August 13, 2025

IceCure Reports Financial & Operational Results for the First Half of 2025

$10 million two-times over-subscribed rights offering creates cash runway to anticipated FDA marketing authorization decision for ProSense® in women aged 70+ with early-stage low risk breast cancer

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

CAESAREA, Israel, Aug. 13, 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 six months ended June 30, 2025.

During the second quarter of 2025, IceCure concluded a productive meeting with the leadership of the U.S. Food and Drug Administration's ("FDA") Center for Devices and Radiological Health ("CDRH") regarding the Company's De Novo marketing authorization request for ProSense® in the treatment of early-stage low risk breast cancer when combined with adjuvant endocrine therapy for women aged 70 and over which represents approximately 46,000 patients annually in the U.S., alone.

The FDA requested that IceCure conduct a study after marketing authorization has been granted (the "Post-Market Study"), with the aim of producing additional data in this indication. IceCure has presented its Post-Market Study plan to the FDA and, upon the CDRH's approval of such plan, the FDA's final marketing authorization decision is expected.

"The Post-Marketing Study plan was fully submitted to the FDA and we have an ongoing dialog with the agency. We believe the plan reflects a comprehensive and well-structured approach," stated Eyal Shamir, IceCure CEO. "The FDA reviewed the plan and asked us to provide additional information which we are actively working to complete. Assuming the FDA finds the supplemental data satisfactory, we remain optimistic that approval will be granted before year-end 2025."

"As we continue to gain wider ProSense® adoption in the U.S., we are experiencing a positive shift in Europe toward greater utilization of our cryoablation system, specifically for breast cancer. While ProSense® has been approved for breast cancer and other indications in Europe, we believe this recent uptick in breast cancer cryoablation with ProSense® in Europe is likely the result of our successfully concluded ICE3 study and the growing body of evidence from independent studies."

"We believe that regulatory and commercial momentum, as well as continued strong clinical results from independent studies, have given our long-term shareholders even more confidence in our ability to execute on a substantial market and treatment opportunity. On August 1, 2025, we closed a rights offering that was approximately two times over-subscribed, yielding gross proceeds of $10 million, and signaling strong support from our shareholder base," Shamir concluded.

Upcoming value-driving milestones expected include:

- FDA marketing authorization decision for ProSense® in women aged 70+ with early-stage low risk breast cancer;
- Terumo Corporation, IceCure's partner in Japan, is expected to file for regulatory approval of ProSense® for breast cancer in Japan before the end of 2025;
- Following IceCure's submission of its next-generation XSense™ system to the Israeli Ministry of Health, the Company is working with the authorities to finalize approval;
- Driving further commercial adoption and demand, ProSense® will be featured in workshops and hand-on trainings at key global breast imaging and interventional radiology events in September 2025, including at the European Society of Breast Imaging and the Cardiovascular and Interventional Radiology Society of Europe; 10 independent studies of ProSense® cryoablation have been accepted for presentations at these conferences; and
- Additional value-driving clinical data may be forthcoming, as independent researchers are modeling their clinical trials on ICE3; this includes the PRECISE trial in Italy and an upcoming trial at Universidade Federal de São Paulo, Brazil ("UNIFESP").

Second quarter 2025 and recent ProSense® clinical data and commercial activities:

- ProSense® was featured at the Japanese Breast Cancer Society Conference; Professor Eisuke Fukuma, a highly regarded cryoablation expert and ProSense® user, presented updated breast cancer cryoablation data from an independent study of over 600 women from 2006 to 2023 showing a **99% recurrence free rate;**
- A 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;
- At the Society of Breast Imaging 2025 Breast Imaging Symposium, two sold-out breast cryoablation courses featured hands-on training with ProSense®;

- ProSense® was featured at 7 key events at the European Conference on Interventional Oncology 2025; independent studies of ProSense® were featured in scientific sessions and abstracts including data from the THERMAC trial stating **91% of patients would choose thermal ablation** over breast conserving surgery

Financial Results for the Six Months Ended June 30, 2025

Revenue for the six months ended June 30, 2025 was $1,250,000 compared to $1,754,000 for the six months ended June 30, 2024, that included recognition of $100,000 from a distribution agreement and other services in Japan. As previously announced, shipments of product sales worth more than $200,000, that were scheduled for delivery during the second quarter of 2025, were delayed due to the Israel-Iran conflict in June 2025. Payments for these orders, which were primarily from ProSense® distributors in global markets outside of the U.S., were received by IceCure during the second quarter of 2025 and recorded on the Company's balance sheet as deferred sales.

Gross profit for the six months ended June 30, 2025 was $349,000 compared to $799,000 for the six months ended June 30, 2024. Gross margin for the six months ended June 30, 2025 was 28% compared to 46% for the six months ended June 30, 2024. Non-GAAP gross profit for the six months ended June 30, 2025 was $349,000 compared to $699,000 for the six months ended June 30, 2024. Non-GAAP gross margin for the six months ended June 30, 2025 was 28% compared to 42% for the six months ended June 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 attributable to the decrease of 24% 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 six months ended June 30, 2025 were $3,375,000 compared to $3,536,000 for the six months ended June 30, 2024. The decrease was primarily due to a reduction in payroll and related benefits and clinical trials costs as the Company concluded the ICE3 study in 2024.

Sales and marketing expenses for the six months ended June 30, 2025 were $2,146,000 compared to $2,296,000 million for the six months ended June 30, 2024. General and administrative expenses for the six months ended June 30, 2025, were $1,870,000 compared to $1,845,000 for the six months ended June 30, 2024.

Total operating expenses for the six months ended June 30, 2025 decreased to $7,391,000 from $7,677,000 for the six months ended June 30, 2024. The decrease in operating expenses was attributable to reductions in research and development and sales and marketing expenses, due to the Company's initiative to reduce non-critical operating expenses, which were partially offset by a minor increase in general and administrative expenses.

Net loss for the six months ended June 30, 2025 was $6,952,000, or $0.12 per share

compared to a net loss of $6,690,000, or $0.14 per share, for the same period last year.

As of June 30, 2025, the Company had cash and cash equivalents, including short-term deposits, of approximately $5.38 million, including a $2 million bridge loan from its major shareholder. During the first half of 2025, the Company raised $2.65 million in net proceeds from the sale of 2,127,961 ordinary shares under its at-the-market offering facility.

On August 1, 2025, the Company strengthened its balance sheet as it successfully closed on a $10 million funding through a rights offering, which was approximately two times oversubscribed. The Company plans to repay the $2 million bridge to its major shareholder during the month of August 2025.

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, August 13, 2025, at 11:00 am EDT
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 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: the belief that the Post-Marketing Study plan reflects a comprehensive and well-structured approach; the belief that regulatory approval based on the Post-Marketing Study plan will be granted before year-end 2025; the belief that the increasing popularity in ProSense® in Europe is the result of the ICE3 study and the growing body of evidence from independent studies; the belief that regulatory and commercial momentum, as well as continued strong clinical results from independent studies, have given the Company's long-term shareholders more confidence in the Company's ability to execute on a substantial market and treatment opportunity; the belief that the rights offering signalled strong support from the Company's shareholder base; the impending FDA final marketing authorization decision; Terumo Corporation's expected regulatory filing for ProSense® regulatory approval; the expected response from regulatory authorities in Israel for XSense™; the expectation that ProSense® will be featured in workshops and hand-on trainings at key global breast imaging and interventional radiology events in September 2025, including at the European Society of Breast Imaging and the Cardiovascular and Interventional Radiology Society of Europe; and the possibility that additional value-driving clinical data may be forthcoming, including from the PRECISE trial in Italy and an upcoming trial at UNIFESP. 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.

IR Contact:

Email: investors@icecure-medical.com
Michael Polyviou
Phone: 732-232-6914

ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	As of June 30, 2025	As of December 31, 2024
	(Unaudited)	
	U.S. dollars in thousands	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	5,383	7,564
Trade receivables	122	221
Inventory	2,329	1,988
Prepaid expenses and other receivables	1,186	981
Total current assets	9,020	10,754
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	48	46
Right-of-use assets	392	524
Property and equipment, net	1,129	1,252
Total non-current assets	1,569	1,822
TOTAL ASSETS	10,589	12,576
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade payables	1,161	1,232
Lease liabilities	301	298
Loan from related party	2,010	-
Employees and other current liabilities	4,167	3,984
Total current liabilities	7,639	5,514
NON-CURRENT LIABILITIES		
Long-term lease liabilities	59	161
Total non-current liabilities	59	161
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 58,696,960 shares and 56,568,999 shares as of June 30, 2025 and December 31, 2024, respectively		
Additional paid-in capital	115,222	112,280
Accumulated deficit	(112,331)	(105,379)
Total shareholders' equity	2,891	6,901
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	10,589	12,576

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

	Six months ended June 30,	
	2025	**2024**
	U.S. dollars in thousands (except per share data)	
Revenues	1,250	1,754
Cost of revenues	901	955
Gross profit	349	799
Research and development expenses	3,375	3,536
Sales and marketing expenses	2,146	2,296
General and administrative expenses	1,870	1,845
Operating loss	7,042	6,878
Finance income, net	(90)	(188)
Net loss and comprehensive loss	6,952	6,690
Basic and diluted net loss per share	0.12	0.14
Weighted average number of shares outstanding used in computing basic and diluted loss per share	58,155,523	47,850,703

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

	Six months ended June 30,	
	2025	**2024**
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(6,952)	(6,690)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	151	167
Share-based compensation	295	410
Exchange rate changes in cash and cash equivalents, short-term deposits and restricted long term deposits	(52)	79
Other finance cost	10	(8)
Changes in assets and liabilities:		
Decrease (increase) in trade receivables	99	(222)
Decrease (increase) in prepaid expenses and other receivables	(205)	170
Decrease (increase) in inventory	(341)	306
Decrease in right of use assets	173	135
Increase (decrease) in trade payables	(71)	193
Decrease in lease liabilities	(140)	(143)
Increase in employees and other current liabilities	183	388
Net cash used in operating activities	(6,850)	(5,215)
Cash flows from investing activities		
Investment in short-term deposits	-	(1,373)
Withdrawal of short-term deposits	-	1,065
Investment in restricted long term deposits	-	(10)
Purchase of property and equipment	(28)	(34)
Net cash provided by (used in) investing activities	(28)	(352)
Cash flows from financing activities:		
Loan from related party	2,000	-
Issuance of ordinary shares, net of issuance costs	2,647	4,727
Net cash provided by financing activities	4,647	4,727
Decrease in cash and cash equivalents	(2,231)	(840)
Cash and cash equivalents at the beginning of the year	7,564	10,533
Effect of exchange rate fluctuations on balances of cash and cash equivalents	50	(41)
Cash and cash equivalents at the end of period	5,383	9,652
Non-cash activities		
Obtaining a right-of-use asset in exchange for a lease liability	41	64

APPENDIX A
NON-GAAP RECONCILIATIONS (Unaudited)

U.S. dollars in thousands	Six Months ended June 30, 2025		Six Months ended June 30, 2024	
GAAP gross profit	$ 349		$ 799	
Revenue from Exclusive Distribution Agreement	-		(100)	
Non-GAAP gross profit	$ 349		$ 699	
GAAP gross margin %	28	%	46	%
Sales of systems and disposables	1,250		1,654	
Non-GAAP gross profit	$ 349		$ 699	
Non-GAAP gross margin %	28	%	42	%

Logo - https://mma.prnewswire.com/media/2319310/IceCure_Medical_Logo.jpg

View original content:https://www.prnewswire.com/news-releases/icecure-reports-financial--operational-results-for-the-first-half-of-2025-302528890.html

SOURCE IceCure Medical