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 November 2023 (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

CONTENTS

On November 15, 2023, IceCure Medical Ltd. (the "Company") issued a press release titled: "IceCure Medical Files Appeal with U.S. FDA Requesting a Review of its De Novo Classification for ProSense® in Early-Stage Breast Cancer," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K (the "Report").

On November 15, 2023, the Company issued a press release titled "IceCure Medical Reports Financial Results as of and for the Nine Months Ended September 30, 2023 and Provides Update on Recent Operational Highlights," a copy of which is furnished as Exhibit 99.2 with this Report.

The first four paragraphs and the section titled "Forward Looking Statements" in the press release furnished as Exhibit 99.1 herewith and the press release furnished as Exhibit 99.2 (other than the second, third and fourth paragraphs thereof) 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, 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and Exchange Commission, to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

EXHIBITS

Exhibit No.	
99.1	Press release titled: "IceCure Medical Files Appeal with U.S. FDA Requesting a Review of its De Novo Classification for ProSense® in Early-Stage Breast Cancer."
99.2	Press release titled: "IceCure Medical Reports Financial Results as of and for the Nine Months Ended September 30, 2023 and Provides Update on Recent Operational Highlights."

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: November 15, 2023

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

IceCure Medical Files Appeal with U.S. FDA Requesting a Review of its De Novo Classification for ProSense® in Early-Stage Breast Cancer

- ***Objective is to reopen file to address comments and find appropriate comparator group that is more representative of the patient population the Company is seeking to treat with its ProSense® system***

- ***Company seeks to complete the review process, establish special controls, and finalize classification of ProSense®***

CAESAREA, Israel, November 15, 2023 -- IceCure Medical Ltd. (Nasdaq: ICCM), developer of the ProSense® System, a minimally-invasive cryoablation technology that destroys tumors by freezing as an alternative to surgical tumor removal, today announced it has filed a request for supervisory review ("appeal") under 21 CFR 10.75 with the U.S. Food and Drug Administration ("FDA") regarding the agency's denial of the Company's De Novo Classification Request for treating patients with early-stage, low risk breast cancer.

IceCure filed the De Novo request with the FDA in October 2022 based on interim data from its ICE3 breast cancer study for the Breakthrough Indication of early-stage (Luminal A T1 invasive) low-risk breast cancer patients. The interim ICE3 results, which estimate a five-year 95.7% recurrence free rate, and 100% doctor and patient satisfaction with cosmetic results, were submitted in the De Novo request in an effort to make the breakthrough minimally-invasive cryoablation procedure available to women in the U.S. sooner.

On September 20, 2023, IceCure announced that the FDA denied its De Novo request. The Company believes the FDA's response is largely due to the agency's choice of comparator group against which the ICE3 interim results were evaluated. During the appeal process, the Company is committed to working with the FDA to identify a comparator group that is more appropriate and representative of the patient population it is seeking to treat with its ProSense® system. Per the FDA's guidelines, IceCure expects a response to its appeal by the end of January 2024.

The ICE3 study is expected to be completed in the first quarter of 2024 following the last patient's five-year follow-up exam. Furthermore, the FDA's decision regarding the De Novo Classification request for breast cancer has no effect on ProSense®'s FDA cleared authorization for other indications in the U.S., and patients continue to have access to and benefit from ProSense® for those indications. Outside of the U.S., ProSense® is approved for early-stage breast cancer in numerous countries, including in the European Union, Brazil, and China.

"We believe the appeal process allows us to work with the FDA to identify an appropriate comparator group and that a subsequent analysis of the data may support the granting of the De Novo submission and marketing authorization," commented Eyal Shamir, Chief Executive Officer. "Furthermore, we believe the wealth of published studies in the scientific literature, including meta-studies, offer proper comparator groups that demonstrate that ProSense® is a minimally invasive alternative solution as compared to the current standard of care lumpectomy, in the Breakthrough Indication of early-stage, low-risk breast cancer patients."

About ProSense®

ProSense® cryoablation is a minimally invasive, non-surgical, outpatient 40-minute procedure that only requires a local 1% lidocaine injection (similar to its use by dentists when performing certain dental procedures) enabling the patient to remain alert during the procedure and then walk out of the doctor's office to resume their day. Cryoablation costs less than the current standard of care breast cancer surgery of lumpectomy or partial mastectomy, which requires general anesthesia and has cosmetic consequences.

About IceCure Medical

IceCure Medical (Nasdaq: 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.

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 objectives in its appeal of the FDA's De Novo Classification request; its plans to work with the FDA to identify a comparator group that is more appropriate and representative of the patient population seeking to be treated with the ProSense® system; the expected response from the FDA to the Company's appeal by the end of January 2024; the expected timing to complete the ICE3 trial in the first quarter of 2024; and that a subsequent analysis of the ICE3 data may lead to granting of the De Novo submission and marketing authorization. Historic results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials will suggest identical or even similar conclusions. 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. Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among others: our planned level of revenues and capital expenditures; our available cash and our ability to obtain additional funding; our ability to market and sell our products; legal and regulatory developments in the United States and other countries; our ability to maintain our relationships with suppliers, distributors and other partners; our ability to maintain or protect the validity of our patents and other intellectual property; our ability to expose and educate medical professionals about our products; political, economic and military instability in the Middle East, specifically in Israel; as well as those factors set forth in the Risk Factors section of the Company's Annual Report on Form 20-F for the year ended December 31, 2022 filed with the SEC on March 29, 2023, and other documents filed with or furnished to the SEC which are 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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IceCure Medical Reports Financial Results as of and for the Nine Months Ended September 30, 2023, and Provides Update on Recent Operational Highlights

- ***ProSense® system and disposables sales continue upward trend compared to the equivalent prior year period***
- ***Expanded regulatory footprint, growing body of evidenced-based data, and distribution agreements demonstrate an increasing acceptance of minimally invasive alternatives to standard of care cancer treatment***
- ***ICE3 trial remains on track and expected to be completed in the first quarter of 2024***
- ***Conference call scheduled for today at 10 am EST***

CAESAREA, Israel, November 15, 2023 – IceCure Medical Ltd. (Nasdaq: ICCM) ("IceCure" or the "Company"), developer of the ProSense® System, a minimally-invasive cryoablation technology that destroys tumors by freezing as an alternative to surgical tumor removal, today reported financial results as of and for the nine months ended September 30, 2023, as well as operational and recent corporate developments.

"First, I must make it clear that although Israel is engaged in a war with Hamas, IceCure remains more focused than ever on bringing our life-preserving technology to people around the world for improved healthcare outcomes. While our team and everyone in Israel is personally impacted by the war, IceCure continues to push ahead. We achieved several key objectives during the third quarter, including significant approvals in Brazil and Canada," stated Eyal Shamir, Chief Executive Officer.

"Furthermore, we believe the positive interim data from our ICE3 trial and the expanding body of independently conducted trials and published scientific data is an overwhelmingly strong testament to ProSense®'s path to widescale adoption across numerous indications, globally. While we have received clearance from the U.S. Food and Drug Administration ("FDA") for general minimally invasive cryoablation applications, including kidney, liver, and benign breast tumors, our primary objective is to gain marketing clearance for breast cancer, so that women will have an alternative treatment to the current standard of care, lumpectomy."

"With this aim, and with the U.S. representing the largest opportunity for ProSense®, we are continuing with the ICE3 trial, and we expect that it will be completed in the first quarter of 2024, when the final patient will have her five-year follow-up examination. In the interim, we have filed an appeal with the FDA regarding its decision on our De Novo filing for breast cancer and look forward to productive communications regarding the comparator and discussing the requested indication with the agency."

Filed Appeal with U.S. FDA Regarding Decision on the Company's Marketing Clearance Application of ProSense® in the Treatment of Early-stage Breast Cancer

- In October 2022, IceCure filed a De Novo Classification request with the FDA for regulatory approval of ProSense® for the indication of early-stage (Luminal A T1 invasive) low-risk breast cancer patients, who are at high risk for surgery (not suitable for surgical alternatives) based on interim data from its ICE3 breast cancer study. Based on the strength of the interim data, the Company believed there was a rare and unique opportunity to submit a De Novo Classification request and make its minimally-invasive ProSense® cryoablation procedure available to women sooner for this important and underserved indication. In September 2023, the FDA denied the Company's De Novo request. The FDA's decision has no bearing on patients in the U.S. for indications already cleared by the FDA, as these patients still have access to ProSense® for treatments on these indications. On November 14, 2023, the Company filed an appeal with the FDA focused on the FDA's choice of the comparator group for the Company's ICE3 study data. Through its appeal, IceCure seeks to come to an understanding with the FDA on an appropriate comparator group and subsequent analysis of the data that may lead to marketing clearance for ProSense for this indication.
- **ICE3 Study Expected to be Completed in Q1 2024:** With fewer than 20 patients left to undergo their five-year follow-up examinations, the Company anticipates the last patient will return for her final follow-up examination in the first quarter of 2024.

Independent, Non-sponsored Studies Initiated by ProSense® Users Reporting Efficacy and Safety Data Add to the Growing Body of Evidence in Peer Reviewed Journals and Conferences

- **Women Deemed Inoperable for Breast Cancer Treated with ProSense® Had Tumor Reduction Rate of 93.43% to 96.81%:** Findings from an independent breast cancer study, performed by a leading radiologist in Italy, were presented in a poster titled "Assessing the outcome of cryoablation treatment on different molecular subtype of low-grade breast cancer" at the European Society of Breast Imaging Annual ("EUSOBI") Scientific Meeting that was recently held in Valencia, Spain in September. At six months after treatment, women with the molecular subtype Luminal-A had the best outcomes, with a tumor reduction rate of 96.81% as compared to women with Luminal-B, who had a tumor reduction rate of 93.43%. Therefore, the disappearance of lesions and absence of residual malignant cells in Luminal-A group is considered to be predictive for the complete effectiveness of the treatment.
- **ProSense® had a 96.8% Success Rate in Another Independent Breast Cancer Study That Validated its Safety & Efficacy as an Outpatient Procedure:** Women with early-stage breast cancer who declined surgery at the University Hospital Lucus Augusti in Lugo, Spain, were treated with ProSense®. The median follow-up was 10 months, with a range of 0 to 40 months. Cancer progression was observed in 1 patient (1/31, 3.2%). No major complications were seen and the procedure was well tolerated by all patients. The success rate was 96.8% as reported in a poster presentation titled "Cryoablation for the treatment of early-stage breast cancer in patients who decline surgery" by Dr. Graña-López at EUSOBI.
- **Independent Scientific Paper by Doctors Using ProSense® was Published in *Journal of Breast Imaging***: A scientific paper titled "Cryoablation Therapy for Early-Stage Breast Cancer: Evidence and Rationale" presented the advantages of cryoablation over surgery in early-stage breast cancer patients. The paper was co-authored by ProSense® users Dr. Robert C. Ward and Dr. Alexander B. Sevrukov, who both cited ICE3 interim results as evidence of the safety and efficacy of cryoablation in early-stage breast cancer.
- **Substantial Additional Data Currently Being Generated by 19 Ongoing Studies:** In addition to IceCure's own studies, ICE3 for early-stage breast cancer and ICESECRET for kidney cancer, 17 independent studies of ProSense® in various indications are ongoing, with many more expected to commence. Twelve studies have already been published and there are 13 studies in breast cancer that are published and are ongoing.

Regulatory Approvals in Key Growth Markets, Appointment of VP Sales North America, and Participation at Prestigious Conferences Continue to Expand Global Footprint and Utilization of ProSense

- **Regulatory Approvals Received in Canada and Brazil:** Health Canada, the Canadian government's regulatory agency, has approved the ProSense® System, introducers, and disposable cryoprobes as cryosurgical tools for numerous indications. The ProSense® System also received regulatory approval as a Class III device from the Brazilian Health Regulatory Agency ("ANVISA") for indications for oncology, which includes the ablation of benign and malignant tissues in the breast, prostate, kidney, lung, liver, musculoskeletal, and skin tissue, for palliative intervention and other indications. ProSense®'s disposable cryoprobes and introducers were previously registered as Class II devices by ANVISA.

- **Appointed VP of Sales, North America to Accelerate Commercialization in the U.S. and Canada:** IceCure appointed Shad Good, a seasoned healthcare executive, as Vice President of Sales for North America. His primary responsibility is to build out the Company's sales infrastructure in anticipation of the broader commercialization of ProSense® in the U.S. He most recently worked with a market leader in minimally invasive breast diagnostic and therapeutic devices, which are sold in 45 countries.

- **Expanded Distribution of ProSense® in Portugal with Upfront Sales of Systems and Probes:** IceCure entered into a non-exclusive distribution agreement with Medicinália Cormédica – MC Medical, Lda. ("MC Medical"), the largest distributor of third-party medical devices in Portugal. MC Medical made an initial purchase of two ProSense® systems, along with disposable cryoprobes and introducers.

- India's First Breast Cancer Cryoablation Performed with ProSense® & ICE3 Results**Presented at BISICON 2023:** IceCure participated the 10th Annual Conference of the Breast Imaging Society of India (BISICON 2023) in conjunction with its in-country distributor, Novomed, in October 2023. ProSense® was featured at Novomed's booth, where doctors had the opportunity to get hands-on experience with the cryoablation system. Results from IceCure's ICE3 study were presented by the study's Co-Primary Investigator, Dr. Kenneth R. Tomkovich, during a session titled "Pushing the boundaries—minimally invasive cancer therapies".

- **ProSense® Featured at Hands-On Cryoablation Session & Symposium at CIRSE 2023 Annual Congress**: IceCure participated in the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) 2023 Annual Congress in Copenhagen, Denmark in September, where a tumor ablation hands-on device training with ProSense® was conducted. Additionally, a symposium titled "Cryoablation using a liquid nitrogen, single probe system: from simple to complex cases" was conducted by two leading interventional radiologists who used ProSense®, one of whom conducted a cryoablation endometriosis study. Outcomes of the published endometriosis study demonstrated cryoablation's efficacy rate of 92.8% per patient and 93.6% per nodule in avoiding secondary surgery. In addition, the system's capabilities and advantages were presented for several case studies.

- **Professor Eisuke Fukuma, who has Performed 600+ ProSense® Breast Cancer Procedures, Led a Symposium with ProSense® at 16th Thai Breast Symposium:** A cryoablation symposium titled, "Cryoablation Emerging as Effective Treatment for Breast Cancer" was led by Professor Fukuma, Director of the Breast Center at Kameda Medical Center in Japan, at the 16th Thai Breast Symposium in Bangkok, Thailand in August. IceCure participated at the conference in conjunction with the Terumo Corporation, the Company's exclusive distributor in Japan and Thailand.

Financial and Operating Results as of and for the Nine Months Ended September 30, 2023

For the nine months ended September 30, 2023, the Company reported an 11% increase in ProSense® systems and disposable probes sales to $1.7 million, compared to $1.5 million for the nine months ended September 30, 2022, driven by higher sales in the U.S. and China. Revenues for the nine months ended September 30, 2023, were $1.97 million compared to $2.15 million for the nine months ended September 30, 2022, due to the end of revenue recognition from the exclusive distribution rights agreement with Terumo Corporation in Japan, which was partially offset by an increase in ProSense® systems and disposables sales.

Gross profit was $0.73 million for the nine months ended September 30, 2023, compared to $0.98 million for the nine months ended September 30, 2022. Gross margin was 37% for the nine months ended September 30, 2023, compared to 46% for the nine months ended September 30, 2022. The decrease in gross profit and gross margin was primarily attributable to the decrease in revenue recognition from the Terumo distribution agreement.

Research and development expenses for the nine months ended September 30, 2023, were $6.39 million compared to $6.89 million for the nine months ended September 30, 2022. The decrease was primarily due to a reduction in development expenses of IceCure's next-generation single-probe system and a decrease in clinical and regulatory costs.

In support of ongoing global commercial adoption and in anticipation of increasing U.S. commercial efforts, sales and marketing expenses for the nine months ended September 30, 2023, were $3.23 million, compared to $2.24 million for the nine months ended September 30, 2022. General and administrative expenses for the nine months ended September 30, 2023, narrowed by 30% to $3.27 million, compared to $4.67 million for the nine months ended September 30, 2022. A portion of the decrease was also due to a decrease in director and officer insurance costs.

Total operating expenses for the nine months ended September 30, 2023, were $12.89 million, compared to $13.79 million for the nine months ended September 30, 2022. The decrease in operating expenses was primarily attributable to reductions in general and administrative expenses, which were partially offset by the increase in sales and marketing expenses.

Net loss reported for the nine months ended September 30, 2023, decreased by 11% to $11.66 million, or $0.26 per share, compared with a net loss of $13.03 million, or $0.35 per share, for the same period last year.

As of September 30, 2023, the Company had cash and cash equivalents, including short-term deposits, of approximately $13.2 million, compared to $23.66 million as of December 31, 2022. To ensure the Company is in a position to achieve its near-term objectives, IceCure has implemented an expense reduction plan that will reduce its non-revenue generating and clinical efforts costs, lowering the monthly cash utilization and ensuring it can meet its primary goals in 2024.

Conference call & webcast info:

November 15, 2023, at 10:00 am EST
US: 1-888-642-5032
Israel/International: +972-3-9180610
A live webcast will be available at: veidan.activetrail.biz/IcecureQ3-2023
A recording of the webcast will be available for a limited time at: ir.icecure-medical.com/

About IceCure Medical

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Forward Looking Statements

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ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	As of September 30, 2023 (Unaudited)	As of December 31, 2022 (Audited)
	U.S. dollars in thousands	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	3,826	23,659
Deposits	9,369	-
Restricted deposit	296	296
Trade accounts receivables	108	78
Inventory	2,646	2,857
Prepaid expenses and other receivables	906	1,240
Total current assets	17,151	28,130
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	33	34
Right-of-use assets	722	668
Property and equipment, net	1,515	1,356
Total non-current assets	2,270	2,058
TOTAL ASSETS	19,421	30,188
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade accounts payable	1,129	714
Lease liabilities	221	167
Other current liabilities	2,905	3,455
Total current liabilities	4,255	4,336
NON-CURRENT LIABILITIES		
Long-term lease liabilities	379	430
Total non-current liabilities	379	430
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 45,642,184 and 45,623,434 shares as of September 30, 2023 and December 31, 2022, respectively		
Additional paid-in capital	101,853	100,831
Accumulated deficit	(87,066)	(75,409)
Total shareholders' equity	14,787	25,422
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	19,421	30,188

ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Nine months ended September 30,	
	2023	2022
	U.S. dollars in thousands (except per share data)	
Revenues	1,974	2,146
Cost of revenues	1,243	1,162
Gross profit	731	984
Research and development expenses	6,390	6,886
Sales and marketing expenses	3,234	2,238
General and administrative expenses	3,268	4,667
Operating loss	12,161	12,807
Financial expenses (income), net	(504)	219
Net loss and comprehensive loss	11,657	13,026
Basic and diluted net loss per share	0.255	0.354
Weighted average number of shares outstanding used in computing basic and diluted loss per share	45,626,332	36,820,132

ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Nine months ended September 30,	
	2023	2022
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(11,657)	(13,026)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	240	174
Share-based compensation	1,007	1,353
Exchange rate changes in cash and cash equivalents and short-term deposits	203	477
Changes in assets and liabilities:		
Decrease (increase) in trade accounts receivables	(30)	260
Decrease in prepaid expenses and other receivables	334	1,693
Decrease (increase) in inventory	211	(743)
Decrease in prepaid expenses and other long-term assets	1	-
Decrease in right of use assets	118	163
Increase (decrease) in trade accounts payable	415	(279)
Decrease in lease liabilities	(169)	(242)
Increase (decrease) in other current liabilities	(550)	555
Decrease in other long-term liabilities	-	(549)
Net cash used in operating activities	(9,877)	(10,164)
Cash flows from investing activities		
Investment in short-term deposits	(9,369)	(1,776)
Purchase of property and equipment	(399)	(791)
Net cash used in investing activities	(9,768)	(2,567)
Cash flows from financing activities		
Exercise of options	15	-
Exercise of pre-funded warrants	-	1
Net cash provided by financing activities	15	1
Decrease in cash and cash equivalents	(19,630)	(12,730)
Cash and cash equivalents at beginning of the year	23,659	25,621
Effect of exchange rate fluctuations on balances of cash and cash equivalents	(203)	(454)
Cash and cash equivalents at end of period	3,826	12,437
Non-cash activities		
Obtaining a right-of-use asset in exchange for a lease liability	172	-