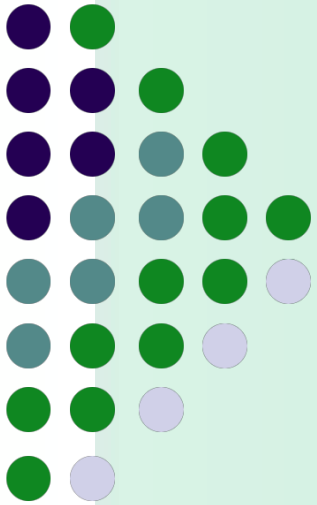
Medifocus, Inc.

OTCQB: MDFZF TSXV: MFS

www.medifocusinc.com

A Leader in Focused Heat Thermotherapy for the Treatment of Benign Prostatic Hyperplasia and Breast Cancer



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.

December 2018

Medifocus Inc. Overview

Medifocus develops and commercializes minimally-invasive, focused-heat systems for the treatment of cancerous and benign tumors. The Company is incorporated in Ontario, Canada with its headquarters Columbia, Maryland.

Medifocus owns two technology platforms with comprehensive patent protection:

1. **Endo-Thermotherapy platform:** a catheter-basis, focused-heat technology platform that utilizes natural body openings to deliver precise microwave thermotherapy to diseased sites. The revenue-generating Prolieve ® Transurethral Thermodilatation™ (TUTD™) System is U.S. FDA-approved for treatment of Benign Prostatic Hyperplasia **(**BPH)

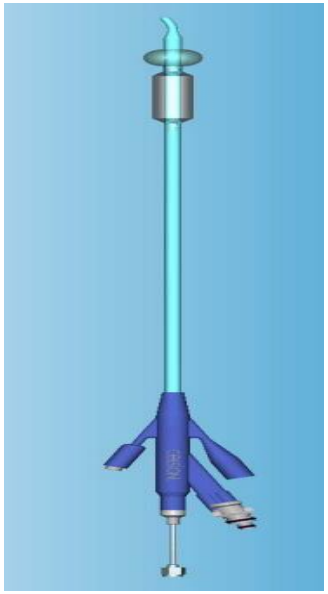
2. **Adaptive Phase Array (APA) Microwave Focusing platform** delivers precisely focused microwave heating to the tumor, shrinking large tumors and eradicating microscopic cancer cells within the tumor margin making minimally invasive breast conservation surgery or non-surgical treatment options viable.

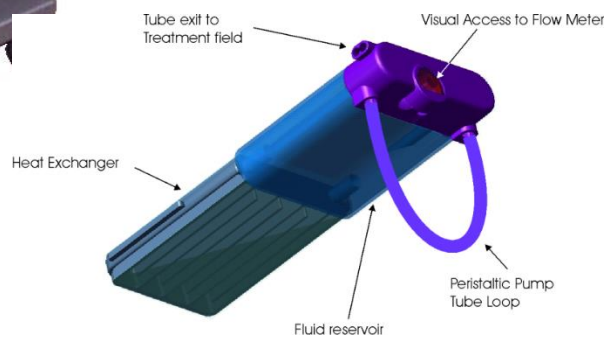
Prolieve® Transurethral Thermodilatation™ System

- First product developed based on the Endo-thermotherapy Technology Platform
- FDA approved for the treatment of Benign Prostatic Hyperplasia (BPH), a medical term for enlargement of prostate
- 50% of men over age 50 and 90% over age 70 will develop symptoms of BPH
- BPH symptoms Includes urgency, nocturia, hesitancy, weak stream, dysuria, retention and intermittency
- The quality of life of BPH sufferers are badly compromised
- Most other treatment options are either less effective, or have many side effects, or both
- Approx. $100 million were spent in the development and commercialization of Prolieve ®

Prolieve® Console

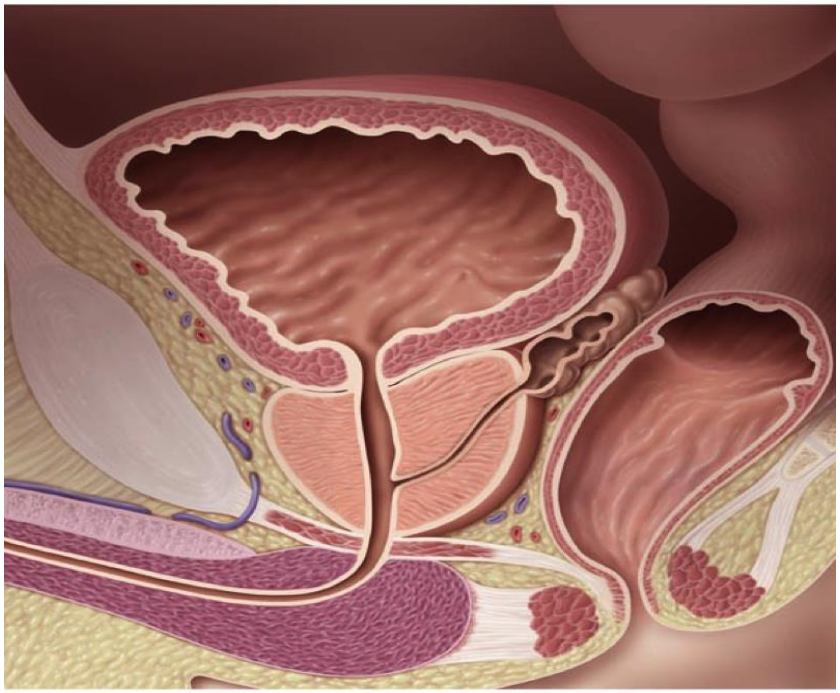
Patented Catheter with Dilating Balloon



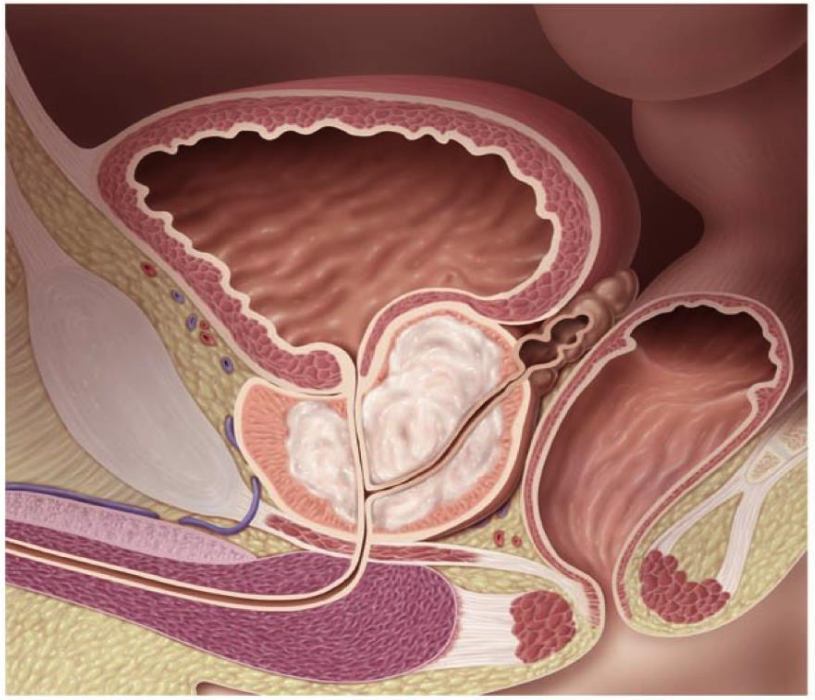


BPH with Aging

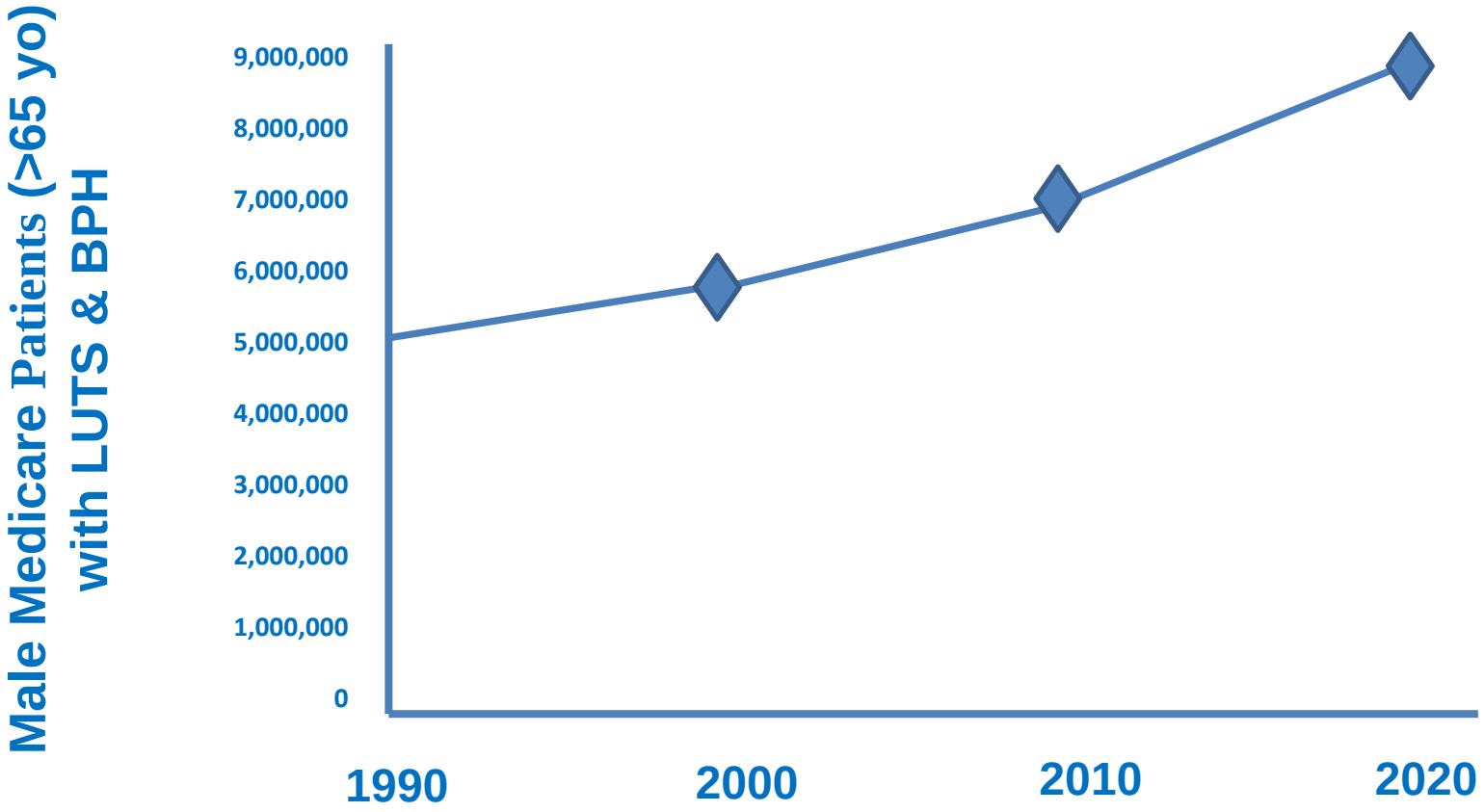
Normal Prostate



BPH with Constricted Urethra



Prevalence of Symptomatic BPH



Weiner DM et al. Urology. 1997;49:335-342.

TURP Complications

Clot Retention	16 %
Urethral Stricture	8.4%
Transfusions	7.0%
TUR Syndrome	0.9%
Incontinence	1.3%

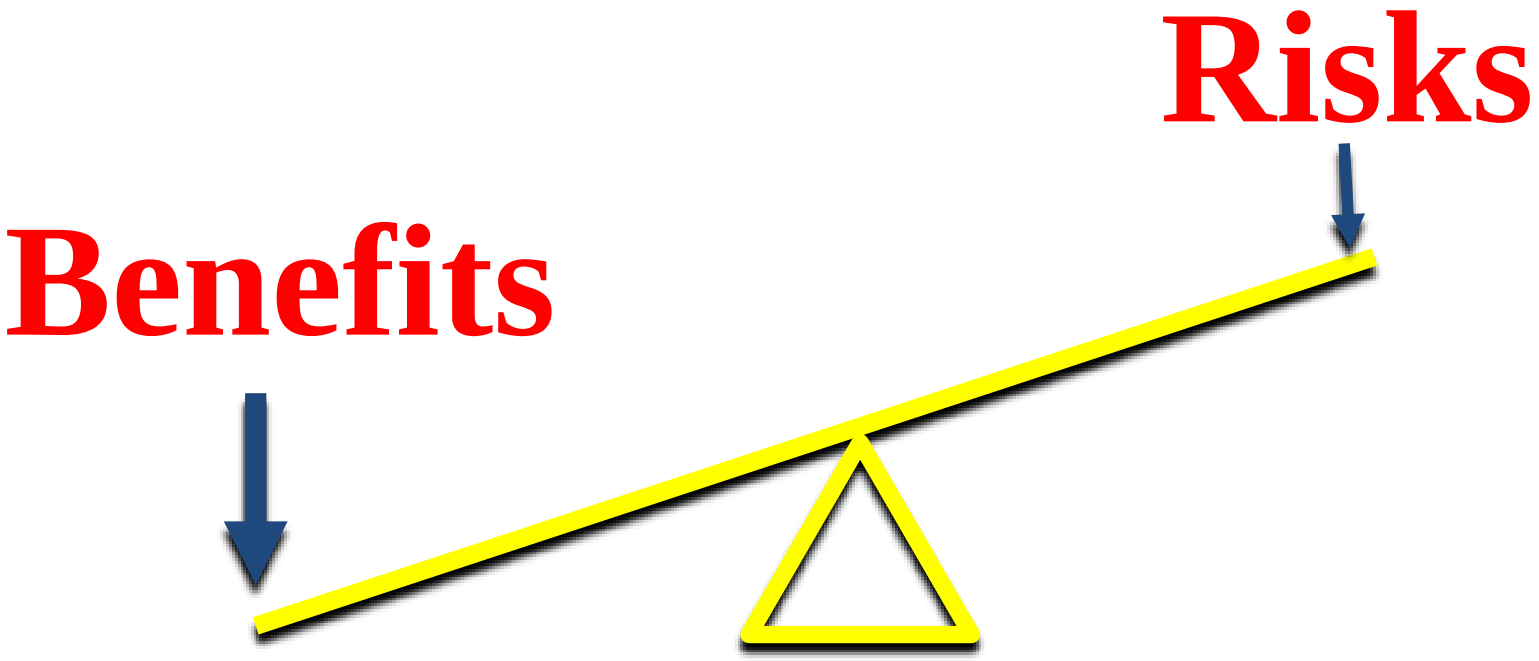
Hoffman RM, et al: J Urol 2003. 169: 210-215

Side Effects of BPH Drug Therapy

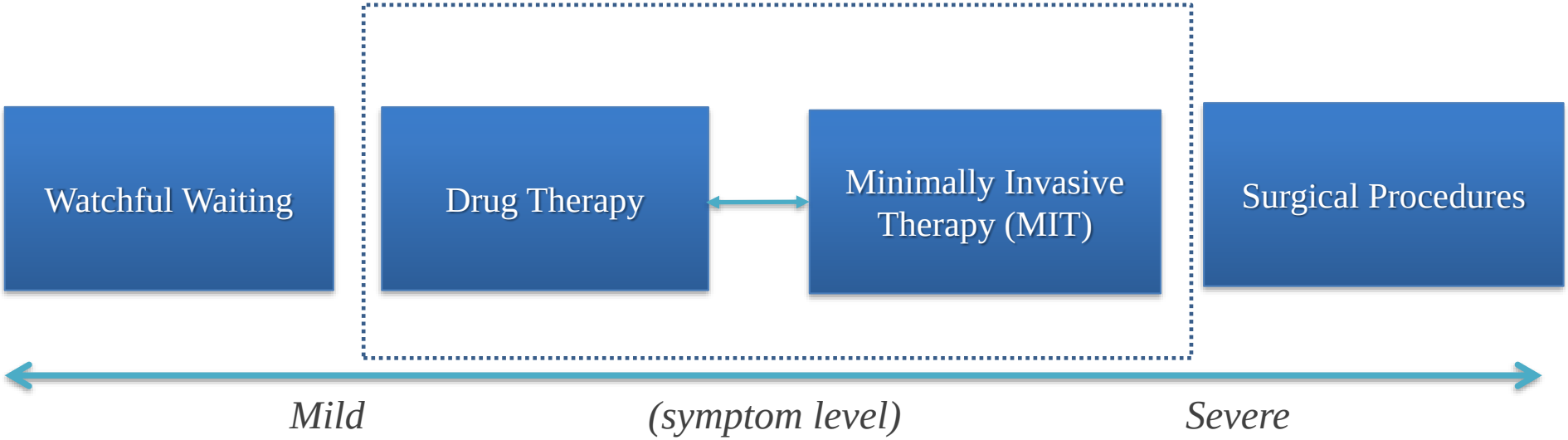
- **Alpha Blockers**
  - Dizziness & Syncope
  - Fatigue
  - Nasal Congestion
  - Diminished Ejaculation
  - Intraoperative Floppy Iris Syndrome (IFIS)

- **5 ARIs**
  - Erectile dysfunction
  - Decreased Libido
  - Diminished Ejaculation
  - Gynecomastia

Personalized Treatment for Symptomatic BPH

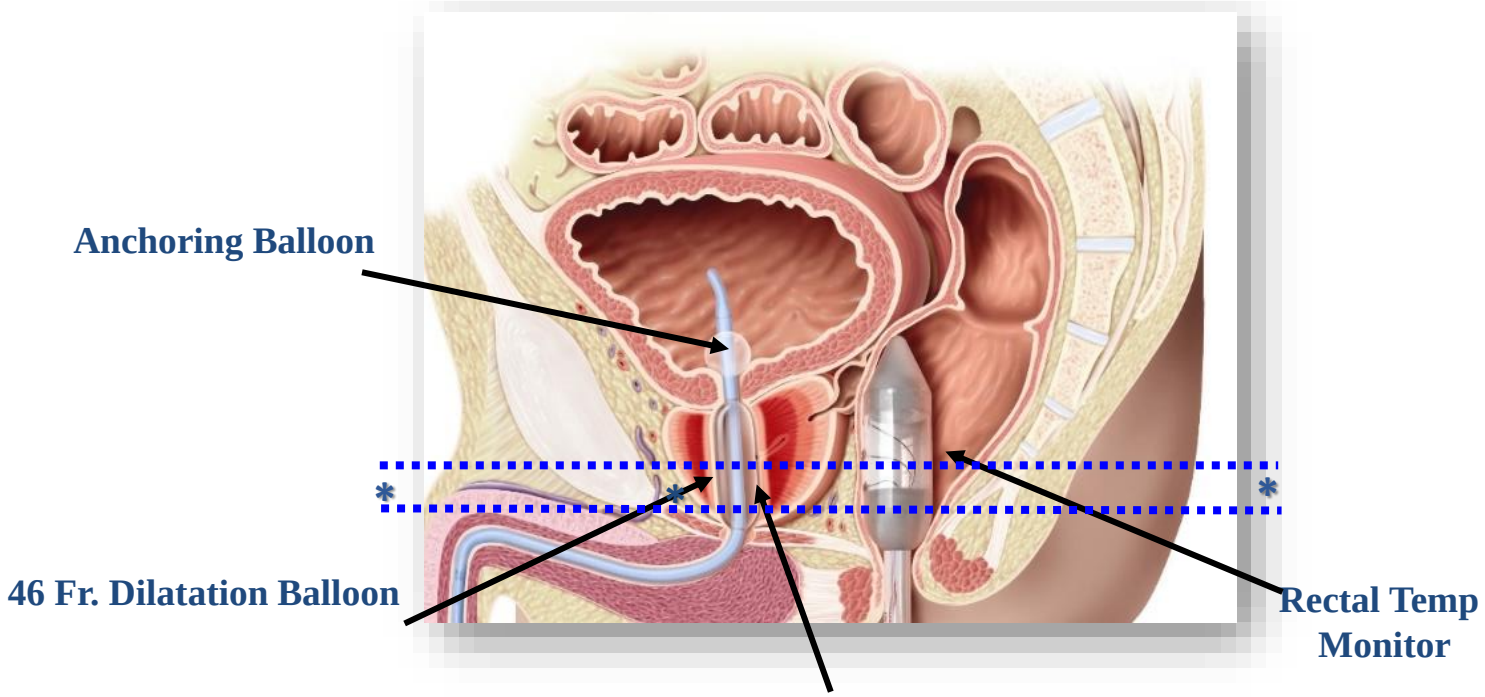


Treatment Algorithm for BPH Patients



Prolieve® Thermodilatation™

The Only Transurethral ThermoDilatation™ (TUTD ™) with a Patented 46 Fr. Dilating Balloon

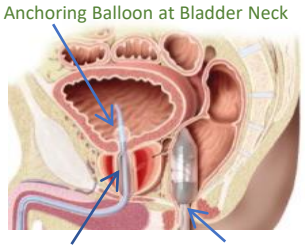


***A 1.2 cm Microwave Antenna is Positioned At the Base of the Prostate Gland**

Prolieve® Transurethral Thermodilatation™ Advantages
The Only TUTD™

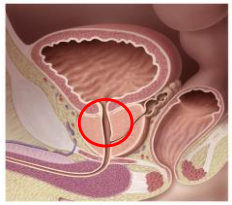
- **The Only TransUrethral ThermoDilatation™ (TUTD) with a Patented Dilating Balloon**
- **A 45-minute In-Office Procedure Performed Under Local Anesthesia**
- **Proven Safety and Efficacy Records - Over 100,000 Cases Performed in the U.S.**

BPH with Obstruction
Before Prolieve®
Treatment



Thermotherapy
Combined with
Balloon Dilatation

Rectal Temp.
Monitor



Patent Prostatic Urethra
After Prolieve®
(With a **Natural Biological Stent**)

A Safe & Effective Alternative to BPH Medications & Surgery

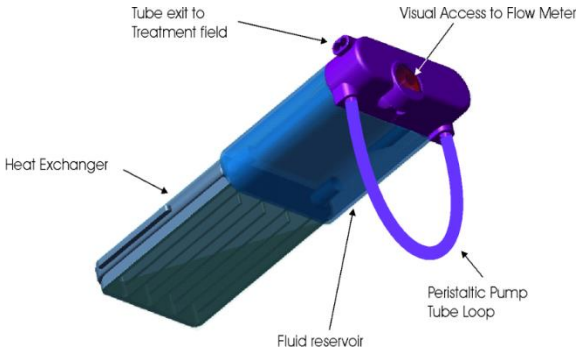
- ✓ **Minimal/No Sexual Side Effects (E.D. & Retrograde Ejaculation)**
- ✓ **Proven Long-Term Safety, Efficacy & Durability**
- ✓ **No Foreign Bodies/Clips/Anchors embedded within the Urinary Tract**
- ✓ **No Puncture of Prostatic Urethra to minimize Pain & Hemorrhage**
- ✓ **Improved Patient Comfort & No/Few Post-Treatment Catheterization**

"Prevention of BPH Progression"

12-Year FDA Post Market Study
of Prolieve®-Treated Patients with 5-Year Follow-ups
Now Completed and Accepted

- ✓ **85% Post-Treatment Catheter-Free Rate**
- ✓ **Minimal/No Sexual Side Effects**
  - *Erectile Dysfunction: 0.3 per 100 person-year*
  - *Retrograde Ejaculation: 0.3 per 100 person-years*
- ✓ **Improvement of Mean AUA Symptom Score**
  - *Baseline = 20.1 vs. Year 5 = 12.8*
- ✓ **Improvement of Peak Flow Rate (Qmax)**
  - *Baseline = 8.6 mL/sec vs. Year 5 = 12.8 mL/sec*
- ✓ **Improvement of Quality of Life (QoL) Score**
  - *Baseline = 22.0 vs. Year 5 = 16.5*
- ✓ **Stabilization of BPH Symptoms**
  - *83% reported No Progression at Year 5*
- ✓ **Stabilization of Serum PSA and Prostate Size**

The Prolieve® System



Clinical Applications of Prolieve®

FDA -approved Prolieve ® generating revenue

Prolieve ® + limited clinical study

Prolieve ® Focal Thermotherapy

BPH Market

- $150 MM (annual) minimally invasive treatment market in U.S. (1)
- $8 billion (annual) BPH drug market potential worldwide (4) (including potential patients on watchful waiting)

Prostatitis Market

- Unmet medical need worldwide
- 9% male suffer from prostatitis in their life time (3)
- $3.6 billion (annual) drug (Zithromax) market in U.S. alone (4)

Prostate Cancer Market

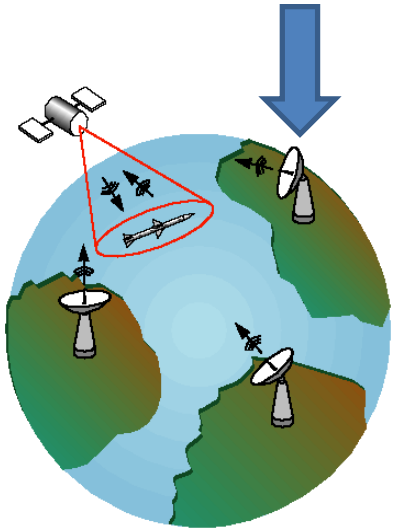
- 1.1 million male diagnosed with prostate cancer worldwide in 2012 (5)
- $17 billon in surgical, radiation and drug worldwide in 2012 and growing (6)

1) Medtech Insight
2) Decision Resources (estimated $4.8 billion BPH drug sales in major developed countries in 2010)
3) 2010 USA Census
4) Internal estimates
5) World Health Organization
6) BCC Research

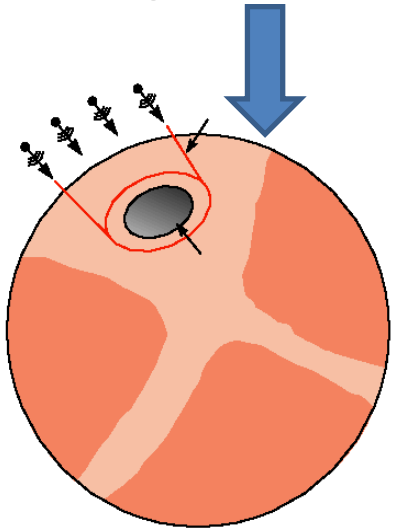
MIT Adaptive Phased Array Technology Platform (50 + Patents)

- Adaptive Phased Array (APA) technology originally developed by MIT for the Star War missile defense system, licensed exclusively to Medifocus for medical applications
- Directs precision-focused microwave energy at tumors to shrink or eradicate them without undue harm to surrounding tissue
- US$16M has been spent on developing the APA platform

To detect and destroy an enemy missile, microwave energy is targeted on it, simultaneously nullifying enemy jamming

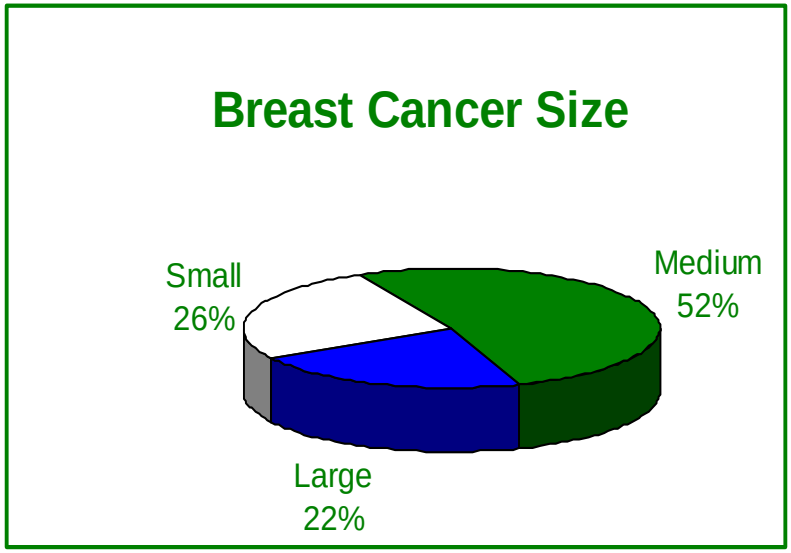


Microwave focused heat is targeted on the tumor while simultaneously nullifying any energy that would burn surrounding tissue



Breast Cancer Problems

- Over 2.0 million new cases of breast cancer diagnosed worldwide each year
- Patients and surgeons desire Breast Conservation Surgery (BCS)
- Neoadjuvant Chemotherapy attempts to shrink tumors prior to surgery to enable BCS (instead of mastectomy) – low success rate of approximately 22%
- Minimize Positive Margins after Surgery.
- Room for improvement to current SoC



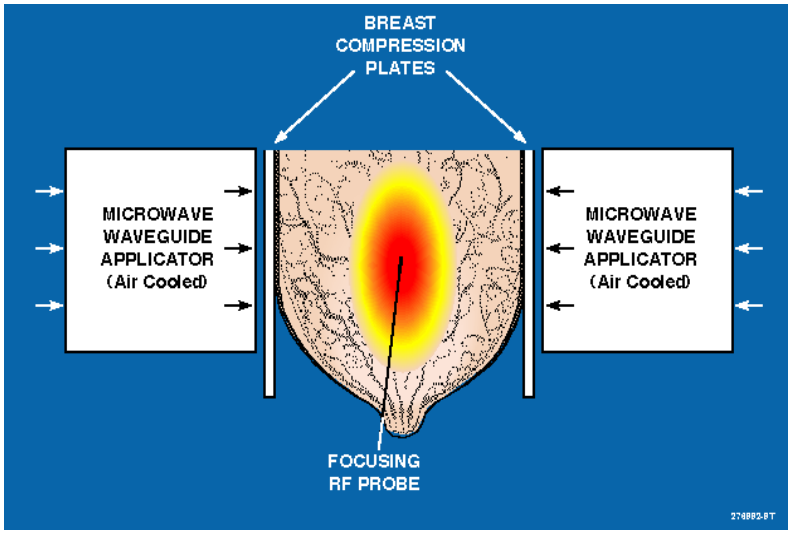
The Medifocus APA Solution

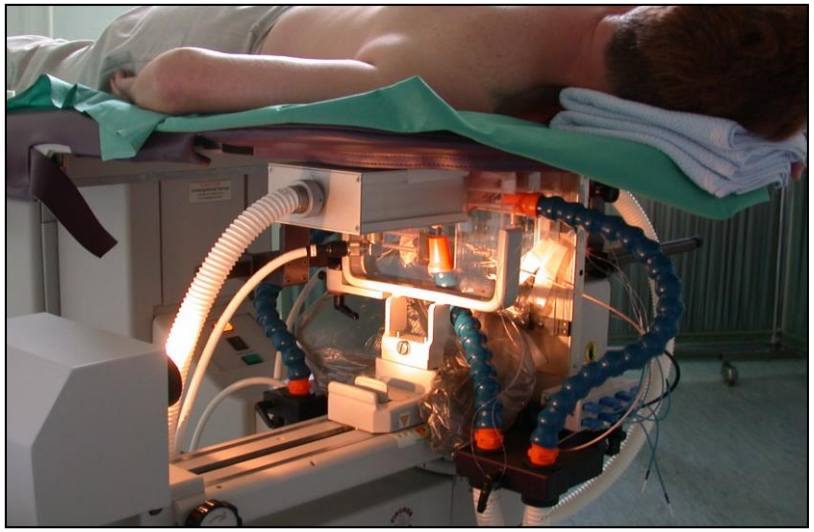
Huge Untapped Market for Breast Cancer Treatments: $16B Direct Cost in USA Alone

- Proven, proprietary, focused-heat treatment technology shrinks tumors and reduces tumor burden in the breast
- Medifocus team developed the system with patented technology from Massachusetts Institute of Technology (MIT)
- Positive results in initial FDA clinical trials
- Completed systems ready to enter its final pivotal clinical trial

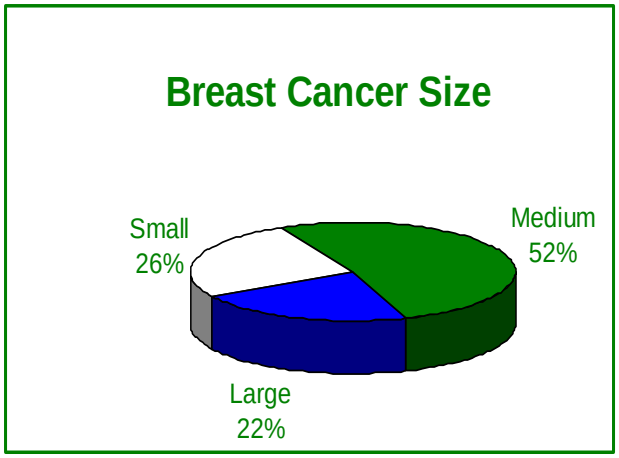
APA 1000 Breast Cancer System

- 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 ºC) combined with chemotherapy achieves an average of 88% tumor size reduction, improving surgical outcomes!





Breast Cancer Treatment Market Opportunity For APA Platform



Treatment Outcome	Chemotherapy Alone	Focused Heat + Chemotherapy
Tumor Size Reduction (Large Tumors)	58.8%	88.4% [1] ✔
Treatment Outcome	**Surgery Alone**	**Focused Heat +Surgery**
Positive Margins (Small Tumors)	10%	0% [1] ✔

[1]as demonstrated in Phase II clinical trials

- Large Breast Tumors – when focused heat is added to Neoadjuvant Chemotherapy, tumor size is significantly reduced thus can avoid the need for mastectomies. Chemotherapy alone - **low conversion success rate ≈ 22%*** from mastectomy to breast conservation**
- Small Breast Tumors – when focused heat alone is used prior to surgery – positive margin rate was 0% compared to 10% which did not receive the heat treatment – **potentially reducing recurrent rates**
- Medifocus Breast Cancer System can address majority of the Breast Cancer treatment marketplace

* Susan Komen for the Cure
**National Cancer Institute
***NSABP Study

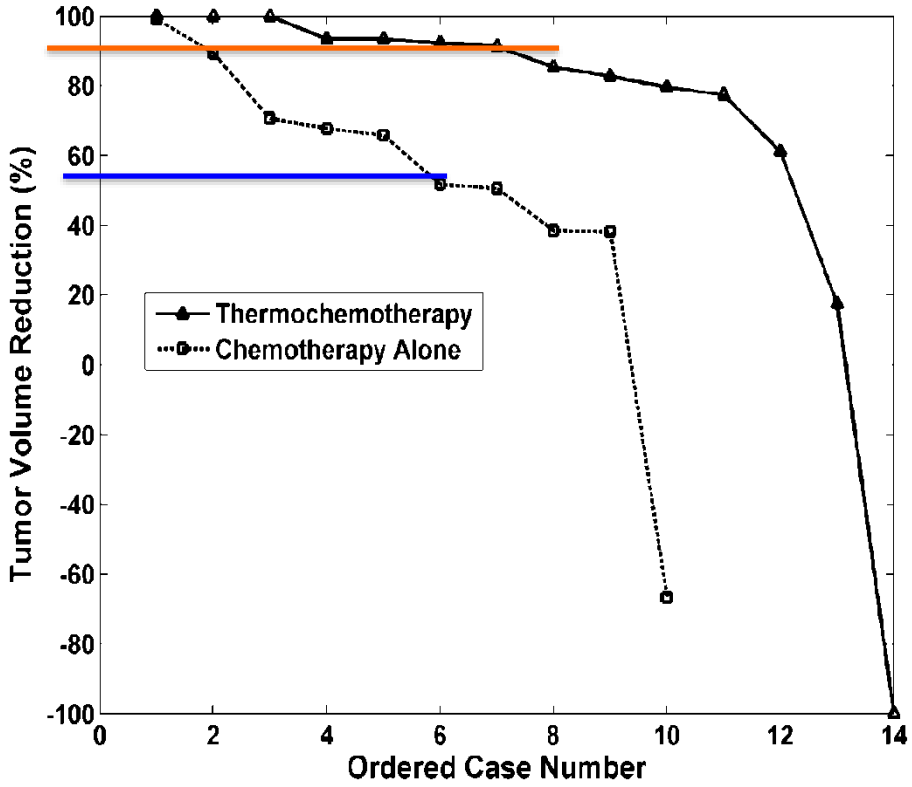
FDA Clinical Results

- **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, Feb. 2004)**
  - Established optimum safe heat treatment dose (25 patients)
- **Phase II FDA Multi-center Randomized Study** **(Vargas, Cancer Therapy, Vol. 5, published online Nov. 25, 2007)**
  - Patients indicated for mastectomy and neoadjuvant chemotherapy.
  - 40% additional improvement in tumor shrinkage when the Focused Heat System was used in conjunction with neoadjuvant Chemotherapy (34 patients)
- **Phase II FDA Multi-center Randomized Study** **(Dooley, Cancer Therapy, Vol.6, published online Aug 25, 2008)**
  - Patients with early stage breast cancer and indicated for BCS (Heat alone)
  - 0 of 34 had positive margins with Pre-operative Focused Heat and 4 of 41 or almost 10% had positive margins in the control arm. (75 patients)

Conclusion: Focused heat can be indicated for use to both early stage and large advanced stage breast cancer

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)

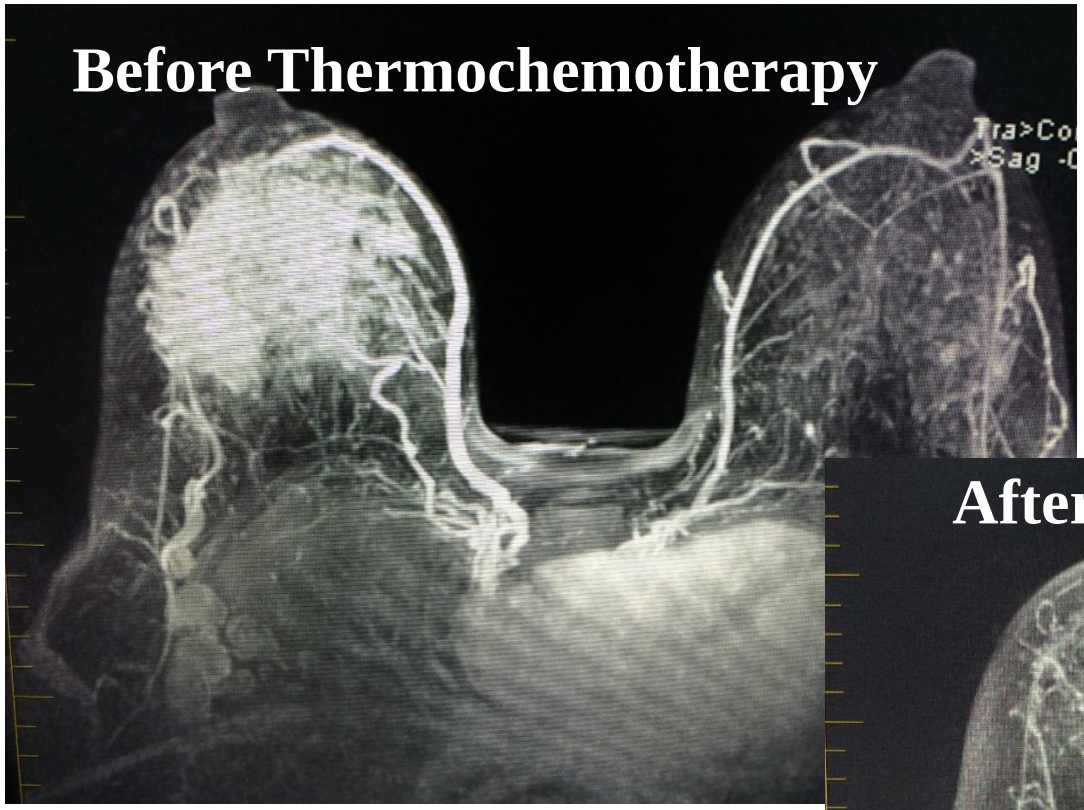
Chemo Alone: 58.8% (Median)

P=0.048

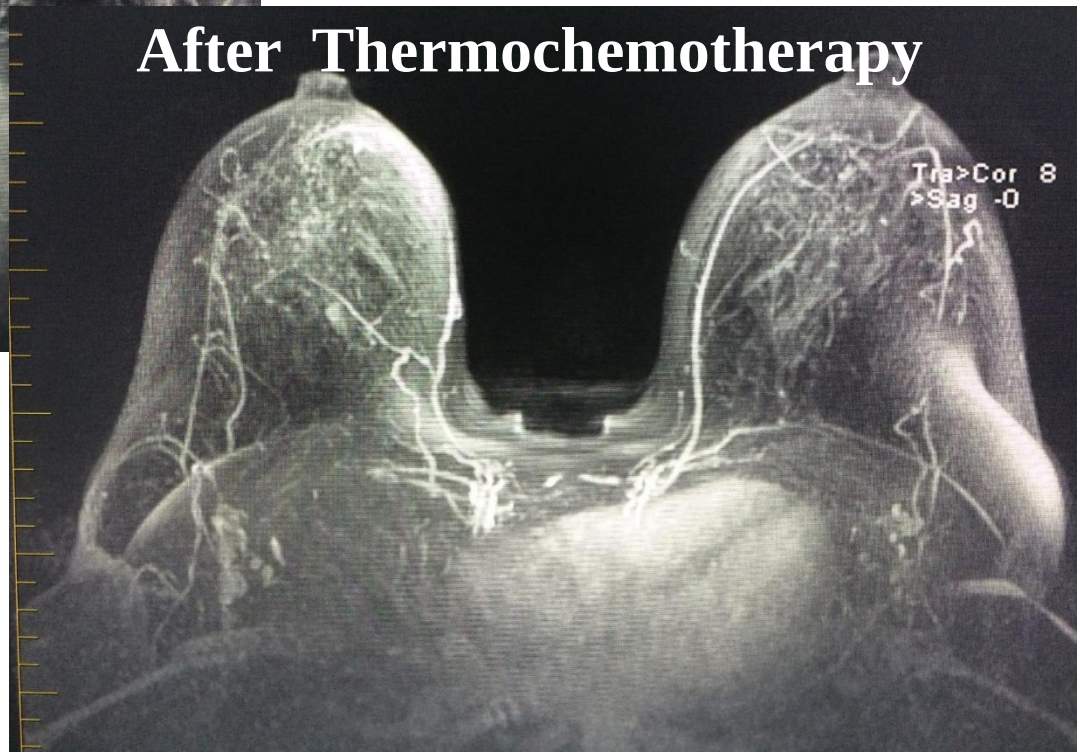
Vargas et al, *Cancer Therapy*, Vol 5, Nov. 2007

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

APA 1000 Phase III Case : Complete Clinical Response



40 y.o. Female
Right 9 cm Intraductal Ca
ER+, PR+, HER2-, Nodes+
Chemo x4: AD + AC + T
APA 1000 x3



Keyserlingk, et al., March 2015
-presented at the 25th Annual Interdisciplinary Breast Center Conference, Las Vegas, NV

Additional Breast Cancer Opportunity For APA

1. **Early Stage tumor:**

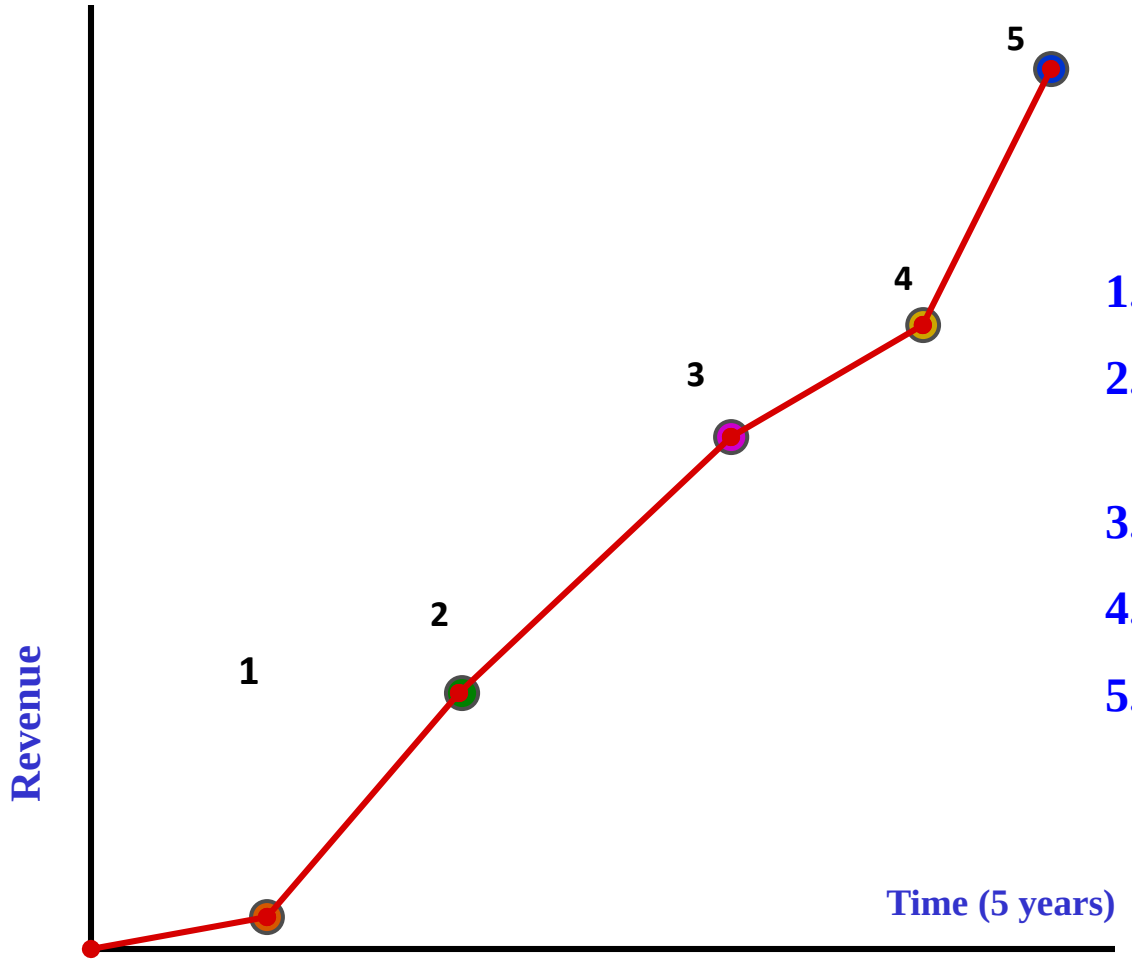
   - Develop early stage breast cancer study with partner or alone
   - Study protocol submission by TBD (study design and engineering cost: $100K)
     - Timeline for approval of protocol depends on FDA review and comments
   - Clinical sites will be the same as the locally advanced breast cancer study sites – significant cost and time saving to initiate study (Costs TBD)

2. **Recurrent Chest Wall (RCW)**

   - Submit RCW PMA supplemental approval to FDA by TBD (for early revenue). Costs for engineering, software and testing : $100K
   - No clinical trial for PMA supplemental approval is required **if used with radiation**
     - Timeline for supplemental approval depends on FDA review and comments
     - If approved, the target market will be the radiation oncology centers
   - Potential partnering with partner or go alone (clinical trials will be required for new indication of use with chemo or gene, cost and time TBD)

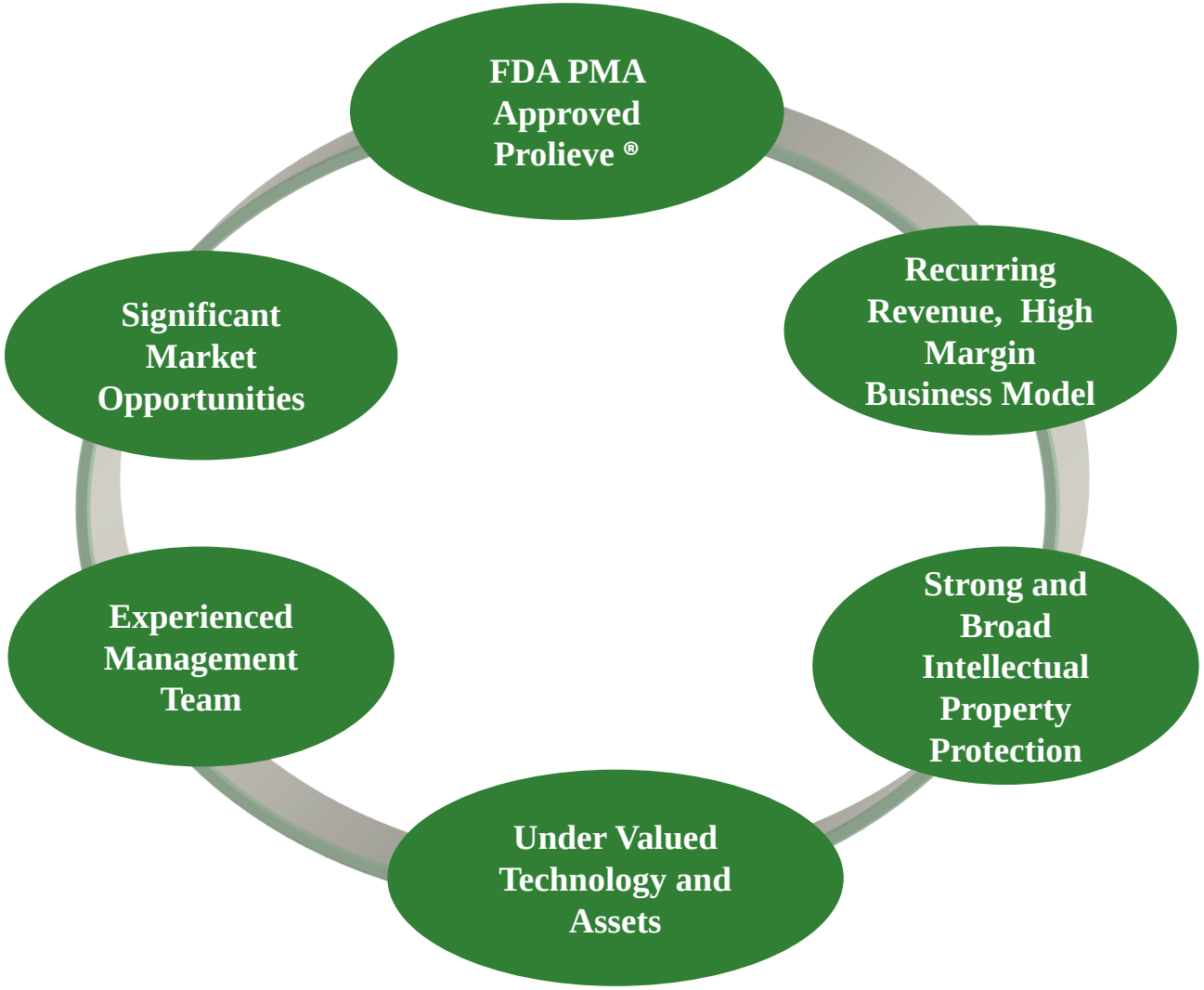
Completed APA 1000 Systems Ready for Pivotal Study

Value Proposition for Medifocus Breast Cancer Device



1. **Recurrent Chest Wall**
2. **Local Advanced Breast Cancer**
3. **Primary Small Tumor**
4. **DCIS Pre-cancerous**
5. **Benign Lesion**

Investment Highlights



- Issued shares: 180,000,000
- Market Cap.: $4 million
- $100 million were spent in the development and commercialization of Prolieve ®
- $16M has been spent on developing the APA platform

As shown in the last page, the Company‘s management has focused on improving operational efficiency and reducing expenses in the past two years, and achieved remarkable results. The current stock price has yet to reflect the value of the Company’s technology assets and potentials. If the funds are available in the future, the Company will increase its efforts in public relations and roadshows to increase the trading volume and value of the stock.