

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 August 2022
(Report No. 2)

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 August 29, 2022, IceCure Medical Ltd. (the "Company") issued a press release titled: "IceCure Submits Regulatory Filing in Vietnam for Approval of ProSense®." A copy of this press release is furnished herewith as Exhibit 99.1.

The first two paragraphs and the section titled "Forward-Looking Statements" in the press release are 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 Submits Regulatory Filing in Vietnam for Approval of ProSense®."](#)

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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: August 29, 2022

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

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IceCure Submits Regulatory Filing in Vietnam for Approval of ProSense®

Company is rapidly expanding its global regulatory and commercial reach

CAESAREA, Israel, August 29, 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 it has submitted a regulatory filing with the Department of Medical Equipment and Construction (“DMEC”) of Vietnam’s Ministry of Health for the ProSense System and accessories.

The application covers indications including benign and malignant breast tumors, benign and malignant lung tumors, benign and malignant liver tumors, kidney cancer, ablation of cancerous or malignant tissue, musculoskeletal tumors, and other indications.

Vietnam’s medical device market was valued at \$1.4 billion in 2019 and was projected to grow 10% annually through 2024, according to the U.S. Department of Commerce, with overall healthcare expenditures in the country totaling \$17 billion. Liver, lung, and breast cancer were the three most prevalent cancers in Vietnam in 2020 according to the World Health Organization.

“Asia is a significant market for ProSense and Vietnam is one of the fastest growing healthcare markets in the region. Having started the regulatory process in Vietnam, we anticipate high interest from potential distributors in the country,” stated IceCure CEO, Eyal Shamir. “This comes on the heels of our recent successes in the region with Shanghai Medtronic Zhikang Medical Devices Co. Ltd. in China and Terumo in Japan, Singapore, and Thailand.”

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 its regulatory approval process in Vietnam for various indications through the Ministry of Health’s DMEC, potential high interest from potential distributors in the country. 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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