
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 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 offices)

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 Regulations S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7): _____

CONTENTS

On February 24, 2022, the Registrant made available an updated corporate presentation on its website. A copy of the corporate presentation is attached hereto as Exhibit 99.1.

The information contained in this presentation does not constitute a prospectus or other offering document, nor does it constitute or form part of any invitation or offer to sell, or any solicitation of any invitation or offer to purchase or subscribe for, any securities of the Company or any other entity, nor shall the information or any part of it or the fact of its distribution form the basis of, or be relied on in connection with, any action, contract, commitment or relating thereto or to the securities of the Company.

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EXHIBIT INDEX

Exhibit No.

99.1 [Corporate Presentation, dated February 24, 2022](#)

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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: February 24, 2022

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

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Freezing cancer in its tracks

IceCure Medical enabling non-surgical, treatment of cancerous tumors



Corporate Presentation | February 2022

(NASDAQ & TASE: ICCM)
icecure-medical.com



Nasdaq & TASE: ICCM

Forward Looking Statement

Disclaimer:

IMPORTANT: The following applies to this document, the oral presentation of the information in this document by IceCure Medical Ltd. (the "Company", "we" or "us") and any question and answer session that follows the oral presentation (collectively, the "Presentation"). This Presentation contains express or implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other U.S. federal securities laws. For example, we are using forward-looking statements when we discuss our regulatory, marketing and commercialization strategy, the expected timing of obtaining regulatory approval for our various products, patient trials and clinical data readout, proposed trials that may occur in the future, the timing and implementation of our collaborations with various partners and the execution of definitive agreements relating to such collaborations and the potential benefits and impact our products could have on improving patient health care. These forward-looking statements and their implications are based on the current expectations of our management only and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may be more expensive than we anticipate; results in the laboratory may not translate to equally good results in real clinical settings; our patents may not be sufficient; our products may harm recipients; changes in legislation; inability to timely develop and introduce new technologies, products and applications; and loss of market share and pressure on pricing resulting from competition. Except as otherwise required by law, we undertake no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting us, reference is made to our reports filed from time to time with the U.S. Securities and Exchange Commission.

This Presentation does not constitute or form part of and should not be construed as an offer or the solicitation of an offer to subscribe for or purchase securities of the Company and nothing contained herein shall form the basis of or be relied on in connection with any contract or commitment whatsoever.

No representation, warranty or undertaking, express or implied, is made as to, and no reliance should be placed on, the fairness, accuracy, completeness or correctness of the Presentation. The Presentation has not been independently verified and will not be updated. The Presentation, including but not limited to forward-looking statements, applies only as of the date of this document and is not intended to give any assurances as to future results.



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Introducing ProSense® Non-surgical Next-Generation Cryoablation Technology

Cryoablation is a minimally invasive image guided (US or CT) treatment that uses extreme cold to freeze and accurately destroy diseased tissue within the tumor zone

IceCure's flagship product ProSense® cryoablates tumors quickly and with minimal pain*

Utilizing effective liquid nitrogen (LN2) for maximum freezing, safety and efficacy



<http://www.youtube.com/watch?v=TfhQJ3SN6wQ>

* freezing effect on tissue from cryoablation produces less pain compared to heat ablation



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Company Highlights



ICE3 Breast Cancer Trial
in US for FDA approval in
treating early-stage
breast tumors



Regulatory
approval in 14*
countries
including U.S. and
Europe



Growing number of
global distribution
agreements



Wide market
applications
\$2.4 B tumor ablation
market
by 2026 †



Collaboration with
ASBrS for registry
trial and update of
guidelines



CPT code for
reimbursement
of breast cancer
cryoablation



28 patents in IP
portfolio for advanced
LN₂ technology



Successful
transition from
clinical and R&D
stages to
commercialization



Excellent Patient
& Physician
Feedback

*China – system only †Estimated, according to Grand View Research, Inc. (www.grandviewresearch.com/industry-analysis/tumor-ablation-market) Data is for all tumor ablation technologies and indications, including heat ablation Cryoablation, RF, MW and others. The information herein has not been independently verified by the company



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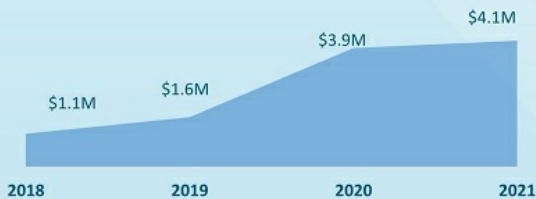
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Well-Financed to Advance Commercialization of ProSense

Cash (12/31/21)*	\$25.6 M
Revenues (YE 12/31/21)*	\$4.1 M
Price (2/15/22)	\$2.9
Market Cap (2/15/22)	\$108 M
Avg. Daily Trading Volume (3 months)	243 K

In 2021, raised \$32M (gross) in private placement and Nasdaq offering led by three accredited investors as well as the controlling shareholder of IceCure

Total Sales (USD)



Well positioned for 2022

*Preliminary estimates based on currently available information. Final results may vary from the preliminary estimates



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Global Presence of IceCure Technology



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Market Opportunities

Tumor Ablation

Tumor Ablation Market Expected To Reach \$2.4 Billion in 2026†

11.2% CAGR

\$1.0B

2018

\$2.4B

2026

(CAGR) Potential driven by non/minimal invasive treatments such as Cryoablation†

↑ Growing cancer burden

↑ Increasing demand for non/minimal-invasive solutions

↑ Push for reduced cost of care by insurers and payers

†Estimated, according to Grand View Research, Inc. (www.grandviewresearch.com/industry-analysis/tumor-ablation-market) Data is for all tumor ablation technologies and indications, including heat ablation Cryoablation, RF, MW and others. The information herein has not been independently verified by the company

US Cryoablation

Breast Tumors

~325K new breast cancer patients estimated in 2020*
10% of female pop. est. to have fibroadenomas**



Breast Cancer



Breast Fibroadenoma

Interventional Radiology

118K New kidney and liver cancer patients in 2021*



Kidney Cancer



Lung Cancer



Bone Cancer



Additional future indications (Such as Prostate Cancer)



Liver

*The National Breast Cancer Foundation, Inc. - <https://www.nationalbreastcancer.org/wp-content/uploads/2020-Breast-Cancer-Stats.pdf>
**<https://www.ncbi.nlm.nih.gov/books/NBK535345/#article-18600.s6>



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Regulatory approvals worldwide



FDA Approval for general minimally-invasive cryoablation applications, specific indications including: Kidney, Liver, Neurology, Fibroadenoma

FDA Breakthrough Devices Designation for T1 invasive breast cancer and/or breast cancer not suitable for surgical alternatives, prostate, kidney, and liver tumors



CE Approval for benign or malignant tissue of: Breast, Lung, Musculoskeletal (bone), Liver & Kidney tumors incl. palliative interventions



Rest of World Approvals:

Israel, Singapore, Hong-Kong, India, Thailand, Australia, South Africa, China (IceSense3 System only) – same clinical indications as CE approval

Russia, Taiwan, Costa-Rica, and Mexico (approved clinical indications may vary)



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Clinical evidence



Breast cancer: ICE3 Trial

- ✓ 98% recurrence free in the ICE3 trial as of April 2021 in small, low-risk, early-stage malignant breast tumors (190 out of the 194 eligible patients did not have recurrence)

Japan Independent Trial*

- ✓ 304 of the 400 patients who were treated with cryoablation between 2006 and 2019; 99% recurrence free rate of breast cancer

Fibroadenoma: Finalized ICE Crystal Trial



Musculoskeletal (Bone):

- ✓ Mainly palliative and local control cases in Israel, Italy, France, and Spain



Kidney cancer: Israel ICE Secret Trial, 120 cases Initial results reported **

- ✓ 45 small kidney masses ($\leq 4\text{cm}$) treated in 42 patients at 1 year follow-up (average follow-up period was 18.2 months)
- ✓ Recurrence free rate was 93%
One serious adverse event was reported



Lung cancer: Japan Independent Clinical Trial *** Peer reviewed article on 101 cases

- ✓ Highlighted that the use of cryoablation treatment with only one needle for the majority of the patients in the trial represented an advantage in comparison to systems that use argon gas, which usually requires the use of 2-3 needles for a procedure on the same tumors size

*Results reported by Professor E. Fukuma at the International Cryosurgery Society Convention, September 2019

**Presented at the European Association of Urology Conference, March 2019

*** Nomori H, Yamazaki I, Shiraishi A, Adachi T, Kanno M. Cryoablation for T1N0M0 non-small cell lung cancer using liquid nitrogen. Eur J Radiol. 2020;133:109334. doi:10.1016/j.ejrad.2020.109334

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ProSense is Superior to Competing Thermal Ablation Technologies

	Cryoablation IceCure ProSense®	Thermal Ablation (Radiofrequency & Microwave)
Pain	Minimal to no pain*	Very painful
Anesthesia	Local	High amount to general
Visualization	Excellent contour under Ultrasound & CT	Limited visualization
Accuracy	High	Low
Immune Response	Positive stimulation	Limited
Procedure Time	10 – 40 min	10 – 30 min

* freezing effect on tissue from cryoablation produces less pain compared to heat ablation



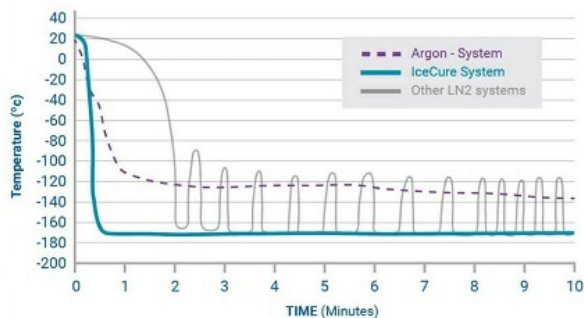
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ProSense® - Advanced Cryoablation Technology

Superior Liquid Nitrogen (LN2) Technology for Optimal Tumor Destruction



✓ Lower stable temperature and faster cooling rate enable better effectiveness in tumor destruction

	3rd Generation IceCure ProSense®	2nd generation Sanarus Visica 2™	1st Generation Galil Medical EndoCare
Tumor Destruction Method	Liquid nitrogen	Liquid nitrogen	Argon gas
Temperature	Constantly low (-160°C)	Not constant	Constantly medium (-120°C)
Office Setting	✓	✓	x
Procedure Time	10-40 mins	10-30 mins	30-60 mins
Cooling Rate	Fast	Medium	Slow
Cooling Gas Pressure	Low	Low	High
Cost of procedure	Low	Low	High



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Breast Tumor Market Activities



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Challenges in Breast Cancer Surgery (Lumpectomy)

- Cost
- Cosmetic outcome
- 14% of patients undergo re-excision after lumpectomy due to unclear margins**
- Recovery time
- Use of operating rooms places an additional strain on hospital resources



** <https://link.springer.com/article/10.1245/s10434-019-07247-5>

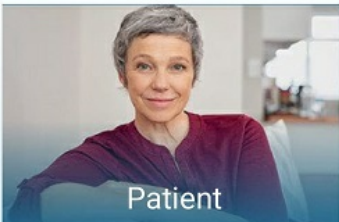


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ProSense® - Value for All



Patient

- ✓ LN2* - Maximum Efficacy
- ✓ Non-surgical
- ✓ Cosmetically Superior
- ✓ Safer, Simpler, Faster & Painless
- ✓ Immediate Recovery
- ✓ Preventing Re-excision After Lumpectomy for Breast Cancer**



Physician

- ✓ Easy to Use, In-office Procedure
- ✓ Low Risk, Safe Procedure
- ✓ LN2 - Maximum Efficacy
- ✓ Faster - More Patients
- ✓ Increased ROI



Insurer

- ✓ Lower Reimbursement Expense Vs. Surgery
- ✓ In-Office Procedure
- ✓ Immediate Recovery
- ✓ LN2 - Maximum Efficacy
- ✓ Patient Demand Drives Reimbursement
- ✓ Value Based Care



Healthcare Provider

- ✓ Patient Demand Drives Reimbursement
- ✓ Faster, In-Office Procedure
- ✓ Low Risk Safe Procedure
- ✓ No New Infrastructure
- ✓ Environmentally & Storage Friendly

*LN2, liquid nitrogen ** <https://link.springer.com/article/10.1245/s10434-019-07247-5>



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Breast Cancer & Benign Tumors U.S. Strategy



**325,000 new breast cancer cases
estimated in 2020*****

Fibroadenoma, Est. 10% of female
pop.****

Regulatory Strategy

- ✓ FDA clearance for general minimally-invasive cryoablation applications
- ✓ FDA clearance for fibroadenoma (benign breast tumors) cryoablation
- ✓ Completed ICE3 study enrollment, promising interim results presented at [2021 ASBrS Annual Meeting](#); Targeting FDA approval for early-stage and high risk to surgery breast cancer specific cryoablation applications
- ✓ FDA granted ProSense® **Breakthrough Devices Designation*** for proposed indications, including for use in the treatment of T1 invasive breast cancer and/or breast cancer not suitable for surgical alternatives

Strategic Partnerships

- ✓ Targeting registry clinical trial with the ASBrS
- ✓ Targeting ASBrS guidelines amendment following trial results
- ✓ Collaboration with ASBrS for CPT3** for breast cancer
- ✓ Targeting CPT1 approval providing reimbursement

*BDD is not an FDA Approval, but a designation granted that can expedite the path to marketing clearance for the breast cancer indication **CPT or Current Procedural Terminology is a medical code used by physicians, health insurance companies and accreditation organizations for reimbursement *** The National Breast Cancer Foundation, Inc. - <https://www.nationalbreastcancer.org/wp-content/uploads/2020-Breast-Cancer-Stats.pdf> ****<https://www.ncbi.nlm.nih.gov/books/NBK535345/article-18600>



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Unique Value Proposition ICE3: Landmark U.S. Breast Cancer Trial

Largest USA controlled multicenter clinical trial ever performed for LN₂ based cryoablation of small, low-risk, early-stage malignant breast tumors as an alternative to surgery

"Cryoablation potentially represents a dramatic improvement in care for appropriate low-risk patients, and at three years post-treatment, the ICE3 trial results are extremely positive. The non-invasive procedure is fast, painless and can be delivered under local anesthesia in a doctor's office. Recovery time is minimal and cosmetic outcomes are excellent with little loss of breast tissue and no scarring. Now, this trial is underscoring the efficacy and safety of the procedure for this patient group."

**Interim results presented in April 2021 ASBrS Meeting by ICE3
investigator Richard E Fine, MD, FACS**

[View full ASBrS Press Release](#)

[View article "Cryoablation Without Excision for Low-Risk, Early-Stage Breast Cancer: 3-Year Interim Analysis of Ipsilateral Breast Tumor Recurrence in the ICE3 Trial"](#)



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ICE3: U.S. Breast Cancer Trial Delivers Interim Results

Patients

194
Eligible
Patients

19
Hospitals
(Incl. Columbia University
Medical Center and Mount Sinai
Beth Israel)

62
Patients Followed For 5 Years*

*By October 2021

Results

97.94%
Recurrence free
as of April 2021
190 out of the 194 eligible
patients did not have recurrence

100%
Safe procedure
No significant device-related
adverse events or
complications have been
reported

98%
Doctor satisfaction
with cosmetic results

No scarring or change to the shape
and size of the breast

95%
Patient satisfaction
with cosmetic results

- ✓ Submitted a pre-submission package to FDA on November 24, 2021
- ✓ Proposed an intended use for early-stage breast cancer and high risk to surgery
- ✓ Suggested a De Novo classification, including a request for a sprint discussion under FDA procedures



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Breast Cancer - China Strategy



国家药品监督管理局
National Medical Products Administration



**416,371 new breast cancer
cases in 2020***

*<https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf>

Regulatory strategy

- ✓ Console approved by NMPA
- ✓ Initiated a registration process for the disposable probes, estimated end of 2022
- ✓ Approved in Hong Kong

Go to market

- ✓ Soft launch – first consoles were sold in Dec 2019 for independent study for breast cancer to a leading breast cancer hospital
- ✓ Ongoing independent clinical trial in two sites, Hong Kong and Shenzhen



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Breast Cancer - Japan Terumo Agreement

Exclusive strategic distribution agreement with Terumo to accelerate commercialization of ProSense® in Japan, Singapore, and Thailand

For >6 years ProSense® has been sold through a Private Import License—now leveraging agreement with Terumo to expand distribution and acquire PDMA approval

TERUMO

\$ 29B* market cap;
\$ 5.9B annual revenue
(2019/2020)



**92,024 new breast cancer cases
in 2020****

*As of February 2021

**<https://gco.iarc.fr/today/data/factsheets/populations/392-japan-fact-sheets.pdf>

Total proceeds of \$ 13.2M for the initial term

- ✓ \$ 5M for initial order and milestone-based payments
- ✓ \$ 4M received

Key terms:

- ✓ Exclusive distribution of ProSense® for breast cancer in Japan & Singapore for 5 years post regulatory approval in Japan
- ✓ Responsible for Japanese regulatory and reimbursement approvals
- ✓ Exclusive distribution in Thailand for 6 years. Total proceeds of \$ 7.2M for the initial term

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FIBROADENOMAS



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ProSense®: Becoming the Standard in Fibroadenoma Therapy

Treating fibroadenomas successfully since clinical trials began in 2012

- ✓ Minimally invasive, in-office alternative to surgical excision
- ✓ Strong clinical support from multi-center trial



60 patients who underwent office-based treatment reported:

(ProSense® cryoablation treatment under ultrasound guidance)

- ✓ Lesions tended to disappear progressively
- ✓ 75% were not palpable at 12-month follow up

Overview of benign breast disease | Author: Michael S. Sabel, MD, Section Editor: Anees B. Chagpar, MD, MSc, MA, MPH, MBA, FACS, FRCS(C) | Deputy Editor: Wenliang Chen, MD, PhD



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Interventional Radiology



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Interventional Radiology: Expanding Product Line

Over 500,000 new people each year are diagnosed with kidney, lung, liver and prostate cancer in the U.S. alone



>2.5M new cases of lung cancer globally by 2025*

- Japan Independent Clinical Trial 101 patients from 2013 – 2019
- Patients with tumor size up to 1.2 cm – no recurrence; Patients with tumor size between 1.3 – 1.7cm, 1 recurrence (4%); Patients with tumor size larger than 1.8 cm – 9 recurrences (33%) indicating local control to be better in smaller tumors ($p < 0.001$) cryoablation treatment with only one needle for the majority of patients in the trial represented an advantage in comparison to systems that use argon gas, which usually requires the use of 2 – 3 needles for a procedure on the same size



488K new cases of kidney cancer globally by 2025*

- ICE Secret Trial (Israel) 120 patients; 141 small kidney masses (≤ 4 cm) treated; **93% lack of enhancement** on CT or MRI in (42 of 45) of cases at 1 year follow-up (average follow-up period was 18.2 months)
- FDA approval for kidney and liver as of Dec 2019
- CPT1 reimbursement in the US



Pain care for bone cancer metastasis

- CPT2 reimbursement in the USA
- CE approval, actively being used for procedures in EU

**Presented at the European Association of Urology Conference, March 2019

*** Nomori H, Yamazaki I, Shiraishi A, Adachi T, Kanno M. Cryoablation for T1N0M0 non-small cell lung cancer using liquid nitrogen. Eur J Radiol. 2020;133:109334. doi:10.1016/j.ejrad.2020.109334

*<https://gco.iarc.fr/tomorrow/en/dataviz/isotype>

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Interventional Radiology - USA Strategy



42K Liver cancer patients**

74K Kidney cancer patients**

Regulatory Strategy

- ✓ FDA approval for general minimally-invasive cryoablation applications
- ✓ FDA approval for kidney and liver as of Dec 2019
- ✓ FDA granted ProSense® **Breakthrough Devices Designation** for proposed indications, including for use in the treatment of prostate, kidney, and liver tumors

Strategic Partnerships

- ✓ CPT1* approval and coverage for Cryo treatments of kidney, liver, lung & bone
- ✓ CPT2 approval and coverage for Cryo treatments of bone cancer

*CPT or Current Procedure Terminology is a medical code used by physicians, health insurance companies and accreditation organizations

** American Cancer Society.s6

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Business Model – Revenue Generators

Console and consumable probe business model

Direct sales and via distributors

- ✓ Direct sales to hospitals, clinics and doctor offices
- ✓ Reselling to distributors
- ✓ Used as a mobile device in different hospitals, clinics, doctor offices in Europe

Console related revenues

- ✓ Sales of consoles
- ✓ Consoles loaned for a minimum purchase of probes per month
- ✓ Service & maintenance – recurring revenue
- ✓ Accessories

Probes and introducers

- ✓ Recurring Revenue



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Proven Leadership Team



Ron Mayron, Chairman of the Board

Served for 20 years in several positions at Teva including as VP – Israel & Africa & CEO of Teva Israel



Shay Levav, VP Clinical, Regulatory & QA

Nearly 20 years' experience in regulatory and quality assurance in the healthcare sector



Eyal Shamir, CEO

Over 15 years as CEO of medical device companies (B-Cure Laser, Hanita Lenses etc.)



Tlalit Bussi Tel-Tzure, VP Biz Dev & Marketing

Over 15 years' experience in Sales, Biz Dev & Marketing in medical devices



Ronen Tsimmerman, CFO and COO

Over 15 years' experience as a CFO of public and private companies



Naum Muchnick, VP R&D

Over 14 years with GE UltraSound



Merav Nir Dotan, VP Human Resources

Over 20 years of experience in human resources and organizational management



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ProSense® Freezing Cancer In Its Tracks

THANK YOU

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