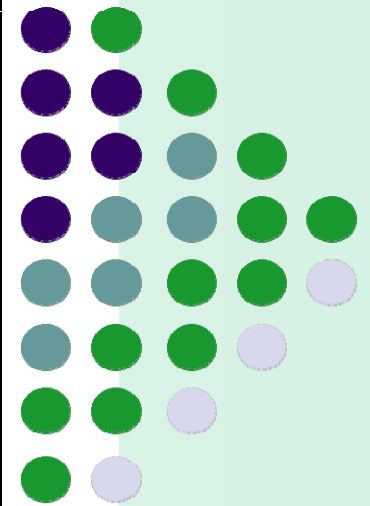


# Medifocus Inc.

*Improving the  
Standard of Care for  
Breast Cancer Treatment*



September 2009

# Company Focus

- **Development and commercialization of a focused heat treatment system for breast cancer**
- **System is ready to enter the final pivotal clinical trial**
- **Complete the final pivotal trial to obtain PMA for breast cancer system in both Canada and the USA**
- **First indication of use for system is combinational therapy with neo-adjuvant chemotherapy to increase shrinkage of large breast tumors to facilitate breast conservation surgery**
- **Expand the same indication to cover medium tumors**
- **Obtain additional indication of use for the system to treat recurrent chest wall cancer in combination with radiation therapy**



# Technology Platform

- **Medifocus licensed the Adaptive Phased Array (APA) microwave focusing technology developed by Massachusetts Institute of Technology (MIT) for detection and destruction of incoming missiles and collaborated with MIT scientist Dr. Alan Fenn to develop the Company's focused heat cancer treatment system technology platform**
- **The technology platform provides the basis for design of tumor targeted focused heat cancer treatment systems capable of delivering precision controlled focused microwave energy at tumor for targeted heating of tumors anywhere in the body in a reliable and repeatable manner**
- **The APA focused heat cancer treatment technology platform is protected by 9 US patents and 20 international patents**



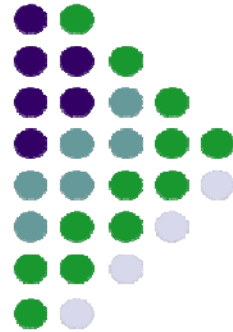
# Business Strategy (1)



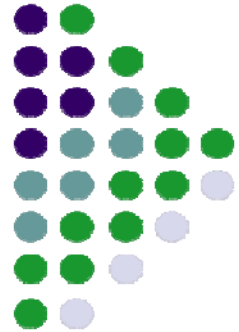
- **Develop the breast cancer treatment system as a tool for surgeons to increase shrinkage and/or eradication of medium and large tumors to facilitate conversion from Mastectomy to breast conservation surgery**
- **Design pivotal trial protocol to ensure meeting of trial endpoint and position for rapid receipt of PMA in the USA and Canada**
- **Focus initial marketing efforts to target the 1,000 surgeons owned private breast cancer centers in the USA and Canada**
- **Distribution strategy is to place system to recover cost (\$50,000) and derive recurring revenue stream from sales of disposable sensors for each treatment (\$1,500 per sensor)**

## Business Strategy (2)

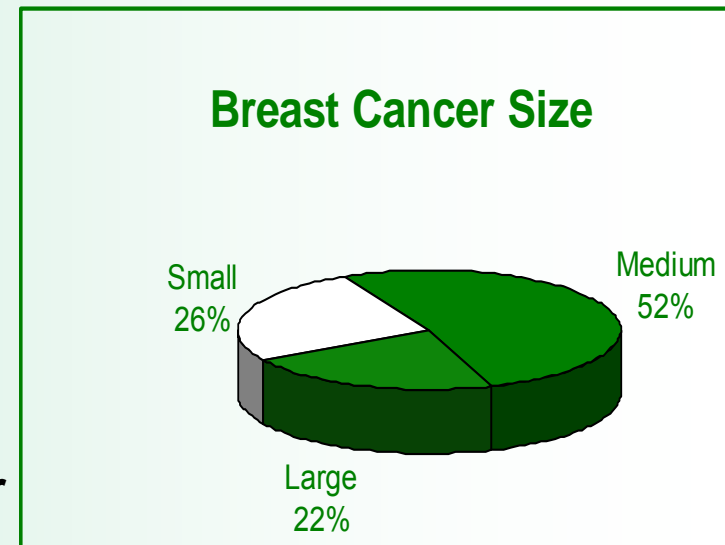
- **Secure adequate insurance reimbursement for focused heat treatment of breast cancer – petition the AMA to grant initial Category III CPT code to allow investigators to bill for insurance payments during clinical trials to create a reimbursement reference data base (\$5,000-\$9,000 received from previous trial)**
- **Secure strategic distribution partners for the marketing and sales of the breast cancer treatment systems worldwide**
- **Secure strategic product and business development partners for collaborative R&D to create a pipeline of focused heat products for treatment of other cancers**



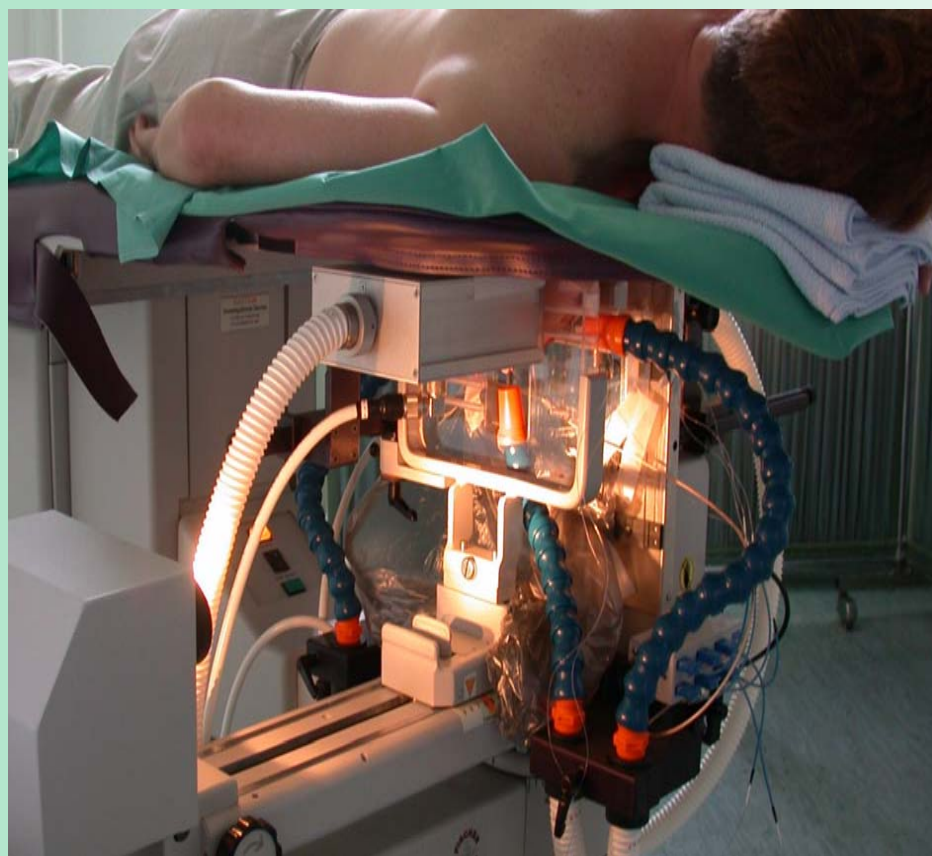
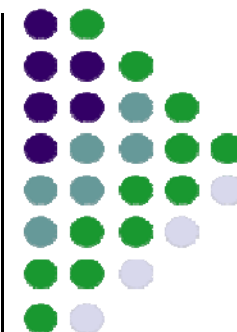
# The Breast Cancer Challenge



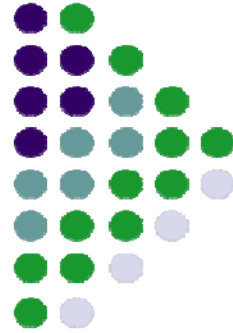
- **Worldwide -- 1.2 million new cases detected each year**
- **Patients and surgeons desire Breast Conservation Surgery (BCS)**
- **Neo-adjuvant Chemotherapy attempts to eradicate or shrink tumors prior to surgery to enable BCS. Low success rate of 58% tumor shrinkage is inadequate**
- **Addition of Medifocus' focused heat treatments significantly increase tumor shrinkage rate of the current chemotherapy treatment from 58% to 88% [Vargas, *Cancer Therapy*, 2007]**
- **Combined focused heat plus chemotherapy treatment more effective for breast cancer tumor shrinkage and eradication**



# The Medifocus, Inc. Solution

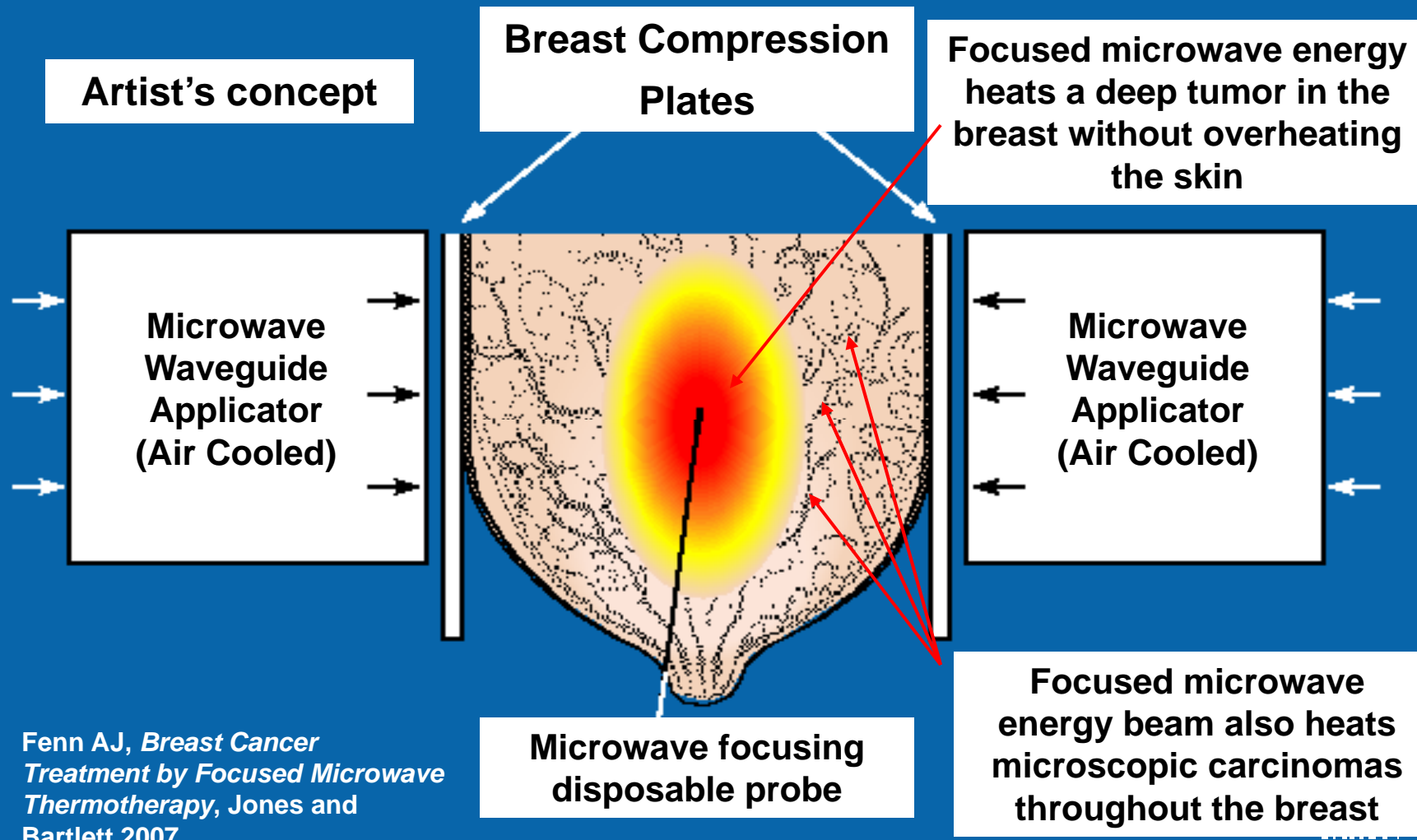


- **Randomized phase-II FDA clinical trials demonstrated that Medifocus' focused-heat treatment in combination with neo-adjuvant chemotherapy shrinks tumors by more than 50% over chemotherapy alone**
- **Significant increase in tumor eradication and shrinkage resulting in increased effectiveness of current chemotherapy treatment**
- **Completed systems ready for use in final pivotal clinical trial**



## Completed Systems Ready for Pivotal Study

# Focused Microwave Breast Thermotherapy Concept



Fenn AJ, *Breast Cancer Treatment by Focused Microwave Thermotherapy*, Jones and Bartlett 2007

# FDA Clinical Study Results

- **Phase I FDA Safety Study**

(Gardner, *Annals of Surgical Oncology*, Vol. 9, No. 4, April 2002)

- Safely heats breast tumors of up to 8 cm in diameter to treatment temperature (10 patients)

- **Phase II FDA Dose Escalation Study**

(Vargas, *Annals of Surgical Oncology*, Vol. 11, No. 2, February 2004)

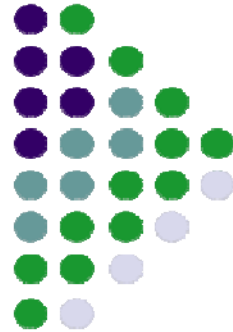
- Established optimum safe heat treatment dose (25 patients)

- **Phase II FDA Multi-center Randomized Study**

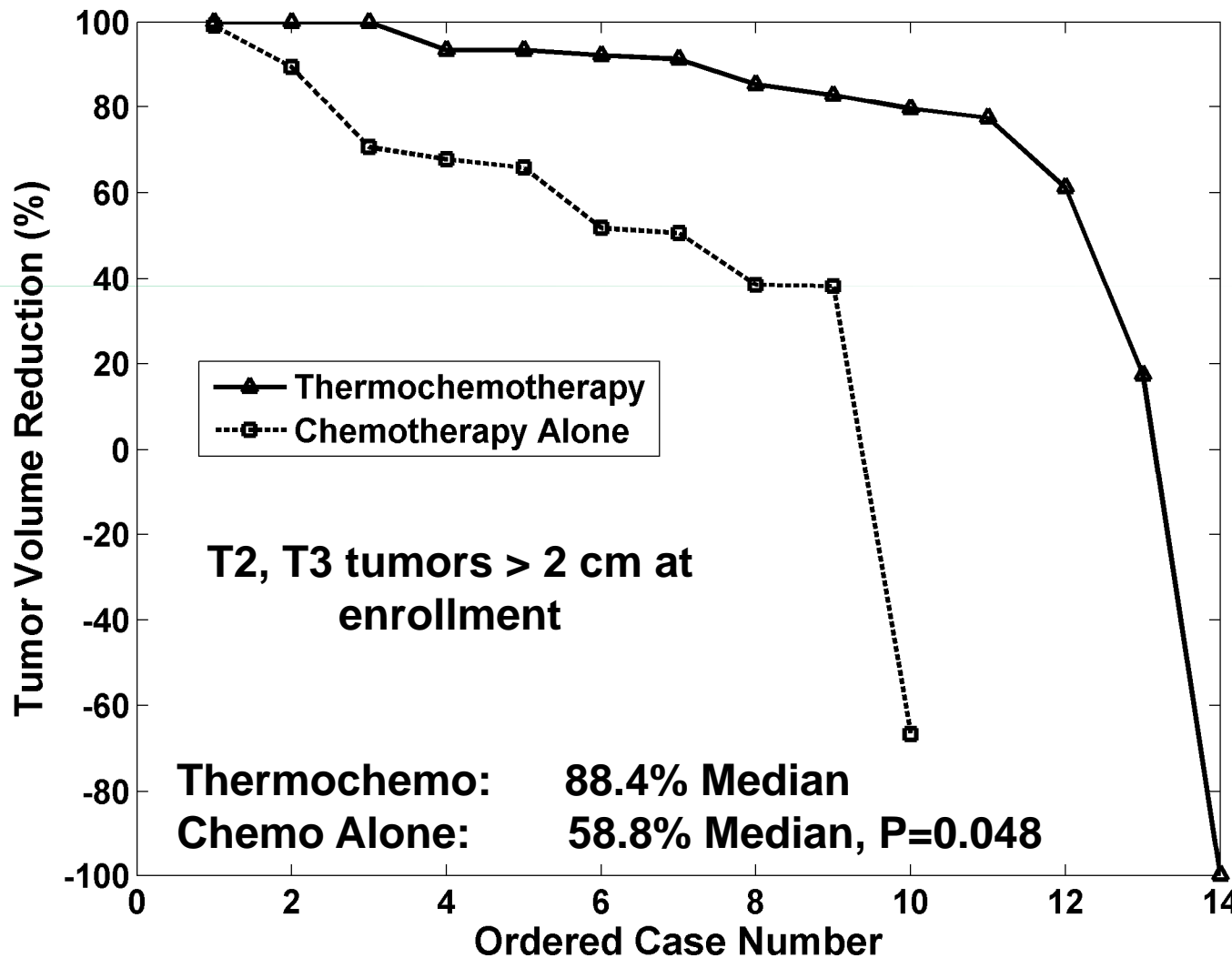
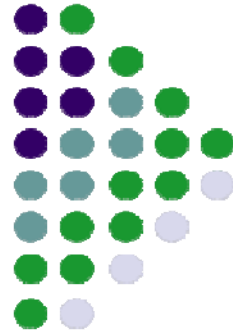
(Vargas, *Cancer Therapy*, Vol. 5, published online November 25, 2007)

- Patients indicated for mastectomy and neo-adjuvant chemotherapy.
- 50% improvement in overall tumor shrinkage (and 3x for eradication) when the Focused Heat System was used in conjunction with neo-adjuvant Chemotherapy (34 patients)

**Conclusion: Very safe and effective**



# Multi-Center Randomized Study Results – Demonstrates Statistical Significant Improvement

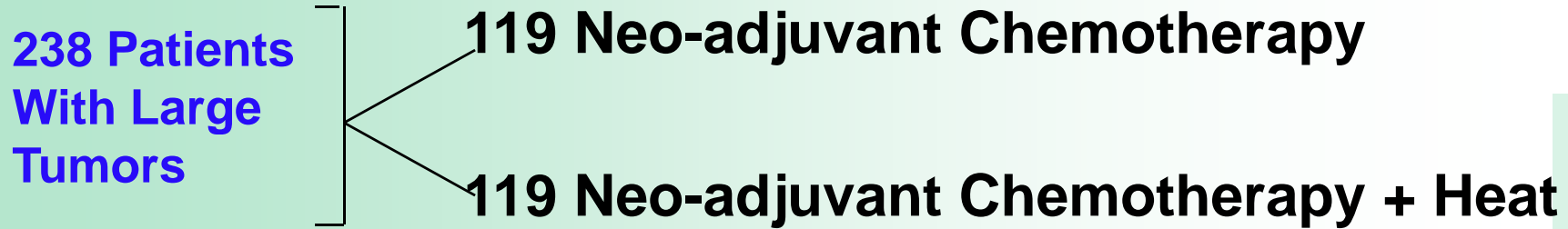
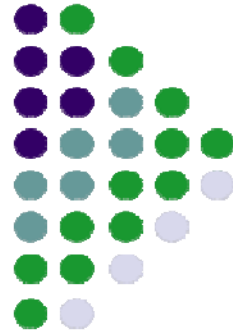


Intent to treat (ITT)  
34 pts

Evaluation Population  
24 pts

Vargas et al,  
*Cancer Therapy*,  
Vol 5, Nov. 2007

# Strategic Final Pivotal Trial Design



**Primary Clinical Endpoint**

Demonstrate 40% or more Tumor Size Reduction over chemotherapy alone

**No. of Focused Heat Treatments**

3 focused heat treatments per patient (Earlier study used only 2 focused heat treatments)

**Mid-Point Analysis**

Go / Early Approval / No Go

**Time Table**

Start	11/09
Midpoint Analysis	6/11
Trial Completion	6/12

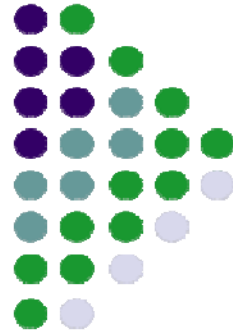
# Regulatory Development

**Medifocus inc. has satisfied all conditions with Health Canada to begin its pivotal study for the treatment of breast cancer pending approval from the Research Ethics Board (REB)**

**In July 2009, the REB from St. Mary Hospital approved the study to take place at Ville Marie Medical Center in Montreal Quebec**

**Medifocus has also submitted an IDE application to the US-FDA in June 2009 to conduct the same pivotal study in the USA**

**POSITIONED TO IMMEDIATELY INITIALIZE  
PIVOTAL STUDY!!!**



# Pivotal Study -- Clinical Sites

## Canadian Clinical Sites

Ville Marie Medical Center  
Montreal, Quebec (Dr. J. Keyserlingk)

North York General Hospital  
Toronto, Ontario (Dr. N. Down)

## USA Clinical Sites

Harbor Medical Center - UCLA  
Los Angeles, California, (Dr. C. Dauphine)

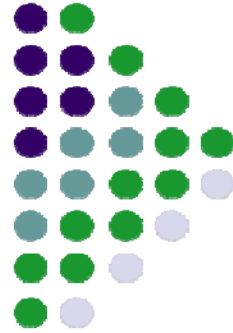
Univ. of Oklahoma Health Sciences Center  
Oklahoma City, Oklahoma, (Dr. W. Dooley)

Comprehensive Breast Center of Coral Springs  
Coral Springs, Florida, (Dr. M. Tomaselli)

St. Joseph's Hospital  
Orange, California, (Dr. J. Harness)



# Comprehensive Intellectual Property Portfolio



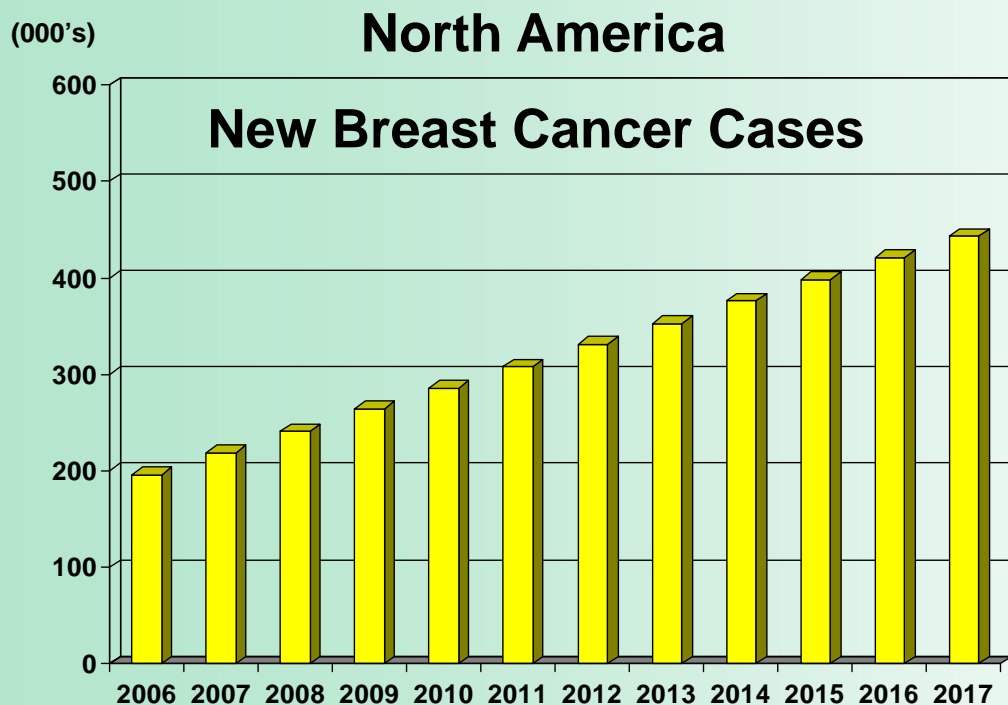
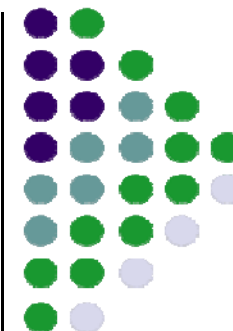
- **Medifocus Patents**

- 5 US patents and 7 International patents issued.
- 31 international applications pending.

- **M.I.T. Patents (Exclusively Licensed to Medifocus)**

- 4 US patents and 13 International patents issued
- 3 International Applications Pending

# Market Potential – Breast Cancer

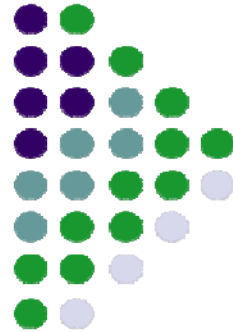


- **New cases to double by 2015**
- **Demographic Driven – Aging Baby Boomer Population**

\* 2006 – American Cancer Society; Canadian Cancer Society

\* 2017 – 16<sup>th</sup> Annual National Interdisciplinary Breast Cancer Conference

# Distribution Strategy



- **Over 1,000 Breast Cancer Centers in North America**
- **Place System to Recover Cost:**  
*(US\$50,000 per system)*
- **Recurring Revenue Stream from Sale of Disposable Sensor for each treatment:**  
*(US\$1,500 ea. x 3 TX = US\$4,500 per patient)*
- **Secure Appropriate Reimbursement for Treatment – initial Category III CPT code already granted:**  
*(US\$5,000 per TX x 3 TX = US\$15,000 per patient)*

# Revenue Model

## Excellent Return on Investment for Individual Breast Center



### Breast Center



#### Equipment

Cost     \$50,000     Individual Breast Center

#### Disposable Accessories

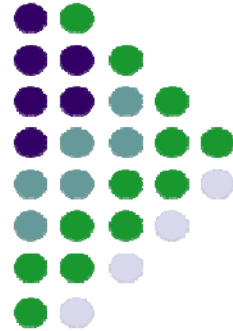


#### REVENUE STREAM PER CENTER

200	Number of days / year
2	No. of Treatments / Day
\$5,000	Gross revenue / Treatment
\$2,000,000	Gross revenue – Individual Breast Center

# Revenue Model

## Tremendous Revenue Potential for Medifocus, Inc.



**Medifocus  
Inc.**



### Equipment

Cost \$50,000 recovered at placement

### Disposable Accessories

#### REVENUE PER SYSTEM

200

Number of days / year

2

No. of Treatments / Day

\$1,500

Revenue / Disposable

\$600,000

Per system placed

After placement of 200 systems, total revenue from sales of disposables would be \$120 million per year



# Early Revenue Opportunity – Recurrent Chest Wall (RCW) Cancer



## Unmet Medical Need

16,000 new patients per year affected  
in North America

Much larger patient population world-wide

## Use System to treat RCW in combination with Radiation

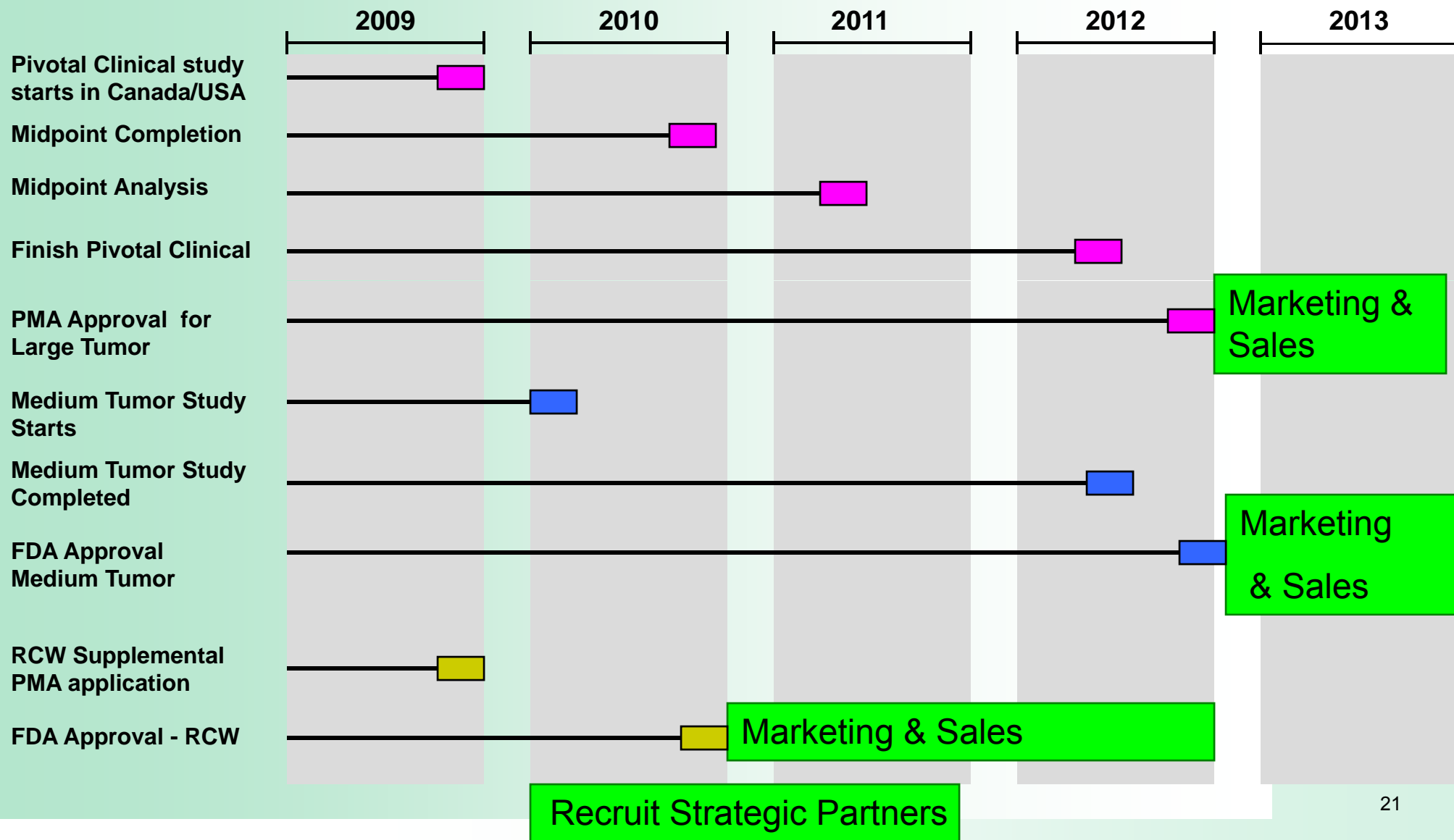
Supplemental PMA Approval in 2010

Duke University Medical Center and other  
strategic clinical collaborators





# Value Driving Events



# Experienced Management Team

## Augustine Cheung, PhD - CEO

- Founder and Former CEO of Celsion Corp. (CLSN:Nasq)
- Successfully led development and commercialization of Thermotherapy systems (Breast Cancer and BPH and others)
- Successfully led development of heat-activated drug delivery technology platforms (Thermodox, phase-III for Liver Cancer)

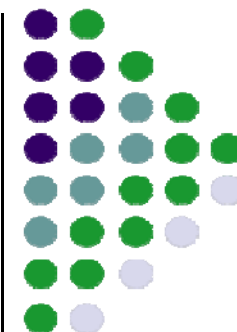
## John Mon - COO

- Former VP of Product Development of Celsion Corp.
- Successful in obtaining PMA and 510K approvals for various heat treatment devices and systems
- Co-authored 12 issued US and international patents

## Dennis Smith - VP, Engineering

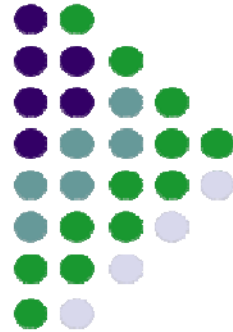
- Previously VP Engineering of Celsion Corp.
- Responsible for the engineering development of the APA Breast cancer treatment system and the commercialization of the “Prolieve Thermodilatation System” for treatment of BPH

***The team worked together in Celsion for over 20 years, and successfully developed and commercialized the “Prolieve Thermodilatation System” for BPH with Boston Scientific as strategic partner and sold the BPH product to Boston Scientific for a return of over \$100 million***

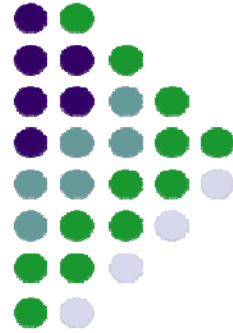


# Financing

- **Medifocus Inc. was formed after the completion of a Qualified Transaction in November 2008 between Medifocus Inc., a Capital Pool Company and Celsion Canada Ltd., a private company that owns the breast cancer treatment system business**
- **The total start-up capital for Medifocus Inc. is \$3,000,000**
- **Medifocus is seeking an investment of \$1.8 million 2009 to provide funding to initiate the pivotal trial in USA and Canada. Additional funding of \$3.0 million will be raised in 2010 to progress the trial midway completion and conduct a mid-trial data analysis to determine if the trial end point is met or exceeded. If the treatment data demonstrate a better than 50% increase in tumor shrinkage over chemotherapy alone, the Company may be in a position to seek early PMA approval**
- **Additional investment of \$3.0 million will be needed to complete the pivotal trial and position the Company for the commercial market launch**



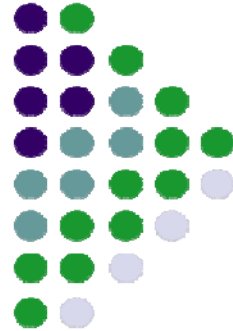
# Share Structure



## Medifocus, Inc. (TSXV – MFS)

Shares Issued and Outstanding	24.3 Million
Warrants	5.2 Million
Common Shares Fully Diluted	29.5 Million

# CONTACT INFORMATION



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