

May 28, 2025



IceCure Medical Reports First Quarter 2025 Financial Results

Recently finalized and delivered proposed post market study plan to the FDA; Awaiting marketing authorization decision for ProSense® in women aged 70+ with early-stage low risk breast cancer

Continues to see rising interest in North America for ProSense®

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

CAESAREA, Israel, May 28, 2025 /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 three months ended March 31, 2025.



IceCure delivered its proposed post market study plan (the "Plan") to the U.S. Food and Drug Administration ("FDA") as a requisite ahead of the FDA's marketing authorization decision for ProSense® in the treatment of early-stage low risk breast cancer when combined with adjuvant endocrine therapy for women aged 70 and over. The FDA's final marketing authorization decision is expected following review and approval of the plan by the FDA's Center for Devices and Radiological Health ("CDRH").

"During the first quarter, we continued to experience momentum in North America where ProSense® sales grew year-over-year. As this market remains a priority for IceCure, we have worked diligently over the past few weeks to prepare the requested Plan, which we delivered to the FDA in a timely manner. Upon the CDRH's review, we are optimistic about a positive outcome on marketing authorization from the FDA in early-stage low risk breast cancer for women aged 70 and over," stated IceCure Medical's CEO, Eyal Shamir. "This indication would cover a sizeable population, of approximately 46,000 women in the U.S. annually, that we believe seeks a patient-friendly minimally invasive option."

"Additionally, we believe that the recent decision by our largest investor and Board member, Mr. Li Haixiang, to provide a \$2 million unsecured loan demonstrates his confidence in our technology and ability to successfully deliver a less invasive, patient-centered care option--one which we see women in other countries are already benefitting from," Shamir concluded.

In addition to the pending FDA decision described above, the Company has several other potential upcoming milestones in 2025:

- Terumo Corporation, IceCure's partner in Japan, is expected to file for regulatory approval of ProSense® for breast cancer in Japan in the second half of 2025
- A response from the regulatory authorities in Israel is expected for the next-generation XSense™
- Additional third-party data on ProSense® are expected to be published in medical journals and presented at prestigious medical conferences

Key Q1 2025 and Recent ProSense® Developments Demonstrate Continued Medical and Commercial Traction Globally Including:

- Strong reception at the American Breast Surgeons Annual Conference (ASBrS) 2025 included IceCure's ICE3 study being named as one of the "Best Papers of 2024" and cryoablation being mentioned favorably during the Presidential Address
- Award winning independent study of ProSense® in breast cancer and hands-on training for breast cryoablation at the Society of Interventional Oncology in Las Vegas
- Publication in *Gland Surgery* of independent study in Japan reported significantly higher satisfaction among patients who underwent ProSense® cryoablation compared to patients who underwent standard of care surgery
- ProSense® cryoablation featured in six studies presented at the St. Gallen International Breast Cancer Conference in Vienna, Austria
- ICESECRET kidney cancer cryoablation study's interim results demonstrating 88.7% recurrence-free rate presented at the European Association of Urology Conference in Madrid, Spain
- ProSense® featured in 7 key events at the European Conference on Interventional Oncology 2025 in Rotterdam, the Netherlands, including three presentations and a hands-on training
- Two sold-out breast cryoablation courses featured hands-on training with ProSense® at the Society of Breast Imaging 2025 Breast Imaging Symposium in Colorado Spring, Colorado

Financial Results for the Three Months Ended March 31, 2025

Revenue representing sales of ProSense® systems and disposable probes for the three months ended March 31, 2025 was \$725,000 compared to \$743,000 for the three months ended March 31, 2024. The 2% decrease in sales was primarily due to a decline in sales in Asia, offset by an increase in sales in Europe and North America. Gross profit for the three months ended March 31, 2025 was \$218,000 compared to \$269,000 for the three months ended March 31, 2024. Gross margin was 30% in the three months ended March 31, 2025 compared to 36% in the three months ended March 31, 2024. The decrease in gross profit and gross margin was attributable to the slight decline in revenue and the change in product mix. GAAP and non-GAAP gross profit and gross margin results were the same for the three

months ended March 31, 2025. Revenues and gross profits are expected to continue to be variable quarter-over-quarter as the Company focuses on building commercial scale sales. The Company does not expect a material change in its revenues before receiving FDA marketing authorization decision.

Research and development expenses for the three months ended March 31, 2025 decreased by 15% to \$1,664,000 compared to \$1,951,000 for the three months ended March 31, 2024. 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 three months ended March 31, 2025 by 24% to \$1,289,000 compared to \$1,038,000 for three months ended March 31, 2024 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 three months ended March 31, 2025 were \$922,000 down slightly from \$930,000 for three months ended March 31, 2024.

Total operating expense for the three months ended March 31, 2025 was \$3,875,000, relatively the same as \$3,919,000 for the three months ended March 31, 2024.

Net loss for the three months ended March 31, 2025 narrowed by 0.6% to \$3,588,000, or \$0.06 per share, compared to a net loss of \$3,609,000, or \$0.08 per share, for the same period last year.

As of March 31, 2025, the Company had cash and cash equivalents, including short-term deposits, of approximately \$6.04 million. As of May 27, 2025, the Company had cash and cash equivalents of approximately \$6.2 million, which includes a \$2 million unsecured bridge loan from Epoch Partner Investments Limited ("Epoch"), the Company's largest shareholder (the "Loan"). The Loan bears an interest rate equal to a 12-month U.S. Treasury bond on May 17, 2025, to be repaid at the earlier of May 17, 2026 or when the Company raises money in an equity transaction in which Epoch participates, other than through an at-the-market facility and/or an equity line. Between January 13, 2025 and May 27, 2025, the Company raised \$2.65 million in net proceeds from the sale of 2,124,429 ordinary shares under its at-the-market offering facility.

Conference call & webcast info:

Wednesday, May 28, 2025, 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/IcecureQ1-2025>

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 the treatment of early-stage low risk breast cancer when combined with adjuvant endocrine therapy for women aged 70 and over; that the FDA's final marketing authorization decision is expected following review and approval of the Company's post market study plan by the CDRH; the Company's optimism about a positive outcome on marketing authorization from the FDA; the Company's belief that the Loan demonstrates Mr. Li Haixiang's confidence in the Company's technology and ability to successfully deliver a less invasive, patient-centered care option; the Company's potential upcoming milestones, including Terumo Corporation's expected filing for regulatory approval of ProSense for breast cancer in Japan, expected regulatory approval in Israel for XSense, and expected additional third-party data on ProSense to be published in medical journals and presented at medical conferences; when it discusses its expectation regarding its revenues; and the prospective repayment of the Loan from Epoch. 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 March 31, 2025	As of December 31, 2024
	(Unaudited)	
	U.S. dollars in thousands	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	6,040	7,564
Trade receivables	300	221
Inventory	2,036	1,988
Prepaid expenses and other receivables	1,065	981
Total current assets	9,441	10,754
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	45	46
Right-of-use assets	449	524
Property and equipment, net	1,169	1,252
Total non-current assets	1,663	1,822
TOTAL ASSETS	11,104	12,576
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade payables	953	1,232
Lease liabilities	272	298
Employees and other current liabilities	3,771	3,984
Total current liabilities	4,996	5,514
NON-CURRENT LIABILITIES		
Long-term lease liabilities	108	161
Total non-current liabilities	108	161
SHAREHOLDERS' EQUITY		
Ordinary shares, no par value; Authorized 2,500,000,000 shares; Issued and outstanding: 58,616,276 shares and 56,568,999 shares as of March 31, 2025 and December 31, 2024, respectively		
Additional paid-in capital	114,967	112,280
Accumulated deficit	(108,967)	(105,379)
Total shareholders' equity	6,000	6,901
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	11,104	12,576

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

	Three months ended March 31,	
	2025	2024
	U.S. dollars in thousands (except per share data)	
Revenues	725	743
Cost of revenues	507	474
Gross profit	218	269
Research and development expenses	1,664	1,951
Sales and marketing expenses	1,289	1,038
General and administrative expenses	922	930
Operating loss	3,657	3,650
Finance income, net	(69)	(41)
Net loss and comprehensive loss	3,588	3,609
Basic and diluted net loss per share	0.06	0.08
Weighted average number of shares outstanding used in computing basic and diluted loss per share	57,639,679	46,736,034

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

	Three months ended March 31,	
	2025	2024
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(3,588)	(3,609)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	89	85
Share-based compensation	125	245
Exchange rate changes in cash and cash equivalents and short time deposits	42	43
Changes in assets and liabilities:		
Increase in trade receivables	(79)	(54)
Decrease (increase) in prepaid expenses and other receivables	(84)	52
Decrease (increase) in inventory	(48)	164
Decrease in right of use assets	101	75
Increase (decrease) in trade payable	(279)	156
Decrease in lease liabilities	(105)	(73)
Increase (decrease) in employees and other current liabilities	(213)	64
Net cash used in operating activities	<u>(4,039)</u>	<u>(2,852)</u>
Cash flows from investing activities		
Withdrawal of short-term deposits	-	529
Withdrawal of (investment in) restricted long term deposits	1	(10)
Purchase of property and equipment	(6)	(28)
Net cash provided by (used in) investing activities	<u>(5)</u>	<u>491</u>
Cash flows from financing activities:		
Issuance of ordinary shares, net of issuance costs	2,562	2,837
Net cash provided by financing activities	<u>2,562</u>	<u>2,837</u>
Increase (decrease) in cash and cash equivalents	(1,482)	476
Cash and cash equivalents at beginning of the year	7,564	10,533
Effect of exchange rate fluctuations on balances of cash and cash equivalents	(42)	(43)
Cash and cash equivalents at end of period	<u><u>6,040</u></u>	<u><u>10,966</u></u>
Non-cash activities		
Obtaining a right-of-use asset in exchange for a lease liability	<u>26</u>	<u>23</u>

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