
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 February 2023

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

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On February 9, 2023, IceCure Medical Ltd. (the "Company") issued a press release titled: "IceCure Medical Announces Preliminary Unaudited 2022 Year-End Financial Results & Recent Operational Highlights," 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, ninth and tenth 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and Exchange Commission, to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 Medical Announces Preliminary Unaudited 2022 Year-End Financial Results & Recent Operational Highlights."](#)

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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: February 9, 2023

IceCure Medical Ltd.

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

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IceCure Medical Announces Preliminary Unaudited 2022 Year-End Financial Results & Recent Operational Highlights

- *Significant regulatory and reimbursement milestones achieved*
- *Positive interim clinical results for ProSense in the treatment of kidney tumors and breast cancer*
- *Fortified balance sheet with \$23.6 million in cash and cash equivalents including short-term deposits as of December 31, 2022*
- *ProSense System and disposable cryoprobe sales continue to increase in the U.S.*

CAESAREA, Israel, February 9, 2023 -- 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 preliminary unaudited year-end financial results for the twelve months ended December 31, 2022.

Revenues decreased to \$3.1 million in 2022, compared to \$4.1 million in 2021. This is due to decreased revenue recognition of approximately \$0.6 million from the distribution agreement with Terumo Corporation and a decrease of sales in most territories by 25%, which was partially offset by a 28% increase in U.S. sales, and higher sales of disposable probes, as previously sold and installed systems were increasingly utilized for procedures in clinical settings. IceCure expects revenues may continue to fluctuate in the near future while the Company awaits a response from the U.S. Food and Drug Administration (“FDA”) on regulatory clearance for ProSense in early-stage breast cancer.

As of December 31, 2022, the Company’s cash and cash equivalents, including short-term deposits, totaled \$23.6 million, compared to \$25.6 million on December 31, 2021. In December 2022, IceCure raised \$14.5 million in an equity financing funding priced at-the-market under Nasdaq rules with no warrants.

“In 2022 we delivered across the board on our goals from regulatory achievements and making progress with respect to obtaining the CPT Category III code for insurance reimbursements, to interim clinical results, to traction in the medical and scientific communities, and commercialization. Our team has worked extremely hard, and we thank the patients who have enrolled in our trials, as well as the increasing number of doctors using ProSense across the world,” stated Eyal Shamir, IceCure’s Chief Executive Officer. “We are well funded to continue to execute on an enormous opportunity to expand the use of cryoablation, delivering better treatment of numerous indications. We believe our recent fund raise, which was completed on very favorable terms given current market conditions, is a testament to IceCure’s technology and our ability to deliver.”

“On the regulatory front, we filed a De Novo classification request with the FDA for Marketing Authorization of our ProSense System with Breakthrough Indication for early-stage, low-risk, breast cancer patients at high risk to surgery. Elsewhere, we filed for approvals in Canada and Vietnam and received approval in Brazil for our cryoprobes.”

“As we await a response from the FDA on our regulatory filing, reimbursement and affordability for patients is critical. We were very pleased to receive the assignment of a \$3,400 CPT Category III code from the Centers for Medicare & Medicaid Services (“CMS”) for breast cancer cryoablation procedure facility fees. Concurrent with potential regulatory clearance, we will continue working with CMS to refine reimbursement codes to include payment for the physician, thereby enabling greater availability and affordability of the ProSense System for breast cancer.”



“The body of clinical data on ProSense continues to grow. Interim results from ICESECRET were recently presented at the Urological Association Conference in Israel which demonstrated ProSense is safe and effective in treating kidney tumors with an 89.5% recurrence-free rate. When filing our De Novo application with the FDA, we submitted the most recent interim ICE3 trial results, which showed there were six cases of ipsilateral breast tumor recurrence (“IBTR”) out of 194 patients, or 3.09%. Our commercial and scientific team, including principal investigators of our trials, have been very active presenting, training, and demonstrating ProSense at medical conferences. The high level of interest in ProSense from patients and the medical community is highly encouraging.”

“IceCure is committed to leading cryoablation technology. We’ve recently received patent allowances for technologies that enable our next generation of systems. We expect our commercial momentum will continue to build in 2023.”

IceCure plans to report full 2022 audited financial results upon filing its annual report on Form 20-F with the U.S. Securities and Exchange Commission (“SEC”).

The above information reflects preliminary, unaudited estimates with respect to certain results of IceCure for the full year ended December 31, 2022, based on currently available information. Because the audit for 2022 is not yet complete, IceCure’s final results may vary from the preliminary estimates.

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 to-date by the FDA 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 and Israeli 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 statement in this press release when it discusses: its expected financial results and continued growth; the expectation that revenues may fluctuate in the near future; the belief that the Company is well funded to continue to execute on expending the use of cryoablation and delivering better treatment; the Company will continue working with CMS to refine reimbursement codes to include payment for physicians, enabling

greater availability and affordability of ProSense; expecting commercial momentum to continue to build in 2023; and awaiting the FDA's response to the Company's regulatory requests for clearance for ProSense in early-stage breast cancer; . 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, 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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