

January 4, 2023



IceCure Medical CEO Issues Letter to Shareholders

CAESAREA, Israel, Jan. 4, 2023 /PRNewswire/ -- [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, today released the following letter to shareholders from its Chief Executive Officer, Eyal Shamir.



Dear Shareholders,

In 2022, we built a strong foundation for the road ahead. IceCure is creating the new standard in tumor therapy, freezing tumors in their tracks through a minimally invasive outpatient procedure that doesn't disrupt lives and aims to eliminate recurrence. We've reported solid data in breast and kidney cancer this year with investigator-initiated studies in several other indications ongoing. Throughout 2022, we've delivered on stated goals by bolstering current customer relationships, developing new partnerships, and innovating the next generation of our cryoablation technology.

2022 Key Achievements

- **Fortified Balance Sheet:** Under very challenging market conditions, we successfully closed a [\\$14.5 million](#) equity financing priced 'at the market' under Nasdaq rules and without warrants. Several of our long-term institutional shareholders participated in the transaction. We believe that our ability to execute this kind of fundraiser in the current market is a testament to investors' confidence in our technology, market strategy, and management team. With the net proceeds of this financing plus our cash balance of \$14.2 million as of the end of the third quarter 2022, we believe we are well funded to continue to execute on the global rollout of ProSense across a broad number of

indications.

- **Submitted for Regulatory Approvals:** We achieved several significant milestones with submission for regulatory approvals in [Canada](#), [Vietnam](#), and our [filing](#) of a De Novo classification request with the U.S. Food and Drug Administration ("FDA") for Marketing Authorization of our ProSense System with Breakthrough Indication for early-stage, low-risk, breast cancer patients at high risk to surgery representing an estimated \$80 million annual addressable market in the U.S.
- **Received Regulatory Approval:** Our cryoprobes and introducers received regulatory approval in Brazil, a key step towards opening the largest market in Latin America.
- **Achieved Reimbursement Milestone in the U.S.:** Our U.S. commercialization efforts made a major move forward with respect to insurance [reimbursement](#) when we received the assignment of a \$3,400 CPT Category III code from the Centers for Medicare & Medicaid Services ("CMS") for breast cancer cryoablation procedures for facility fees.
- **Continued to Execute on Global Commercial Rollout:** In [China](#), we entered into an exclusive distribution agreement with Shanghai Medtronic Zhikang Medical Devices Co. Ltd., an affiliate of Medtronic plc (NYSE:MDT) and Beijing Turing Medical Technology Co. Ltd. ProSense has been installed at numerous new sites in 2022, about half of which were in the U.S., with others in Europe and Southeast Asia. We are highly encouraged by the increasing usage across these sites and sites that were installed previously.
- **Clinical Data Presented & Published:** In the most up-to-date interim data available from our [ICE3](#) study, there were six cases of ipsilateral breast tumor recurrence ("IBTR") out of 194 patients, or 3.09%. Interim analysis from our [ICESECRET](#) study found that ProSense was safe and effective in treating kidneytumors with an 89.5% recurrence-free rate. Additionally, ProSense for breast cancer was [featured](#) in a poster presentation at the Radiological Society of North America's Annual Meeting. Two articles featuring ProSense were published in medical journals; one article published in [Cancers](#) studied the feasibility and safety of ProSense for kidney, bone, liver, lung, and soft tissue and the other article from [Clinics in Oncology](#) studied the use of liquid nitrogen based cryoablation with ProSense in the treatment of metastatic lung cancer.
- **Raised ProSense's Visibility Worldwide:** We were extremely active exhibiting and conducting live ProSense [webinars](#) and demos at medical conferences worldwide including the [Society of Interventional Radiology](#) Annual Scientific Meeting and the [European Conference on Interventional Oncology](#). We launched our breast cancer cryoablation awareness campaign [#FreezeCancerNotYourLife](#) during Breast Cancer Awareness Month. Raising awareness among the patient population and educating clinicians will drive demand for our ProSense procedures.

2023 Objectives

- We await the FDA's response to our regulatory filing, which included efficacy and safety data, for early-stage, low-risk, breast cancer patients at high risk to surgery. Concurrent with potential regulatory clearance, we will continue work with CMS to refine reimbursement codes to enable greater availability and affordability of the ProSense System for breast cancer.
- Ahead of potential FDA clearance, we are increasing commercialization efforts in the U.S. with a focus on breast cancer to address the initial indication market of 43,000 women in the U.S. annually.

- In Europe, we also are increasing our focus on breast cancer and plan to conduct studies in cooperation with our distributors and healthcare providers to collect clinical data and support commercialization. We believe that the regulatory environment in Europe offers our liquid nitrogen-based cryoablation system clear technological and market advantages and we will seek to leverage these benefits in the coming year.
- Globally, we expect continued commercial rollout, regulatory filings, and approvals. As we continue discussions with potential distribution partners in new territories, we are working closely with our current strategic partners Shanghai Medtronic Zhikang Medical Devices Co. Ltd. in Mainland China, Terumo Corporation in Japan and Thailand, and numerous others throughout Europe, Asia, and the Americas to make ProSense procedures widely available across numerous indications.
- We are also continuing to explore cooperations with various strategic players in the industry to optimize the commercial development and rollout of our ProSense technology.

With many accomplishments achieved this past year, IceCure looks forward to a bright and exciting future in 2023. Stay tuned! We wish you all a healthy and prosperous new year.

Sincerely,

Eyal Shamir, CEO
IceCure Medical

About IceCure Medical Ltd.

IceCure Medical Ltd. (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 FDA 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 and Israeli 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 statements in this press release when it discusses its objectives for 2023, including: anticipating the FDA's response to regulatory requests for approvals; further studies and cooperation efforts with distributors and healthcare providers to collect clinical data and commercialization; the continued commercial rollout; the belief that the Company is well funded; regulatory filings and approvals for ProSense and other products; its belief that raising awareness among patients and clinicians of the benefits of minimally invasive cryoablation will drive demand for its ProSense procedures; and its exploration of collaborations with strategic players in the industry. 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 Securities Exchange Commission (the "SEC") on April 1, 2022, as amended, 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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