

May 22, 2023



IceCure Medical Reports First Quarter 2023 Financial & Operational Results

- ***Physician Interest and Adoption of ProSense in the U.S. Builds Momentum as ProSense is Featured at Medical Conferences and Educational Courses***
- ***ProSense was the only Cryoablation System Used in a First-of-its-Kind Cryotherapy Continuing Medical Education (CME) course at the American Society of Breast Surgeons (ASBrS) 2023 Annual Meeting Where a Plan was Presented for a Proposed ASBrS Cryoablation Trial***
- ***Regulatory Approval Received in China for Commercial Use of Disposable Cryoprobes***
- ***Independently Conducted Endometriosis Study Shows 92.8% Efficacy in Avoiding Secondary Surgery***
- ***Conference Call to be Held Today at 10:00 am Eastern Time***

CAESAREA, Israel, May 22, 2023 /PRNewswire/-- [IceCure Medical Ltd.](#) (the "Company" or "IceCure") (Nasdaq: ICCM) (TASE: ICCM) developer of the ProSense® System, a 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, 2023 as well as operational and recent corporate developments.



"ProSense is gaining heightened interest among breast surgeons, breast radiologists, and interventional oncologists globally and particularly in the U.S. where we are focusing our commercialization and marketing efforts. We believe this momentum in the market is bolstered by a broader trend toward minimally invasive procedures," stated IceCure CEO Eyal Shamir.

"We continue to engage with the U.S. Food and Drug Administration ("FDA") following the

October 2022 filing for marketing authorization for ProSense for early-stage low risk breast cancer in patients who are at high risk for surgery. These ongoing discussions are part of the regulatory submission process. Concurrently, we are highly encouraged by the American Society of Breast Surgeons' ("ASBrS") expressed plans for a cryoablation trial. We believe that such a planned trial could potentially establish a new minimally invasive standard for the treatment of low risk, early-stage breast cancer. We further believe it will support our commercialization plans, and raise awareness among ASBrS members, which include 3,000 of the most influential physicians in breast surgery.

"Globally, we continue to build momentum through regulatory submissions and approvals including in China where our IceSense3 system and cryoprobes are now fully approved for commercial use. In addition, we were pleased to learn of the favorable results from an independent study in France where ProSense and another cryoablation technology were used to treat endometriosis. We expect the continued adoption of ProSense through the rest of 2023.

"Our cash position at the end of the quarter remains strong at over \$20 million, and we believe our continued prudent management of our financial resources gives us the confidence to invest in our U.S. commercialization activities as we await the FDA's response."

First Quarter of 2023 and Recent Operating Highlights

- **ProSense and Cryoablation Received High Levels of Interest at ASBrS Meeting—Plans for Cryoablation Study Unveiled:** Surgeons attending the ASBrS 24th Annual Meeting enrolled in the Society's first-ever continuing medical education ("CME") course on cryoablation, which used the ProSense system. During the course led by cryoablation thought leaders, surgeons got first-hand experience using ProSense. They were also presented with interim results from IceCure's ICE3 clinical trial and the proposed plan for a future ASBrS trial that would evaluate cryoablation as a treatment for low risk early-stage breast cancer for women between the ages of 55 to 85. Breast cryoablation was favorably mentioned several times over the course of the 5-day conference including during a keynote speech by ASBrS leadership. Breast surgeons who visited IceCure's booth and participated in other hands-on demonstrations expressed a high level of interest in adopting the system and incorporating it into their practice. A hands-on training for ProSense also took place during the ASBrS Breast Fellows Course in January.
- **ProSense Featured in Breast Session at Society of Interventional Oncology's Annual Scientific Meeting:** Demonstrations on ProSense took place throughout the duration of the conference at IceCure's booth where interventional radiologists engaged with the system and expressed interest. ProSense was also featured in a panel discussion led by doctors currently using the system.
- **ProSense Featured in Workshop "Chest Ablation: Inside and Outside" at the Society of Interventional Radiology Annual Conference:** ProSense was featured as part of a well-attended panel discussion led by ICE3 Trial Co-Primary Investigator, Dr. Kenneth Tomkovich.
- **Received Regulatory Approval in China for Commercial Use of IceSense3 Cryoprobes:** The National Medical Products Administration ("NMPA") of China approved the IceSense3 (ProSense's brand name in China) disposable cryoprobes for

commercial use, to be used in combination with the Company's IceSense3 system console, which was previously approved by the NMPA. Commercialization in China is driven by IceCure's exclusive distribution agreement with Shanghai Medtronic Zhikang Medical Devices Co. Ltd., an affiliate of Medtronic, which includes minimum purchase targets.

- **ProSense Used in Cryoablation Endometriosis Study That Demonstrated 92.8% Efficacy in Avoiding Secondary Surgery:** The ProSense System was one of two types of cryoablation systems used in a single-site study conducted at the Sorbonne University Department of Interventional Radiology and Oncology, Tenon Hospital in Paris, France and published in the *Journal of Vascular and Interventional Radiology*. The independent study and paper were not sponsored by IceCure. The study concluded that percutaneous cryoablation is a safe and effective procedure that significantly reduces pain and obtains local control of extraperitoneal endometriosis. The efficacy rate of cryoablation to avoid secondary surgery was 92.8% per patient and 93.6% per nodule treated. The median pain-free survival rates were 93.75% at 6 months and 82.72% after 36 months. ProSense has regulatory approval in several countries, including FDA clearance for use as a cryosurgical tool in gynecology.
- **Patents Granted in U.S. and Japan:** IceCure received patents in the U.S. and Japan for its novel cryogenic pump, potentially broadening the clinical indications addressed by the Company's platform technology. This patent potentially expands IceCure's portfolio of products with a broader range of thinner cryoprobes and catheters designed for use in other indications, multiple procedures or longer duration procedures without the need to replenish liquid nitrogen.
- **Company's Ordinary Shares to Trade Exclusively on Nasdaq:** IceCure announced its voluntary delisting from the Tel Aviv Stock Exchange ("TASE"). The last day its Ordinary Shares will trade on the TASE will be July 20, 2023, and the Ordinary Shares will be delisted from the TASE on July 24, 2023.

Financial Results as of and for the Three Months Ended March 31, 2023

For the three months ended March 31, 2023, the Company reported revenue of \$0.71 million compared to revenue of \$0.75 million for the three months ended March 31, 2022. In the first quarter of 2023, sales increased in the U.S. and Europe relative to the same quarter last year.

Gross profit was \$0.32 million for the three months ended March 31, 2023, compared to approximately \$0.43 million for the three months ended March 31, 2022. Gross margin was 45% for the three months ended March 31, 2023, compared to 58% for the three months ended March 31, 2022. The decrease in gross margin compared to the same period last year resulted mostly from an increase in manufacturing costs.

Research and development expenses for the three months ended March 31, 2023, were \$2.11 million compared to \$2.39 million for the three months ended March 31, 2022. The decrease was primarily due to a reduction in development expenses of IceCure's next-generation single-probe system, partially offset by an increase in clinical and regulatory activities.

As a result of the Company's expanding commercialization efforts, sales and marketing expenses for the three months ended March 31, 2023, were \$1.08 million, compared to \$0.75 million for the three months ended March 31, 2022.

General and administrative expenses for the three months ended March 31, 2023, were \$1.09 million, compared to \$1.72 million for the three months ended March 31, 2022. The decrease is mainly due to a decrease in the cost of directors' and officers' insurance.

Total operating expenses for the three months ended March 31, 2023, were \$4.28 million, compared to \$4.86 million for the three months ended March 31, 2022. The decrease in operating expenses was primarily attributable to a reduction in research and development expenses and cost of directors' and officers' insurance. Net loss reported for the three months ended March 31, 2023, decreased to \$3.77 million, or \$0.08 per share, compared with a net loss of \$4.45 million, or \$0.12 per share, for the same period last year.

As of March 31, 2023, the Company had cash and cash equivalents, including short-term deposits, of approximately \$20.46 million, compared to \$23.66 million as of December 31, 2022.

Conference call & webcast info:

May 22, 2023, at 10:00 am ET

US: 1-888-642-5032

Israel/International: +972-3-9180609

A live webcast will be available at: <https://veidan.activetrail.biz/IcecureQ1-2023>

A recording of the webcast will be available at: <https://ir.icecure-medical.com/news-events/events-presentations>

About IceCure Medical Ltd.

IceCure Medical Ltd. (Nasdaq: ICCM) (TASE: ICCM) develops and markets ProSense®, an advanced liquid-nitrogen-based cryoablation therapy 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 system is marketed and sold worldwide for the indications cleared and approved to date including in the U.S., Europe, and China.

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 and Israeli 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 statement in this press release when it discusses the heightened interest and momentum in the market for its products, its commercialization and marketing efforts, its regulatory strategy, the ASBrS's plans for a cryoablation trial, its belief that such a trial could establish a new minimally invasive standard for the treatment of low risk, early-stage breast cancer and that it will support its commercialization process and make physicians aware of and participate in the trial being planned, the expected continued adoption of ProSense

through the rest of 2023, its anticipation of the FDA's response to regulatory requests for approvals, the potential of IceCure's product portfolio expansion into thinner cryoprobes and catheters through its granted patents in the U.S. and Japan, expansion of clinical applications and potential market adoption of its minimally-invasive cryoablation technology and the dates related to the voluntary delisting of the Company's ordinary shares from the TASE. . Because such statements deal with future events and are based on IceCure's current expectations, they are subject to various risks and uncertainties and actual results, performance, or achievements of IceCure could differ materially from those described in or implied by the statements in this press release. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, many of which are beyond the control of the Company, including those set forth in the Risk Factors section of the Company's Annual Report on Form 20-F for the year ended December 31, 2022 filed with the SEC on March 29, 2023, 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, 2023 (Unaudited)	As of December 31, 2022 (Audited)
	U.S. dollars in thousands	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	5,594	23,659
Deposits	14,870	-
Restricted deposit	296	296
Trade accounts receivables	143	78
Inventory	2,928	2,857
Prepaid expenses and other receivables	866	1,240
Total current assets	24,697	28,130
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	34	34
Right-of-use assets	620	668
Property and equipment, net	1,527	1,356
Total non-current assets	2,181	2,058
TOTAL ASSETS	26,878	30,188
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade accounts payable	685	714
Lease liabilities	164	167
Other current liabilities	3,643	3,455
Total current liabilities	4,492	4,336
NON-CURRENT LIABILITIES		
Long-term lease liabilities	376	430
Total non-current liabilities	376	430
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 45,623,434 shares as of March 31, 2023 and December 31, 2022, respectively		
Additional paid-in capital	101,187	100,831
Accumulated deficit	(79,177)	(75,409)
Total shareholders' equity	22,010	25,422
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	26,878	30,188

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

	Three months ended March 31,	
	2023	2022
	U.S. dollars in thousands (except per share data)	
Revenues	710	747
Cost of revenues	390	313
Gross profit	320	434
Research and development expenses	2,111	2,394
Sales and marketing expenses	1,075	747
General and administrative expenses	1,091	1,718
Operating loss	3,957	4,425
Financial expenses (income), net	(189)	22
Net loss and comprehensive loss	3,768	4,447
Basic and diluted net loss per share	0.08	0.12
Weighted average number of shares outstanding used in computing basic and diluted loss per share	45,623,434	36,814,335

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

	Three months ended March 31,	
	2023	2022
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(3,768)	(4,447)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	79	52
Share-based compensation	356	450
Exchange rate changes in cash and cash equivalents and short time deposits	8	62
Changes in assets and liabilities:		
Decrease (increase) in trade accounts receivables	(65)	10
Decrease in prepaid expenses and other receivables	374	728
Increase in inventory	(71)	(369)
Decrease in right of use assets	48	29
Decrease in trade accounts payable	(29)	(211)
Decrease in lease liabilities	(57)	(62)
Increase in other current liabilities	188	1,131
Decrease in other long-term liabilities	-	(433)
Net cash used in operating activities	(2,937)	(3,060)
Cash flows from investing activities		
Investment in short-term deposits	(14,870)	-
Purchase of property and equipment	(250)	(144)
Net cash provided by (used in) investing activities	(15,120)	(144)
Increase (decrease) in cash and cash equivalents	(18,057)	(3,204)
Cash and cash equivalents at beginning of the year	23,659	25,621
Effect of exchange rate fluctuations on balances of cash and cash equivalents	(8)	(62)
Cash and cash equivalents at end of period	5,594	22,355

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