
**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 November 2021

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 November 23, 2021, the Registrant issued a press release titled: "IceCure Medical Reports Financial Results as of and for the first Nine Months of 2021 and Recent Corporate Developments." A copy of this press release is furnished herewith as Exhibit 99.1.

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EXHIBIT INDEX

Exhibit No.

99.1 [Press release titled: "IceCure Medical Reports Financial Results as of and for the first Nine Months of 2021 and Recent Corporate Developments."](#)

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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: November 23, 2021

IceCure Medical Ltd.

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

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IceCure Medical Reports Financial Results as of and for the first Nine Months of 2021 and Recent Corporate Developments

CAESAREA, Israel, November 23, 2021 -- IceCure Medical Ltd. (NASDAQ: ICCM) (TASE: ICCM) (“IceCure” or the “Company”), developer of next-generation, minimally-invasive cryoablation technology with ProSense[®] that destroys tumors by freezing as an alternative to surgical tumor removal, today reported its financial results as of and for the nine-month period ended September 30, 2021.

Recent Corporate Developments

- On September 13th, IceCure announced the first peer-reviewed article of its ICE3 Clinical Trial “Cryoablation Without Excision for Low-Risk, Early-Stage Breast Cancer: 3-Year Interim Analysis of Ipsilateral Breast Tumor Recurrence in the ICE3 Trial”. The article was published in the *Annals of Surgical Oncology* by the lead author Dr. Richard Fine, M.D., FACS, an ICE3 investigator who serves as Program Director of the Breast Surgical Oncology Fellowship and as Director of Research and Education at the West Comprehensive Breast Center in Germantown, Tennessee, as the lead author.
- On October 12th, the Company submitted an amendment to the registration certificate for the IceSense3[®] system to China’s National Medical Products Administration (“NMPA”), which, if approved, would allow the disposable IceSense3 Cryoprobes to be sold for commercial procedures in mainland China. Approval of the amendment is expected by the end of 2022, which would be followed by a commercial sales program launch in China in early 2023.
- On October 20th, IceCure announced an expansion of the Company’s global distribution network with an initial distribution agreement in Poland with Mobile SCANMED Systems SP. z o.o. (“Mobile SCANMED Systems”) to exclusively sell the ProSense[®] Cryoablation System and disposables.
- On November 1st, the Company announced a peer-reviewed publication, “VAB and MRI Following Percutaneous Ultra-Sound Guided Cryoablation for Primary Early-Stage Breast Cancer: A Pilot Study in Japan”, that was published in the *Journal of Cancer Therapy* by lead author Dr. Hisanori Kawamoto, M.D., Ph.D. from the Department of Breast Surgery Breast and Imaging Center, St. Marianna University School of Medicine, Japan. The published data from the independent study demonstrated that percutaneous cryoablation presents a potential substitute for lumpectomy of breast tumors <15mm using ProSense.

“This is an exciting time in IceCure’s history, as we continue to generate increasing interest among a growing roster of leading commercial partners around the world to distribute our ProSense Cryoablation System, including forming recent distribution collaborations in Poland, Turkey, India, Brazil and various countries across Asia. This burgeoning interest speaks directly to the potential of our cryoablation system to provide a solution to the significant market demand for minimally-invasive, safe and effective alternatives to surgical tumor removal,” stated Eyal Shamir, Chief Executive Officer of IceCure.

Innovating Cryotherapy Solutions

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Mr. Shamir continued, “In addition, we are steadily making progress advancing our regulatory and commercial strategies within the world’s largest oncology markets, including the U.S., China and the EU. In the U.S., the ICE3 trial is the largest controlled multi-center clinical trial for freezing of small, low-risk, early-stage breast tumors with liquid nitrogen, and we are working towards establishing a regulatory path that is expected to make the ProSense System available as a minimally invasive treatment to early-stage breast cancer patients and breast cancer patients that are considered high-risk for undergoing surgery. In China, we recently announced an update to our strategy for initiating commercial sales for our cryoablation therapy system, pending regulatory approval by the NMPA of an amendment to the registration certificate for the IceSense3 system.”

Financial Results for the Nine-Month Period Ended September 30, 2021

For the nine months ended September 30, 2021, revenue increased by 11% to approximately \$2.75 million, compared to approximately \$2.49 million for the nine months ended September 30, 2020.

Gross profit was \$1.55 million for the nine months ended September 30, 2021, compared to \$1.6 million for the nine months ended September 30, 2020. Gross margin was 56% for the nine-month period ended September 30, 2021, compared to 64% for the nine months ended September 30, 2020. The decrease in gross margin compared to the same period last year is attributable to the changes in the mix of products sold, sales to distributors instead of direct sales to end customers and increase in costs.

Total operating expenses for the nine months ended September 30, 2021 were approximately \$8.15 million, compared to approximately \$4.56 million for the nine months ended September 30, 2020. The increase in operating expenses is primarily attributable to the development of the Company’s next generation cryoablation systems and probes and the Nasdaq-listing-related expenses.

As a result of the increase in the Company’s expenses, net loss reported for the nine-month period ended September 30, 2021 increased to approximately \$6.73 million, or \$0.25 per share, compared to a net loss of approximately \$2.95 million, or \$0.20 per share, for the same period last year.

As of September 30, 2021, the Company had cash and cash equivalents and deposits of approximately \$15.4 million, compared to approximately \$8.2 million as of December 31, 2020. The \$7.2 million increase includes \$15 million in gross proceeds raised in 2021 through a private placement investment in the Company’s shares.

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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 approved to-date by FDA and the European 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 the development of distribution networks for its products, the Company's regulatory strategy and developing a regulatory path towards approvals of its ProSense System and IceSense3 system, commercialization activities and the market opportunity for the Company's ProSense Cryoablation System. 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 Registration Statement on Form F-1 (as amended, the "Form F-1"). Copies of the Form F-1 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 September 30, 2021 (Unaudited)	As of December 31, 2020 (Audited)
U.S. dollars in thousands		
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	15,385	3,502
Deposit	-	4,669
Trade accounts receivables	87	94
Inventory	1,774	1,064

Prepaid expenses and other receivables	494	260
Total current assets	17,740	9,589
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	332	37
Right-of-use assets	1,029	306
Property and equipment, net	576	307
Total non-current assets	1,937	650
TOTAL ASSETS	19,677	10,239
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade accounts payable	839	645
Lease liabilities	194	214
Other current liabilities	3,492	2,855
Total current liabilities	4,525	3,714
NON-CURRENT LIABILITIES		
Long-term lease liabilities	817	118
Other long-term liabilities	519	759
Total non-current liabilities	1,336	877
Total liabilities	5,861	4,591
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 31,877,495 shares and 20,218,220 shares as of September 30, 2021 and December 31, 2020, respectively		
Treasury shares	-	(41)
Additional paid-in capital	69,087	54,225
Accumulated deficit	(55,271)	(48,536)
Total shareholders' equity	13,816	5,648
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	19,677	10,239

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

	Nine months ended September 30,	
	2021	2020
	U.S. dollars in thousands (except per share data)	
Revenues	2,754	2,490
Cost of revenues	1,202	892
Gross profit	1,552	1,598
Research and development expenses	4,276	2,439
Sales and marketing expenses	1,217	831
General and administrative expenses	2,655	1,289
Operating loss	6,596	2,961
Financial expenses (income), net	139	(14)
Net loss and comprehensive loss	6,735	2,947
Basic and diluted net loss per share	0.249	0.196
Weighted average number of shares outstanding used in computing basic and diluted loss per share	27,098,847	15,029,168

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

	Nine months ended September 30,	
	2021	2020
U.S. dollars in thousands		
Cash flows from operating activities		
Net loss	(6,735)	(2,947)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	86	42
Share-based compensation	254	205
Exchange rate changes in cash and cash equivalents and short time deposits	74	26
Changes in assets and liabilities:		
Decrease (increase) in trade accounts receivables	7	(216)
Increase in prepaid expenses and other receivables	(234)	(303)
Increase in inventory	(710)	(471)
Decrease in prepaid expenses and other long-term assets	-	400
Increase in right of use assets	(723)	(123)
Increase (decrease) in trade accounts payable	194	(132)
Increase in lease liabilities	679	90
Increase in other current liabilities	637	447
Increase (decrease) in other long-term liabilities	(240)	663
Net cash used in operating activities	(6,711)	(2,319)
Cash flows from investing activities		
Realization of deposits (Investment of deposits)	4,621	(4,432)
Investment of long term deposits	(295)	-
Purchase of property and equipment	(355)	(159)
Net cash provided by (used in) investing activities	3,971	(4,591)
Cash flows from financing activities		
Issuance of ordinary shares, net of issuance cost	14,586	5,847
Exercise of options to ordinary shares	63	11
Net cash provided by financing activities	14,649	5,858
Increase (decrease) in cash and cash equivalents	11,909	(1,052)
Cash and cash equivalents at beginning of the year	3,502	5,789
Effect of exchange rate fluctuations on balances of cash and cash equivalents	(26)	46
Cash and cash equivalents at end of period	15,385	4,783

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