
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 June 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 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):

CONTENTS

On June 9, 2022, IceCure Medical Ltd. (the "Company") issued a press release titled: "IceCure Medical's ProSense® Cryoablation System Submitted for Regulatory Approval in Brazil." A copy of this press release is furnished herewith as Exhibit 99.1.

This Report of Foreign Private Issuer on Form 6-K is incorporated by reference into the Company's Registration Statements on Form S-8 (File No. [333-262620](#) and File 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 Medical's ProSense® Cryoablation System Submitted for Regulatory Approval in Brazil"](#)

1

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: June 9, 2022

By: /s/ Eyal Shamir

Name: Eyal Shamir

Title: Chief Executive Officer

2



IceCure Medical's ProSense® Cryoablation System Submitted for Regulatory Approval in Brazil

- *Regulatory filing submitted by KTRFIOS, IceCure's distributor in Brazil*
- *Filing includes breast and other cancers, benign tumors, palliative intervention, and other indications*

CAESAREA, Israel, June 9, 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 ("ProSense"), today announced that KTRFIOS IMPORTACAO E EXPORTACAO LTDA., IceCure's distributor in Brazil ("KTRFIOS"), has submitted a regulatory filing to the Brazilian Health Regulatory Agency ("ANVISA") for the approval of ProSense for several indications. KTRFIOS has submitted this regulatory filing as part of an agreement signed with IceCure which includes KTRFIOS's guarantee of at least \$6.6 million in total sales for five years following such regulatory approval and a down payment of \$344,000 for 50% of the initial order.

The indications for use included in the ANVISA application are for oncology, including ablation of benign and malignant tissues in breast, prostate, kidney, lung, liver, musculoskeletal, and skin tissues, as well as for palliative intervention and other indications.

According to the World Health Organization's ("WHO") Cancer Tomorrow | IARC project, Brazil had a population of over 200 million with an estimated 592,000 cancer cases in 2020, 88,500 of which were breast cancer. The WHO expects the number of breast cancer cases in Brazil to rise to 99,800 by 2025. Therefore, IceCure believes there is a clear need for minimally invasive cancer treatments, such as ProSense, in the Brazilian market.

"We are very pleased to be working with KTRFIOS in Brazil, a significant healthcare market in Latin America, and to achieve this major milestone. This regulatory application reflects the broad number of indications for which our ProSense system can provide a highly effective, minimally invasive, and safe method of treatment for cancer patients," stated IceCure CEO Eyal Shamir. "Regulatory approvals in Brazil would add to our global regulatory landscape, which now encompasses various indications across 14 countries, including the U.S. and Europe."

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 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 its regulatory application submission in Brazil, its path towards approval of the ProSense system and the indications included in the regulatory application in Brazil, and the potential penetration of the Company's product in the Brazilian market. 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 SEC on April 1, 2022, 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.

IR Contact:

Ronen Tsimerman
email: ronent@icecure-medical.com