
**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 May 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 May 18, 2022, the Registrant issued a press release titled: "IceCure Medical Reports First Quarter 2022 Financial Results and 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

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EXHIBIT INDEX

Exhibit No.

99.1 [Press release titled: "IceCure Medical Reports First Quarter 2022 Financial Results and 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.

IceCure Medical Ltd.

Date: May 18, 2022

By: /s/ Eyal Shamir
Name: Eyal Shamir
Title: Chief Executive Officer

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IceCure Medical Reports First Quarter 2022 Financial Results and Operational Highlights

- *Conference call scheduled for 8:30 am ET today hosted by management with guest Dr. Richard Fine*
- *Increased commercial activity in the U.S. and globally with several new ProSense® System installations during Q1*
- *Resumption of in-person medical conferences and practitioner site visits boosts ProSense® hands-on demos, trainings, and sales opportunities*
- *American Society of Breast Surgeons' former President presented IceCure's ICE3 trial clinical publication in her speech "Best Papers of 2021" at ASBrS following a thorough literature review of thousands of breast cancer articles published yearly*

CAESAREA, Israel, May 18, 2022 -- 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 quarter ended March 31, 2022 and operational highlights.

Q1 2022 Operational and Financial Highlights

- **Revenues:** Revenues for the first quarter of 2022 were approximately \$0.75 million, 48% lower than approximately \$1.4 million in the same period last year due to lower revenue recognition from its distribution agreements with Terumo for the commercialization of ProSense® to treat malignant breast tumors in Japan, Singapore, and Thailand as recorded in the first quarter of 2021, and due to lower sales in Asia impacted by COVID surges and associated restrictions on commercial activity, partially offset by higher sales in the U.S. The Company expects that quarter-over-quarter revenue may vary in the foreseeable future.
- **Increased Commercial Activity:** With travel restrictions relaxing at the end of 2021, during Q1 2022 several ProSense® Systems were installed at new sites in the U.S. and around the globe including a ProSense® System that was donated to Tata Memorial Hospital in Mumbai by the Israeli General Consulate of Mumbai in collaboration with the Health Ministry of the Government of Maharashtra and the Israel Trade & Economic Mission to Mumbai. IceCure has scheduled and is now able to conduct more on-site support and training with partners and customers around the globe.
- **FDA Filing for Breast Cancer:** Working toward U.S. Food and Drug Administration (FDA) approval for ProSense® in early-stage breast cancer, IceCure filed its pre-submission package with the FDA in November 2021 and continued to work on its full submission during Q1 2022. IceCure plans to suggest a De Novo classification, including a request for a sprint discussion under FDA procedures. The proposed intended use is for early-stage breast cancer patients at high risk from surgery.
- **R&D and Marketing:** IceCure accelerated its next-generation single-probe system development and its clinical, regulatory, and commercial activities in the U.S. and globally. As of March 31, 2022, ProSense® has regulatory approvals and/or has a commercial presence in 20 countries.
- **SIO Conference:** IceCure attended the Society of Interventional Oncology (SIO) 2022 Annual Scientific Meeting in San Francisco and hosted a symposium moderated by Dr. Jack Jennings on the value of liquid nitrogen based cryoablation systems for optimal tumor destruction.



Other Recent Highlights

- **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, 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" 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 before a large audience of breast surgeons and related medical professionals attending the conference in-person and online.
- **ECIO Conference:** At the European Conference on Interventional Oncology (ECIO) in April, 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.

"With the reopening of global travel and healthcare systems' return to relative normalcy throughout most of the world, during the first quarter of 2022 we significantly increased our activity, getting ProSense® in front of more doctors who can purchase and use it to improve patient outcomes," stated IceCure CEO Eyal Shamir. "We were particularly pleased that our ICE3 clinical trial publication was chosen as one of the Best Papers of 2021 by the American Association of Breast Cancer Surgeons, a highly regarded and influential organization that sets the treatment guidelines for breast cancer in the U.S."

Financial Results as of and for the Three Months Ended March 31, 2022

For the three months ended March 31, 2022, revenue decreased by 48% to approximately \$0.75 million, compared to approximately \$1.4 million for the three months ended March 31, 2021. The decrease is due to decreased revenue recognition of approximately \$0.4 million from the distribution agreement with Terumo and a decrease in sales in Asia, partially offset by an increase in sales in the U.S.

Gross profit was approximately \$0.43 million for the three months ended March 31, 2022, compared to approximately \$0.94 million for the three months ended March 31, 2021. Gross margin was approximately 58% for the three month period ended March 31, 2022, compared to approximately 65% for the three months ended March 31, 2021. The decrease in gross margin compared to the same period last year is mostly attributable to the decrease in revenue recognition from the Terumo distribution agreement.



Research and development expenses for the three months ended March 31, 2022 were approximately \$2.4 million compared to approximately \$1.1 million for the three months ended March 31, 2021. The increase is attributed to the acceleration in the development of IceCure's next-generation single-probe system and clinical and regulatory activities.

Sales and marketing and general and administrative expenses, in the aggregate, for the three months ended March 31, 2022 were \$2.5 million compared to approximately \$1 million for the three months ended March 31, 2021. The increase is attributed to the Company's expanding commercialization efforts and to increased Nasdaq listing related expenses.

Total operating expenses for the three months ended March 31, 2022 were approximately \$4.9 million compared to \$2.1 million for the three months March 31, 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 three month period ended March 31, 2022 increased to approximately \$4.4 million, or \$0.12 per share, compared with a net loss of approximately \$1.4 million, or \$0.07 per share, for the same period last year.

As of March 31, 2022, the Company had cash and cash equivalents of approximately \$22.4 million, compared with approximately \$25.6 million as of December 31, 2021.

Conference Call Dial-in Info:

Wednesday, May 18, 2022 at 8:30 am ET

US: 1-888-281-1167

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

Founded in 2006, Israel-based 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 and FDA review, strategic plans, commercial growth, expansion of clinical applications with its minimally-invasive cryoablation technology, advancing regulatory and commercial strategies and expected quarter-over-quarter revenue variations 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 March 31, 2022 (Unaudited)	As of December 31, 2021 (Audited)
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ASSETS

CURRENT ASSETS

Cash and cash equivalents	22,355	25,621
Trade accounts receivables	446	456
Inventory	2,324	1,955
Prepaid expenses and other receivables	1,562	2,290
Total current assets	26,687	30,322

NON-CURRENT ASSETS

Prepaid expenses and other long-term assets	333	333
Right-of-use assets	884	913
Property and equipment, net	805	713
Total non-current assets	2,022	1,959
TOTAL ASSETS	28,709	32,281

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES

Trade accounts payable	670	881
Lease liabilities	230	224
Other current liabilities	4,046	2,915
Total current liabilities	4,946	4,020

NON-CURRENT LIABILITIES

Long-term lease liabilities	617	685
Other long-term liabilities	185	618
Total non-current liabilities	802	1,303
Total liabilities	5,748	5,323

SHAREHOLDERS' EQUITY

Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 35,780,335 shares as of March 31, 2022 and December 31, 2021, respectively		
Pre-funded warrants to ordinary shares, Issued and outstanding: 1,034,000 Pre-funded warrants and zero Pre-funded warrants as of March 31, 2022 and December 31, 2021, respectively	-	-
Additional paid-in capital	85,839	85,389
Accumulated deficit	(62,878)	(58,431)
Total shareholders' equity	22,961	26,958
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	28,709	32,281



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

	Three months ended March 31,	
	2022	2021
	U.S. dollars in thousands (except per share data)	
Revenues	747	1,436
Cost of revenues	313	497
Gross profit	434	939
Research and development expenses	2,394	1,144
Sales and marketing expenses	747	298
General and administrative expenses	1,718	690
Operating loss	4,425	1,193
Financial expenses, net	22	178
Net loss and comprehensive loss	4,447	1,371
Basic and diluted net loss per share	0.12	0.07
Weighted average number of shares outstanding used in computing basic and diluted loss per share	36,814,335	20,739,571



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

	Three months ended	
	March 31,	
	2022	2021
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(4,447)	(1,371)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	52	23
Share-based compensation	450	97
Exchange rate changes in cash and cash equivalents and short time deposits	62	206
Changes in assets and liabilities:		
Decrease (increase) in trade accounts receivables	10	(156)
Decrease (increase) in prepaid expenses and other receivables	728	(109)
Increase in inventory	(369)	(137)
Decrease in right of use assets	29	43
Increase (decrease) in trade accounts payable	(211)	20
Decrease in lease liabilities	(62)	(33)
Increase (decrease) in other current liabilities	1,131	(252)
Decrease in other long-term liabilities	(433)	(174)
Net cash used in operating activities	(3,060)	(1,843)
Cash flows from investing activities		
Investment of deposits	-	4,621
Purchase of property and equipment	(144)	(69)
Net cash provided by (used in) investing activities	(144)	4,552
Cash flows from financing activities		
Issuance of ordinary shares, net of issuance cost	-	8,880
Exercise of options to ordinary shares	-	52
Net cash provided by financing activities	-	8,932
Increase (decrease) in cash and cash equivalents	(3,204)	11,641
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	(62)	(158)
Cash and cash equivalents at end of period	22,355	14,985