
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 31, 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 31, 2022, the Registrant issued a press release titled: "IceCure Medical Announces Preliminary Unaudited 2021 Year-End Financial Results." 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 Announces Preliminary Unaudited 2021 Year-End Financial Results."](#)

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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: January 31, 2022

IceCure Medical Ltd.

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

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IceCure Medical Announces Preliminary Unaudited 2021 Year-End Financial Results

- *Revenue increase driven by sales through distribution agreements for IceCure's groundbreaking minimally-invasive cryoablation tumor destruction technology.*
- *Robust balance sheet supports global rollout of ProSense® System and the Company's pursuit of additional regulatory approvals in the U.S., Japan, and China*

CAESAREA, Israel, January 31, 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 announced preliminary unaudited year-end financial results for the twelve months ended December 31, 2021.

Revenues increased to \$4.1 million in 2021 compared to \$3.9 million in 2020, primarily driven by sales through distribution agreements in Europe and sales of the Company's ProSense® system and probes in the United States.

As of December 31, 2021, the Company's cash and cash equivalents totaled \$25.6 million compared to \$3.5 million for the period ending December 31, 2020, as a result of the two equity raises in 2021 totaling \$32 million.

"2021 was pivotal for IceCure, beginning with a private placement of \$15 million early in the year, listing of our shares on the Nasdaq, followed by an additional \$17 million offering at a greater enterprise value. We have expanded the global distribution network for ProSense® and increased our sales in the United States and Europe. Furthermore, our U.S. ICE3 trial demonstrated supportive data for our cryoablation technology in combating early-stage breast cancer which we reported at various academic meetings," stated Mr. Eyal Shamir, the Chief Executive Officer of IceCure.

"Notably, we remain focused on expansion on all fronts from both a commercial and product development standpoint, and we have also made important progress on the development of our next-generation cryoablation, single-probe, and multi-probe systems with a European patent-pending for our cryogenic pump which will potentially expand clinical applications with cryoablation for bigger tumors or multiple tumors simultaneously."

"In 2022, we intend to further advance our regulatory and commercial strategies in the United States, China, and Japan. We also plan to engage with new strategic commercial partners. One of our major focuses will be additional regulatory approvals in major countries for our business, namely, the United States and China. In the United States, we've already filed a pre-submission package with the Food and Drug Administration (the "FDA") for early-stage breast cancer and high risk to surgery and suggested a De Novo classification based on our ongoing ICE3 clinical trial. We hope that our Breakthrough Device Designation with the FDA will secure priority review," Mr. Shamir concluded.

IceCure plans to report full 2021 audited financial results upon filing its annual report on Form 20-F with the U.S. Securities and Exchange Commission.

The above information reflects preliminary estimates with respect to certain results of IceCure Medical for the full year ended December 31, 2021, based on currently available information. Because the audit for 2021 is not yet complete, IceCure's final results may vary from the preliminary estimates.

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 cancers. 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," "destroys" 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 preliminary results for 2021, pursuit of regulatory approvals and FDA review, expansion of clinical applications with cryoablation for bigger tumors or multiple tumors simultaneously, advancing regulatory and commercial strategies, engagement of new strategic partners and the report of its 2021 unaudited results. 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 3, 2021, 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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