
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 September 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): _____

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On September 23, 2021, the Registrant issued a press release titled: "IceCure Medical Reports Financial Results for the First Half of 2021 and Recent Operating Highlights." 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 for the First Half of 2021 and Recent Operating 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: September 23, 2021

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

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IceCure Medical Reports Financial Results for the First Half of 2021 and Recent Operating Highlights

CAESAREA, Israel, September 23, 2021 -- IceCure Medical Ltd. (NASDAQ: ICCM) (TASE: ICCM) (“IceCure” or the “Company”), developer of the next generation minimally invasive cryoablation technology that destroys tumors by freezing, today reported its financial results as of and for the six-month period ended June 30, 2021.

First Half 2021 and Recent Operating Highlights

- The FDA granted Breakthrough Device Designation for the ProSense® system for treatment of various indications, including the use in treatment of patients with T1 invasive breast cancer and/or patients not suitable for surgical alternatives for the treatment of breast cancer.
- Presented positive interim results from the ICE3 clinical trial for cryoablation of small low-risk breast cancer tumors using the ProSense System at the 22nd Annual Meeting of the American Society of Breast Surgeons (ASBrS) held on April 30, 2021.
- Continued process with the FDA on a regulatory path forward to make ProSense System available to the breast cancer patients that can benefit from the Company’s minimally-invasive cryoablation solution based on the ICE3 clinical trial results.
- Peer reviewed article titled “*Cryoablation Without Excision for Low-Risk, Early-Stage Breast Cancer: 3-Year Interim Analysis of Ipsilateral Breast Tumor Recurrence in the ICE3 Trial*” was published in the Annals of Surgical Oncology. The lead author of the article was Dr. Richard Fine, MD, 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, TN.
- Expanded the Company’s global distribution network, including:
 - o Mutlu Medikim Tibbi Malzeme TIC. A.S. (“Mutlu Medikim A.Ş.”) to exclusively sell the ProSense System in Turkey.
 - o Novomed Ltd, to distribute the ProSense System in certain parts of India. This represents the Company’s second distributor in India.
 - o KTRFIOS IMPORTACAO E EXPORTACAO LTDA to exclusively sell the ProSense System in Brazil.
 - o Asian distribution partnership with Terumo Corporation (Tokyo: 4543, TRUMY:OTC US) expanded to include Thailand, in addition to Japan and Singapore.
- The R&D team has advanced the development of a next generation systems of single probe system and multi probe system, as compared to the current ProSense System that features one probe. These additional probes will allow the new system to treat bigger tumors or more than one tumor in a patient at the same time.
- The Company’s ordinary shares commenced trading on the Nasdaq Capital Market on August 26, 2021.
- Completed the previously announced \$15.0 million private placement, including a U.S. investors.

“I am excited by our team’s growing list of accomplishments throughout the business thus far in 2021. This includes the significant progress we’ve made expanding the global distribution network for our ProSense Cryoablation System. This steady growth is especially impressive taking into account the impact of the ongoing global pandemic. I have great appreciation for the team we’ve put together and their continued efforts to bring our system to patients,” commented Eyal Shamir, Chief Executive Officer of IceCure.

“As the most commonly diagnosed cancer, breast cancer continues to be a serious life-threatening disease with an estimated 325,000¹ new breast cancer cases diagnosed in the U.S. in 2020, and more than 2.3 million new cases worldwide in 2020². The incidence of breast cancer is expected to continue to rise, with the U.S. National Cancer Institute estimating a 50% increase in new cases of breast cancer in 2030³. As such, we have dedicated a tremendous amount of our time and resources towards treating breast cancer with our ProSense System, which we believe enables shorter, simpler, and cost-effective procedures with lower risk of complications,” continued Mr. Shamir. “We are working relentlessly to establish a regulatory path towards making the ProSense System available to early-stage breast cancer patients in the U.S. or high-risk patients to surgery as a minimal invasive treatment.”

“Being a Nasdaq listed company has made it easier for global institutional investors to be part of our journey. It also helps us expand our global reach and execute on our international expansion through a distribution network of leading medical device companies and distributors across Europe, Asia, the Middle East, and Latin America. These partners provide specialized local experience and resources to navigate each country’s regulatory pathways and distribution needs. We believe there are tremendous opportunities to continue building out this network with new and existing partners in additional countries and territories,” concluded Mr. Shamir.

Financial Results for the Six-Month Period Ended June 30, 2021

For the six months ended June 30, 2021, revenue increased by 12% to approximately \$2.1 million, compared to approximately \$1.9 million for the six months ended June 30, 2020.

Gross profit was \$1.2 million for the six months ended June 30, 2021, which is relatively unchanged compared to the six months ended June 30, 2020. Gross margin was 58% for the six-month period ended June 30, 2021, compared to 62% for the six months ended June 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, and sales to distributors instead of direct sales to end customers.

Total operating expenses for the six months ended June 30, 2021 were approximately \$4.9 million. Total operating expenses for the six months ended June 30, 2020 were approximately \$2.8 million. The increase in operating expenses is 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 of the Company’s expenses, net loss reported for the six-month period ended June 30, 2021, increased to approximately \$3.8 million, or \$0.16 per share, compared with a net loss of approximately \$1.6 million, or \$0.11 per share, for the same period last year.

As of June 30, 2021, the Company had cash and cash equivalents of approximately \$18.6 million, compared with approximately \$3.5 million as of December 31, 2020.

About IceCure Medical

Founded in 2006, Israel-based IceCure Medical (NASDAQ: ICCM) (TASE: ICCM) develops and markets 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, after receiving certain FDA and CE approvals.

End Notes:

- ¹ The National Breast Cancer Foundation, Inc. - <https://www.nationalbreastcancer.org/wp-content/uploads/2020-Breast-Cancer-Stats.pdf>
- ² The World Health Organization (WHO) - <https://www.who.int/news-room/fact-sheets/detail/breast-cancer>
- ³ National Cancer Institute - <https://www.cancer.gov/news-events/cancer-currents-blog/2015/breast-forecast>

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, commercialization activities and the market opportunity for the Company’s ProSense Cryoablation System in Turkey, India, Brazil and other countries across the Middle-East, Europe, Asia, and Latin America. 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 filed with the SEC on August 10, 2021. Copies 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, 2021 (Unaudited)	As of December 31, 2020 (Audited)
	U.S. dollars in thousands	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	18,613	3,502
Deposit	-	4,669
Trade accounts receivables	94	94
Inventory	1,465	1,064
Prepaid expenses and other receivables	363	260
Total current assets	20,535	9,589
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	331	37
Right-of-use assets	287	306
Property and equipment, net	504	307
Total non-current assets	1,122	650
TOTAL ASSETS	21,657	10,239
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade accounts payable	804	645
Lease liabilities	180	214
Other current liabilities	3,223	2,855
Total current liabilities	4,207	3,714
NON-CURRENT LIABILITIES		
Long-term lease liabilities	92	118

Other long-term liabilities	731	759
Total non-current liabilities	823	877
Total liabilities	5,030	4,591
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 31,772,935 shares and 20,218,220 shares as of June 30, 2021 and December 31, 2020, respectively		
Treasury shares	-	(41)
Additional paid-in capital	69,010	54,225
Accumulated deficit	(52,383)	(48,536)
Total shareholders' equity	16,627	5,648
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	21,657	10,239

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

	Six months ended June 30,	
	2021	2020
	U.S. dollars in thousands (except per share data)	
Revenues	2,073	1,855
Cost of revenues	880	698
Gross profit	1,193	1,157
Research and development expenses	2,730	1,434
Sales and marketing expenses	625	496
General and administrative expenses	1,584	846
Operating loss	3,746	1,619
Financial expenses (income), net	101	(21)
Net loss and comprehensive loss	3,847	1,598
Basic and diluted net loss per share	0.156	0.106
Weighted average number of shares outstanding used in computing basic and diluted loss per share	24,696,706	15,024,278

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

	Six months ended June 30,	
	2021	2020
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(3,847)	(1,598)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	50	26
Share-based compensation	184	137
Exchange rate changes in cash and cash equivalents and short time deposits	97	12
Changes in assets and liabilities:		
Increase in trade accounts receivables	-	(153)
Increase in prepaid expenses and other receivables	(103)	(205)
Increase in inventory	(401)	(403)
Decrease in prepaid expenses and other long-term assets	-	19
Decrease (increase) in right of use assets	19	(117)
Increase in trade accounts payable	159	19
Increase (decrease) in lease liabilities	(59)	79
Increase in other current liabilities	368	433
Increase (decrease) in other long-term liabilities	(28)	909
Net cash used in operating activities	(3,561)	(842)
Cash flows from investing activities		
Realization of deposits	4,621	-
Investment of long term deposits	(295)	-
Purchase of property and equipment	(247)	(112)
Net cash provided by (used in) investing activities	4,079	(112)

Cash flows from financing activities		
Issuance of ordinary shares, net of issuance cost	14,586	-
Exercise of options to ordinary shares	56	5
Net cash provided by financing activities	14,642	5
Increase (decrease) in cash and cash equivalents	15,160	(949)
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	(49)	(12)
Cash and cash equivalents at end of period	18,613	4,828

Innovating Cryotherapy Solutions

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