November 19, 2025

IceCure Reports Financial & Operational Results for the Nine Months Ended September 30, 2025

Momentum building in the U.S. and rising interest globally following landmark FDA marketing
authorization for local cryoablation treatment of low-risk breast cancer

Demand for ProSense® systems expected to accelerate in 2026

Total U.S. population of approximately 200,000 patients, includes women aged 70+, those not suitable for surgery and benign breast tumors

Conference call to be held today, November 19, 2025 at 10:00 am Eastern Time

CAESAREA, Israel, Nov. 19, 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 option to surgical tumor removal, today reported financial results as of and for the nine months ended September 30, 2025.

In October 2025, the U.S. Food and Drug Administration ("FDA") granted marketing authorization to IceCure's De Novo application for the ProSense® cryoablation system for the local treatment of breast cancer in patients ≥70 years of age with biologically low-risk tumors ≤1.5 cm in size and treated with adjuvant endocrine therapy.

"This was a landmark quarter for IceCure and the patients we aim to serve," said Eyal

Shamir, Chief Executive Officer of IceCure Medical. "The FDA's marketing authorization for ProSense® in low-risk breast cancer in women aged 70 and over marks a historic milestone and validates years of rigorous clinical research, positioning IceCure at the forefront of minimally invasive breast cancer care. In addition to the 46,000 patients that are 70+, we believe there are an additional 88,000 patients not suitable for or willing to go through surgery and approximately 63,000 patients with benign breast tumors who can also benefit from cryoablation."

"The immediate response to the FDA's decision has been overwhelming and we are getting interest in the U.S. and globally from new potential users including breast surgeons, interventional and breast radiologists who are asking for demonstrations and installations," added Mr. Shamir. "Over the past few months, we've seen an uptick in probe sales to our installed base of existing ProSense® users in the U.S. and internationally. Further expanding ProSense®'s availability, we recently received regulatory approval in Switzerland for indications including breast cancer."

"Our U.S. sales team is hard at work. We expect ProSense® installations and procedure volume to increase and are very optimistic about our commercial traction," Shamir concluded.

Upcoming Catalysts

- **Commercial momentum expected to accelerate** in the U.S. and globally following ProSense®'s FDA's marketing authorization for early-stage breast cancer.
- **ProSense® expected to rollout to 30 clinical/commercial sites** across the U.S. pending the FDA's anticipated review and agreement with IceCure's Post-Market Study protocol. This study will run parallel to the commercial roll out of ProSense®, which has already launched for the authorized breast cancer indication. 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.
- **Additional reimbursement coverage** may potentially become available for ProSense® procedures based on factors including the FDA's marketing authorization in early-stage breast cancer, post-market activity, and recommendations from professional medical associations. ProSense® currently has reimbursement under the CPT III code which covers $3,800 of facility costs, which is expected to increase to slightly over $4,000 effective January 2026.
- **Regulatory submission expected in Japan** by Terumo Corporation, IceCure's partner in Japan, in the first half of 2026 for approval of ProSense® in breast cancer.

Third Quarter 2025 and Recent Operational and Clinical Highlights

- **FDA Marketing Authorization for ProSense®** – The FDA granted marketing authorization for ProSense® for the treatment of low-risk breast cancer in women aged 70 and above and patients not suitable for surgery, a landmark achievement that opens the U.S. market for IceCure's technology as a minimally invasive alternative to surgery. Special controls were included in the FDA's authorization including any other company wishing to file for 510(k) marketing authorization for a different cryoablation system to treat breast cancer will be required to submit 5 years of follow-up data and that the system be liquid-nitrogen based system and use 10-gauge cryoprobes.
- **Post-Market Study Protocol Submitted to FDA** – The post-market study is expected

to include approximately 400 patients at 30 sites, and the established reimbursement code may be used to support claims and reimbursement for the study procedures. IceCure will provide an update when the post-market study protocol is approved by the FDA.

- **Regulatory Approval in Switzerland** – ProSense® and its cryoprobes are now cleared for commercial sales in Switzerland for indications including the treatment of malignant or benign tissue of the breast, lung, liver, kidney, and musculoskeletal (bone), including palliative interventions.
- **Regulatory and IP Milestones for XSense™ in Israel, U.S., and Japan**– Israel granted regulatory approval for the next-generation XSense™ Cryoablation System for breast cancer and other indications. XSense™ and its cryoprobes received a Notice of Allowance for patents in the U.S. and Japan, further strengthening intellectual property protection for IceCure's platform.
- **ProSense® Featured at High-Impact Medical Conferences** – High-level presentations by Key Opinion Leaders, data presentations, and hands-on trainings were conducted at the 2025 annual meeting of the Cardiovascular and Interventional Radiological Society of Europe ("CIRSE"), the annual Japanese Breast Cancer Society Conference, the 2025 European Society of Breast Imaging ("EUSOBI") Congress, Aptitude Health's Targeted Medical Education (TME) Take the Lead in Breast Cancer Care Fall Summit 2025 in New Orleans which focused on breast surgeons, as well as a 2-day hands on training at the Percutaneous Breast Treatment Course at Careggi Hospital in Italy.
- **Brazilian Medical Delegation Convenes at IceCure for Meetings with Clinical Department and KOLs in Israel** – A delegation of doctors from Brazil and France including 5 interventional radiologists and 1 breast surgeon, met at IceCure's offices for a clinical overview and roundtable discussions featuring presentations regarding on-going clinical trials for breast cancer cryoablation from Dr. Toulsie Ramtohul, Interventional Radiologist from the Institut Curie in Paris and Dr. Vanessa Sanvido, Breast Surgeon, at HCor Hospital in Sao Paolo. The group also observed live clinical cases at Bnai Zion and Beilinson Medical Centers.
- **Multiple Independent Clinical Studies Validating ProSense® Presented and Published Across Various Indications**
- Lung Cancer
    - Study published in *PLOS Once* reported that IceCure's cryoablation system combined with radiation therapy successfully treated non-small cell lung cancer ("NSCLC") with 92% disease-specific 5-year survival.
- Endometriosis
    - Study published in the *Journal of Personalized Medicine* reported a significant reduction in pain and high procedural efficacy in abdominal wall endometriosis. Further, pain scores declined from a median of 8 on a scale of 0-10 to a median of 0 for patients who had ProSense® cryoablation procedure.
- Breast Cancer
    - Data from two studies presented at the annual Japanese Breast Cancer Society Conference reported a 99% recurrence-free rate and 0% breast cancer local recurrence rate.
    - Positive results from four independent studies presented at CIRSE 2025 including the PRECICE trial in Italy, which encompasses a wider population of patients than IceCure's ICE3 trial, a study on Hormone Receptor Positive (HR+) breast cancer in France, and two additional studies in Italy on HR+ breast cancer

and cryoablation in combination with hormone therapy.
- Two new publications from the independent THERMAC trial showing high complete ablation rates and 95% patient satisfaction were published in the *Journal of Surgical Oncology* and in *Radiology.*
- Strong presence at EUSOBI 2025 with results from five independent studies conducted in Italy, Spain, and Turkey, demonstrating de-escalation of breast cancer care.

Financial Results for the Nine Months Ended September 30, 2025

Revenue for the nine months ended September 30, 2025, was $2,100,000 compared to $2,416,000 for the nine months ended September 30, 2024, which included the recognition of $100,000 from a distribution agreement and other services in Japan. With the FDA's marketing clearance for ProSense® in low-risk breast cancer granted in October of 2025, the Company expects continued fluctuations in quarterly revenues as commercial activities ramp up in the U.S. and globally. The $316,000 decline in sales was due to a decrease in sales in Japan, other territories in Asia, and North America, and was partially offset by an increase in sales in Latin America.

Gross profit for the nine months ended September 30, 2025, was $626,000, compared to $1,034,000 for the nine months ended September 30, 2024. Gross margin was 30% in the nine months ended September 30, 2025, compared to 43**%** in the nine months ended September 30, 2024. Non-GAAP gross profit for the nine months ended September 30, 2025 was $626,000 compared to $934,000 for the nine months ended September 30, 2024. Non-GAAP gross margin for the nine months ended September 30, 2025 was 30% compared to 40% for the nine months ended September 30, 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 of 9% in revenue from sales of ProSense® systems and disposables probes. 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 nine months ended September 30, 2025 were $5,137,000, compared to $5,401,000 in the nine months ended September 30, 2024, primarily reflecting a reduction in service providers and consultants and clinical trials costs as the Company concluded its ICE3 study in 2024.

Sales and marketing expenses for the nine months ended September 30, 2025 were $3,061,000, compared to $4,041,000 for the nine months ended September 30, 2024, primarily reflecting a reduction in service providers and consultants. General and administrative expenses for the nine months ended September 30, 2025 were $3,306,000, compared to $2,763,000 nine months ended September 30, 2024, reflecting an increase primarily in service providers, consultants and share based compensation.

Total operating expenses for the nine months ended September 30, 2025 declined to $11,504,000 from $12,205,000 for the nine months ended September 30, 2024. The decrease in operating expenses was attributable to reductions in research and development, and sales and marketing expenses, and partially offset by increases in general and

administrative expenses.

Net loss for the nine months ended September 30, 2025, was $10,811,000, or $0.18 per share, relatively unchanged compared to a net loss of $10,839,000, or $0.22 per share, for the same period last year.

As of September 30, 2025, the Company had cash, cash equivalents, including short-term deposits, of approximately $10.0 million, compared to $7.6 million as of December 31, 2024. In July 2025, the Company successfully completed a rights offering, which was approximately two times oversubscribed, raising $10 million in gross proceeds to support commercialization of ProSense® and of the next-generation XSense™ system.

During the first ten months of 2025, the Company raised $5.87 million in net proceeds from the sale of 5,425,806 ordinary shares under its at-the-market offering facility bringing its cash balance as of October 31, 2025 to $11.8 million.

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:
Wednesday, November 19, 2025, at 10:00 am EST
US: 1-888-407-2553
Israel/International: +972-3-918-0696
A live webcast will be available at: https://www.veidan-conferenceing.com/icecure
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 potential and expected benefits of the FDA's marking authorization for ProSense®; anticipated U.S. and global commercial traction; the planned rollout of ProSense® to clinical and commercial sites pending FDA review and agreement with post-market study plans; potential reimbursement coverage and code updates; the timing and outcome of Terumo Corporation's planned regulatory submission in Japan; the expected design, timing, and impact of the post-market study; the Company's expectations regarding procedure volume, installations, and sales momentum; and future regulatory, clinical, and commercial developments for ProSense® and XSense™. 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 September 30, 2025	As of December 31, 2024
	(Unaudited)	
	U.S. dollars in thousands	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	4,971	7,564
Short-term deposits	5,034	-
Trade receivables	104	221
Inventory	2,711	1,988
Prepaid expenses and other receivables	836	981
Total current assets	13,656	10,754
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	49	46
Right of use assets	314	524
Property and equipment, net	1,059	1,252
Total non-current assets	1,422	1,822
TOTAL ASSETS	15,078	12,576
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade payables	1,151	1,232
Lease liabilities	264	298
Employees and other current liabilities	4,333	3,984
Total current liabilities	5,748	5,514
NON-CURRENT LIABILITIES		
Long-term lease liabilities	24	161
Total non-current liabilities	24	161
SHAREHOLDERS' EQUITY		
Ordinary shares, no par value; Authorized 2,500,000,000 shares; Issued and outstanding: 68,963,210 shares and 56,568,999 shares as of September 30, 2025 and December 31, 2024, respectively for each of the periods		
Additional paid-in capital	125,496	112,280
Accumulated deficit	(116,190)	(105,379)
Total shareholders' equity	9,306	6,901
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	15,078	12,576

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

	Nine months ended September 30,	
	2025	**2024**
	U.S. dollars in thousands (except per share data)	
Revenues	2,100	2,416
Cost of revenues	1,474	1,382
Gross profit	626	1,034
Research and development expenses	5,137	5,401
Sales and marketing expenses	3,061	4,041
General and administrative expenses	3,306	2,763
Operating loss	10,878	11,171
Finance income, net	(67)	(332)
Net loss and comprehensive loss	10,811	10,839
Basic and diluted net loss per share	0.18	0.22
Weighted average number of shares outstanding used in computing basic and diluted loss per share	60,567,124	49,167,379

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

	Nine months ended September 30,	
	2025	**2024**
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(10,811)	(10,839)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	224	250
Share-based compensation	1,102	650
Exchange rate changes in cash and cash equivalents and restricted long-term deposits	118	33
Non-Cash short-term deposits interest income	(34)	-
Changes in assets and liabilities:		
Decrease (increase) in trade receivables	117	(37)
Decrease in prepaid expenses and other receivables	145	197
Decrease (increase) in inventory	(723)	294
Decrease in right of use assets	251	202
Increase (decrease) in trade payables	(81)	747
Decrease in lease liabilities	(212)	(202)
Increase in employees and other current liabilities	349	337
Net cash used in operating activities	(9,555)	(8,368)
Cash flows from investing activities		
Investment in short-term deposits	(5,000)	(1,373)
Withdrawal of short-term deposits	-	1,902
Investment in restricted long-term deposits	-	(10)
Purchase of property and equipment	(31)	(66)
Net cash provided by (used in) investing activities	(5,031)	453
Cash flows from financing activities:		
Proceeds from issuance of ordinary shares and Pre-Funded Warrants, net of issuance costs	11,822	8,086
Proceeds from Warrants Exercise	292	-
Net cash provided by financing activities	12,114	8,086
Increase (decrease) in cash and cash equivalents	(2,472)	171
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	(121)	(33)
Cash and cash equivalents at end of period	4,971	10,671
Non-cash activities		
Obtaining a right-of-use asset in exchange for a lease liability	41	89

APPENDIX A
NON-GAAP RECONCILIATIONS (Unaudited)

	Nine months ended September 30,	
U.S. dollars in thousands	**2025**	**2024**
GAAP gross profit	$ 626	$ 1,034
Revenue from Exclusive Distribution Agreement	-	(100)
Non-GAAP gross profit	$ 626	$ 934
GAAP gross margin %	30 %	43 %
Sales of systems and disposables	2,100	2,316
Non-GAAP gross profit	$ 626	$ 934
Non-GAAP gross margin %	30 %	40 %

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