March 17, 2026

IceCure Reports 2025 Full Year Financial & Operational Results

Record 4th quarter and full year sales of $1.3 million and $3.4 million, respectively

Strong commercial momentum for ProSense® in the U.S. and globally following FDA clearance in low-risk breast cancer and medical society recommendations

30 hybrid commercial-clinical sites to be added for FDA approved post-marketing study in addition to growing pipeline of potential commercial customers

IceCure Applies to Expand Regulatory Approval in Canada for ProSense® Cryoablation to Include the Treatment of Low-Risk Breast Cancer

Conference call to be held today at 11:00 am Eastern Time

CAESAREA, Israel, March 17, 2026 /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 option to surgical tumor removal, today reported record sales as of and for the twelve months ended December 31, 2025 as well as recent commercial and clinical updates.

Three significant events are expected to drive commercial adoption of ProSense®:

- The American Society of Breast Surgeons' ("ASBrS") updated 2026 "*Resource Guide on the Use of Transcutaneous and Percutaneous Ablation for the Treatment of Benign and Malignant Tumors of the Breast*" recommends cryoablation as an option for selected patients with biologically low-risk early-stage breast cancer. The updated

guidance represents an important step toward broader clinical adoption of IceCure's ProSense® cryoablation system.
- The U.S. Food and Drug Administration ("FDA") approved the study design for IceCure's post-marketing study for ProSense® in the treatment of low-risk breast cancer. Patient enrollment for the "ChoICE" study is expected to commence by the second half of 2026, with at least 80 patients enrolled in the first year of the study. The ChoICE study is expected to enroll and treat 400 patients within 36 months across 30 clinical sites in the U.S. which can be used commercially.
- On March 16, 2026, the Company submitted a Class III amendment application to Health Canada seeking to expand its current regulatory approval to include the use of the ProSense® cryoablation system for the treatment of early-stage, low-risk invasive breast cancer in patients aged 60 years and older. The application is supported by data from IceCure's ICE3 clinical study, the largest study of its kind, which served as the basis for the FDA's marketing clearance of ProSense® in the treatment of low-risk breast cancer. Under the proposed indication in Canada, up to 7,130 number of women would be eligible for breast cancer cryoablation. A decision is expected during the second half of 2026, subject to the agency's standard review procedures and potential follow-up questions.

"2025 was a pivotal year for IceCure. Following the FDA's clearance for cryoablation of low-risk breast cancer in October, we had record sales in the fourth quarter and fiscal year, which were driven by growing global adoption of ProSense®. We believe we are just at the beginning of this favorable trend," stated Eyal Shamir, Chief Executive Officer of IceCure. " The recent ASBrS recommendation issued in March 2026, supports cryoablation as a treatment option and represents powerful validation of our technology and its role in modern breast cancer care. We are seeing increasing interest from physicians, hospitals, and patients around the world, and we believe these milestones position IceCure to accelerate adoption, expand installations, and continue advancing our mission of providing a minimally invasive alternative that improves outcomes and patient quality of life."

Shad Good, IceCure's VP of Sales North America, added, "Momentum in the U.S. market continues to build as three important factors have converged: FDA clearance of ProSense®, reimbursement, and new professional society guidelines supporting cryoablation for selected breast cancer patients. We are seeing a clear uptick in engagement from hospitals and clinics, increased cryoprobe orders from existing customers, and a growing pipeline of new sites evaluating the system. With plans to expand our commercial infrastructure and launch our post-marketing study across 30 clinical sites, we believe we are well positioned to significantly broaden access to ProSense® and drive meaningful commercial growth in North America."

Upcoming Catalysts

- **Further commercial momentum and conversion of sales pipeline into signed contracts and installed systems** expected in North America and globally.
  - Organic demand from patients and doctors is further advanced by positive word-of-mouth and media coverage, as seen in a recent news segment featuring a new ProSense® installation at Thomas Hospital in Alabama.
  - Physician-focused outreach at the leading U.S.-based breast cancer conferences in April 2026—the ASBrS Annual Meeting and the Society of Breast Imaging Symposium

—is expected to result in a more immediate response from doctors, due to FDA clearance and medical society recommendations.

- **Expected to on-board 30 hybrid commercial-clinical sites across the U.S. are expected to open** following the FDA's recent approval of IceCure's ChoICE post-marketing study protocol. These 30 planned sites, while treating study participants, will also be active commercial sites where any appropriate patient seeking treatment with ProSense® cryoablation may be treated. Both clinical study and commercial procedures will be eligible for CPT III reimbursement. Several potential customers in IceCure's U.S. pipeline have indicated they would move forward with purchase and installations upon the FDA's approval of the post-marketing study protocol.
- **Expanded reimbursement coverage is expected** for low-risk breast cancer procedures following FDA marketing clearance and the new ASBrS guidelines which recommend cryoablation for select patients. ProSense® currently has reimbursement under the CPT III code which covers ~$4,000 of facility costs, and this may increase by up to an additional $900in early 2027 if the Company's submission for Transitional Pass-Through ("TPT") payment is approved later this year. IceCure also plans to submit for CPT I code reimbursement in the second quarter of this year, and expects a response by early 2027, with CPT I expected to go effective in early 2028.
- **More regulatory submissions are expected**. IceCure's distributor in Japan, Terumo Corporation, is expected to file for regulatory approval for ProSense® in the treatment of breast cancer in the first half of 2026.

Additional Recent Operational and Clinical Highlights

- **2025 marked an all-time sales record in Europe, reflecting strong demand and expanded market presence -** The FDA's marketing clearance in the U.S. for low-risk breast cancer had a direct positive influence on European markets, as expected. Regulatory validation in the U.S. increased confidence and adoption internationally, especially in Europe. In markets where IceCure already had activity, the Company saw expanded usage including new clinical applications, particularly in breast cancer, beyond interventional oncology.
- **Recent installations of ProSense® in the U.S. range from small clinics, to mid-sized hospitals, to a globally recognized prestigious hospitals network**– A hospital network that is widely regarded as the leading hospital in the U.S. and one of the top in the world now has ProSense® installations at two of its larger sites and is expected to purchase additional ProSense® systems. A major university teaching hospital in the southern U.S. recently purchased ProSense®. These are two examples representing the profile of potential customers in IceCure's pipeline.
- **Thomas Hospital of Infirmary Health, the largest not-for-profit, non-governmental healthcare system in Alabama, purchased and installed ProSense®** - The first breast cancer cryoablation procedures in the state of Alabama were performed at Thomas Hospital with ProSense®. A local CBS news affiliate station aired an engaging news segment regarding a 90 year-old patient who was treated for low-risk breast cancer with ProSense® and walked out 30 minutes later to continue her active day. See the segment HERE. The hospital's purchase was made possible by the Thomas Hospital Foundation, a nonprofit organization dedicated to supporting Thomas Hospital to access state-of-the-art medical technology to offer innovative and compassionate care for their patients. IceCure is currently in talks with numerous regional hospitals across the U.S. with a profile similar to Thomas Hospital.

- **Shero Imaging, a St. Louis, Missouri based privately owned and operated clinic, is the first clinic in the state to offer breast cancer cryoablation with ProSense® -** Shero Imaging is an example of how an advanced breast imaging center can grow beyond diagnostics into treatment with ProSense®. IceCure estimates that there are approximately 8,700 breast imaging facilities in the U.S., with 3,000 to 4,000 of them being privately owned and 800 – 1,500 dedicated women's breast imaging centers, similar to Shero.
- **During 2025, ProSense® was featured in a record number of peer-reviewed publications and conference presentations** - 16 principal investigators presented at 10 conferences across the globe including the U.S., Europe, and Asia, covering indications including breast, musculoskeletal and kidney cancer.
- **An independent study published in *Clinical Breast Cancer* reports ProSense® cryoablation produces excellent outcomes including reduced anxiety and improved quality of life –** this single-center prospective study conducted at the Breast Diagnostic Unit of Careggi University Hospital in Italy reports ProSense® is a safe and effective treatment for early-stage breast cancer, demonstrating a positive impact on patient quality of life (QoL), including reduced pain (VAS score), reduced anxiety, and improved overall well-being with the largest improvements seen in physical wellbeing
- **In an independent study using ProSense® resulted in 92.9% volume reduction of fibroadenoma one-year post-cryoablation** - The investigator-initiated study titled "Cryoablation for fibroadenoma with liquid nitrogen-based system: A retrospective analysis of prospectively collected data" was published in the peer-reviewed journal PLOS One. ProSense® cryoablation has FDA-clearance for fibroadenomas. The study, which is believed to be the first to evaluate larger lesions and use multiple cryoprobe relocations, may impact treatment guidelines issued by medical societies for large non-cancerous breast tumors.
- **Several independent international studies underway are increasing global exposure to ProSense® among patients and physicians** - The SIX study led by Dr. Vanessa Sanvido, a leading breast surgeon in Brazil, and the PRECICE study in Italy, led by Prof. Franco Orsi, an interventional radiologist and key opinion leader, are heavily promoting their studies on social media to recruit patients. This is expected to lead not only to valuable clinical data, but also to increased patient awareness of cryoablation as a minimally invasive treatment option for low-risk breast cancer.

Financial Results for the Twelve Months Ended December 31, 2025

Revenue for the twelve months ended December 31, 2025, increased to $3,379,000 from $3,291,000 for the twelve months ended December 31, 2024, which included the recognition of $100,000 from a distribution agreement and other services in Japan. The increase in sales was due to an increase in sales in Europe, Latin America, North America and China, partially offset by a decrease in sales in Japan.

Gross profit for the twelve months ended December 31, 2025, was $1,226,000 compared to $1,451,000 for the twelve months ended December 31, 2024. Gross margin was 36% in the twelve months ended December 31, 2025, compared to 44**%** in the twelve months ended December 31, 2024. Non-GAAP gross profit for the twelve months ended December 31, 2025 was $1,226,000 compared to $1,351,000 for the twelve months ended December 31, 2024. Non-GAAP gross margin for the twelve months ended December 31, 2025 was 36%

compared to 42% for the twelve months ended December 31, 2024. The changes in non-GAAP gross profit and non-GAAP gross margin, which exclude revenue from the exclusive distribution agreements and other services in Japan, was mostly attributable to the decrease in revenue from the exclusive distribution agreements and other services in Japan, an increase in our cost of revenues in 2025, mostly in raw materials, subcontractors, auxiliary material costs, and an increase in payroll and related benefits and other costs. 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 twelve months ended December 31, 2025 were $7,433,000 compared to $7,096,000 in the twelve months ended December 31, 2024, primarily reflecting an increase in clinical trials and payroll and related benefits which were partially offset by a reduction in our development expenses for the XSense system .

Sales and marketing expenses for the twelve months ended December 31, 2025 were $4,358,000, compared to $6,296,000 for the twelve months ended December 31, 2024 primarily reflecting mainly a reduction in costs associated with consultants and professional services related to our De Novo classification approval case with the FDA and the associated convening of the Advisory Panel, a decrease in travel and a decrease in payroll and related benefits expenses. The Company expects sales and marketing expenses to increase in 2026 as IceCure enhances its market penetration efforts in the U.S. following FDA clearance for low-risk breast cancer at the end of 2025. General and administrative expenses for the twelve months ended December 31, 2025 were $4,529,000, compared to $3,755,000 for the twelve months ended December 31, 2024 reflecting an increase primarily in payroll and related benefits mostly attributed to increase in share-based compensation expenses and the depreciation of the USD against the NIS.

Total operating expenses for the twelve months ended December 31, 2025 declined to $16,320,000 from $17,147,000 for the twelve months ended December 31, 2024. The decrease in operating expenses was attributable to the decrease in sales and marketing expenses, partially offset by the decrease in gross profit and the increase in research and development and general and administrative expenses.

Net loss narrowed for the twelve months ended December 31, 2025, to $15,057,000, or $0.24 per share, compared to a net loss of $15,318,000, or $0.30 per share, for the twelve months ended December 31, 2024.

As of December 31, 2025, cash and cash equivalents, including short-term deposits, totaled $8,897,000, compared to $7,564,000 as of December 31, 2024.

Conference call & webcast info:
Tuesday, March 17, 2026, at 11:00 am EST
US: 1-888-407-2553
Israel/International: +972-3-918-0696
A live webcast will be available at: https://www.veidan-conferencing.com/icecure-investors
A recording of the webcast will be available at: ir.icecure-medical.com.

About IceCure Medical

IceCure Medical (Nasdaq: ICCM) develops and markets advanced liquid-nitrogen-based cryoablation therapy systems for the destruction 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 option to 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 Statement

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 strong commercial momentum for ProSense; updated ASBrS guidance representing an important step toward broader clinical adoption of ProSense; the expected timing and patient enrollment and treatment for the ChoICE post-marketing study; growing global adoption of ProSense and increasing interest from physicians, hospitals and patients; plans to expand the Company's sales team and broaden access to ProSense to drive meaning commercial growth in North America; expectations to increases to CPT code reimbursement and coverage; a decision by Health Canada on the Company's Class III amendment application is expected during the second half of 2026; that more regulatory submissions are expected, including by Terumo Corporation which is expected to file for regulatory approval for ProSense in Japan in the treatment of breast cancer in the first half of 2026; hospitals and clinics expected to purchase additional ProSense systems; that several studies are underway which are expected to lead to valuable clinical data and increased patient awareness of cryoablation as a minimally invasive treatment option for low-risk breast cancer; and that the Company expects sales and marketing expenses to increase in 2026 as IceCure enhances its market penetration efforts in the U.S. 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, 2025	As of December 31, 2024
	U.S. dollars in thousands	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	8,897	7,564
Trade receivables	331	221
Inventory	2,625	1,988
Prepaid expenses and other receivables	752	981
Total current assets	12,605	10,754
NON-CURRENT ASSETS		
Right-of-use assets	239	524
Property and equipment, net	993	1,252
Long-term restricted deposits	51	46
Total non-current assets	1,283	1,822
TOTAL ASSETS	13,888	12,576
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade payables	863	1,232
Lease liabilities	204	298
Employees and employees related benefits	2,659	2,757
Other current liabilities	1,098	1,227
Total current liabilities	4,824	5,514
NON-CURRENT LIABILITIES		
Long-term lease liabilities	13	161
Total non-current liabilities	13	161
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 73,122,293 shares and 56,568,999 shares as of December 31, 2025 and December 31, 2024, respectively		
Additional paid-in capital	129,487	112,280
Accumulated deficit	(120,436)	(105,379)
Total shareholders' equity	9,051	6,901
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	13,888	12,576

ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,	
	2025	**2024**
	U.S. dollars in thousands (except per share data)	
Revenues	3,379	3,291
Cost of revenues	2,153	1,840
Gross profit	1,226	1,451
Research and development expenses	7,433	7,096
Sales and marketing expenses	4,358	6,296
General and administrative expenses	4,529	3,755
Operating loss	15,094	15,696
Finance income, net	(37)	(378)
Net loss and comprehensive loss	15,057	15,318
Basic and diluted net loss per share	0.24	0.30
Weighted average number of shares outstanding used in computing basic and diluted loss per share	63,579,251	50,876,790

ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2025	2024
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(15,057)	(15,318)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	295	332
Share-based compensation	1,373	869
Exchange rate changes in cash and cash equivalents and long-term restricted deposits	(114)	39
Changes in assets and liabilities:		
Increase in trade receivables	(110)	(118)
Decrease (increase) in prepaid expenses and other receivables	229	(237)
Decrease (increase) in inventory	(637)	287
Decrease in right of use assets	327	271
Increase (decrease) in trade payables	(369)	730
Decrease in lease liabilities	(284)	(256)
Increase (decrease) in employees and employees related liabilities	(98)	764
Increase (decrease) in other current liabilities	(129)	74
Net cash used in operating activities	(14,574)	(12,563)
Cash flows from investing activities		
Investment in short-term deposits	(5,000)	(1,373)
Withdrawal of short-term deposits	5,000	1,902
Withdrawal of (investment in) restricted deposits	-	(12)
Purchase of property and equipment	(36)	(71)
Net cash provided by (used in) investing activities	(36)	446
Cash flows from financing activities:		
Loan from related party	2,000	-
Repayment of loan from relate party	(2,000)	-
Proceeds from issuance of ordinary shares, warrants and pre-funded warrants, net of issuance costs	15,539	9,187
Proceeds from warrants and pre-funded warrants exercise	295	-
Net cash provided by financing activities	15,834	9,187
Increase (decrease) in cash and cash equivalents	1,224	(2,930)
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	109	(39)
Cash and cash equivalents at end of period	8,897	7,564
Non-cash activities		
Obtaining a right-of-use asset in exchange for a lease liability	41	116

APPENDIX A
NON-GAAP RECONCILIATIONS

U.S. dollars in thousands	Year ended December 31, 2025	2024
GAAP gross profit	$ 1,226	$ 1,451
Revenue from Exclusive Distribution Agreement and other services	-	(100)
Non-GAAP gross profit	$ 1,226	$ 1,351
Sales of systems and disposables	3,379	3,191
Non-GAAP gross profit	$ 1,226	$ 1,351
Non-GAAP gross margin %	36 %	42 %

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