

August 14, 2023



IceCure Medical Reports First Half 2023 Financial & Operational Results: Global Adoption of Cryoablation Technology Gaining Momentum

- *Company awaits FDA's response to its regulatory filing for early-stage low risk breast cancer in patients who are at high risk for surgery*
- *Renowned physician, Dr. Robert Ward, to participate on the Company's conference call scheduled for today at 10am EDT*

CAESAREA, Israel, Aug. 14, 2023 /PRNewswire/ -- [IceCure Medical Ltd.](#) (Nasdaq: ICCM) ("IceCure" or the "Company"), 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 six months ended June 30, 2023, as well as operational and recent corporate developments.



Second Quarter Highlights and Recent Achievements

- *Successful transition from clinical stage to commercial stage continues as ProSense received regulatory approvals in Canada and China*
- *Accelerated adoption with new distribution agreement in Portugal*
- *Cryoablation achieved a 92.8% efficacy in avoiding secondary surgery during a physician-sponsored cryoablation study of endometriosis, which affects about 10% of women who are at reproductive age globally, or 190 million people according to the World Health Organization (WHO)*

"Our goal this year is to successfully transition from a development/clinical stage to a commercial stage company. I believe the regulatory clearances for ProSense in Canada and China demonstrate that we are well on our way to achieving our objective," stated IceCure Chief Executive Officer, Eyal Shamir. "We remain highly committed to this strategy and believe it will be significantly enhanced upon U.S. Food and Drug Administration (FDA) approval. The FDA review is continuing to progress and is consistent with the standard de novo review process. We remain highly engaged with the FDA and we look forward to its pending response. We are also implementing our go-to market strategy through greater market awareness and are working to increase reimbursement for ProSense procedures in order to make it accessible to those seeking a non-invasive alternative to a lumpectomy, today's standard of care."

Second Quarter of 2023 and Recent Operating Highlights

- **ProSense Used in American Society of Breast Surgeons (ASBrS) Annual Meeting's 1st Ever Course on Cryoablation:** At the ASBrS 24th Annual Meeting, the Society's first-ever continuing medical education ("CME") course on cryoablation was conducted using the ProSense system. Attending surgeons got first-hand experience using ProSense and were presented interim results from IceCure's ICE3 clinical trial. A high level of interest in cryoablation was expressed from attending surgeons and from ASBrS leadership during the annual meeting.
- **Regulatory Approvals Received in Canada and China:** Health Canada, the Canadian government's regulatory agency, has approved the ProSense System, introducers, and disposable cryoprobes as cryosurgical tools for numerous indications. China's National Medical Products Administration ("NMPA") approved the IceSense3 (ProSense's brand name in China) disposable cryoprobes for commercial use in combination with the Company's IceSense3 system console, which was previously approved by the NMPA.
- **Expanded Distribution of ProSense into Portugal with Upfront Sales of Systems and Probes:** IceCure entered into a non-exclusive distribution agreement with Medicinália Cormédica – MC Medical, Lda. ("MC Medical"), the largest distributor of third-party medical devices in Portugal. MC Medical made an initial purchase of two ProSense consoles, along with disposable cryoprobes and introducers.
- **ProSense at a Leading Hospital in India is 1st in the Country to Offer Breast Cancer Cryoablation:** ProSense was installed and inaugurated at Kovai Medical Center and Hospital ("KMCH") in Coimbatore, India. To the Company's knowledge, this constitutes the first instance of cryoablation for breast cancer treatment offered in the country.
- **92.8% Efficacy in Avoiding Secondary Surgery Reported in a Study That Used ProSense for Cryoablation of Endometriosis:** A study published in the *Journal of Vascular and Interventional Radiology* and conducted at the Sorbonne University Department of Interventional Radiology and Oncology, Tenon Hospital in Paris, France, concluded that percutaneous cryoablation is a safe and effective procedure that significantly reduces pain and obtains local control of extraperitoneal endometriosis. ProSense was one of two types of cryoablation systems used in the single-site study. The efficacy rate of cryoablation to avoid secondary surgery was 92.8% per patient and 93.6% per nodule treated. Median pain-free survival rates were 93.75% at 6 months and 82.72% after 36 months. The independent study and paper were not sponsored by IceCure.

Financial Results as of and for the Six Months Ended June 30, 2023

For the six months ended June 30, 2023, the Company reported a 9% increase in revenues to \$1.65 million compared to revenues of \$1.5 million for the six months ended June 30, 2022. A 32% increase was reported for revenues from sales of systems and disposable probes for the six months ended June 30, 2023, which were \$1.37 million compared to \$1.03 million for the six months ended June 30, 2022, driven by higher sales in the United States, China, and other territories, partially offset by a decrease in sales in Europe. Revenue recognition from the exclusive distribution rights agreement in Japan with Terumo Corporation was \$274 thousand compared to \$484 thousand for the six months ended June 30, 2022.

Gross profit was \$0.75 million for the six months ended June 30, 2023, compared to approximately \$0.82 million for the six months ended June 30, 2022. Gross margin was 46% for the six months ended June 30, 2023, compared to 54% for the six months ended June 30, 2022. The decrease in gross profit and gross margin is primarily attributable to the decrease in revenue recognition from the Terumo distribution agreement.

Research and development expenses for the six months ended June 30, 2023, were \$4.19 million compared to \$4.65 million for the six months ended June 30, 2022. The decrease is primarily due to a reduction in development expenses of IceCure's next-generation single-probe system and a decrease in clinical and regulatory costs.

In anticipation of ramping up U.S. commercial efforts, sales and marketing expenses for the six months ended June 30, 2023, were \$2.25 million, compared to \$1.53 million for the six months ended June 30, 2022.

General and administrative expenses for the six months ended June 30, 2023, were \$2.35 million, compared to \$3.34 million for the six months ended June 30, 2022. The decrease is mainly due to a decrease in directors' and officers' insurance costs.

Total operating expenses for the six months ended June 30, 2023, were \$8.79 million, compared to \$9.52 million for the six months ended June 30, 2022. The decrease in operating expenses was primarily attributable to a reduction in research and development expenses and directors' and officers' insurance costs.

Net loss reported for the six months ended June 30, 2023, decreased to \$7.66 million, or \$0.17 per share, compared with a net loss of \$8.97 million, or \$0.24 per share, for the same period last year.

As of June 30, 2023, the Company had cash and cash equivalents, including short-term deposits, of approximately \$16.7 million, compared to \$23.66 million as of December 31, 2022.

Conference call & webcast info:

August 14, 2023, at 10:00 am ET

US: 1-888-642-5032

Israel/International: +972-3-9180610

A live webcast will be available at: <https://veidan.activetrail.biz/IcecureQ2-2023>

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

About IceCure Medical

IceCure Medical (Nasdaq: 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: its goal to transition from a clinical stage to commercial stage company; and its looking forward to a response from the FDA as to the Company's ProSense de novo review process; and that Class III device clearance in Brazil for the Company's probes is expected by the end of Q1 2024.

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 June 30, 2023 (Unaudited)	As of December 31, 2022 (Audited)
	<u>U.S. dollars in thousands</u>	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	3,031	23,659
Deposits	13,648	-
Restricted deposit	296	296
Trade accounts receivables	118	78
Inventory	2,751	2,857
Prepaid expenses and other receivables	589	1,240
Total current assets	<u>20,433</u>	<u>28,130</u>
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	34	34
Right-of-use assets	706	668
Property and equipment, net	1,520	1,356
Total non-current assets	<u>2,260</u>	<u>2,058</u>
TOTAL ASSETS	<u><u>22,693</u></u>	<u><u>30,188</u></u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade accounts payable	652	714
Lease liabilities	208	167
Other current liabilities	2,995	3,455
Total current liabilities	<u>3,855</u>	<u>4,336</u>
NON-CURRENT LIABILITIES		
Long-term lease liabilities	399	430
Total non-current liabilities	<u>399</u>	<u>430</u>
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 45,623,434 shares as of June 30, 2023 and December 31, 2022, respectively		
Additional paid-in capital	101,505	100,831
Accumulated deficit	(83,066)	(75,409)
Total shareholders' equity	<u>18,439</u>	<u>25,422</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u><u>22,693</u></u>	<u><u>30,188</u></u>

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

	Six months ended June 30,	
	2023	2022
	U.S. dollars in thousands (except per share data)	
Revenues	1,647	1,512
Cost of revenues	893	694
Gross profit	754	818
Research and development expenses	4,190	4,649
Sales and marketing expenses	2,253	1,533
General and administrative expenses	2,349	3,342
Operating loss	8,038	8,706
Financial expenses (income), net	(381)	262
Net loss and comprehensive loss	7,657	8,968
Basic and diluted net loss per share	0.168	0.244
Weighted average number of shares outstanding used in computing basic and diluted loss per share	45,623,434	36,814,382

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

	Six months ended June 30,	
	2023	2022
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(7,657)	(8,968)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	158	104
Share-based compensation	674	885
Exchange rate changes in cash and cash equivalents and short-term deposits	98	562
Changes in assets and liabilities:		
Decrease (increase) in trade accounts receivables	(40)	272
Decrease in prepaid expenses and other receivables	651	1,287
Decrease (increase) in inventory	106	(696)
Decrease in right of use assets	62	95
Increase (decrease) in trade accounts payable	(62)	56
Decrease in lease liabilities	(90)	(172)
Increase (decrease) in other current liabilities	(460)	279
Decrease in other long-term liabilities	-	(549)
Net cash used in operating activities	(6,560)	(6,845)
Cash flows from investing activities		
Investment in short-term deposits	(13,648)	(4,277)
Purchase of property and equipment	(322)	(493)
Net cash used in investing activities	(13,970)	(4,770)
Cash flows from financing activities		
Exercise of pre-funded warrants	-	1
Net cash provided by financing activities	-	1
Increase (decrease) in cash and cash equivalents	(20,530)	(11,614)
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	(98)	(539)
Cash and cash equivalents at end of period	3,031	13,468
Non-cash activities		
Obtaining a right-of-use asset in exchange for a lease liability	100	-

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