

# FREEZING CANCER IN ITS TRACKS

Next generation cryoablation technology enabling non-surgical, in-office treatment of cancer tumors



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# **OUR MISSION:**

To lead the New Gold Standard of Tumor Cryoablation Therapy





### IceCure at a Glance...



### Medical device company (TASE: ICCM.TA)

- **ProSense**® for cryoablation of benign and malignant tumors i.e. (Breast, Kidney, Lung, Bone, Liver)\*
- Superior, Safe, Fast and Cost-effective minimally-invasive treatments
- **FDA Approval** for general minimally-invasive cryoablation applications, specific indications including:
  - Kidney, Liver, Neurology
  - Fibroadenoma
- CE Approval for benign or malignant tissue of: Breast, Lung, Musculoskeletal (bone), Liver & Kidney tumors incl. palliative interventions
- NMPA (China) clearance for console, in process for probes

#### **Business model**

Console and consumable probe

### **Unique Value Proposition**

- Breast Cancer Treatment Solution, alternative to surgery
- **CPT 3** for breast cancer cryoablation
- ICE3 breast cancer trial, Interim results in Q2 2021
- Targeting FDA-specific approval for breast cancer cryoablation
- CPT1 expected in 2022
- Targeting Registry Trial in collaboration with the ASBrS

### Global Install base US, Europe and Asia

- Successful Transition from clinical and R&D to commercialization
- 2020 announced Deals \$ 3.4M, x 2.1 of 2019 revenue
- Strategic Exclusive Distribution Agreement: Terumo
  Corporation (a company with \$5.9B annual sales) for breast
  cancer cryoablation in Japan and Singapore

\*in certain regions

## **COVID-19 Driving ProSense® Market Adoption**



### **Surgery Delays, Cancellations & Backlogs**

>4700 attributable deaths per year in England due to a 3-month delay in tumor removal surgery

### **Cancer Patients Are Most At Risk**

<u>Higher rates of mortality</u> among COVID-19 patients who also have cancer

# Healthcare institutions urgently seek new solutions to:

- ✓ Reduce hospitalization & clinic visits
- ✓ Reduce demands on Emergency Rooms
- ✓ Protect workers & patients
- ✓ Reduce strain on resources & lower costs
- ✓ Reduce virus transmission



# Introducing ProSense®: Next Generation Cryoablation Technology



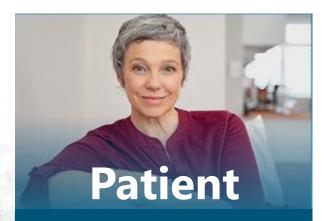
- IceCure's flagship product,
   ProSense®, is a minimally invasive,
   non-surgical solution that destroys
   tumors quickly and painlessly
- Utilizing effective liquid nitrogen (LN2) for maximum freezing, safety and efficacy



https://www.youtube.com/watch?v=TfhQJ3SN6wQ

### PROSENSE®: Value for All





- ✓ Non-surgical
- ✓ Cosmetically Superior
- ✓ Safer, Simpler, Faster& Painless
- ✓ Immediate Recovery



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



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



- ✓ Patient Demand Drives Reimbursement
- ✓ Faster, In-Office Procedure
- ✓ Low Risk Safe Procedure
- **✓** No New Infrastructure
- Environmentally & storage friendly

### **Tumor Ablation Market Opportunity**



# \$1.03 BILLION

IN 2018\*

Tumor ablation market
Expected to reach
\$2.4 Billion in 2026\*

### **11.2% GROWTH**

(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

# **US Cryoablation Market Opportunity**

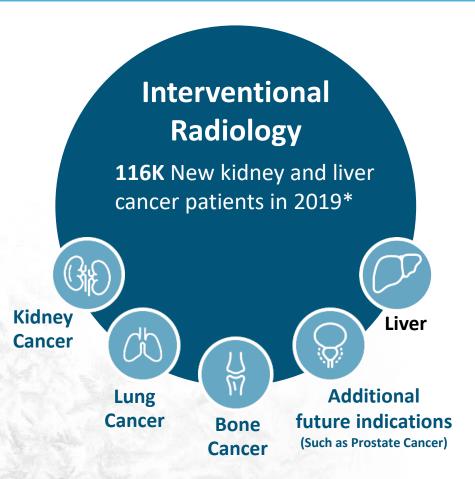


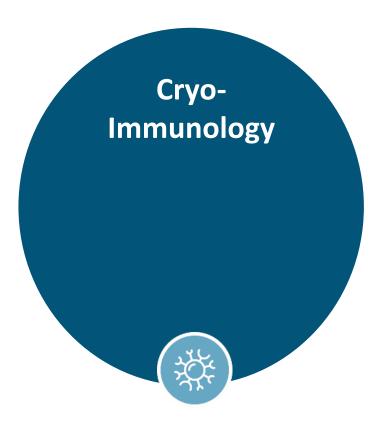
### **Breast Tumors**

**320K** New breast cancer patients in 2019\* **10%** of female pop. est. to have fibroadenomas\*\*



Breast Fibroadenoma





### **Technology Platform for Cardiac Atrial Fibrillation**

<sup>\*</sup>Sources: American Cancer Society

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

# Rising Market Interest for Cryo-Based and Women Health Solutions







### \$110 Million in 2016

Britain's BTG acquired Israeli tumor freezing company, Galil Medical





#### \$200 Million in 2018

Merit Medical acquired "Cianna Medical" (a leader in wire-free breast localization)





#### \$4.2 Billion in 2018

Boston Scientific acquired BTG (including Galil Medical)





### \$85 Million in 2018

Hologic acquired "Faxitron Bioptics" (Leader in Digital Specimen Radiography)





#### \$185 Million in 2019

Varian Medical Systems acquired Endocare, Scion Medical (Argon & Helium) Cryoablation from Healthtronic (USA)





### \$125 Million in 2018

Hologic acquired "Focal Therapeutics" (implantable marker for breast conserving surgery)





# Unique Value Proposition ICE3: Landmark US Breast Cancer Trial



The largest USA controlled multilocation clinical trial ever performed for nitrogen-based cryoablation of small, low-risk, early stage malignant breast tumors

206

**Patients treated** 

60

Patients followed for at least 3 years

19

Hospitals

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

98%

Recurrence free as of Oct 2018

(105 out of 107 who has more than 12 months FU)

100%

Safe procedure

No significant device-related adverse events or complications have been reported

**76%** 

Resumed daily lives within 48 hours of procedure

All patients released home on the day of the procedure

95%

Patient and doctor satisfaction with cosmetic results

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



# **Breast Cancer & Benign Tumors USA Strategy**



### **Regulatory strategy**

- ✓ FDA clearance for general minimally-invasive cryoablation applications
- FDA clearance for fibroadenoma cryoablation
- ✓ Completed ICE3 study enrollment
- ✓ ICE3 interim result Q2 2021
- Targeting FDA approval for breast cancer specific cryoablation applications



- ✓ Targeting registry clinical trial with the ASBrS
- ✓ Targeting ASBrS guidelines amendment following registry trial results

#### Reimbursement – CPT\*

- ✓ Collaboration with ASBrS for CPT3 for breast cancer
- ✓ Targeting CPT1 approval providing reimbursement



# **Breast Cancer International Strategy**



### **Regulatory Status**

- ✓ CE approval in EU
- Regulatory approvals for: Thailand, India, Australia,
   Singapore, Hong Kong and others
- ✓ Strategic partner (Terumo) targeting PMDA approval in Japan
- China NMPA approval for Console, targeting approval for probes

#### Reimbursement

✓ Strategic partner (Terumo) to target reimbursement following PMDA approval in Japan

#### **Clinical Data**

- ✓ Italy & Germany Key opinion leaders collecting clinical data
- ✓ Japan Ongoing independent trials with ~ 400 patients
- ✓ Hong Kong\China Ongoing independent trials in 2 hospitals
- ✓ China –2<sup>nd</sup> independent trial expected in 2020

#### Commercialization

✓ EU, Asia



# **Breast Cancer Japan Terumo Agreement**



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



\$ 28B\* market cap; \$ 5.9B annual revenue (2019/2020)

### Total proceeds of \$ 13.2M for the initial term

- ✓ \$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

First right of refusal for Thailand market distribution

\*As of July 27, 2020





### **Market opportunity**



368,000

new breast cancer cases in 2018\*



Early detection is increasing every year

### Regulatory path

- Console approved by CFDA
- ✓ Initiated a registration process for the consumable probes
- ✓ 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

# **Superior to Competing Thermal Ablation Technologies**

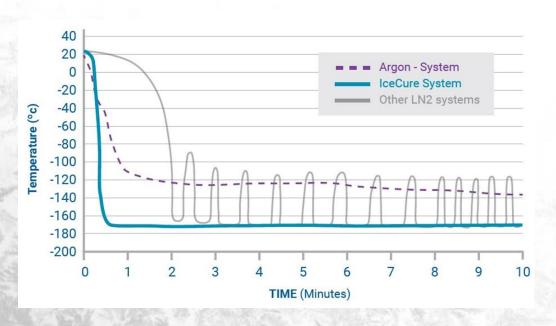


	Cryoablation IceCure ProSense®	Thermal Ablation (RF & MW)
Pain	Minimal to no pain	Very painful
Anesthesia	Local	High amount to general
Visualization	Excellent contour under Ultrasound & CT	Limited visualization
Accuracy	High	Low
Immune Response	Positive stimulation	limited
Procedure Time	10-40 min	10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

# ProSense®: The Most Advanced Cryoablation Technology



# **Superior Liquid Nitrogen (LN2) Technology for Optimal Tumor Destruction**



- ✓ Lower stable temperature
- √ Faster cooling rate for larger lethal zone

	3rd Generation IceCure ProSense®	2nd generation Sanarus Visica 2™	
Tumor Destruction Method	Liquid nitrogen	Liquid nitrogen	Argon gas
Temperature	Constantly low (-160°C)	Not constant	Constantly medium (-120°C)
Office Setting	<b>✓</b>	<b>✓</b>	×
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

### **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**

Recurring revenue



### **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 Lanses etc.)



Tlalit Bussi Tel-Tzure – VP BizDev & Marketing
Over 15 years' experience in Sales, BizDev & Marketing
in medical devices



Ronen Tsimerman, 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 Ultra Sound



# Why invest in IceCure?



Exclusive distribution agreement with Terumo Corporation



 $(\epsilon)$ 

FDA and CE Cleared



Well positioned for future BC specific commercialization

ICE3 Trial



Collaboration with ASBrS for registry trial and update of guidelines



Wide Market Applications; \$2.4 Billion Tumor Ablation Market by 2026



Excellent Patient & Physician Feedback



Superior LN2 Technology, Strong IP Portfolio with 28 patents



Successful transition from clinical and R&D stages to commercialization



CPT 3 for Breast Cancer Cyroablation



# PROSENSE® FREEZE CANCER IN ITS TRACKS

### **THANK YOU**

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# Appendices



**Interventional Radiology** 



Cryolmmunology



**Fibroadenoma** 



### IceCure's Target Geographies & Markets





**USA**\*







42K

74K

320K

patients

Liver cancer Kidney cancer New breast cancer patients patients in 2019 Fibroadenoma, Est. 10% of female pop. \*\*



Europe\*\*\*\*





403K

**523K** 

Kidney & liver New breast cancer cancer patients patients in 2018



Japan\*\*\*







**71K** 

Kidney & liver cancer patients

86K

New breast cancer patients in 2018

**125K** 

Lung cancer patient

<sup>\*</sup>Sources: American Cancer Society.s6

<sup>\*\*</sup>https://www.ncbi.nlm.nih.gov/books/NBK535345/#article-18600

<sup>\*\*\*</sup>https://ganjoho.jp/en/professional/statistics/brochure/2018 en.html

<sup>\*\*\*\*</sup>http://gco.iarc.fr/tomorrow/graphic-isotype?type=0&population=900&mode=population&sex=0&cancer=39&age\_group=value&apc\_male=0&apc\_female=0

# **Interventional Radiology**





# 403K worldwide kidney cancer cases in 2018 (CAGR of 2.4%)

- Ongoing trial and collaborative clinical research in Israel
- FDA approval for kidney and liver, as of Dec 2019
- CPT1 reimbursement in the US



# 2M worldwide lung cancer cases in 2018 (CAGR of 1.8%)

Ongoing independent trial in Japan of more than 300 patients



# Pain care for bone cancer metastasis

CPT2 reimbursement in the USA



### **CryoImmunology studies underway**

Collaborations with Memorial Sloan Kettering Cancer Center Case University and Cleveland clinic investigating Cryoablation with immunotherapy

# 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

vs. 2M in 2018 (CAGR of 1.8%).



478K new cases of kidney cancer globally by 2025

vs. 403K in 2018 (CAGR of 2.4%).







- ✓ FDA approval for general minimallyinvasive cryoablation applications
- ✓ FDA approval for kidney and liver, as
  of Dec 2019

### **Reimbursement – CPT\***

 ✓ CPT 1 approval and coverage for Cryo treatments of kidney and liver



# Renal Cancer: Ongoing trial and collaborative clinical research, Israel



ВАСК

# EARLY TREATMENT SUCCESS

### 93 PATIENTS

With 108 small kidney masses (≤ 4cm) treated



93% Lack of enhancement on CT or MRI in (42 of 45) of cases at 1 year follow-up.



Investigators found the ProSense® system to be safe, effective and without serious adverse events.

Led by Prof. Ofer Nativ, Head of the Urological Department, Bnai Zion Medical Center, Israel and Dr. Robert Sachner, Head of Interventional Radiology, Bnai Zion Medical Center, Israel



### **Bone Cancer Palliative treatment**



ВАСК

### Reducing pain in less than 10 minutes:







"One of the most important benefits coming from the last two years using IceCure cryoablation among the older ablation devices is that the treatment is completely unpainful. It means that usually the patient does not feel any pain during the treatment or afterwards."

> Franco Orsi, MD. Director of Interventional Oncology, European Institute of Oncology, Milan, Italy





# Lung Cancer: Ongoing Independent Trial in Japan



ВАСК

# ENCOURAGING EARLY EVALUATION

### >300 PATIENTS

Treated to date

100% Overall survival rate after ProSense® therapy vs. ~78% after radiation at three-year follow-up on ~30 T1mi +T1a +T1b cancer patients (<2cm mass)

Led by Dr. Hiroaki Nomori, M.D., Ph.D., Chairman of the Department of General Thoracic Surgery, Kameda Medical Center, Japan. (from July 2019 –Chairman of the Department of General Thoracic Surgery Kashiwa medical center)

Hiraki T. Lung Radiofrequency Ablation: Educational Lectures (EL2-1); Cryomedicine 2017: The 44th Annual Meeting of the Japanese Society for Low Temperature Medicine.



# Cryolmmunology Studies Underway



ВАСК

### **Collaborations**

### investigating cryoablation with immunotherapy



Memorial Sloan Kettering Cancer Center



Breast Cryoimmunology (Bristol-Myers)



Case University and Cleveland clinic

# **Support from Experts:**



"I have been using the ProSense® system for all my cryoablation procedures for the past year. I have plenty of experience using the typical argon-based systems — and IceCure offers several advantages over those systems.

First, the rate of freeze is much faster. We know from studies this is important to enhance the anti-cancer immune response from cryoablation. Second, the cost per procedure is less, not only because you can achieve larger ablation zones with a single needle, but also because liquid nitrogen is less expensive than gases needed for the other systems.

I feel that the fast freezing and consistent ablation provided by the ProSense® system is essential to our work in generating a systemic immune response combining cryoablation with the injection of immunotherapy."

Jason R. Williams, MD, Director of Interventional Oncology, Williams Cancer Institute, Atlanta, GA and Mexico City, Mexico







### **American Society of Breast Surgeons (ASBrS) Oct 2018 Guidelines:**

"Cryoablation is currently approved for treatment of benign and malignant soft tissue tumors. FDA. Currently, there are no specific technologies that have FDA approval for breast tumors. Participation in registries and clinical trials evaluating the use of these technologies with and without surgical excision of a breast malignancy is advised as early data emerges on their efficacy"

Feedback from 2018 Radiology Society of North America (RSNA) Annual Meeting:

..."Cryoablation - the destruction of cancer cells through freezing - shows early indications of effectiveness in treating women with low-risk breast cancers, according to research being presented today at the annual meeting of the Radiological Society of North America (RSNA)".....





# **ProSense®: Becoming the Gold** Standard in Fibroadenoma Therapy



**Treating** fibroadenomas successfully since clinical trials began in 2012



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

### **Announced deals USD K\***



Territory	Announced deals USD K*	Expected Delivery
Terumo Japan	1,911	2020
Terumo Singapore	153	H1/2020
South Africa	195	2020
India	187	2020
Germany	121	H1/2020
Thailand	544	H1/2020
Spain	193	2020
Romania	86	2020
Other not announced sales		2020
Total	3,389	

H1/2020\*\* Revenue was USD 1,855K, 15% higher than 2019 total Revenue

\* The announced deals are recorded here as filed to TASE. Actual sales may differ from the above

\*\* Un reviewed and un audited

