
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 December 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 office)

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 Regulation S-T Rule 101(b)(1): ☐

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

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On December 5, 2022, IceCure Medical Ltd. (the “Company”) issued a press release titled: “IceCure Medical Reports Financial Results for the Nine Months Ended September 30, 2022 and Provides Update on Recent Operational Highlights,” a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K (the “Report”).

The first paragraph, the bullet points under the section titled “Third Quarter 2022 Commercial and Operational Highlights,” and the sections titled “Financial Results for the Nine Months Ended September 30, 2022,” and “Forward-Looking Statement” are incorporated by reference into the Company’s Registration Statements on Form F-3 (Registration No. [333-258660](#) and Registration No. [333-267272](#)) and Form S-8 (Registration No. [333-262620](#) and Registration 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and Exchange Commission, to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 No.

99.1	Press release titled: “IceCure Medical Reports Financial Results for the Nine Months Ended September 30, 2022 and Provides Update on 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: December 5, 2022

IceCure Medical Ltd.

By: /s/ Eyal Shamir

Name: Eyal Shamir

Title: Chief Executive Officer



IceCure Medical Reports Financial Results for the Nine Months Ended September 30, 2022 and Provides Update on Recent Operational Highlights

- *Conference call is scheduled for 8:00 a.m. EST today with guest speaker Dr. Hania Bednarski, oncoplastic breast surgeon and cryoablation specialist skilled in using the ProSense System*
- *Regulatory filings submitted in the United States for ProSense for treatment in breast cancer*
- *Achievement of Medicare coverage code for case-by-case reimbursement*
- *Regulatory approval received in Brazil for ProSense cryoprobes and introducers for treatment in several indications*
- *Regulatory filings submitted in Canada and Vietnam for ProSense for treatment in numerous indications*

CAESAREA, Israel, December 5, 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 nine months ended September 30, 2022 and operational and commercial highlights for the third quarter.

Third Quarter 2022 Commercial and Operational Highlights

- **FDA De Novo Classification Request Filed for Marketing Authorization of ProSense with Breakthrough Indication of Early-Stage Low-Risk Breast Cancer Patients at High Risk to Surgery:** Shortly after the end of the third quarter, IceCure submitted a De Novo Classification Request regulatory filing with the U.S. Food and Drug Administration ("FDA") for marketing authorization based on ICE3 clinical trial ("ICE3") interim analysis of ProSense for the indication of early-stage (Luminal A T1 invasive) low-risk breast cancer in patients who are at high risk to surgery (not suitable for surgical alternatives). This indication alone represents approximately 43,000 women in the U.S. annually. Following the release of final ICE3 5-year follow-up data, expected in the first half of 2024, IceCure plans to file for a broader indication with the FDA, reflecting the entire study population of early-stage (Luminal A T1 invasive) low-risk breast cancer for patients age 60 and over, representing approximately 65,000 women in the U.S. annually. Luminal A breast cancer for women of all ages is estimated at 144,000 cases annually in the U.S. In the future, IceCure intends to explore more indications for additional subgroups that are part of the total group of Luminal A breast cancer.
 - **Medicare Coverage Milestone Achieved for Reimbursement:** In November, the Centers for Medicare & Medicaid Services ("CMS") assigned ProSense breast cancer cryoablation procedures with a CPT Category III code—0581T to ambulatory payment classification 5091, Level 1 Breast/Lymphatic Surgery and Related Procedures—which will go into effect on January 1, 2023. Under the CPT Category III code, IceCure's procedure is priced for coverage by the CMS at approximately \$3,400 for the facility fee alone. Additional coverage, including payment for the physician, is expected upon establishment of the permanent CPT Category I code, which is conditioned on several factors including the Company's receipt of FDA marketing authorization of ProSense for breast cancer.
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- **ProSense Cryoprobes and Introducers Receive Regulatory Approval in Brazil:** ProSense cryoprobes and introducers, essential single-use disposable components of ProSense, received regulatory approval from the Brazilian Health Regulatory Agency (“ANVISA”) for several indications including breast and other cancers, benign tumors, and palliative intervention. As ProSense is considered a Class III medical device, the application was filed separately with ANVISA and is currently pending approval.
- **Regulatory Applications Filed in Canada and Vietnam:** As part of its global market rollout, IceCure submitted a regulatory filing with the Department of Medical Equipment and Construction (“DMEC”) of Vietnam’s Ministry of Health for ProSense and accessories. The application covers numerous indications including benign and malignant breast tumors. IceCure also submitted a regulatory filing with Health Canada for approval of ProSense and its cryoprobes for the treatment of numerous indications including benign and malignant breast tumors and other indications.

“We have edged closer to commercialization of ProSense for breast cancer in the U.S. with our recent FDA filing for marketing approval, and the assignment of a Medicare CPT III reimbursement code. IceCure has taken a leadership role in the industry based on our vast ICE 3 breast cancer cryoablation clinical data and by receiving the CMS’s first payment assignment for cryoablation of breast cancer,” stated IceCure’s CEO Eyal Shamir. “While our quarterly revenues may continue to fluctuate in the near future, increased sales of our disposable cryoprobes during the current nine month period ended September 30, 2022 point to greater end-user adoption and more people being treated with ProSense. We believe this is a positive indication for the market acceptance of our liquid-nitrogen-based cryoablation therapy which will translate into sales.”

Financial Results for the Nine Months Ended September 30, 2022

For the nine months ended September 30, 2022, revenue decreased by 22% to approximately \$2.1 million, compared to approximately \$2.8 million for the nine months ended September 30, 2021. The decrease is due to decreased revenue recognition of approximately \$0.5 million from the distribution agreements with Terumo Corporation and a decrease in sales of new systems, which was partially offset by higher sales of disposable probes as previously sold and installed systems were utilized for procedures in clinical settings. For the nine months ended September 30, 2022, sales in the U.S. and Europe increased by 65% and 37%, respectively, compared to the same period in 2021. The increase in sales in the U.S. and Europe was offset by a decrease in sales in Asia and other territories.

Gross profit was approximately \$1 million for the nine months ended September 30, 2022, compared to approximately \$1.6 million for the nine months ended September 30, 2021. Gross margin was approximately 46% for the nine months ended September 30, 2022, compared to approximately 56% for the nine months ended September 30, 2021. The decrease in gross margin compared to the same period last year was attributable to the decrease in sales and in revenue recognition from the Terumo distribution agreement.

Research and development expenses for the nine months ended September 30, 2022 were approximately \$6.9 million, compared to approximately \$4.3 million for the nine months ended September 30, 2021. The increase was attributed to acceleration in the development of IceCure’s next-generation single-probe system and due to clinical and regulatory activities.



Sales, marketing and general and administrative expenses for the nine months ended September 30, 2022 were approximately \$6.9 million, compared to approximately \$3.9 million for the nine months ended September 30, 2021. The increase was attributed to the Company's expanding commercialization efforts and to increased Nasdaq listing-related expenses.

Total operating expenses for the nine months ended September 30, 2022 were approximately \$13.8 million, compared to approximately \$8.2 million for the nine months ended September 30, 2021. The increase in operating expenses was primarily 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 nine months ended September 30, 2022 increased to approximately \$13 million, or \$0.35 per share, compared with a net loss of approximately \$6.7 million, or \$0.25 per share, for the same period last year.

As of September 30, 2022, the Company had cash and cash equivalents including short-term deposits of approximately \$14.2 million, compared to approximately \$25.6 million as of December 31, 2021.

Conference Call Dial-in Info:

Monday, December 5, 2022 at 8:00 am EST

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, potential market adoption and future sales of its minimally-invasive cryoablation technology, advancing regulatory and commercial strategies and expected quarter-over-quarter revenue variations and other key business and operational 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.

IR Contact:

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ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

As of	As of
September 30,	December 31,
2022	2021
(Unaudited)	(Audited)
U.S. dollars in thousands	

ASSETS

CURRENT ASSETS

Cash and cash equivalents	12,437	25,621
Short-term deposits	1,756	-
Restricted deposit	295	-
Trade accounts receivables	196	456
Inventory	2,698	1,955
Prepaid expenses and other receivables	597	2,290
Total current assets	17,979	30,322

NON-CURRENT ASSETS

Prepaid expenses and other long-term assets	35	333
Right-of-use assets	750	913
Property and equipment, net	1,330	713
Total non-current assets	2,115	1,959

TOTAL ASSETS

	20,094	32,281
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LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES

Trade accounts payable	602	881
Lease liabilities	191	224
Other current liabilities	3,470	2,915
Total current liabilities	4,263	4,020

NON-CURRENT LIABILITIES

Long-term lease liabilities	476	685
Other long-term liabilities	69	618
Total non-current liabilities	545	1,303

Total liabilities

	4,808	5,323
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SHAREHOLDERS' EQUITY

Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 36,835,554 and 35,780,335 shares as of September 30, 2022 and December 31, 2021, respectively

Additional paid-in capital	86,743	85,389
Accumulated deficit	(71,457)	(58,431)
Total shareholders' equity	15,286	26,958

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY

	20,094	32,281
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ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Nine months ended September 30,	
	2022	2021
	U.S. dollars in thousands (except per share data)	
Revenues	2,146	2,754
Cost of revenues	1,162	1,202
Gross profit	984	1,552
Research and development expenses	6,886	4,276
Sales and marketing expenses	2,238	1,217
General and administrative expenses	4,667	2,655
Operating loss	12,807	6,596
Financial expenses, net	219	139
Net loss and comprehensive loss	13,026	6,735
Basic and diluted net loss per share	0.354	0.249
Weighted average number of shares outstanding used in computing basic and diluted loss per share	36,820,132	27,098,847



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

	Nine months ended September 30,	
	2022	2021
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(13,026)	(6,735)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	174	86
Share-based compensation	1,353	254
Exchange rate changes in cash and cash equivalents and short time deposits	477	74
Changes in assets and liabilities:		
Decrease in trade accounts receivables	260	7
Decrease (increase) in prepaid expenses and other receivables	1,693	(234)
Increase in inventory	(743)	(710)
Decrease (increase) in right of use assets	163	(723)
(Decrease) Increase in trade accounts payable	(279)	194
(Decrease) Increase in lease liabilities	(242)	679
Increase in other current liabilities	555	637
Decrease in other long-term liabilities	(549)	(240)
Net cash used in operating activities	<u>(10,164)</u>	<u>(6,711)</u>
Cash flows from investing activities		
Realization (investment in) of deposits	(1,776)	4,621
Investments of long term deposits	-	(295)
Purchase of property and equipment	(791)	(355)
Net cash provided by (used in) investing activities	<u>(2,567)</u>	<u>3,971</u>
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	-	63
Net cash provided by financing activities	<u>1</u>	<u>14,649</u>
Increase (decrease) in cash and cash equivalents	<u>(12,730)</u>	<u>11,909</u>
Cash and cash equivalents at beginning of the year	<u>25,621</u>	<u>3,502</u>
Effect of exchange rate fluctuations on balances of cash and cash equivalents	<u>(454)</u>	<u>(26)</u>
Cash and cash equivalents at end of period	<u>12,437</u>	<u>15,385</u>