
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 2024

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

CONTENTS

On December 5, 2024, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure's ProSense® Cryoablation Safe and Effective in Destruction of Kidney Tumors with 88.7% Recurrence-Free Rate Based on Interim ICESECRET Study Results," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.

The first, second and fourth paragraphs and the section titled "Forward Looking Statements" in the press release attached herewith as Exhibit 99.1 are incorporated by reference into the Company's Registration Statements on Form F-3 (Registration Nos. [333-258660](#) and [333-267272](#)) and Form S-8 (Registration Nos. [333-270982](#), [333-264578](#), [333-262620](#) and [333-281587](#)), filed with the Securities and Exchange Commission, to be a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

EXHIBIT INDEX

| Exhibit No. | |
|-------------|--|
| 99.1 | Press release dated December 5, 2024 titled "IceCure's ProSense® Cryoablation Safe and Effective in Destruction of Kidney Tumors with 88.7% Recurrence-Free Rate Based on Interim ICESECRET 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.

Date: December 5, 2024

ICECURE MEDICAL LTD.

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

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IceCure's ProSense® Cryoablation Safe and Effective in Destruction of Kidney Tumors with 88.7% Recurrence-Free Rate Based on Interim ICESECRET Study Results

- *Data confirm previous results showing that ProSense® cryoablation is highly effective for kidney tumors ≤ 3 cm and a safe procedure for kidney tumors ≤ 5 cm in people ineligible for surgery*
- *Interim results presented at the Israeli Urological Association Conference in Eilat, Israel*
- *ProSense® is approved for benign and malignant kidney tumors in the U.S., Europe and numerous other countries*

CAESAREA, Israel, December 5, 2024 – IceCure Medical Ltd. (Nasdaq: ICCM) (“IceCure”, “IceCure Medical” or the “Company”), developer of minimally-invasive cryoablation technology that destroys tumors by freezing as an alternative to surgical tumor removal, today announced interim results from the Company’s ICESECRET study of cryoablation for patients with small renal masses (“SRM”) who cannot be offered kidney preserving surgery. Data were presented on December 5, 2024 at the Israeli Urological Association Conference in Eilat, Israel. The presentation titled “Renal Mass Cryoablation - Interim Analysis of ICESECRET Study” was delivered by Dr. Keren Boguslavsky of Bnai Zion Medical Center.

Results were reported at a mean follow-up period of 36 months for 111 patients with 117 lesions. A summary of the key results were:

- In 91 patients (approximately 82%), no tumor recurrence was observed.
- Following an additional cryoablation procedure for the same tumor in 13 patients, the success rate for the overall population was 83.8%, with a mean follow-up time of 39.6 months. In patients without a history of kidney cancer with one tumor ≤ 3 cm, the success rate was 88.7%.
- Freezing of the renal tumor, including safety margins of 0.5 cm, was achieved in 95.6% of the procedures demonstrating high efficacy in cases without anatomic limitation for ice ball creation.
- Four procedure-related serious adverse events were reported, three of which were mild and treated conservatively. One severe complication was observed seven months after the cryoablation procedure.
- Renal function was preserved, on an average basis across the patient cohort, with no significant change in creatinine and hemoglobin levels compared to baseline.
- The procedure time, relative to the standard of care as supported by and documented in medical literature, was short at approximately 25 minutes.

“The ability to offer cryoablation for kidney cancer is a large unmet need, particularly in patients who are ineligible for kidney preserving surgery. We are very pleased that ICESECRET’s latest interim results present ProSense® as a safe and effective option for these patients. These results are particularly important since ProSense® is already approved for the as a cryosurgical tool in the destruction of malignant and benign tumors of the kidney in key markets including the U.S. and Europe,” stated IceCure’s Chief Executive Officer, Eyal Shamir.

According to the American Journal of Roentgenology, small renal masses, which may be malignant or benign tumors in the kidney, have been increasing in incidence over the past two decades. According to the American Cancer Society, in 2024, in the United States, an estimated 81,610 new cases of kidney cancer will have been diagnosed, with approximately 14,390 dying from the disease. Globally, there were more than 434,000 new cases of kidney cancer in 2022 and about 156,000 deaths according to World Cancer Research Fund International.

About ICESECRET

ICESECRET, a prospective, multicenter, single-arm clinical trial is being performed at Bnai Zion Medical Center in Haifa, Israel and Shamir Medical Center in Zerin, Israel and is being led by Principal Investigator Prof. Halahmi Sarel. The trial includes 114 patients (138 lesions) with localized SRM of ≤ 5 cm that were ablated with ProSense® cryoablation under CT guidance. Follow-up visits are performed six weeks, six months, one year, and then annually up to five 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 ProSense®

The ProSense® Cryoablation System is a minimally invasive cryosurgical tool that provides the option to destroy tumors by freezing them. The system uniquely harnesses the power of liquid nitrogen to create large lethal zones for maximum efficacy in tumor destruction in benign and cancerous lesions, including breast, kidney, lung, and liver.

ProSense® enhances patient and provider value by accelerating recovery, reducing pain, surgical risks, and complications. With its easy, transportable design and liquid nitrogen utilization, ProSense® opens that door to fast and convenient office-based procedures for breast tumors.

About IceCure Medical

IceCure Medical (Nasdaq: ICCM) develops and markets advanced liquid-nitrogen-based cryoablation therapy systems for the destruction 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 Company’s flagship ProSense® system is marketed and sold worldwide for the indications cleared and approved to date including in the U.S., Europe and China.

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