# Medifocus, Inc.

## OTCQX: MDFZF  TSXV: MFS

**www.medifocusinc.com**

Except for historical information, the statements made in this presentation are forward-looking statements involving significant risks and uncertainties. These risks and uncertainties, including those related to the future financial projections and business strategy of the Company, can be found in the Company's filings with the regulatory authorities.

**October 2015**

# Company Summary

**Medifocus Inc. develops and commercializes minimally invasive focused heat systems for the treatment of cancerous and benign tumors.**

**The Company owns a fully protected (via patents) position in two technology platforms:**

- **Endo-thermotherapy platform, a catheter-basis focused heat technology platform that utilizes natural body openings to deliver precise microwave thermotherapy to the diseased sites.**
- **Adaptive Phased Array (APA) Microwave Focusing platform that precisely focused microwave energy at tumor center to induce shrinkage or eradication of tumors without undue harm to surrounding tissue.**

**Signed exclusive licensing and development agreement with Duke for heat-activated and tumor-targeted immunotherapy technology.**

**The Company is based in Columbia, Maryland.**

# Products &Technology Platforms

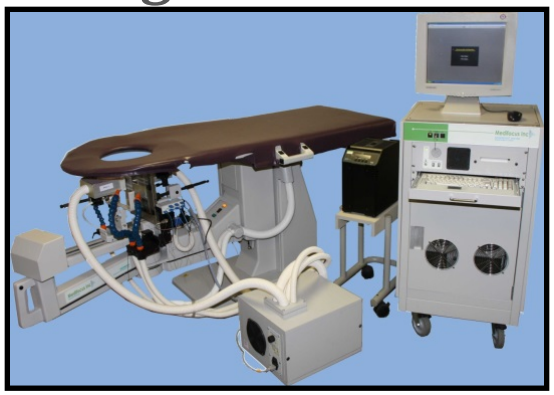
Covered by 100 + Issued and Pending US and International Patents

## Endo-thermotherapy Platform

- A catheter-based focused heat technology platform
- **Prolieve: FDA approved for benign prostatic hyperplasia (BPH) in commercial sales**
- Over 100k patients treated with Prolieve
- Future products: systems for prostate, cervical, & esophageal cancers

## Adaptive Phased Array (APA) Microwave Focusing Platform

- Precision microwave focusing technology invented by MIT
- **APA 1000 Breast Cancer System in pivotal Phase III trial**
- Future products: systems for treatment of surface/subsurface subsurf and deep-seated cancers



# Prolieve: Revenue-Generating

- FDA approved for the treatment of BPH (enlarged prostate)
- 50% of men over 50, and 90% of men over 70 are affected by BPH
- Current Medicare reimbursement rate: $2,200
- Razor/blade revenue model: 60% gross margin on disposable kit
- Positioned to penetrate the multi-billion dollar BPH drug market by providing mobile service treatment in GPs' offices
- China FDA approval in process opening a new potential market

# BPH Treatment Options and Market Potential

Traditional Surgery
TURP

+

Thermotherapy
(Prolieve & others)
and Laser Surgery

**Surgical and Minimally Invasive Treatment Market for BPH is $150 million in the U.S.**

**Medifocus' goal is to become the market leader in this space based on Prolieve's safety profile and effectiveness**

**Prolieve's thermo-dilitation treatment could be marketed to BPH patients on drug therapy or watchful waiting ($8 billion market potential)**

**Patients on Prescription Drug**
Alpha-blocker
5 reductase inhibitors
Combination
**$4 billion** in major
industrialized countries

Medifocus Inc

Two large target groups for the more effective, safer and cheaper Prolieve treatment

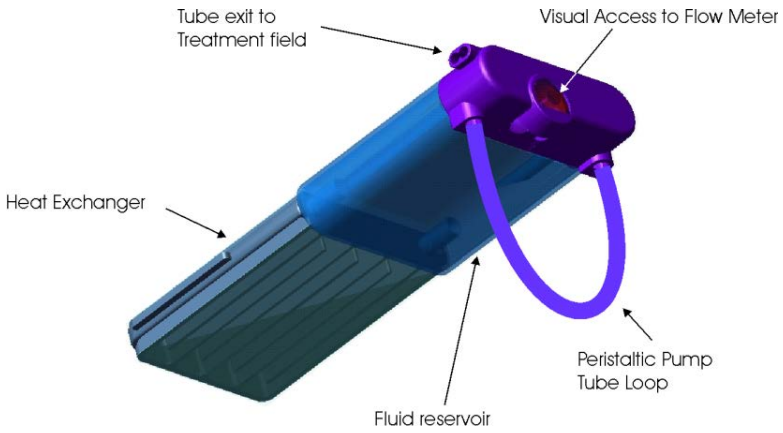
**Watchful Waiting**
Patients choosing not to take drugs due to side effects, low success rate and high costs

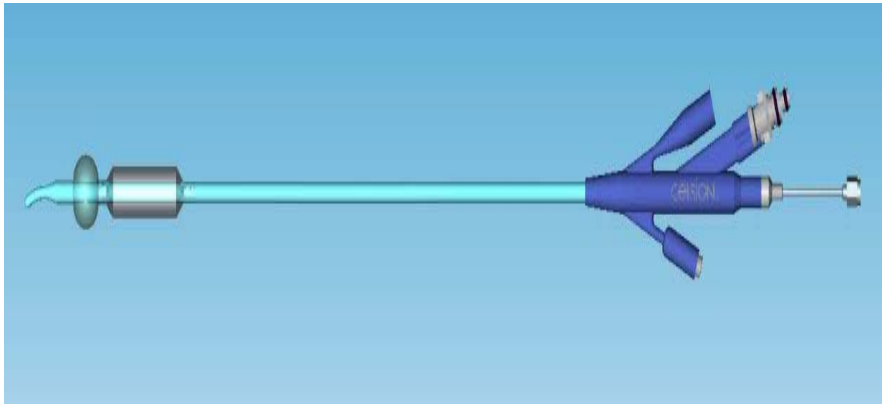
**Prolieve = Treatment of Choice (Safe, effective, minimal side effect)**

Source: Medtech Insight; Decision Resources Group

# Prolieve Treatment Module and Disposables

Treatment Module: minimal or no cost to doctors.



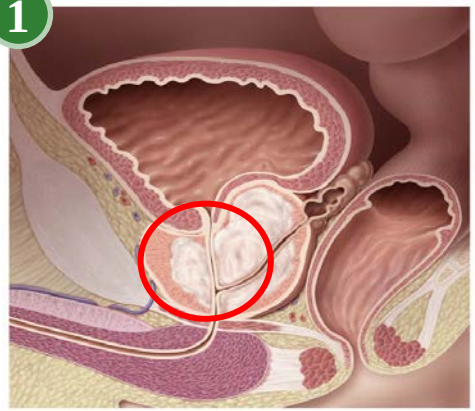
Disposable treatment catheter provides a recurring revenue source

# Prolieve Treatment Procedure

## Heat + Dilation = Biological Stent → Immediate Relief

### Constricted Urethra

1

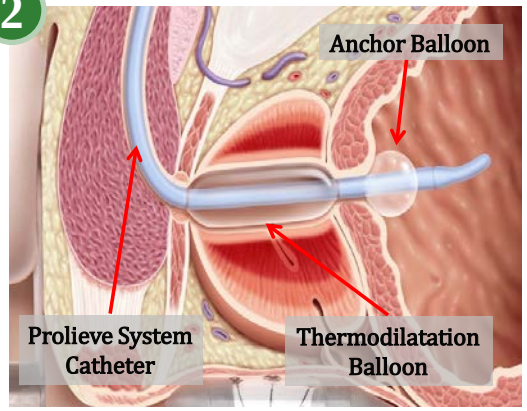


***BEFORE*** *Prolieve Treatment*

### Placement of Prolieve

*Proprietary heat/dilation catheter*

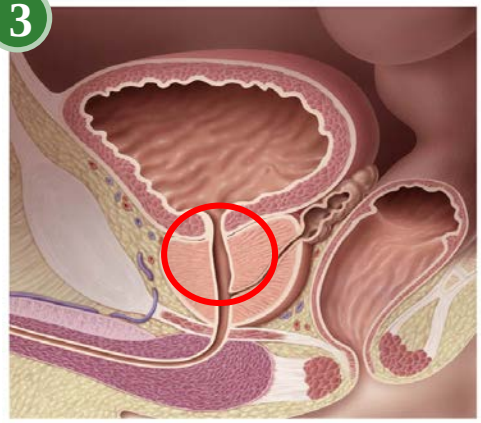
2




*45-minute in office treatment, no general anesthesia or incision*

### Biological Stent

3



*Formed in the Urethra* ***AFTER*** *Prolieve Treatment*

# APA 1000 Breast Cancer System - Phase III

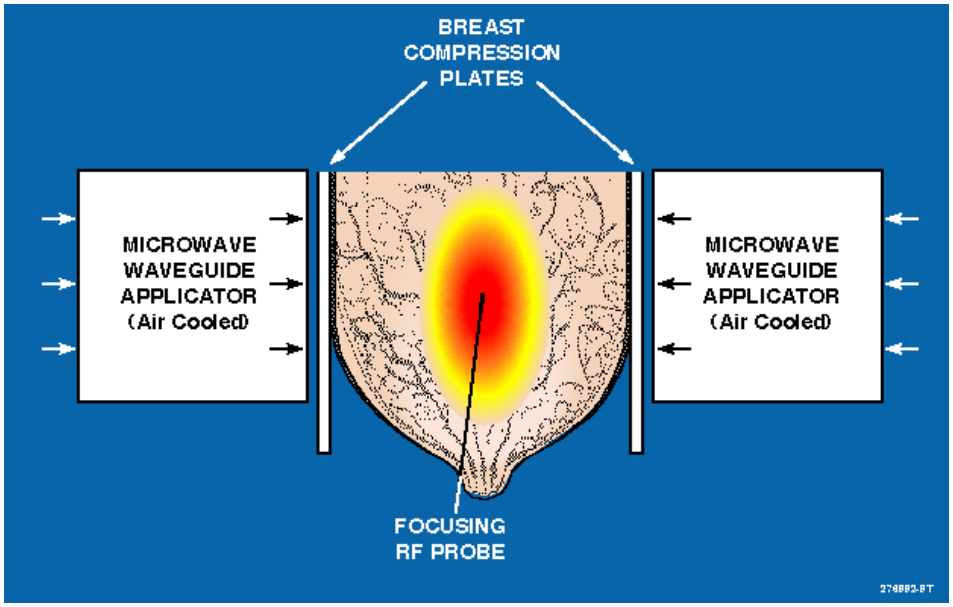
- Over 1.6 million new cases of Breast Cancer diagnosed annually
- Highly successful Phase I, II, II A and II B trials completed
- Pivotal Phase III already initiated in U.S. and Canada
- Estimated cost: $7 million for Phase III trial
- Razor/ Razorblade business model similar to Prolieve

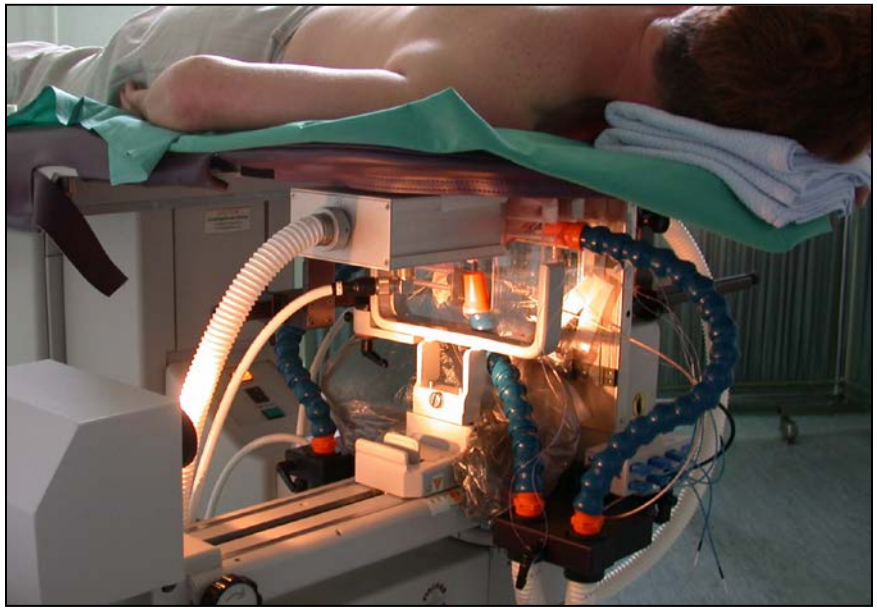
# Adaptive Phased Array Focused Microwave Breast Thermotherapy System


- **Microfocus APA 1000, Adaptive Microwave Phased Array Thermotherapy System**
- **Designed with a value added approach:**
    1. **Larger breast tumors**
    2. **Small early stage breast tumors**
    3. **DCIS**
    4. **Recurrent Chest Wall (RCW)Disease**
    5. **Benign breast lesions.**

# APA 1000 Breast Cancer System – Phase III

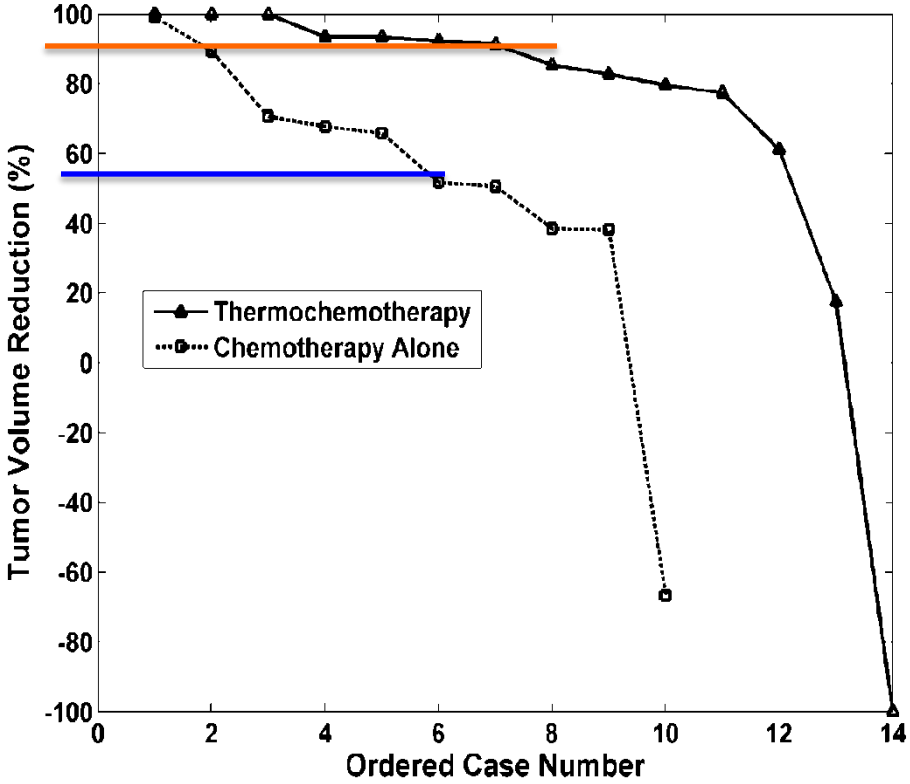
- An RF needle probe inserted at tumor center provides feed-back signal to focus microwave energy at tumor center to induce shrinkage or eradication without harming surrounding tissue
- Focused microwave energy beam also destroys microscopic tumors along its path throughout the breast. (Selective heating of breast tumors due to higher water content)
- Focused heat (43-44˚ C) combined with chemotherapy achieves an average of 88% tumor size reduction, **improving surgical outcomes!**
- **Value proposition (Same treatment system can be used for most stages of breast cancer, including recurrent chest wall, primary small tumor, DCIS Pre-cancerous and benign lesion)**



# Completed Phase II Multi-Center Randomized Study Results

## Demonstrate Statistical Significant Improvement




Evaluation Population 24pts

T2, T3 tumors > 2 cm at enrollment

Thermochemo:88.4% (Median)

Chemo Alone: 58.8% (Median)

P=0.048

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

**With neo-adjuvant chemotherapy, focused heat can significantly improve breast cancer patients' chance for survival and breast conservation**

# APA 1000 Final Pivotal Phase III Trial Design

**High Probability of Meeting the End Point**

| | |
|---|---|
| **238 Patients with Large Tumors** | **119 neo-adjuvant chemotherapy**<br>**119 neo-adjuvant chemotherapy + heat** |
| **Primary Clinical Endpoint** | To demonstrate 40% or more in tumor shrinkage over chemotherapy alone (control arm)<br>• **50% increase in tumor shrinkage with chemo + heat over chemo alone already observed in Phase II**<br>• **More heat dose to be used (two heat treatments in Phase II and three in Phase III), thus better results are expected than in Phase II**<br>• **High probability of meeting or exceeding endpoint**<br>• **Early submission for PMA possible if 50% or more tumor shrinkage is attained** |

# Product Strategy

- **For Prolieve**:

  1. Restructured Prolieve Business U.S.
  2. Establish distribution network in major international markets
  3. Update Prolieve (Marketing/Retooling)

- **For APA 1000:**

  1. Accelerate Phase III clinical trials by activating more sites in the U.S.
  2. Initiate new sites in China and India to expedite patient enrollment

- **For Future Product Pipeline:** collaboration with strategic partners to develop new products for treatment of various cancers utilizing our technology platforms

# Heat Activated ImmunoTherapy

**Duke University Medical Center**

- "A method for selective expression of therapeutic genes by hyperthermia", and "Target tumor therapy by use of recombinant adenovirus vectors that selectively replicate in hypoxic regions of tumors."

- Adenoviral delivery construct which releases IL-12 upon temperature rise within tumor and its vicinity to effect immunotherapy for treatment of diseases

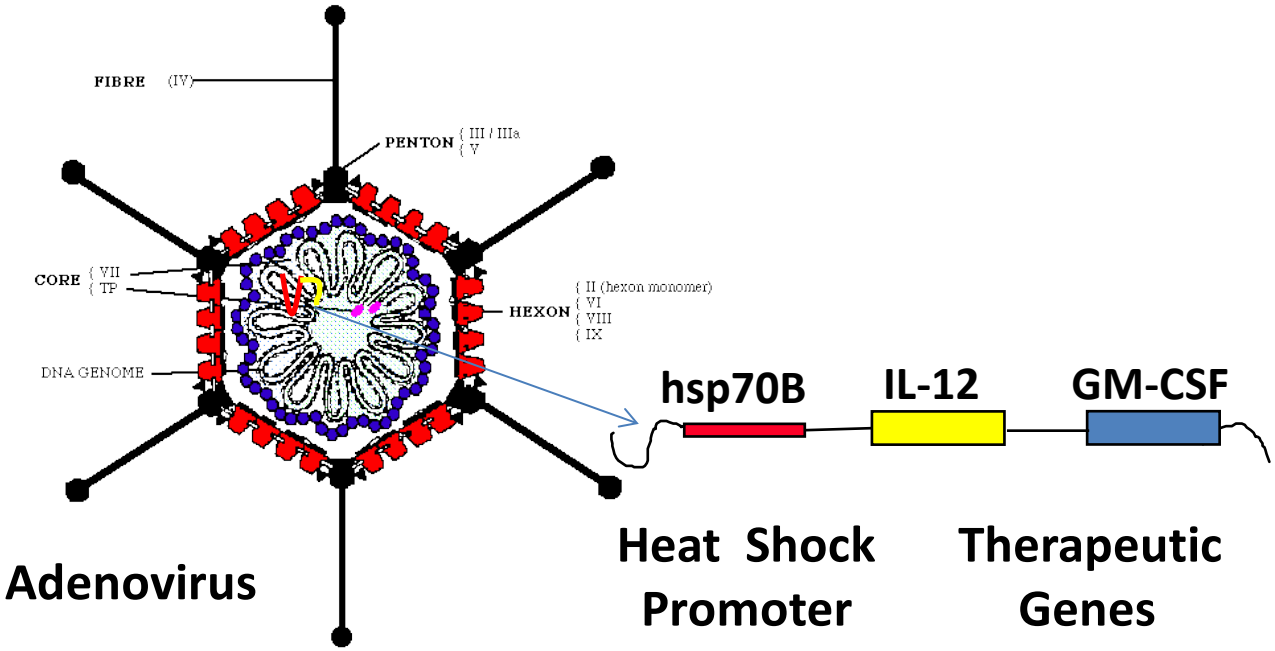
- Exclusively licensed the technology from Duke University

- Present an immediate opportunity for Medifocus to become and active participant in the molecular and genetic therapeutics marketplace

# Heat Activated Immunotherapy

1. Develop tumor targeting heat-activated immunotherapeutics for cancer treatments to increase efficacy and reduce treatment induced toxicities

2. To reposition Medifocus from a medical device company to immunotherapuetic bio pharmaceutical to increase shareholders value



# Focused Heat Technology + Heat Activated Immunotherapy

## Synergy & Enormous Market Valuation Potential

### 100 + Issued and Pending US and International Patents

1. Medifocus has fully developed focused heating technologies for treatment of the prostate and breast.

2. Medifocus has licensed from with Duke University for a patented immunotherapy (Thermoactivated IL12) platform technology. The thermoactivated IL12 uniquely increases the gene expression ( activity ) of IL12 when the temperatures are elevated and expression is turned off at baseline temperatures.

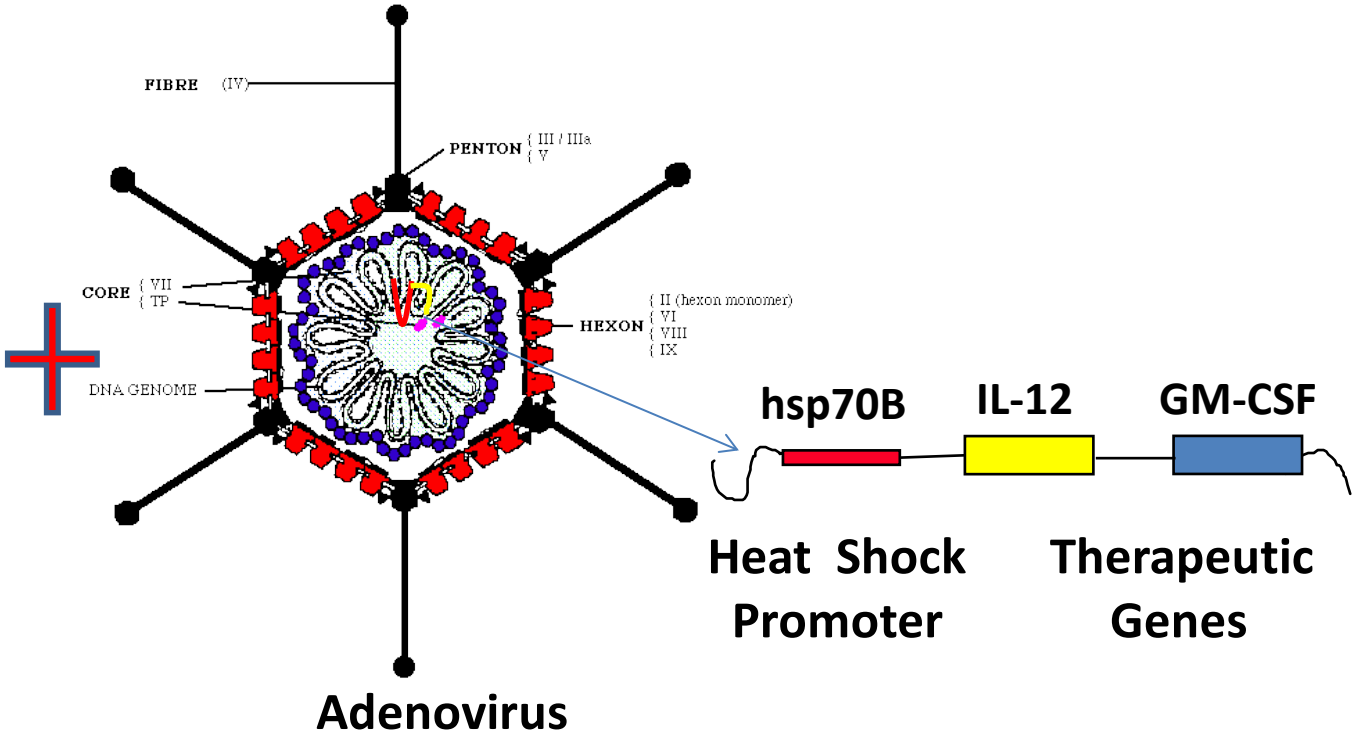
3. The synergistic combination of these technologies enhances the gene expression. Medifocus' patented localized heating technology can control gene activity. Localizing the gene activity at the diseased site reduces systemic toxicity and increases treatment efficacy.

# First Heat Activated Immunotherapy Application

## Treatment of Prostate Cancer

Platform (Prolieve) + Immunotherapy (Thermoactivated IL12)

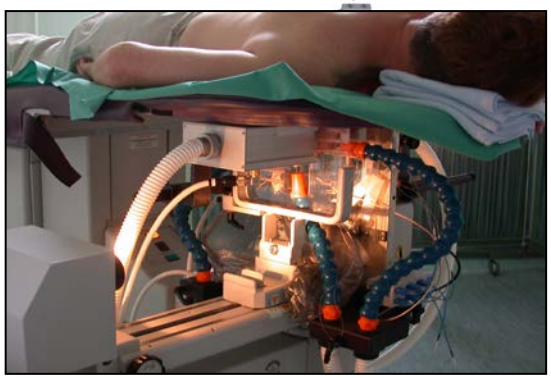
Multi $Billion Prostate Cancer Treatment Marketplace

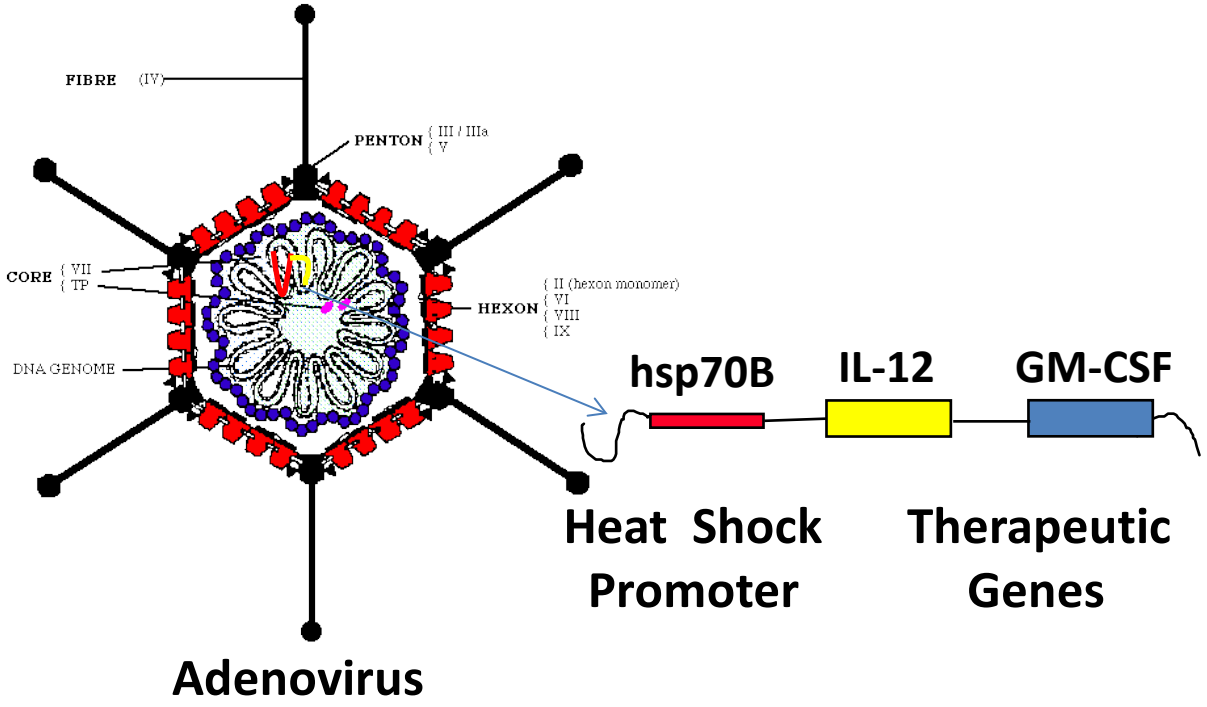


# Second Heat Activated Immunotherapy Application

## Treatment of Breast Cancer

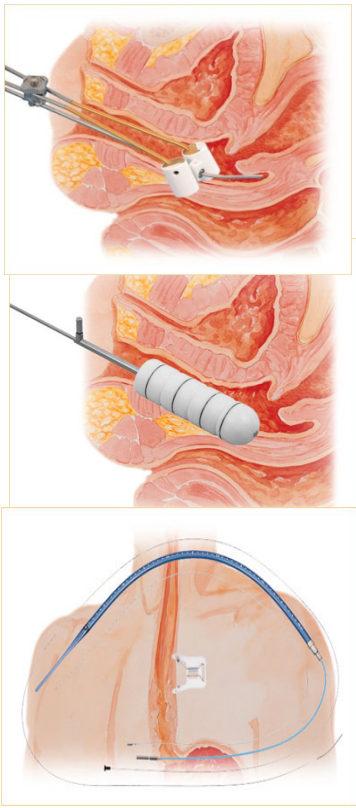
Platform ( Microfocus APA 1000) + immunotherapy (Thermoactivated IL12)
Targeting breast cancer treatment marketplace

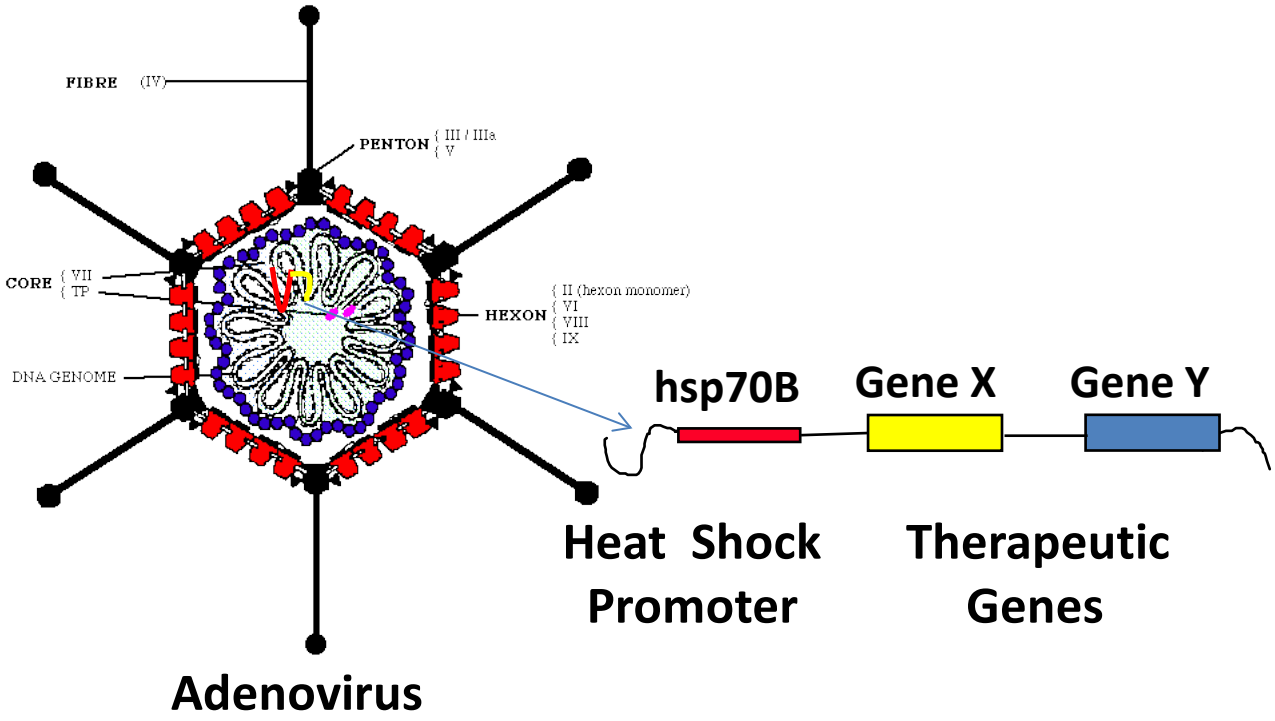




# Other Heat Activated Immunotherapy Applications

**Other heating Systems + Immunotherapy (Thermoactivated IL12) targeting other diseased sites (liver, ovarian, head, neck, and etc.)**





# Management Team with Industry Experience

## Dr. Augustine Y. Cheung, PhD (Founder & CEO)

- Former faculty of University of Maryland School of Medicine and George Washington University
- Founder and former CEO of Celsion Corp. (NASDAQ: CLSN), successfully developed multiple focused heat based devices targeting cancer and other diseases

## Mr. John Mon (COO)

- Significant life sciences experience, holds many patents in the area of thermotherapy for the treatment of cancer, achieved FDA approvals for IDE/PMA/510K submissions
- Previously V.P. of business and product development, General Manager, and Director of Celsion

## Mr. Mirsad Jakubovic (CFO)

- A Chartered Accountant and Director of Finance and Administration for Havana House Cigar and Tobacco Merchants Ltd.
- Former Director of Finance and Administration for Swatch Group Canada Ltd.

## Mr. Douglas Liu(VP, Corporate and Business Development)

- Former Assistant to Chief Financial Officer and Shareholders Administration Manager at Celsion
- Private investor in various biotech startup/public companies and independent consultant in corporate finance

# Investment Opportunity

## Background ( Attributes for Success)

1. Comprehensive and valuable intellectual property portfolio (over 100 USA and Foreign Patents)
2. FDA approved product generating revenue
3. Completed reorganization of Prolieve business to position for future growth and profitability
4. FDA Approval for Pivotal Phase III Breast Cancer treatment study. (Additional study planned)
5. Planning to Uplist to NASDAQ
6. Duke agreement providing entry into exciting immunotherapy space
7. Target to submit application to begin Phase I clinical trial for the heat activated immunotherapy in 2016