



**EHMET**health

# Mission

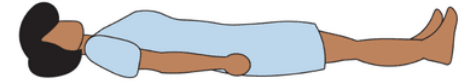
Provide breast cancer patients with access to radiation therapy that is safe, effective and cost-efficient.

Ehmet Health's MammoKnife™ precision radiotherapy is designed to deliver effective therapy while reducing or eliminating damage to the heart and lungs.

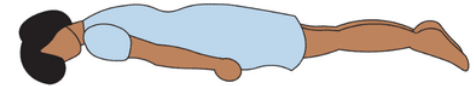
**“Women with breast cancer may be at increased risk of cardiovascular disease, including heart failure,”** *American Heart Association.*

# Current Standard of Care

- May damage the heart and lungs through the chest wall because patient is frequently dosed in supine or “face up” position.
- Even when treatment is performed in a prone or “face down” position, current radiation therapy devices have limited access to the breast.
- May burn or scar healthy skin and breast tissue requiring one or more reconstructive surgeries with undesirable outcomes and secondary complications.



**Supine**



**Prone**

# Current Standard of Care

## Current radiotherapy for breast cancer

**Is not designed for the breast.** *Current devices allow limited access to the breast and are not well suited to deliver modern treatment methods—advanced techniques already used in other types of cancer such as prostate and brain using both cyber and gammaknife procedures.*

**Is costly to install, operate and maintain.** *Site costs for current radiotherapy typically exceed \$6.5 million. Permitting process is lengthy and requires shielded bunkers, dedicated support staff, and substantial infrastructure.*

# Psychological Impact....Trauma

“How am I going to look after treatment?”



“What will this do to my body?”

“How does this negatively affect my health?”

“How will treatment impact my life?”

# MammoKnife Innovation

Ehmet Health is the first to offer self-shielded linear accelerators designed to treat breast cancer in the prone position and be deployed without the need for a vault.



*MammoKnife Animation*

# The MammoKnife Difference

## **Prone Positioning**

Isolation of breast from organs at risk for superior treatment and minimized secondary dose

## **Integrated Imaging**

With integrated target imaging we reduce the need for a separate CT simulator and allow for adaptive planning reimbursement and targeted treatment

## **360° Rotation**

Allows for delivery of optimized non-invasive accelerated partial breast, true intensity-modulated treatment plans, multi-target techniques, and radiosurgery of the breast while sparing healthy organs

## **Self-Shielded Structure**

Can be on a mobile platform allowing for a dramatically reduced cost of ownership in addition to a significantly lower installation timeframe

## **Leverage Current Standards**

6-MV Linear accelerator is the standard for whole or partial breast irradiation with boost, can be used for stereotactic surgery, compatible with most treatment planning systems and uses existing CPT codes for reimbursement

# Integrated Shielding → Treatment Mobility

May be deployed where patients are; not restricted to hospital radiotherapy facilities

Cost pressures are fueling a trend away from traditional hospitals to outpatient treatment in lower-cost, specialty-focused centers

Attractive reimbursement for therapeutic in contrast to diagnostic procedures

May significantly multiply the revenue stream of free-standing specialty centers while reducing the cost of treatment



# Unmet Needs: Rural Radiotherapy

One-fifth of women live in rural areas representing 70,000 new cases

Only 3% of all radiation oncologists practice in rural areas; over 70% (2,100+) of counties in the United States do not have a radiation oncologist

Average rural patient travels at least an hour each way for treatment, increasing the cost of treatment and impact on both economic and family well being

The MammoKnife's compact design extends treatment options both in low income and rural areas improving the level of care and reducing the patient's costs

[Challenges of Rural Cancer Care in the United States, Journal of Oncology, September 2015](#)

# Mobile Product Development

## Mobile Platform

[\*Click to play 3D design animation\*](#)



The MammoKnife's design as a compact self-shielded device allows for deployment on a standard trailer allowing for a first of its kind platform delivering precision therapy in a mobile setting.

Further development may deliver a turn-key system that can be deployed to any urban or rural location partnering with community medicine and outpatient centers.

# Worldwide Market

## \$6 Billion Market Potential

The MammoKnife market includes not only traditional treatment centers, but surgery centers, women's health centers and outpatient clinics already expanding service to include oncology

16,675 Estimated Global Market (Units needed for treatment of all estimated cancer cases)

- US & Canada – 3,650 Units
- European Union – 3,500 Units

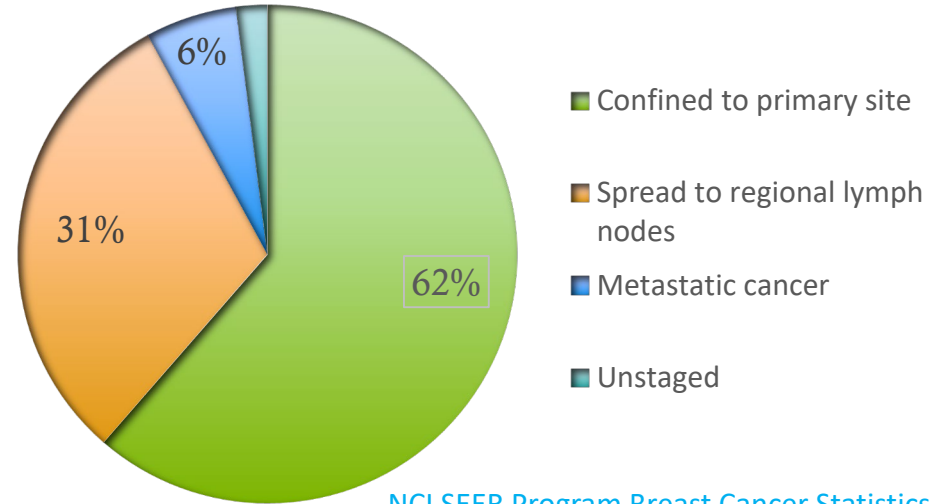
Additional potential markets worldwide based on small footprint and limited facility requirements

[Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries, CA: A Cancer Journal for Clinicians](#)

# Lumpectomy + Radiation

“For women with early-stage breast cancer ..., studies indicate that breast-conserving surgery plus radiation therapy results in long-term outcomes equivalent to, and possibly even better than, mastectomy.”

[Cancer Facts and Figures 2018, American Cancer Society](#)



[NCI SEER Program Breast Cancer Statistics](#)

More than 60% of patients may be candidates for lumpectomy and/or precision MammoKnife radiotherapy.

# Breast Cancer Ehmet Health Market

\$4.2 Billion market, 10 Year Mammoknife Device Sales Revenue

- Estimate capturing 10% of global market in a 10-year sales period
- Pay per use model
- 1668, units sold with a \$2.5M List Price = \$4.2 Billion

\$375 Million Annual Maintenance Revenue (8-10% of selling price)

- Maintenance revenue begins second of year of device ownership
- Device service life estimated at 7-10 years

Additional Revenue Sources

- Mobile market introduces additional direct sales or leasing options
- Leases can be daily, weekly, or monthly depending on health centers' needs

# Revenue Potential

## \$4.2 Billion 10 Year Device Sales Revenue

- Estimate capturing 10% of global market in a 10 year sales period with single unit sales
- Pay per use model
- 1668 units sold with a \$2.5M List Price = \$4.2 Billion

## \$375 Million Annual Service Revenue (8-10% of selling price)

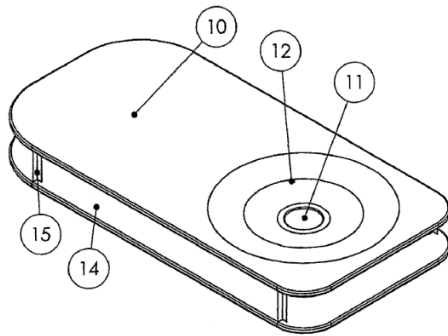
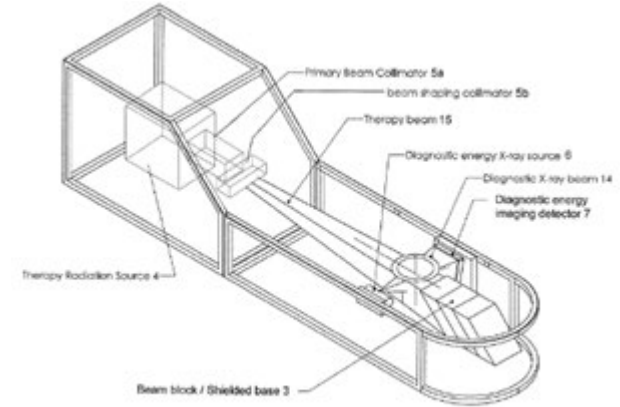
- Service revenue begins second of year of device ownership
- Device service life estimated at 7-10 years

## Additional Revenue Sources

- Mobile market introduces additional direct sales or leasing options

# Patent Position

**US Patent 7,526,066** issued April 28, 2009. This issued patent covers the MammoKnife self-shielded radiation therapy machine and carves out space for the self-shielded system in the particular configuration of the prone breast system we have developed into a working prototype.



**US Patent 8,272,088** issued Sep, 2012. “Patient support system for full access prone position breast radiotherapy.” This patent covers the ClearVue™ table and the design principles embodied in it.

**US Patent 8,483,354** issued July 9, 2013. “Reducing imaging artifacts.” This patent covers the anti-artifact insert for the ClearVue™ table and other patient support devices.

# Leaders in Innovation



Products developed by team members include:  
MiniCAT ENT CBCT Scanner, XCat Portable CBCT Scanner,  
XoranConnect Online Viewer, NeuMoDx 288 Molecular System, NeuMoDx 96  
Molecular System, ClearVue Imaging Board, Mevion S250 Proton Therapy  
System, i-CAT Dental CBCT Scanner, PhotoElectronCorp Photon Radiosurgery  
System and INTRABEAM (Acquired by Zeiss International), industry first  
commercial 3D SPECT reconstruction and cardiac multiplanar software  
(Medtronic/Medical Data Systems)





# Grant Funding

**The MammoKnife team developed the proof-of-concept system with a \$2.1mm NIST ATP grant and is currently collaborating on follow on submittals with members of the world's leading cancer programs.**

- NIH Small Business Innovation and Research (SBIR)
  - Phase I – proof of concept: \$225K 1 year
  - Phase II – development: \$1.5mm total 2-3 years
  - Above budget limits can be exceeded for cancer treatment devices
- NIH Academic / Industrial partnership grants
  - Focus on commercialization of promising technology (in contrast to research)
  - 3–5 year project funding ~\$650K / year (more with NIH approval)
  - Requires at least one industry and one academic partner
  - Several grant applications anticipated
    - Basic MammoKnife development / commercialization
    - Advanced imaging for integrated treatment planning
    - Integrated diagnostic breast imaging and biopsy
- Anticipate a mix of the above grant instruments for funding development

# Grant Funding

- Non-dilutive, complementary capital for development
- Project scientific personnel have long history of grant-funded research
  - Team-members have been fully grant-funded for 30+ years as either principal or co-investigator on NIH, DoE, and DoD grants
  - Guided grant-funding strategy at conebeam CT spinoff (\$6.6mm SBIR awards)
- ~\$2.1mm NIST ATP grant funded development and testing of MammoKnife prototype
  - Follow-on grant funding will be sought through various NIH National Cancer Institute programs Basic MammoKnife development / commercialization
  - Advanced imaging for integrated treatment planning
  - Integrated diagnostic breast imaging and biopsy

# Platform Technology

Ehmet Health will create designs with inherit scalability and modularity resulting in shorter development cycles for future products and markets.

## INTELLECTUAL PROPERTY



- Pediatric Extremity Treatment
- Robotic Guided Needle Biopsy
- Ultrasound Tumor Ablation

# Potential Value for Partners

An expanded market reach to broader rural America and urban communities:

- Installing MammoKnife at cancer centers, outpatient surgery centers, and women's health centers allows partners to increase services and availability
- System will provide additional branding and marketing opportunities
- Corporate owned Mobile MammoKnife units could be leased to multiple health care systems creating new revenue opportunities and extending market reach for partners

Access to End-to-End data and statistics for diagnosis and treatment

- Apply AI and deep data analysis to improve effectiveness of current solutions
- Streamline future research and enable faster integration of new technologies

# Offering

Ehmet Health is seeking up to \$5mm in initial funding with an additional \$15mm over the course of the next 36 months:

## Use of Proceeds:

- First commercial version of MammoKnife for 510k testing and further development
- Established research and development collaborations units with 4 premier healthcare systems for clinical development with 10 additional in progress
- Introduce precision radiation therapy to the global community through broad social media, additional partners and trade show presence
- File additional patents supporting further functionality and use

# Achievements

**2016**

Ehmet Health formed with the driving premise of commercializing medical devices serving unmet needs in the medical field

**2017**

Awarded first multimillion-dollar contract by one of the largest healthcare systems and a national cancer institute center to design and implement an advanced robotic imaging solution for a first of its kind proton radiotherapy center

**2018**

Received FDA 510(k) for its X-Ray positioning system and led multidisciplinary team to patient treatment at a center previously mired in delay

**2019**

Further developed imaging positioning system to establish center as one of the highest volume openings over first six months of any proton center worldwide.

# Management Team

**Michael Teicher**, *Chief Executive Officer*, brings over 20 years of operational, financial and advisory leadership on healthcare strategy, operations, and capital markets.

**Neal Clinthorne**, *Chief Technology Officer*, is a world-renowned Research Professor Emeritus in Radiology from the University of Michigan. He has written nearly 100 peer reviewed articles and has been granted over 20 patents in the area of advanced medical imaging technology.

**Alan Sliski**, *Chief Scientific Officer*, is a prolific entrepreneur and scientist with a specialty in radiation therapy systems. Mentor in residence at the prestigious Harvard physics facility and holds 24 patents.

**Michael D Kaswan, MBA, CFO**, is a seasoned healthcare executive with nearly 20 years of finance and operational administration in both the public and private sector. Michael is a Harvard MBA and has held numerous executive roles.

**Julia E. Williams**, is an advisor and Global Director, Oncology Services & Solutions for ZRG Partners specializing in cancer and research for the last 18 years and is a sitting member on both National Cancer Committees advisory council to the Koman foundation.

**\*Collectively the founders have created devices the have generated over 7 billion dollars in revenue.**



# Advisory Team

**Greg Lane**, Executive Vice President and Chief Administrative Officer of McLaren Health Care Corporation. Greg is a graduate of the University of Michigan and received his Juris Doctorate from Detroit College of Law, where he served as Editor-in-Chief of the Law Review. Prior to joining McLaren, Mr. Lane was in private legal practice and specialized in corporate and health care law. Mr. Lane is the current 2018-2019 Chair of Michigan Health and Hospital Association (MHA). Mr. Lane also serves on several other Boards, and his professional affiliations include the State Bar of Michigan, the American Bar Association, the American Health Lawyers Association and the American College of Healthcare Executives.

**William (Bill) Anderson**, William Anderson is a C-level executive and a seasoned marketer, merchandiser, and start-up entrepreneur with global experience. Bill served as the Chief Marketing Officer and Chief Merchandising Officer for Carrefour a \$135 billion dollar retailer with a world-wide market presence. He has previously held senior merchandising and marketing, positions at similar companies including Federated Department Stores, Ames Department Stores and Oshman's Sporting Goods. He is also an experienced start up entrepreneur having founded Domain Home Furnishings (home furnishings retail), Leisure Concepts Management (real estate investment), and Gluuteny, Inc (gluten-free bakeries), with private equity backing. Mr. Anderson holds a BS from Columbia University in Industrial Engineering & Operations Research and an MBA from Harvard Business School.

**Ari I. Wirtschafter MD.**, double Board Certified in Otolaryngology-Head and Neck Surgery as well as Sleep Medicine. Dr. Wirtschafter is currently Chief of Surgery at Boca Raton Regional Hospital, and Co-Chairman of one of the nation's largest ENT practices in the United States. Dr. Wirtschafter was named Otolaryngologist of the Year for 2011 for the State of Florida. He is Past President of the Florida Society of Otolaryngology - Head and Neck Surgery, and is the state representative to the Medicare Advisory Committee for the State of Florida, Puerto Rico and the Virgin Islands. Dr. Wirtschafter is also an Executive Board Member of the Network of Florida Otolaryngologist as well as an Assistant Professor - Florida Atlantic University College of Medicine.



# Pro Forma for 2020 and Beyond

	Year 1	Year 2	Year 3	Year 4	Year 5
Orders	-	-	14	22	37
MammoKnife Backlog	-	-	\$24,500,000	\$38,500,000	\$64,750,000
Units sold per year	-	-	5	12	31
<b>Revenue</b>					
Equipment	-	-	\$8,750,000	\$21,000,000	\$54,250,000
Services	-	-	-	\$750,000	\$1,800,000
<b>Total Revenue</b>	-	-	\$8,750,000	\$21,750,000	\$56,050,000
<b>Total COGS</b>	-	-	\$4,250,000	\$10,762,500	\$27,700,000
<b>Gross Margin</b>	-	-	\$4,500,000	\$10,987,500	\$28,350,000
R&D	\$4,086,059	\$4,959,986	\$4,176,752	\$5,847,453	\$7,601,689
SG&A Expenses	\$1,146,941	\$1,662,286	\$2,108,992	\$3,690,736	\$6,274,251
<b>Total Operating Expenses</b>	\$5,233,000	\$6,622,272	\$6,285,744	\$9,538,189	\$13,875,940
<b>EBITDA</b>	<b>-\$5,233,000</b>	<b>-\$6,622,272</b>	<b>-\$1,785,744</b>	<b>\$1,449,311</b>	<b>\$14,474,060</b>

Note: 2019 estimated total revenue of \$905,000 with breakeven net profit.

