
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 December 2022
(Report No. 3)

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 office)

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 Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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On December 19, 2022, IceCure Medical Ltd. (the "Company") issued a press release titled: "IceCure's ProSense Safe and Effective in Treating Kidney Tumors with 89.5% Recurrence-Free Rate Based on Interim Study Results", a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K (the "Report").

The first, second, third and fifth paragraphs and section titled "Forward Looking Statements" in the press release furnished herewith are incorporated by reference into the Company's Registration Statements on Form F-3 (Registration No. [333-258660](#) and Registration No. [333-267272](#)) and Form S-8 (Registration No. [333-262620](#) and Registration No. [333-264578](#)), filed with the Securities and Exchange Commission, to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit No.

99.1 [Press release titled: "IceCure's ProSense Safe and Effective in Treating Kidney Tumors with 89.5% Recurrence-Free Rate Based on Interim Study 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.

IceCure Medical Ltd.

Date: December 19, 2022

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

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IceCure's ProSense Safe and Effective in Treating Kidney Tumors with 89.5% Recurrence-Free Rate Based on Interim Study Results

- *ICESECRET study interim findings presented at the Urological Association Conference in Eilat, Israel*
- *ProSense was found to be a safe and effective treatment method for renal lesions smaller than 5 cm in patients not suitable for kidney-preserving surgery*
- *ProSense is approved for the treatment of benign and malignant kidney tumors in the U.S., Europe, and numerous other countries*

CAESAREA, Israel, December 19, 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, today announced interim results from the ICESECRET study for the treatment of patients with small renal masses ("SRM") who cannot be offered kidney-preserving surgery. Data were presented on December 14, 2022 at the Urological Association Conference in Eilat, Israel. The presentation titled "Renal Mass Cryoablation - Interim Analysis ICESECRET Study" was delivered by Dr. Nasir Said of Bnai Zion Medical Center.

According to the presentation, out of the 115 patients enrolled, 107 patients (112 lesions) returned for follow-up with a mean duration of 22.8 months and a range 12-60 months.

- In a subgroup of patients with no previous history of kidney cancer on the same kidney and a lesion ≤ 3 cm, an 89.5% recurrence-free rate was observed at a mean follow-up time of 22.2 months when the procedure protocol was followed.
- The recurrence-free rate was 85.1% for the 107 patients (91 patients, including 13 patients who underwent a second cryoablation), at a mean follow-up period of 16.5 months.
- 5 serious adverse events were reported, 4 of which were of mild severity and were treated conservatively and resolved within 1-5 days, with one severe complication of a new onset of ipsilateral hydronephrosis 7 months after the cryoablation procedure that led to nephrectomy.
- Cryoablation time and hospitalization time were relatively short, up to approximately 25 minutes and 2 days, respectively.
- The presentation concluded that, based on these interim results, cryoablation is safe and effective for treating renal masses under 5 cm.

According to the American Journal of Roentgenology, small renal masses, which may be malignant or benign tumors in the kidney, have been rising in incidence over the past two decades. According to the American Cancer Society, in 2022, in the U.S., an estimated 79,000 new cases of kidney cancer will be diagnosed, with about 14,000 dying from the disease. Globally, there were more than 430,000 new cases of kidney cancer in 2020 and about 180,000 deaths according to World Cancer Research Fund International.

"These impressive interim results demonstrate the value of ProSense for urologists and interventional radiologists as a therapeutic alternative when patients are not eligible for surgery," stated IceCure's Chief Executive Officer, Eyal Shamir. "We believe the findings will support further use of ProSense in the jurisdictions in which our cryoablation system is approved for use with benign and malignant tissues of the kidney. The growing body of data on ProSense's efficacy and safety across a broad range of indications supports commercialization momentum, particularly in facilities that benefit from one device that can be used across multiple specialties."

ICESECRET, a prospective, multicenter, single-arm clinical trial is being performed at Bnai-Zion Medical Center, Haifa, Israel, and Shamir Medical Center, Zerifin, Israel, and led by Principal Investigator Prof. Halahmi Sarel. The trial included 115 patients (138 lesions) with localized SRM of ≤ 5 cm who were treated with ProSense cryoablation under CT guidance. Full engulfment of the renal lesion, including a safety margin of 0.5 cm was achieved in approximately 96% of the procedures where there was no anatomical limitation. Follow-up visits are performed 6 weeks, 6 months, 1 year, and then annually up to 5 years after the procedure. During the follow-up visits, data related to local recurrence, based on CT imaging, is collected. Safety was determined by monitoring procedure-related adverse events throughout the study.

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 U.S. Food and Drug Administration 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. 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: the interim study results for ICESECRET; the value of ProSense for urologists and interventional radiologists as a therapeutic alternative when patients are not eligible for surgery; the Company's belief that the interim results from ICESECRET will support further use of ProSense in the jurisdictions in which the Company's cryoablation system is approved for use with benign and malignant tissues of the kidney; and the commercialization momentum from a growing body of data on ProSense's efficacy and safety. 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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