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 2024 (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
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 26, 2024, IceCure Medical Ltd. (the "Company") issued a press release titled "IceCure Medical Reports 36% Sales Growth in the First Nine Months of 2024 Driven by Global Adoption of ProSense® Cryoablation," a copy of which is furnished as Exhibit 99.1 with this Report of Foreign Private Issuer on Form 6-K.

The press release attached herewith as Exhibit 99.1, excluding the 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, 333-262620 and 333-281587), filed with the Securities and Exchange Commission, to be a part thereof from the date on which this Report of Foreign Private Issuer on Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

EXHIBIT INDEX

Exhibit No.	
99.1	Press release dated November 26, 2024 titled "IceCure Medical Reports 36% Sales Growth in the First Nine Months of 2024 Driven by Global Adoption of ProSense® Cryoablation"

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 26, 2024

By: /s/ Ronen Tsimerman
Name: Ronen Tsimerman
Title: Chief Financial Officer

Exhibit 99.1

IceCure Medical Reports 36% Sales Growth in the First Nine Months of 2024 Driven by Global Adoption of ProSense® Cryoablation

FDA Marketing Authorization Decision on Early Stage-Low Risk Breast Cancer Expected in Q1 2025

Conference call to be held today at 10:00 am Eastern Time

CAESAREA, Israel, November 26, 2024 – IceCure Medical Ltd. (Nasdaq: ICCM) ("IceCure", "IceCure Medical" or the "Company"), developer of 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, 2024. Sales of ProSense® consoles and disposable probes increased by 36%. Gross profits increased by 41%, while non-GAAP gross profits grew by 104%. Gross margins increased to 43%, while non-GAAP gross margin increased to 40%, compared to 27% in the same period in 2023].

On November 7, 2024, the U.S. Food and Drug Administration's ("FDA") Medical Device Advisory Committee Panel (the "Advisory Panel") voted in favor of ProSense®'s benefit-risk profile in early-stage low risk breast cancer.

Near-Term Value Enhancing Catalysts

- The FDA will review and evaluate the Advisory Panel's recommendation and is expected to make a final decision regarding marketing authorization of ProSense® in early-stage, low risk breast cancer with endocrine therapy in the first quarter of 2025.
- Interim results of the Company's ICESECRET, a prospective, multicenter, single-arm clinical trial of ProSense® for the cryoablation of kidney cancer, are expected to be released in December 2024.
- Terumo Corporation, IceCure's partner in Japan, is expected to file for regulatory approval of ProSense® for breast cancer in Japan in 2025, with the aim of receiving regulatory clearance.
- The Company expects that additional third-party data on ProSense® will be published in medical journals and presented at prestigious medical conferences throughout 2025.

"While our efforts have remained focused on the U.S. marketing authorization for ProSense® in early-stage breast cancer, the impressive 36% sales growth for the first nine months ended September 30, 2024, compared to the same period last year, demonstrates our commitment to working with our global partners to accelerate the adoption and increase the utilization of ProSense®," stated IceCure Medical's CEO, Eyal Shamir. "As we near the end of 2024, it goes without saying that it is shaping up to be a transformative year for IceCure. We successfully completed the ICE3 trial and published top line data. Furthermore, the positive outcome of the FDA Advisory Panel earlier this month brings us to the cusp of potential marketing authorization, which, if received, would allow us to offer women a non-surgical alternative to lumpectomy. We believe, based on current global sales growth and further awareness, understanding, and education of ProSense®, our cryoablation system will be an indispensable tool for breast surgeons, interventional radiologists and interventional oncologists, and patients alike."

"The FDA Advisory Panel meeting further elevated the awareness of ProSense® and our goal upon the FDA reaching its decision is to build out the sales infrastructure and footprint to meet expected demand," Shamir concluded.

Large Body of Published Data on ProSense®'s Efficacy & Safety Continues to Grow

The following is a list of published studies during and subsequent to the third quarter:

- IceCure's ICE3 5-Year trial results were published in the peer-reviewed *Annals of Surgical Oncology Journal*: "ProSense® cryoablation without excision for early-stage, low-risk breast cancer demonstrates 96.3% recurrence free rate."
- Study published in the *British Journal of Radiology* demonstrates ProSense® is a safe procedure with 97.7% technical success rate for cryoablation of tumors of the lung, bone, and soft tissues.
- Largest multi-institutional study of its kind: "Cryoablation of Primary Breast Cancer in Patients Ineligible for Clinical Trials" reports positive data; published in the *American Journal of Roentgenology*.
- ProSense® destroyed 100% of breast cancer tumors per an independent study of patients who chose cryoablation instead of surgery; published in the *British Journal of Radiology*.
- European study provides more evidence supporting ProSense® cryoablation for metastatic and recurrent breast cancer; published in highly influential peer-reviewed journal, *Cancers*.
- 99.74% recurrence free rate for women with breast cancer who underwent cryoablation with ProSense® in Japan; presented at 32nd Annual Meeting of the Japanese Breast Cancer Society.
- ProSense® featured in six global studies on cryoablation of breast tumors at the 2024 European Society of Breast Imaging Conference:
    - Image guided cryoablation for low-risk breast cancers: results and imaging findings of the ICE3 trial.
    - The treatment of breast cancer with percutaneous thermal ablation: results of the THERMAC trial in the Netherlands.
    - The treatment of breast cancer with percutaneous thermal ablation: cosmetic outcome and patient satisfaction in the Netherlands.
    - Assessment of pain level and quality of life in breast cancer patients treated with ultrasound-guided cryoablation in Italy.
    - Single-center experience with percutaneous cryoablation for benign and malignant breast lesions in Romania: tumor reduction and safety.
    - Single center experience with percutaneous cryoablation of fibroadenomas in Hungary: volume reduction and safety.

An article published in the European Journal of Cancer Prevention on November 6, 2024 outlines the recently launched PRECICE study which will exclusively use ProSense® for the study of cryoablation of early stage, low risk breast cancer - an independent prospective observational study of 233 women aged 50 and older with unifocal, small,

clinically node-negative, luminal A and B breast cancer at the prestigious European Institute of Oncology in Milan, Italy.

Financial Results for the Nine Months Ended September 30, 2024 Demonstrate Accelerating Growth of ProSense® Adoption and Utilization

Sales of ProSense® systems and disposable probes for the nine months ended September 30, 2024 increased by 36% to $2,316,000 compared to $1,700,000 for the nine months ended September 30, 2023. The growth was primarily attributable to sales in Europe, the U.S., Japan and other territories in Asia which were partially offset by a decrease in sales in China. Total revenue for the nine months ended September 30, 2024 increased by 22% to $2,416,000 from $1,974,000 for the nine months ended September 30, 2023 due to an increase in the sale of ProSense® systems and disposables, which was partially offset by a decrease in revenue recognition and other services in Japan of $100,000 and $274,000 in the first nine months of 2024 and 2023, respectively.

Gross profit for the nine months ended September 30, 2024 increased by 41% to $1,034,000 from $731,000 for the nine months ended September 30, 2023. Non-GAAP gross profit more than doubled for the nine months ended September 30, 2024 to $934,000 from $457,000 for the nine months ended September 30, 2023, an increase of $477,000 or 104%. Gross margin increased to 43% in the nine months ended September 30, 2024 compared to 37% in the nine months ended September 30, 2023. Non-GAAP gross margin for the nine months ended September 30, 2024 increased to 40% from 27% for the nine months ended September 30, 2023. The increase in non-GAAP gross profit and non-GAAP gross margin, which exclude revenue from the exclusive distribution agreements and other services in Japan, was attributable to the increase of 36% in revenue from sales of ProSense® systems and disposables. Non-GAAP gross profit and non-GAAP gross margin are financial measures that may be defined as "non-GAAP financial measures" by the U.S. Securities and Exchange Commission ("SEC"). For a reconciliation of these non-GAAP financial measures to the nearest comparable GAAP measure, see Appendix A to this press release.

Research and development expenses for the nine months ended September 30, 2024 decreased by 15% to $5,401,000 compared to $6,390,000 for the nine months ended September 30, 2023. The decrease was primarily due to a reduction in development expenses for the XSense™ System, which received FDA authorization in June 2024, and a decrease in clinical and regulatory costs as the Company concluded the ICE3 study in March 2024. Sales and marketing expenses increased for the nine months ended September 30, 2024 to $4,041,000 compared to $3,234,000 for the nine months ended September 30, 2023 as the Company focused on increased global marketing to support growing sales and in anticipation of potential marketing authorization for ProSense® in early-stage breast cancer in the U.S. General and administrative expenses for the nine months ended September 30, 2024 decreased to $2,763,000 from $3,268,000 for the nine months ended September 30, 2023, reflecting the Company's continued prudent budgeting and operating efficiencies.

Total operating expenses for the nine months ended September 30, 2024 decreased to $12,205,000 from $12,892,000 for the nine months ended September 30, 2023. The decrease in operating expenses was attributable to reductions in research and development and general and administrative expenses, due to the Company's initiative to reduce non-critical operating expenses, which were partially offset by an increase in sales and marketing expenses.

Net loss for the nine months ended September 30, 2024 decreased to $10,839,000, or $0.22 per share compared to a net loss of $11,657,000, or $0.26 per share, for the same period last year.

As of September 30, 2024, the Company maintained a solid balance sheet with cash and cash equivalents, including short-term deposits, of approximately $10.7 million. As of October 31, 2024, the Company had cash and cash equivalents of approximately $10.0 million. During the first nine months of 2024, the Company raised $8.1 million in net proceeds from the sale of 8,974,195 ordinary shares under its at-the-market offering facility.

Use of Non-U.S. GAAP Measures

In addition to disclosing financial results prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP"), this press release contains certain financial measures which may be defined as "non-GAAP financial measures" by the SEC. The Company defines non-GAAP gross profit as gross profit less revenue from exclusive distribution agreements and other services. The Company has provided non-GAAP gross profit in this press release because it is a key measure used by management and the board of directors as an indication of our gross profit from sales of our systems and disposables and management believes that it is useful to investors' understanding and assessment of the Company's gross profit without the impact of revenue recorded from the Company's exclusive distribution agreements and other services. The Company has provided a reconciliation below of non-GAAP gross profit and non-GAAP gross margin to the most directly comparable financial measure calculated and presented in accordance with U.S. GAAP. The non-GAAP financial measures disclosed by the Company should not be considered in isolation or as a substitute for, or superior to, financial measures calculated in accordance with U.S. GAAP and the financial results calculated in accordance with U.S. GAAP and reconciliations to those financial results should be carefully evaluated.

Conference call & webcast info:

Tuesday, November 26, 2024, at 10:00 am EST
US: 1-888-407-2553
Israel/International: +972-3-918-0696
A live webcast will be available at: https://Veidan.activetrail.biz/IcecureQ3-2024
A recording of the webcast will be available at: ir.icecure-medical.com/

About ProSense®

The ProSense® Cryoablation System is a minimally invasive cryosurgical tool that provides the option to destroy tumors by freezing them. The system uniquely harnesses the power of liquid nitrogen to create large lethal zones for maximum efficacy in tumor destruction in benign and cancerous lesions, including breast, kidney, lung, and liver.

ProSense® enhances patient and provider value by accelerating recovery, reducing pain, surgical risks, and complications. With its easy, transportable design and liquid nitrogen utilization, ProSense® opens that door to fast and convenient office-based procedure for breast tumors.

About IceCure Medical

IceCure Medical (Nasdaq: ICCM) develops and markets advanced liquid-nitrogen-based cryoablation therapy systems for the destruction 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 Company's flagship ProSense® 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: the impending FDA decision regarding marketing authorization of ProSense® in early-stage, low risk breast cancer in the first quarter of 2025; the interim results of the Company's ICESECRET expected in December 2024; filing for regulatory approval of ProSense® for breast cancer in Japan in 2025 by Terumo Corporation; the Company's expectation that additional third-party data on ProSense® will be published in medical journals and presented at prestigious medical conferences throughout 2025; the belief that the Company's sales growth demonstrates its commitment to working with global partners to accelerate the adoption and increase the utilization of ProSense®; the belief that the full year 2024 is shaping up to be a transformative year for IceCure; the belief that the positive outcome of the FDA Advisory Panel brings the Company closer to potential marketing authorization; the belief that the Company's cryoablation system will be an indispensable tool for breast surgeons, interventional radiologists and interventional oncologists, and patients alike; and the Company's goals upon the FDA reaching its marketing authorization decision. Historical 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. 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: the Company's planned level of revenues and capital expenditures; the Company's available cash and its ability to obtain additional funding; the Company's ability to market and sell its products; legal and regulatory developments in the United States and other countries; the Company's ability to maintain its relationships with suppliers, distributors and other partners; the Company's ability to maintain or protect the validity of its patents and other intellectual property; the Company's ability to expose and educate medical professionals about its 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, 2023 filed with the SEC on April 3, 2024, 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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Todd Kehrli
Phone: 310-625-4462

ICECURE MEDICAL LTD.
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	As of September 30, 2024 (Unaudited)	As of December 31, 2023
	U.S. dollars in thousands	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	10,671	10,533
Short-term deposits	-	529
Trade receivables	140	103
Inventory	1,981	2,275
Prepaid expenses and other receivables	547	744
Total current assets	13,339	14,184
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	44	34
Right-of-use assets	566	679
Property and equipment, net	1,329	1,513
Total non-current assets	1,939	2,226
TOTAL ASSETS	15,278	16,410
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade payables	1,249	502
Lease liabilities	264	223
Employees and other current liabilities	3,483	3,146
Total current liabilities	4,996	3,871
NON-CURRENT LIABILITIES		
Long-term lease liabilities	222	376
Total non-current liabilities	222	376
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding 54,778,879 shares and 45,729,684 shares as of September 30, 2024 and December 31, 2023, respectively		
Additional paid-in capital	110,960	102,224
Accumulated deficit	(100,900)	(90,061)
Total shareholders' equity	10,060	12,163
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	15,278	16,410

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

	Nine Months ended September 30,	
	2024	2023
	U.S. dollars in thousands (except per share data)	
Revenues	2,416	1,974
Cost of revenues	1,382	1,243
Gross profit	1,034	731
Research and development expenses	5,401	6,390
Sales and marketing expenses	4,041	3,234
General and administrative expenses	2,763	3,268
Operating loss	11,171	12,161
Finance income, net	(332)	(504)
Net loss and comprehensive loss	10,839	11,657
Basic and diluted net loss per share	0.22	0.26
Weighted average number of shares outstanding used in computing basic and diluted loss per share	49,167,379	45,626,332

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

	Nine Months ended September 30,	
	2024	2023
	U.S. dollars in thousands	
Cash flows from operating activities		
Net loss	(10,839)	(11,657)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	250	240
Share-based compensation	650	1,007
Exchange rate changes in cash and cash equivalents and short time deposits	33	203
Non-cash short-term deposits interest	-	(369)
Changes in assets and liabilities:		
Increase in trade receivables	(37)	(30)
Decrease in prepaid expenses and other receivables	197	334
Decrease in inventory	294	211
Decrease in prepaid expenses and other long-term assets	-	1
Decrease in right of use assets	202	118
Increase in trade payables	747	415
Decrease in lease liabilities	(202)	(169)
Increase (decrease) in employees and other current liabilities	337	(550)
Net cash used in operating activities	(8,368)	(10,246)
Cash flows from investing activities		
Investment in short-term deposits	(1,373)	(17,700)
Withdrawal of short-term deposits	1,902	8,700
Investment in restricted long-term deposits	(10)	-
Purchase of property and equipment	(66)	(399)
Net cash provided by (used in) investing activities	453	(9,399)
Cash flows from financing activities:		
Exercise of options	-	15
Issuance of ordinary shares, net of issuance costs	8,086	-
Net cash provided by financing activities	8,086	15
Increase (decrease) in cash and cash equivalents	171	(19,630)
Cash and cash equivalents at beginning of the year	10,533	23,659
Effect of exchange rate fluctuations on balances of cash and cash equivalents	(33)	(203)
Cash and cash equivalents at end of period	10,671	3,826
Non-cash activities		
Obtaining a right-of-use asset in exchange for a lease liability	89	172

APPENDIX A

NON-GAAP RECONCILIATIONS (Unaudited)

U.S. dollars in thousands	Nine Months ended September 30, 2024	2023
GAAP gross profit	$ 1,034	$ 731
Revenue from Exclusive Distribution Agreement	(100)	(274)
Non-GAAP gross profit	$ 934	$ 457
Sales of systems and disposables	2,316	1,700
Non-GAAP gross profit	$ 934	$ 457
Non-GAAP gross margin %	40%	27%