



Freezing Cancer in its Tracks

IceCure Medical enabling non-surgical
treatment of cancerous tumors

(Nasdaq: ICCM)

[IceCure-Medical.com](https://www.icecure-medical.com)

February 2024

Forward Looking Statement

This presentation of IceCure Medical Ltd. (the “Company”) contains “forward-looking statements”. Words such as “expects”, “intends”, “plans,” “believes,” “seeks,” “estimates,” and similar expressions or variations of such words are intended to identify forward-looking statements. For example, the Company is using forward-looking statements when it discusses the market potential for its products and technology; future sale of products ; its cash position; business, regulatory, marketing and commercialization strategy; the expected timing of obtaining regulatory approval for its various products; completion of patient trials and clinical data readout; proposed trials that may occur in the future; and the potential benefits and impact our products could have on improving patient health care. Forward-looking statements are not historical facts, and are based upon management’s current expectations, beliefs and projections, many of which, by their nature, are inherently uncertain. Such expectations, beliefs and projections are expressed in good faith. However, there could be no assurance the management’s expectations, beliefs and projections will be achieved, and actual results may differ materially from what is expressed or indicated by the forward-looking statements. Forward-looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward-looking statements. For a more detailed description of the risks and uncertainties affecting the Company, the reference is made to the Company’s reports filed from time to time with the Securities and Exchange Commission (the “SEC”), including, but not limited to, the risks detailed in the Company’s Form 20-F for the year ended December 31, 2022, filed with the SEC on March 29, 2023. Forward-looking statements speak only as of the date the statements are made. The company assumes no obligation to update forward-looking statements to reflect actual results, subsequent events or circumstances, changes in assumptions or changes in other factors affecting forward-looking information except to the extent required by applicable securities laws. If the Company does update on or more forward-looking statements, no inference should be drawn that the Company will make additional update with respect thereto or with respect to other forward-looking statements.

Introducing ProSense® Non-surgical Next-Generation Cryoablation Technology

- Cryoablation is a minimally invasive image guided, ultrasound (US) or computerized tomography (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 pain¹
- Utilizing effective liquid nitrogen (LN2) for maximum freezing, safety and efficacy



<https://vimeo.com/863898490/31b00932ce?share=copy>

¹ Freezing effect on tissue from cryoablation produces less pain compared to heat ablation

Company Highlights



Regulatory approvals in 15 countries, including the U.S., China and multiple in the E.U.



Growing number of global distribution agreements



Wide market applications
\$2.4 billion tumor ablation market by 2028¹



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



Collaboration with ASBrS for registry trial and update of guidelines



Reimbursement: CPT III for breast cancer cryoablation facility fee established



30 patents in IP portfolio for advanced LN2 technology



Successful transition from clinical and R&D stages to commercialization

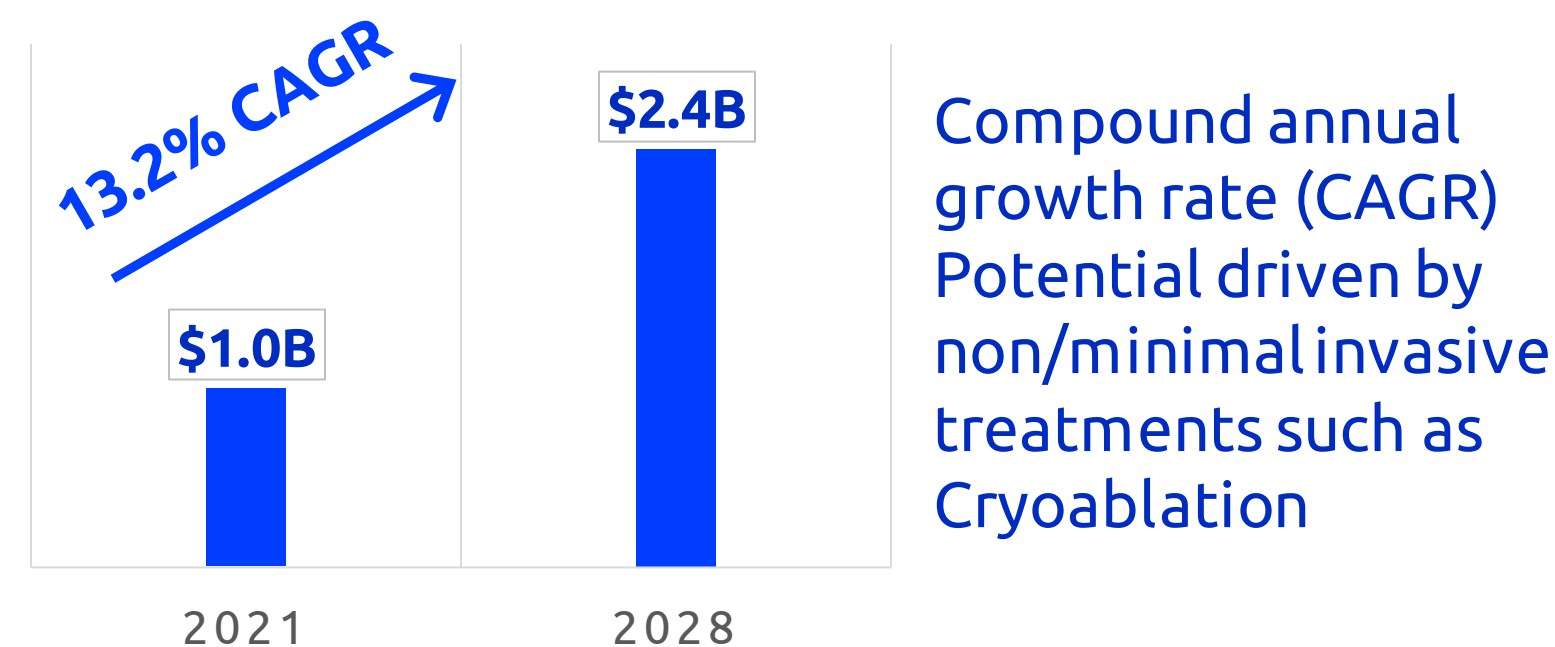


Excellent patient & physician feedback

¹ 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

Market Opportunities

Tumor Ablation Market Expected To Reach \$2.4 Billion in 2028¹



↑ Growing cancer burden

↑ Increasing demand for non/minimal-invasive solutions

↑ Push for reduced cost of care by insurers and payers

US Cryoablation

Breast Tumors

- Targeting approximately 288,000 new invasive breast cancer patients estimated in 2022²
- 10% of female population estimated to have fibroadenomas³

Interventional Radiology

- 81,800 new kidney cancer cases⁴ in 2023
- 41,210 new liver cancer cases⁵ in 2023
- 238,340 new lung cancer cases⁶ in 2023



¹ 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

² American Cancer Society – About Breast Cancer.

<https://www.cancer.org/content/dam/CRC/PDF/Public/8577.00.pdf>

³ <https://www.ncbi.nlm.nih.gov/books/NBK535345/#article-18600.s6>

⁴ <https://www.cancer.org/cancer/types/kidney-cancer/about/key-statistics.html>

⁵ <https://www.cancer.org/cancer/types/liver-cancer/about/what-is-key-statistics.html>

⁶ <https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html>

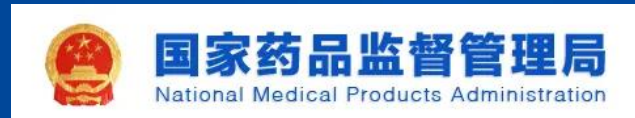
Regulatory Approvals Worldwide

- **FDA** Approval for general minimally-invasive cryoablation applications, specific indications including: kidney, liver, neurology, fibroadenoma

- **FDA De Novo Classification Request** for marketing authorization for early-stage breast cancer; IceCure to submit full ICE3 dataset April 2024

- **CE Approval for benign or malignant tissue of:**

Breast, Lung, Liver, Kidney, and Musculoskeletal (bone), including palliative interventions



- **NMPA approval in China** for the IceSense3 System and disposable cryoprobes for similar clinical indications as CE approval

- **Rest of World Approvals:**

India, Thailand, Israel, Brazil, Canada, Singapore, Hong Kong, Australia, South Africa for similar clinical indications as CE approval

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

ProSense® is Superior to Competing Thermal Ablation Technologies

	Cryoablation IceCure ProSense®	Thermal Ablation (Radiofrequency & Microwave)
Pain	Minimal to no pain*	Very painful
Anesthesia	Local	Heavy sedation/ Full anesthesia
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



Breast Tumor Market Activities



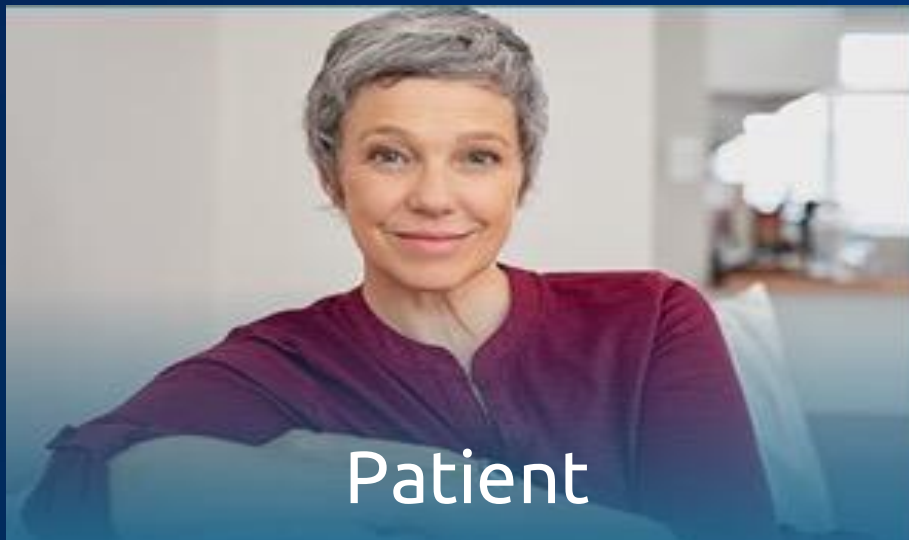
Challenges in Breast Cancer Surgery (Lumpectomy)

- Cost
- Cosmetic outcome
- 14% - 20% of patients undergo re-excision after lumpectomy due to unclear margins¹
- Recovery time
- Use of operating rooms places an additional strain on hospital resources



¹ <https://link.springer.com/article/10.1245/s10434-019-07247-5>; https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.576

ProSense® - Value for All



Patient

- ✓ LN2¹ - Maximum Efficacy
- ✓ Non-surgical
- ✓ Cosmetically Superior
- ✓ Safer, Simpler, Faster & Painless
- ✓ Immediate Recovery
- ✓ Preventing Re-excision After Lumpectomy for Breast Cancer²



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

¹ LN2, liquid nitrogen ² <https://link.springer.com/article/10.1245/s10434-019-07247-5>; https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.576



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 anaesthesia in a doctor’s office.

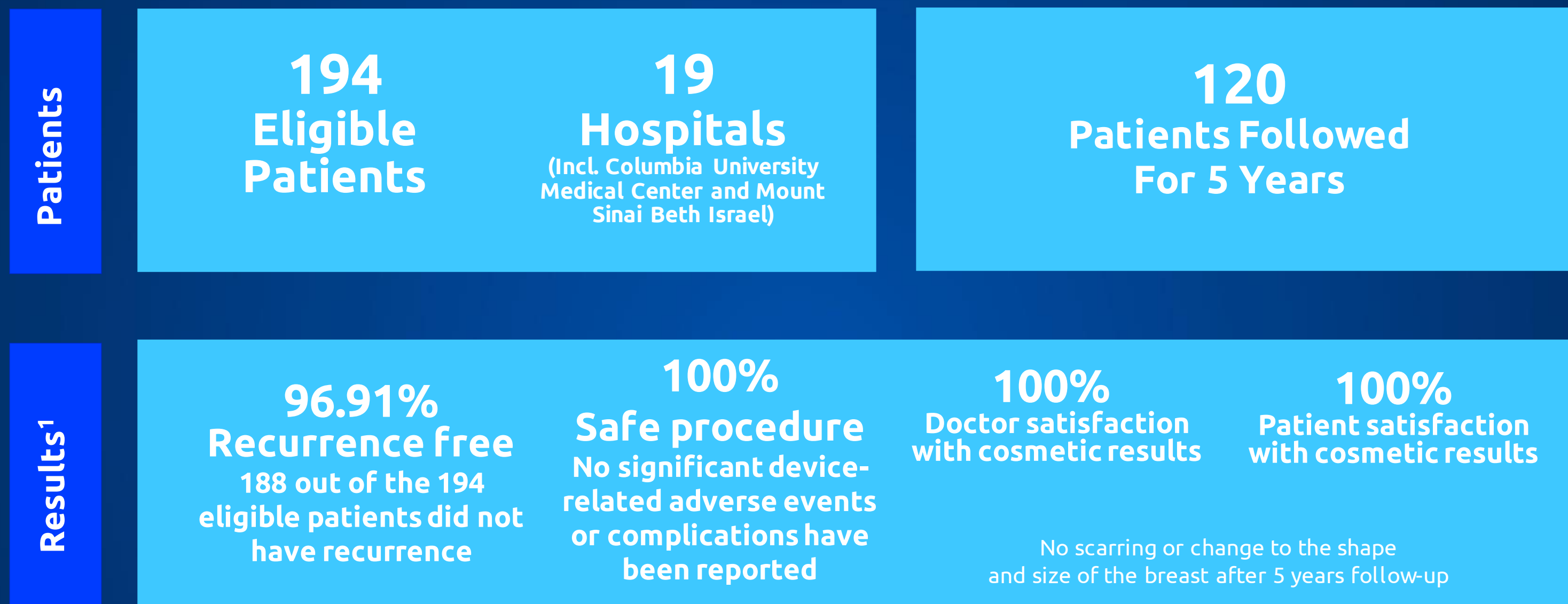
Recovery time is minimal and cosmetic outcomes are excellent with little loss of breast tissue and no scarring. Now, this trial is underscoring the efficacy and safety of the procedure for this patient group.”

[View full ASBrS Press Release](#)

April 2021 Interim results presented at the 2021 Annual ASBrS Meeting by
ICE3 investigator Richard E Fine, MD, FACS

[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”](#)

ICE3: U.S. Breast Cancer Trial Interim Analysis



The survival-based estimate for the 5-year IBTR is 4.3%¹ with a one-sided 95% confidence level, upper bound of 8.4% for the entire study population

¹ Data updated October 2022

Independent Studies Confirm ICE3 Results

96.8%
Success rate

In women with early-stage breast cancer who declined surgery

Study conducted by Principal Investigator Lucía Graña-López, MD, PhD, a radiologist who specializes in breast and women's imaging, Head of the Breast Unit at University Hospital Lucus Augusti, Spain—presented at European Society of Breast Imaging Annual Scientific Meeting 2023
Read more [HERE](#)

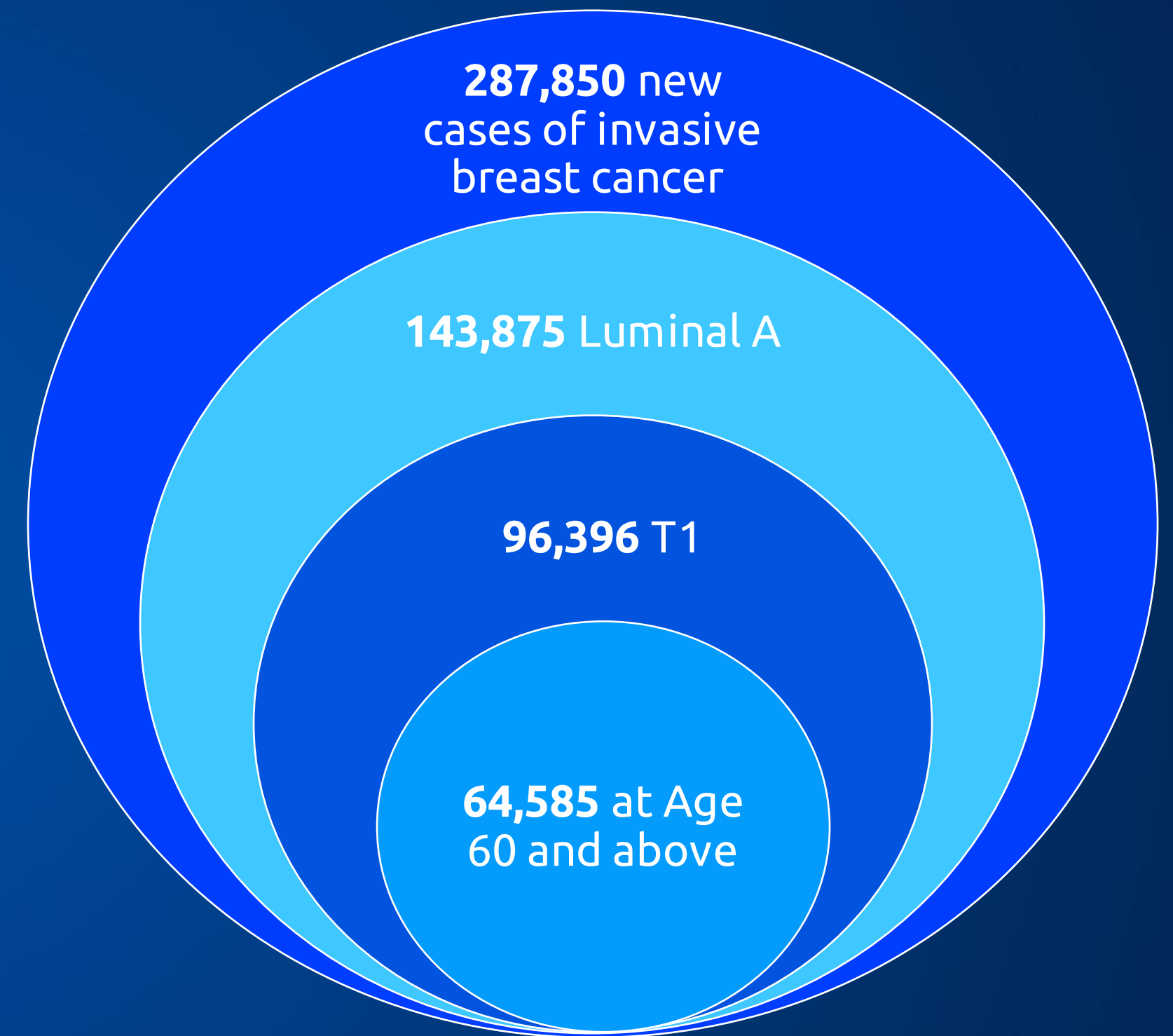
93.4% - 96.8%
Tumor reduction rate

In women deemed inoperable for breast cancer

Study conducted by Principal Investigator Dr. F. Di Naro, of Azienda Ospedaliero-Universitaria Careggi, Diagnostic Senology Unit, Florence, Italy—presented at European Society of Breast Imaging Annual Scientific Meeting 2023
Read more [HERE](#)

U.S. Clinical Market Analysis of Invasive Breast Cancer – 2022

- According to the American Cancer Society, there are more than 300,000¹ breast cancer patients each year. (350,000 in 2023)
- 287,850 are invasive breast cancer²
- Luminal-A is the most common subtype and represents 50%-60% of all breast cancers³
- Tumor Size distribution suggests T1 is 67% of all sizes⁴
- 67% are women at the age of 60 and above



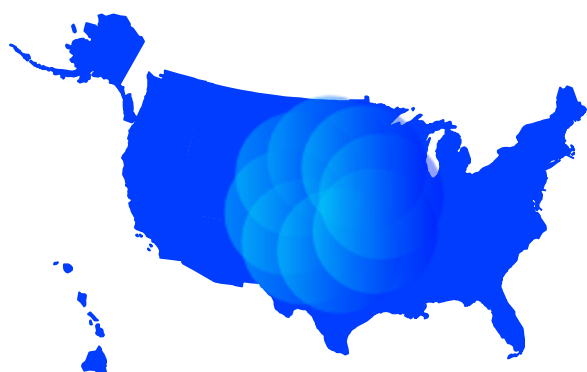
¹ American Cancer Society: [https://www.cancer.org/cancer/types/breast-cancer/about/how-common-is-breast-cancer.html#:~:text=It%20is%20about%2030%25%20\(or,\(DCIS\)%20will%20be%20diagnosed.](https://www.cancer.org/cancer/types/breast-cancer/about/how-common-is-breast-cancer.html#:~:text=It%20is%20about%2030%25%20(or,(DCIS)%20will%20be%20diagnosed.)

² American Cancer Society – About Breast Cancer. - <https://www.cancer.org/content/dam/CRC/PDF/Public/8577.00.pdf>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4127612/>

⁴ <https://www.nejm.org/doi/full/10.1056/nejmoa1600249>

Breast Cancer & Benign Tumors - U.S. Strategy



**350,000 new breast cancer cases
estimated in 2023²**

Fibroadenoma, Est. 10% of female pop.³

- **Regulatory Strategy**

- ✓ FDA clearance for general minimally-invasive cryoablation applications & for fibroadenoma (benign breast tumors) cryoablation
- ✓ FDA granted ProSense® Breakthrough Devices Designation¹ (BDD)
- ✓ Completed ICE3 study enrollment
- ✓ Full study 5-year follow up to be completed February 2024
- ✓ FDA granted IceCure's appeal to reopen its De Novo Classification request for ProSense® in early-stage breast cancer; FDA requests that IceCure submit the following by April 2024:
 - Final 5-year dataset for the full ICE3 study population
 - Analysis of the full ICE3 dataset compared to results from the LUMINA study; LUMINA is a 3rd party study in women with low-risk Luminal A breast cancer treated with lumpectomy and adjuvant hormone therapy published in August 2023
 - Real-world data from the use of ProSense® globally, including post-market commercial use in territories where ProSense® is approved for breast cancer, and data from independent third-party studies

- **Market Access**

- ✓ Exploring Strategic Partnerships
- ✓ ASBrS presented a plan for a future ASBrS trial that would evaluate cryoablation as a treatment for low risk early-stage breast cancer for women between the ages of 55 to 85
- ✓ Building relationships with professional organizations in breast radiology (SBI, SIO, SIR)

¹ BDD is not an FDA Approval, but a designation granted that can expedite the path to marketing clearance for the breast cancer indication of those commonly used by providers to report their services and procedures;

Breast Cancer – US Healthcare Economics & Reimbursement

• Healthcare Economics

- ✓ Cryoablation costs less than standard-of-care lumpectomy
- ✓ Minimally invasive outpatient procedure with no general anesthesia needed
- ✓ Reduces risk of re-excision which is 14%-20%¹ in lumpectomy
- ✓ Patient demand drives reimbursement

• Reimbursement

- ✓ IceCure's application to Centers for Medicare & Medicaid Services (CMS) is the first and only Medicare coverage approval of cryoablation procedure for breast cancer
- ✓ CMS assigned CPT Category III² code 0581T to ambulatory payment classification 5091, Level 1 Breast/Lymphatic Surgery and Related Procedures
- ✓ Priced for coverage by the CMS at approximately \$3,400 for the facility fee alone
- ✓ Additional coverage, including payment for the physician, is expected upon establishment of the permanent CPT Category I² code, which is conditioned on factors including the Company's receipt of FDA marketing authorization of ProSense® for breast cancer

¹ <https://link.springer.com/article/10.1245/s10434-019-07247-5> ; https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.576

² CPT or Current Procedural Terminology is a medical code used by physicians, health insurance companies and accreditation organizations for reimbursement. CPT Category I: The largest body of codes, consisting of those commonly used by providers to report their services and procedures. CPT Category II: Temporary codes used to report emerging and experimental services and procedures. Source: <https://www.aapc.com/resources/medical-coding/cpt.aspx#:~:text=CPT%C2%AE%20Category%20I%3A%20The,and%20experimental%20services%20and%20procedures>



Breast Cancer - China Strategy



Shanghai Medtronic
Zhikang Medical Devices Co. Ltd



**416,371 new breast
cancer cases in 2020¹**

- **Regulatory Approval**

- ✓ Console and disposable probes approved by the National Medical Products Administration (NMPA) in China for benign or malignant tissue of the breast, lung, musculoskeletal (bone), liver & kidney tumors including palliative interventions

- **Go to Market**

- ✓ Shanghai Medtronic Zhikang Medical Devices Co. Ltd. – signed exclusive distribution agreement with a minimum purchase target of \$3.5M in the first 3 years
- ✓ 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

¹ <https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf>

Breast Cancer - Terumo Japan Agreement



Exclusive strategic distribution agreement with Terumo to accelerate commercialization of ProSense® in Japan & Thailand

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



\$ 20 B¹ market cap
\$ 4.3 B² annual revenue

92,024 new breast cancer cases in 2020³

- 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 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

1 As of April 2023; 2 (TTM 6/30/22); 3 <https://gco.iarc.fr/today/data/factsheets/populations/392-japan-fact-sheets.pdf>

ProSense® for 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



Interventional Radiology Market Activities



Interventional Radiology Applications

- Cancer



Kidney
Cancer



Lung
Cancer



Bone
Cancer



Liver
Cancer

Over 600,000 ¹ people each year are diagnosed with kidney, lung, liver and prostate cancer in the U.S. alone

- Women's Health



Endometriosis

More than 6.5 million² women in the U.S. have endometriosis

1 - <https://www.cancer.org/cancer/types.html>

2 - <https://www.womenshealth.gov/a-z-topics/endometriosis>

Interventional Radiology - USA Strategy



42K Liver cancer patients²

74K Kidney cancer patients²

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

Reimbursement

- ✓ CPT I¹ approval and coverage for Cryo treatments of kidney, liver, lung & bone
- ✓ CPT II¹ approval and coverage for Cryo treatments of bone cancer

¹ CPT or Current Procedure Terminology is a medical code used by physicians, health insurance companies and accreditation organizations. CPT Category I: The largest body of codes, consisting of those commonly used by providers to report their services and procedures. CPT Category II: Supplemental tracking codes used for performance management. Source: <https://www.aapc.com/resources/medical-coding/cpt.aspx#:~:text=CPT%C2%AE%20Category%20I%3A%20The,and%20experimental%20services%20and%20procedures>

² American Cancer Society.s6

Interventional Radiology: Expanding Product Line

Clinical Data Demonstrates ProSense®'s



Lung Cancer

77%-100% recurrence-free rate

Independent Clinical Trial in Japan with ProSense®:

- No recurrence in patients with tumor size up to 1.2 cm
- 4% recurrence in patients with tumor size between 1.3 – 1.7cm
- 33% recurrence in patients with tumor size larger than 1.8 cm
- Read more [HERE](#)



Kidney Cancer

89.5% recurrence-free, **92%** Disease-free Survival

IceCure's ICESECRET ProSense® Trial Interim Results:

- Safe & effective treatment method for renal lesions ≤ 5 cm in patients not suitable for kidney preserving surgery
- 89.5% were recurrence free at mean follow-up of period of 22.2 months
- Read more: [HERE](#)

Independent Study with ProSense®

- 92% recurrence free at mean follow-up of period of 22.2 months
- 100% secondary control rate when recurrent lesions treated
- Read more: [HERE](#)



Endometriosis

92.8% avoid secondary surgery

ProSense® One of Two Systems Used in Independent Study:

- Efficacy rate in avoiding secondary surgery was 92.8% per patient and 93.6% per nodule treated
- Median pain-free survival rates were 93.75% at 6 months and 82.72% after 12 months, 24 months, and 36 months collectively
- Read more: [HERE](#)



Global Presence of IceCure Technology



Business Model – Revenue Generators

Console and consumable probe business model

Direct sales and via distributors

- ✓ Direct sales to hospitals, clinics and doctor offices
- ✓ Sales through distributors
- ✓ Used as a mobile device in different hospitals, clinics, doctor's 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



Well-Financed to Advance Commercialization of ProSense®

Ticker

	ICCM
Share Price (1/30/24)	\$1.48
Market Cap (1/30/24)	\$68 M
Shares Outstanding (9/30/23)	46 M
Avg. Daily Trading Volume (3 months)	2 M
2023 Revenue (preliminary unaudited results)	\$3.2 M
Cash, Cash Equivalents, and Short- Term Deposits (12/31/23) (preliminary unaudited results)	\$11.0 M

- **Last public offering - December 2022**
- **Several of the Company's long-term institutional shareholders participated**
- **Priced at-the-market**
- **Ordinary shares, no warrants**

The company has no outstanding warrants or debt

Well positioned for commercial, development, and regulatory advancements

Upcoming Milestones and Strategy

- ICE3 study's last patient expected to complete her 5-year follow-up February 2024
- Topline 5-year results from full ICE3 dataset to be reported April 2024
- IceCure to submit all FDA requested data for its De Novo Classification request for marketing clearance in early-stage breast cancer April 2024
- Data expected from 19 ongoing studies of ProSense® worldwide in 2024 and beyond
- Direct sales of systems and disposable probes in U.S. led by newly appointed VP of Sales North America
- Growing number of distribution partnerships to drive sales in rest of world with numerous recent regulatory approvals

ProSense® gaining global recognition as the leading cryoablation system for minimally invasive procedures in a \$2.4 billion tumor ablation market

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



Eyal Shamir, CEO

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



Ronen Tsimerman, CFO and COO

Nearly 20 years' experience as a CFO of public and private companies



Tlalit Bussi Tel-Tzure, VP Biz Dev & Marketing

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



Shad Good, VP Sales North America

Nearly 20 years of medical device sales and leadership with experience in minimally invasive breast diagnostic and therapeutic systems



Shay Levav, VP Clinical, Regulatory & QA

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



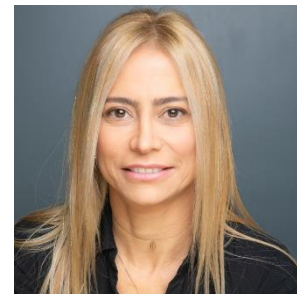
Merav Nir Dotan, VP Human Resources

Over 20 years of experience in human resources and organizational management



Naum Muchnick, VP R&D

Nearly 20 years of experience in medical device design, engineering, and operations, including over 13 years with GE UltraSound



Galit Bar Malik, VP Operations & Service

Over 20 years of experience medical device operations

Thank You!

Eyal Shamir – CEO

Ronen Tsimerman – CFO/COO

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