinical and regulatory costs as the Company concluded the ICE3 study in March 2024. Sales and marketing expenses increased for the twelve months ended December 31, 2024 by 42% to \$6,296,000 compared to \$4,437,000 for the twelve months ended December 31, 2023 as the Company focused on increased global marketing to support growing sales and in anticipation of potential marketing authorization for ProSense® in early-stage breast cancer in the U.S. General and administrative expenses for the twelve months ended December 31, 2024 decreased by 10% to \$3,755,000 from \$4,166,000 for the twelve months ended December 31, 2023, reflecting the Company's continued prudent budgeting and operating efficiencies.

Total operating expenses for the twelve months ended December 31, 2024 increased by 2% to \$17,147,000 from \$16,876,000 for the twelve months ended December 31, 2023. The increase in operating expenses was attributable to an increase in sales and marketing expenses, which were partially offset by reductions in research and development and general and administrative expenses, due to the Company's initiative to reduce non-critical operating expenses.

Net loss for the twelve months ended December 31, 2024 increased by 5% to \$15,318,000, or \$0.30 per share, compared to a net loss of \$14,652,000, or \$0.32 per share, for the same period last year.

As of December 31, 2024, the Company had cash and cash equivalents, including short-term deposits, of approximately \$7.6 million. As of March 24, 2025, the Company had cash and cash equivalents of approximately \$6.0 million. Between January 13, 2025 and March 24, 2025, the Company raised \$2.6 million in net proceeds from the sale of 2,047,277 ordinary shares under its at-the-market offering facility.

Use of Non-U.S. GAAP Measures

In addition to disclosing financial results prepared in accordance with 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:

US: 1-888-407-2553

Israel/International: +972-3-918-0696

A live webcast will be available at: https://Veidan.activetrail.biz/IcecureQ4-2024

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 Asia.

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: prospective FDA De Novo marketing authorization for ProSense in early-stage low risk breast cancer with endocrine therapy; the belief that sales data from North America, Europe and Japan may show that a positive marketing clearance outcome in the U.S. may lead to higher adoption of ProSense®; the belief that marketing authorization of ProSense in the U.S. is expected to drive further sales momentum in global markets; the expected filing by Terumo Corporation for regulatory approval for ProSense for breast cancer in Japan; that regulatory approval for the nextgeneration XSense is expected in Israel; and that additional third-party data on ProSense® are expected to be published in medical journals and presented at prestigious medical conferences throughout 2025. 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, 2024 filed with the SEC on March 27, 2025, 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 December 31, 2024 U.S. dollars	As of December 31, 2023 in thousands
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	7,564	10,533
Short-term deposits	-	529
Trade receivables	221	103
Inventory	1,988	2,275
Prepaid expenses and other receivables	981	744
Total current assets	10,754	14,184
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	46	34
Right-of-use assets	524	679
Property and equipment, net	1,252	1,513
Total non-current assets	1,822	2,226
TOTAL ASSETS	12,576	16,410
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade payables	1,232	502
Lease liabilities	298	223
Employees and other current liabilities	3,984	3,146
Total current liabilities	5,514	3,871
NON-CURRENT LIABILITIES		
Long-term lease liabilities	161	376
Total non-current liabilities	161	376
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 56,568,999 shares and 45,729,684 shares as of December 31, 2024 and December 31, 2023, respectively		
Additional paid-in capital	112,280	102,224
Accumulated deficit	(105,379)	(90,061)
Total shareholders' equity	6,901	12,163
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	12,576	16,410
TOTAL ENGLISHED MAD DIMILLIOLDENO EQUIT		

ICECURE MEDICAL LTD. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

Year ended
December 31,

	December 51,	
	2024	2023
	U.S. dollars in thousands (except per share data)	
Revenues	3,291	3,229
Cost of revenues	1,840	1,929
Gross profit	1,451	1,300
Research and development expenses	7,096	8,273
Sales and marketing expenses	6,296	4,437
General and administrative expenses	3,755	4,166
Operating loss	15,696	15,576
Finance income, net	(378)	(924)
Net loss and comprehensive loss	15,318	14,652
Basic and diluted net loss per share	0.30	0.32
Weighted average number of shares outstanding used in computing basic and diluted loss per share	50,876,790	45,638,030

ICECURE MEDICAL LTD. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

Year ended December 31, 2024 2023 U.S. dollars in thousands Cash flows from operating activities (15,318)(14,652)Adjustments to reconcile net loss to net cash used in operating activities: 332 323 Depreciation 869 Share-based compensation 1,310 Exchange rate changes in cash and cash equivalents and deposits 39 (25)Non-cash short-term interest on deposits (29)Changes in assets and liabilities: (118)(25)Increase in trade receivables 496 Decrease (increase) in prepaid expenses and other receivables (237)582 Decrease in inventory 287 Decrease in right of use assets 271 182 Increase (decrease) in trade payables 730 (212)Decrease in lease liabilities (256)(191)Increase (decrease) in Employees and other current liabilities 838 (309)Net cash used in operating activities (12,563)(12,550)Cash flows from investing activities Investment in short-term deposits (1,373)(500)1,902 Withdrawal of short-term deposits 296 Withdrawal of (investment in) restricted deposits (12)Purchase of property and equipment (71)(480)Net cash provided by (used in) investing activities 446 (684)Cash flows from financing activities: Exercise of options to ordinary shares 83 Issuance of ordinary shares, net of issuance costs 9,187 9,187 83 Net cash provided by financing activities Increase (decrease) in cash and cash equivalents (2,930)(13,151)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 (39)25 7,564 10,533 Cash and cash equivalents at end of period Non-cash activities 116 193 Obtaining a right-of-use asset in exchange for a lease liability

APPENDIX A NON-GAAP RECONCILIATIONS

U.S. dollars in thousands	Year ended December 31,	
	2024	2023
GAAP gross profit	\$ 1,451	\$ 1,300
Revenue from Exclusive Distribution Agreement and other services	(100)	(274)
Non-GAAP gross profit	\$ 1,351	\$ 1,026
Sales of systems and disposables	3,191	2,955
Non-GAAP gross profit	\$ 1,351	\$ 1,026
Non-GAAP gross margin %	42	% 35 %

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