
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 January 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): _____

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On January 5, 2022, the Registrant announced a letter to its shareholders by Chief Executive Officer, Eyal Shamir. A copy of this letter is furnished herewith as Exhibit 99.1.

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EXHIBIT INDEX

Exhibit No.

99.1 [The Registrant's Letter to its Shareholders by Chief Executive Officer, Eyal Shamir, dated January 5, 2022.](#)

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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: January 5, 2022

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

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IceCure Medical CEO Issues Letter to Shareholders

CAESAREA, Israel, January 5th, 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, today released the following letter to shareholders from its Chief Executive Officer, Eyal Shamir.

Dear Shareholders,

As we enter the new year, I wanted to provide our shareholders with an update regarding our 2021 achievements and to outline key business objectives for 2022.

We are pleased with the progress of the ICE3 clinical trial to date and are encouraged by excellent patient and physician feedback. Notably, we announced positive interim results from our ICE3 trial at the American Society of Breast Surgeons, or “ASBrS,” and the Radiological Society of North America, or “RSNA,” conferences, demonstrating the efficacy and safety of minimally invasive cryoablation using the ProSense® system. Additionally, positive results from an independent study in Japan using the ProSense system were published, further validating the use of our system to eliminate small tumors in breast cancer. We have also made important progress on the development of our next-generation system, which will allow for additional clinical applications with cryoablation technology. Further, the European Patent Office notification of an intention to grant a patent for our cryogenic pump will enable ongoing development of our next-generation cryoablation systems and is a step towards expansion to further clinical applications.

We have transitioned from R&D to commercialization in the U.S., Europe, and Asia and are continuing to advance our regulatory and commercial strategies within the world’s largest oncology markets. We have expanded our global distribution network. We have also listed our shares on the Nasdaq following a private placement of \$15 million early in the year, and later raised additional \$17 million in an underwritten offering in a much higher enterprise valuation. We are now, well-financed to continue this momentum and accelerate our business. This steady growth is on account of our loyal shareholders who have supported us and provided us with the opportunity to raise additional capital, in a challenging market environment. We are immensely grateful to our major shareholders for their trust and continued support. We realize it has been a controversial time to access the capital markets, but growth and opportunity are at the forefront of our mission at IceCure. As we focus on the larger mission to help patients that can benefit from our innovative technology, we will meet our obligation to fund the company independent of day-to-day market activity.



I have immense appreciation for our team and their continued efforts to bring the ProSense system to patients, setting new standards in tumor therapy. In addition to breast cancer, we are also making strides to apply our technology to kidney, liver, lung and bone cancers. We have also grown our employee base, with a particular focus on building out our R&D team and hired a VP of Human Resources to support our expansion.

- In 2022, we intend to continue US commercial expansion activity and add new strategic and commercial partners globally. One of our major focuses in 2022 will be the regulatory clearance in major territories for our business – the United States, China, and Japan. In China, we expect the National Medical Products Administration, or (“NMPA,”), to complete its evaluation of the amendment by the end of 2022, which, if approved, would allow the disposable IceSense3 Cryoprobes to be sold for commercial procedures in mainland China.
- In the United States we plan on pursuing Food and Drug Administration, or “FDA,”-specific approval for breast cancer with ongoing ICE3 clinical trial; Since we were granted breakthrough device designation, or “BDD,” for our ProSense system, the pre-submission package included a request for a sprint discussion under FDA procedures.
- We are cooperating with our strategic partner, Terumo Corporation, to further advance the regulatory process for our products in Japan.
- We also intend to focus on the continued development of next generation single probe system and multi-probe system, as compared to the current ProSense System that features a single probe, which will provide us with the ability to treat larger tumors or more than one tumor in a patient at the same time.

I am excited by the Company’s list of accomplishments in 2021, highlighted below, and look forward to continued success in 2022.

2021 Key Achievements

Regulatory

- Granted Breakthrough Device Designation from the, “FDA,” 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.
- Submitted a pre-submission package to the FDA in which we proposed an intended use for early- stage breast cancer and high risk to surgery for our IceCure family systems and requested a De Novo classification. Since we were granted “BDD,” for our ProSense system, the pre-submission package included a request for a sprint discussion under FDA procedures.
- Submission of an amendment to the registration certificate for the IceSense3® system to China’s “NMPA,” which, if approved, would allow the disposable IceSense3 Cryoprobes to be sold for commercial procedures in mainland China.



**Research (Clinical and Development)
Single & Multi-probe systems**

- 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 ASBrS held on April 30, 2021.
- Promotion of interim data from the ICE3 Clinical Trial by Co-Primary Investigator Dr. Kenneth Tomkovich at the Radiologists Society of North America (RSNA) on November 30. Dr. Tomkovich's presentation, "Primary Treatment of Low Risk Breast Cancers Using Image-Guided Cryoablation: A 6 Year Update of the ICE3 Trial" was selected to be featured in a daily bulletin by RSNA, the largest radiology society in the world with over 48,000 members in the United States, representing 31 radiologic sub-specialties sharing state-of-the-art radiological innovations.
- Publication of 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" in the *Annals of Surgical Oncology*, led by 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.
- Publication of peer-reviewed independent study titled "VAB and MRI Following Percutaneous Ultra-Sound Guided Cryoablation for Primary Early-Stage Breast Cancer: A Pilot Study in Japan" 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.

Commercial

- Expanded the Company's global distribution network, including:
 - Mutlu Medikim Tibbi Malzeme TIC. A.S. ("Mutlu Medikim A.Ş.") to exclusively sell the ProSense System in Turkey;
 - Novomed Ltd, to distribute the ProSense System in certain parts of India. This represents the Company's second distributor in India;
 - KTRFIOS IMPORTACAO E EXPORTACAO LTDA to exclusively sell the ProSense System in Brazil;
 - Asian distribution partnership with Terumo Corporation (Tokyo: 4543, TRUMY:OTC US) expanded to include Thailand, in addition to Japan and Singapore; and
 - Mobile SCANMED Systems SP. z o.o. to exclusively sell the ProSense system and disposables in Poland.



Financial

- Ordinary shares commenced trading on the Nasdaq Capital Market .
- Completed the previously announced \$15.0 million private placement, including U.S. investors, and a \$17.0 million follow-on offering.

2021 was a pivotal year for Ice Cure. We look forward to further advancing our commercial and clinical activities in 2022 towards our mission to become the new gold-standard for cryoablation tumor therapy. We are focused on the long-term potential of the company and the broad potential of our minimally-invasive cryoablation technology, validated by our many accomplishments in 2021 and prospective events in the coming year.

We thank each of our shareholders, and value you for your continued support of IceCure.

Sincerely,

Eyal Shamir

Chief Executive Officer

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 its plans, intentions and focuses for year 2022. 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 December 8, 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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