## 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 April 2023 (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 <u>Caesarea, 3079504 Israel</u> (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 April 20, 2023, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure's ProSense System Used in Endometriosis Cryoablation Study That Demonstrated Efficacy Rate of 92.8% to Avoid Secondary Surgery".

A copy of the Company's press release is furnished with this Report of Foreign Private Issuer on Form 6-K as Exhibit 99.1.

The first, second, third and fifth paragraphs in the press release furnished herewith are incorporated by reference into the Company's Registration Statements on Form F-3 (File Nos. 333-264578 and 333-264578 and 333-262620), 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 System Used in Endometriosis Cryoablation Study That Demonstrated Efficacy Rate of 92.8% to Avoid Secondary Surgery."

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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: April 20, 2023

## IceCure Medical Ltd.

By: /s/ Eyal Shamir

Name: Eyal Shamir Title: Chief Executive Officer



## IceCure's ProSense System Used in Endometriosis Cryoablation Study That Demonstrated Efficacy Rate of 92.8% to Avoid Secondary Surgery

- ProSense System among the two types of systems used in the study
- Pain-free survival rates of 93.75% at 6 months and 82.72% at 36 months post-procedure
- 190 million women globally live with endometriosis, for which there is no cure; current treatments aim to control symptoms
- Data presented at Society of Interventional Radiology 2023 Annual Scientific Meeting by lead investigator Francois H. Cornelis, MD, PhD

**CAESAREA, Israel,** April 20, 2023 -- IceCure Medical Ltd. (Nasdaq: ICCM) (TASE: ICCM) developer of minimally-invasive cryoablation technology, the ProSense® System, that destroys tumors by freezing as an alternative to surgical tumor removal, today announced that its ProSense system was used in a single-site study conducted at the Sorbonne University Department of Interventional Radiology and Oncology, Tenon Hospital in Paris, France by lead investigator Francois H. Cornelis, MD, PhD and a team of doctors. The study titled "Pain-Free Survival After Percutaneous Image-Guided Cryoablation of Extraperitoneal Endometriosis" was published in the *Journal of Vascular and Interventional Radiology*. The independent study and published paper were not sponsored by IceCure. Dr. Cornelis presented the study data at the Society of Interventional Radiology 2023 Annual Scientific Meeting on March 8, 2023.

Cryoprobes used in the study were of two types: IceCure's ProSense cryoprobe and Varian's V-probe. The purpose of the study was to retrospectively evaluate the pain-free survival of percutaneous (minimally invasive, through the skin) image-guided cryoablation of symptomatic extraperitoneal endometriosis ("EE"). 42 patients with a total of 47 lesions were treated. Patients were made aware that cryoablation was offered as a minimally invasive alternative to surgery, and that a surgical procedure may be performed if cryoablation failed. According to the published study, the therapeutic options thus far to avoid the progression of endometriosis and reduce symptoms have been limited to hormonal agents and wide surgical excision. During the last decades, minimally invasive techniques such as cryoablation have been suggested as a promising option to treat abdominal wall endometriosis with satisfactory outcomes and low morbidity.

Based on the following study outcome data, the study concluded that percutaneous cryoablation is a safe and effective procedure that significantly reduces pain and obtains local control of EE. The median follow-up was 13.5 months after cryoablation. The study's conclusions included:

- Efficacy rate of cryoablation to avoid secondary surgery was 92.8% per patient and 93.6% per nodule treated
- Median pain-free survival rates were 93.75% at 6 months and 82.72% after 12 months, 24 months, and 36 months
- Pain decreased from a median of 8/10 on the visual analogue scale to 0/10 at the last follow-up (P < 0.0001)
- 4 patients had an adverse event in the days following the procedure, 1 patient had a severe adverse event.

"We are grateful to Dr. Cornelis and the team of doctors at Sorbonne University and Tenon Hospital, where the data was collected, for having used our ProSense system, in addition to those from another company, as part of this independent study. Tenon Hospital institution is highly regarded in the field of gynecology and interventional radiology. We believe that the independent study has demonstrated the value of cryoablation in treating endometriosis, a chronic and painful condition in dire need of an effective minimally invasive treatment," stated Eyal Shamir, IceCure's Chief Executive Officer. "The ProSense system has regulatory approval in several countries, including FDA clearance for use as a cryosurgical tool in gynecology, and we are pleased that doctors now have more evidence of cryoablation's efficacy in patients with extraperitoneal endometriosis."



According to the World Health Organization, endometriosis affects about 10% of women who are at reproductive age globally, or 190 million people. Endometriosis is a chronic disease associated with severe, life-impacting symptoms. Many individuals suffering from it have limited awareness of the condition causing a lengthy delay between onset of symptoms and diagnosis. Current treatments are aimed at controlling symptoms. EE may be observed incidentally but more often on surgical scars in women with or without a history of endometriosis.

### About IceCure Medical

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 cleared and approved to date including in the U.S., Europe, and China.

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