
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

For the month of August 2022

Commission file number: 001-40753

ICECURE MEDICAL LTD.
(Translation of registrant's name into English)

7 Ha'Eshel St., PO Box 3163
Caesarea, 3079504 Israel
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7): _____

CONTENTS

On August 15, 2022, the Registrant issued a press release titled: “IceCure Medical Reports Financial Results for the First Half of 2022 and Recent Operational Highlights.” A copy of this press release is furnished herewith as Exhibit 99.1.

This Report of Foreign Private Issuer on Form 6-K is incorporated by reference into the Registrant’s Registration Statements on Form S-8 (File No. [333-262620](#) and File No. [333-264578](#)), filed with the Securities and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

EXHIBIT INDEX

<u>Exhibit No.</u>	
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99.1	Press release titled: “IceCure Medical Reports Financial Results for the First Half of 2022 and Recent Operational Highlights.”
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 15, 2022

IceCure Medical Ltd.

By: /s/ Eyal Shamir

Name: Eyal Shamir

Title: Chief Executive Officer

IceCure Medical Reports Financial Results for the First Half of 2022 and Recent Operational Highlights

- *Conference call scheduled for 4:30 p.m. EDT today*
- *Exclusive distribution agreement signed with Shanghai Medtronic Zhikang Medical Devices Co. Ltd. for IceSense3 cryoablation systems with minimum purchase target of \$3.5 million in first 3 years of the contract; first systems to be delivered in 2022*
- *In Q2, IceCure participated in 10 conferences and events to feature ProSense® including the American Society of Breast Surgeons annual meeting where IceCure's ICE3 trial clinical publication was presented as one of the "Best Papers of 2021"*

CAESAREA, Israel, Aug. 15, 2022 /PRNewswire/ -- IceCure Medical Ltd. (NASDAQ: ICCM) (TASE: ICCM) ("IceCure" or the "Company"), developer of minimally-invasive cryoablation technology, the ProSense® System, that destroys tumors by freezing as an alternative to surgical tumor removal ("ProSense"), today reported financial results as of and for the six months June 30, 2022 and operational and commercial highlights for the second quarter.

Q2 2022 Commercial & Operational Highlights

- ***Distribution Deal in China with Shanghai Medtronic Zhikang Medical Devices Co. Ltd.:*** IceCure's wholly-owned subsidiary, IceCure (Shanghai) MedTech Co., Ltd. ("IceCure Shanghai"), signed an exclusive distribution agreement for IceSense3 (ProSense's brand name in China) cryoablation systems with Shanghai Medtronic Zhikang Medical Devices Co. Ltd. an affiliate of Medtronic plc (NYSE: MDT) ("Medtronic"), the largest medical device company in the world, and Beijing Turing Medical Technology Co. Ltd. ("Turing"). The first IceSense3 systems are expected to be delivered and revenues booked in 2022. Shanghai Medtronic Zhikang Medical Devices Co. Ltd. will be the exclusive distributor of the IceSense3 and its disposable probes in mainland China for an initial period of three years, with minimum purchase targets of \$3.5 million for this period. While Shanghai Medtronic Zhikang Medical Devices Co. Ltd. conducts all marketing, sales, and certain professional training, Turing will be responsible for the import, installation, and after-sales service of IceSense3 systems in mainland China. China's health regulatory body, the National Medical Products Administration ("NMPA"), has approved the IceSense3, and IceCure has submitted an amendment application to the registration certificate for approval of the disposable probes, which, if approved, will allow the Company to sell its disposable IceSense3 Cryoprobes for commercial use. IceCure expects to receive NMPA approval for the probes by the end of 2022.
 - ***ProSense Systems Sold, Installed, and Operational in Several New Sites:*** During the second quarter, ProSense Systems were sold, installed, and have become operational in several clinics worldwide including in the U.S. at the MANA Breast Center in Arkansas, and Georgia Breast Care in Georgia, as well as within healthcare facilities in Turkey and Poland—where the first breast fibroadenoma procedures were conducted with ProSense in those countries. A new site in France and an established site in Israel conducted their first breast cancer procedures with ProSense.
 - ***Regulatory Applications Filed in Brazil and Canada:*** IceCure continues to expand its regulatory status across the globe with recent applications filed in China for its IceSense3 disposable probes, in Brazil for its ProSense System for several indications including breast and other cancers, benign tumors, palliative intervention, and in Canada for the ProSense System in numerous indications including benign and malignant breast tumors, kidney cancer, benign and malignant lung tumors, benign and malignant liver tumors, musculoskeletal tumors, ablation of benign and malignant tissues, and other indications.
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- **ProSense Featured at SIR 2022 Annual Meeting in Breast Cancer Cryoablation Categorical Course:** ProSense was featured in a categorical course titled “Cryoablation for the Treatment of Breast Cancer: Breast Interventions for the Interventionalist” at the Society of Interventional Radiology (SIR) Annual Scientific Meeting in Boston by a panel of experts in radiology and breast cancer. ProSense was well received by physicians, potential U.S.-based customers including medical clinics and hospitals and international distributors interested in partnership with IceCure.
- **ASBrS Conference - ICE3 Trial Selected as one of “Best Papers of 2021” for Annual Presentation from Thousands of Articles Published Annually:** At the 23rd Annual Meeting of the American Society of Breast Surgeons (ASBrS) in April 2022, IceCure’s publication titled “Cryoablation without Excision for Low-Risk Early-Stage Breast cancer: 3-Year Analysis of ipsilateral Breast Tumor Recurrence in the ICE3 Trial” that was published in the *Annals of Surgical Oncology* was selected by past ASBrS president, Helen Pass, MD, Co-Director of the Stamford Health Breast Center, Chief of Breast Surgery at Stamford Hospital, and Clinical Professor of Surgery at Columbia University, for her annual presentation following a comprehensive literature review. Dr. Pass’ presentation was made to a large audience of breast surgeons and related medical professionals attending the conference in-person and online.
- **ECIO Conference – Hands-on Demos and Interim Results Presentation:** At the European Conference on Interventional Oncology (ECIO) in April 2022, IceCure’s ICE3 breast cancer trial interim results, originally published on April 29, 2021, were presented by Dr. Kenneth R. Tomkovich, the study’s Co-Primary Investigator. Hands-on training sessions with the ProSense System were provided by IceCure and physicians well-experienced with the system. IceCure also hosted a well-attended symposium, moderated by Professor Franco Orsi and other physicians, demonstrating their results and experience with the ProSense System for various applications.
- **SBI/ACR Conference – ProSense Ablation Course:** At the Society of Breast Imaging (SBI) / American College of Radiology (ACR) Conference in May 2022, ProSense users Marilyn Roubidoux, MD, FACR, FSBI, Professor of Radiology at the University of Michigan School of Medicine and Robert C. Ward, MD spoke about breast tumor ablation in the course “Tumor Ablation (Cryo and others).” The IceCure exhibition booth was well-attended by conference participants who expressed interest in the ProSense System.

“The second quarter of 2022 marked continued momentum in the commercial rollout of our cryoablation systems highlighted by our exclusive distribution agreement in China with Shanghai Medtronic Zhikang Medical Devices Co. Ltd., an affiliate of Medtronic, the world’s largest medical device company. We believe this is a very strong endorsement of our technology, and the increased market interest we’re seeing globally confirm our view,” stated IceCure CEO Eyal Shamir. “Based on the level of commercial interest during and after the second quarter, we expect the number of these system installations and sales may potentially increase. We believe that this activity will be reflected in our revenues in the future.”

Financial Results for the Six Months Ended June 30, 2022

For the six months ended June 30, 2022, revenue decreased by 27% to approximately \$1.5 million, compared to approximately \$2.1 million for the six months ended June 30, 2021. The decrease is due to decreased revenue recognition of approximately \$0.4 million from the distribution agreements with Terumo Corporation and a decrease in sales in Asia, partially offset by an increase in sales in the U.S. and Europe.

Gross profit was approximately \$0.8 million for the six months ended June 30, 2022, compared to approximately \$1.2 million for the six months ended June 30, 2021. The gross margin was approximately 54% for the six months ended June 30, 2022, compared to approximately 58% for the six months ended June 30, 2021. The decrease in gross margin compared to the same period last year is attributable to the decrease in sales and in revenue recognition from the Terumo distribution agreement.

Research and development expenses for the six months ended June 30, 2022 were approximately \$4.6 million compared to approximately \$2.7 million for the six months ended June 30, 2021. The increase is attributed to acceleration in the development of IceCure's next-generation single-probe system and due to clinical and regulatory activities.

Sales and marketing and general and administrative expenses, in the aggregate, for the six months ended June 30, 2022 were \$4.9 million compared to approximately \$2.2 million for the six months ended June 30, 2021. The increase is attributed to the Company's expanding commercialization efforts and to increased Nasdaq listing-related expenses.

Total operating expenses for the six months ended June 30, 2022 were approximately \$9.5 million compared to \$4.9 million for the six months ended June 30, 2021. The increase in operating expenses is attributable to increased development, commercialization, and Nasdaq listing-related activities.

As a result of lower revenue and increased operation activities, net loss reported for the six months ended June 30, 2022 increased to approximately \$9.0 million, or \$0.24 per share, compared with a net loss of approximately \$3.8 million, or \$0.16 per share, for the same period last year.

As of June 30, 2022, the Company had cash and cash equivalents including short-term deposits of approximately \$17.7 million, compared with approximately \$25.6 million as of December 31, 2021.

Conference Call Dial-in Info:

Monday, August 15, 2022 at 4:30 pm EDT

US: 1-888-642-5032

Israel/International: +972-3-9180609

A replay of the conference call will be available on IceCure's website at: <https://ir.icecure-medical.com/news-events/events-presentations>

About IceCure Medical

IceCure Medical (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 to-date by the U.S. Food and Drug Administration and approved in Europe with the CE Mark.

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 statement in this press release when it discusses pursuit of regulatory approvals in various jurisdictions, strategic plans, commercial growth, expansion of clinical applications and potential market adoption of its minimally-invasive cryoablation technology, advancing regulatory and commercial strategies and expected quarter-over-quarter revenue variations and other key business highlights for future periods. 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, 2021 filed with the SEC on April 1, 2022, which is 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, 2022 (Unaudited)	As of December 31, 2021 (Audited)
U.S. dollars in thousands		
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	13,468	25,621
Short-term deposits	4,257	-
Trade accounts receivables	184	456
Inventory	2,651	1,955
Prepaid expenses and other receivables	1,003	2,290
Total current assets	21,563	30,322
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	330	333
Right-of-use assets	818	913
Property and equipment, net	1,102	713
Total non-current assets	2,250	1,959
TOTAL ASSETS	23,813	32,281
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade accounts payable	937	881
Lease liabilities	195	224
Other current liabilities	3,194	2,915
Total current liabilities	4,326	4,020
NON-CURRENT LIABILITIES		
Long-term lease liabilities	542	685
Other long-term liabilities	69	618
Total non-current liabilities	611	1,303
Total liabilities	4,937	5,323
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 36,814,554 and 35,780,335 shares as of June 30, 2022 and December 31, 2021, respectively		
Additional paid-in capital	86,275	85,389
Accumulated deficit	(67,399)	(58,431)
Total shareholders' equity	18,876	26,958
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	23,813	32,281

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

	Six months ended June 30,	
	2022	2021
	U.S. dollars in thousands (except per share data)	
Revenues	1,512	2,073
Cost of revenues	694	880
Gross profit	818	1,193
Research and development expenses	4,649	2,730
Sales and marketing expenses	1,533	625
General and administrative expenses	3,342	1,584
Operating loss	8,706	3,746
Financial expenses, net	262	101
Net loss and comprehensive loss	8,968	3,847
Basic and diluted net loss per share	0.244	0.156
Weighted average number of shares outstanding used in computing basic and diluted loss per share	36,814,382	24,696,706

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

	Six months ended	
	June 30,	
	2022	2021
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(8,968)	(3,847)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	104	50
Share-based compensation	885	184
Exchange rate changes in cash and cash equivalents and short time deposits	562	97
Changes in assets and liabilities:		
Decrease in trade accounts receivables	272	-
Decrease (increase) in prepaid expenses and other receivables	1,287	(103)
Increase in inventory	(696)	(401)
Decrease in right of use assets	95	19
Increase in trade accounts payable	56	159
Decrease in lease liabilities	(172)	(59)
Increase in other current liabilities	279	368
Decrease in other long-term liabilities	(549)	(28)
Net cash used in operating activities	(6,845)	(3,561)
Cash flows from investing activities		
Realization (investment in) of deposits	(4,277)	4,621
Investments of long term deposits	-	(295)
Purchase of property and equipment	(493)	(247)
Net cash provided by (used in) investing activities	(4,770)	4,079
Cash flows from financing activities		
Issuance of ordinary shares, net of issuance cost	-	14,586
Exercise of pre-funded warrants	1	-
Exercise of options to ordinary shares	-	56
Net cash provided by financing activities	1	14,642
Increase (decrease) in cash and cash equivalents	(11,614)	15,160
Cash and cash equivalents at beginning of the year	25,621	3,502
Effect of exchange rate fluctuations on balances of cash and cash equivalents	(539)	(49)
Cash and cash equivalents at end of period	13,468	18,613