



EXECUTIVE SUMMARY

Ehmet Health is addressing a 4-billion-dollar worldwide market with a precision radiotherapy device dedicated to the treatment of breast cancer. A Delaware entity with offices in Plymouth, Michigan, Ehmet Health was founded with the goal of commercializing devices that serve unmet needs and drive better outcomes for patient, provider and payor. We are a consortium of health care focused engineers, scientists and executives from diverse backgrounds that have collaborated to bring a sense of integrity and execution to the device industry.

Our offices are within the complex of our manufacturing partner and member of our founding team. The facility, an FDA class 1, 2 and 3 manufacturer has been delivering devices to global leaders such as Stryker, Medtronic as well as numerous other fortune 50 companies for decades.

Team members have an extensive history of successful involvement in the medical device development and business communities with emphasis on imaging and radiation therapy. Recent accomplishments include being a key member in completing a first of its kind proton therapy center as well as designing and obtaining FDA 510(k) clearance for its robotic imaging system for in use at the center. Historically, founding members have been first to market to deliver a compact accelerator for proton therapy, point-of-care CBCT, and introducing low-dose image reconstruction techniques for dual- and multi-energy CT. Collectively the team has developed products that have generated over 7 billion dollars in revenue.

Our driving principle is simple: Execute.

The Problem

Each year, Europe and the US alone see over 650,000 new cases of breast cancer with more than 178,000 deaths. To put this into context, imagine a Boeing 747 crashing everyday throughout the year filled with our mothers, daughters, sisters and friends—all from a disease that claims a 95% cure rate. Breast cancer remains the leading cancer in women with a lifetime incidence of one in eight. One quarter of the workload in a typical radiation therapy department is breast cancer treatment and represents the largest proportion. While radiation therapy has benefitted from many advances, therapy equipment and techniques for breast cancer have barely changed in the last decades. Current equipment, designed primarily for the treatment of deep-seated tumors, offers limited access to breast anatomy and is not well suited to deliver modern treatment methods—advanced techniques already used in other types of cancer. Several important issues and trends are affecting the current landscape of breast radiotherapy.

- Long-term complications in breast cancer treatment due to secondary radiation dose is supported by volumes of clinical data. For the first time in history, the American Heart Association issued a warning of the cardiac risks associated with secondary toxicity during treatment most notably for left breast.
- Early detection and modern treatment protocols are leading to longer survival. The focus is now shifting to long-term morbidity associated with conventional breast radiation therapy, better cosmetic outcomes, and

economics. Medical practitioners have initiated protocols to better isolate breast tissue from the rest of the body to reduce complications as well as to deliver more precise breast treatment. Nevertheless, setup time for these protocols is longer than with conventional, supine treatment.

- Advances in radiotherapy allow more complex treatments but increase procedural time increasing the number of machines required for a given patient volume. Given current and forward-looking reimbursement trends, costs associated with radiotherapy machines are economically troubling. Coupled with a rise in the number of cancer patients due to an aging population, increasing life expectancy, and better cancer detection, the demand for efficacious *and* economical treatment devices continues to increase.
- Access to high-quality cancer treatments in both low income and rural areas according to the US Center for Disease Control (CDC) remains a challenge resulting in significantly higher cancer death rates in these drastically underserved communities—not just in the United States but globally.

These issues create an opportunity to provide patients with an innovative tool that not only disrupts current standards but also can bring treatment closer to home. The success of anatomy-focused devices such as the Cyberknife and Gammaknife clearly demonstrates that dedicated devices are not only a true differentiator for a healthcare system but more importantly produce desirable outcomes.

The Solution

The patented Mammoknife is a self-contained, self-shielded radiotherapy instrument dedicated to breast radiation therapy. Treating the breast in the prone position, it avoids secondary heart and lung toxicity associated with conventional radiation therapy. Full 360° breast access allows the radiation dose to be spread over multiple angles potentially improving cosmetic results. Designed solely for breast radiotherapy, the Mammoknife allows radiation oncology sites to free-up significant time on their general-purpose, expensive linear accelerators by moving most breast patients to our device. Self-shielding allows deployment *without the need for a conventional radiation-shielding bunker*, in some cases costing more than \$5M. Mammoknife's siting flexibility enables facilities such as women's health clinics, surgery centers and outpatient centers to offer the profitable business of radiation therapy often much closer to the patient's home. With its self-shielded design, the unit can be deployed as part of a mobile operation allowing precision radiotherapy to areas that currently either do not have facilities within proximity or low-income areas—both historically underserved (CDC 2017).

Being “substantially equivalent” in that it can perform the same treatments as presently marketed devices, **the MammoKnife qualifies for the FDA 510(k) regulatory clearance pathway and does NOT require clinical trials. Moreover, reimbursement codes in the United States for the therapies delivered by the machine are already in place.** This greatly simplifies the path to market and removes significant risk and cost of commercialization.

What's Required

Ehmet is currently seeking a Series A round of \$5mm and up to an additional \$10mm over the next 24 to 36 months for commercialization and delivery of our first five units. We intend to supplement growth thereafter through venture debt of up to an additional \$25mm for the acquisition of inventory to meet demand. At the end of the initial financing period over the course of the next 24-36 months we will have FDA and CE clearance and clinical units in operation in both the US, Europe and Africa. Our current business plan is based on independent operation leading to profitability. We have completed the technical milestones and have demonstrated the concept with prototype and clinical collaboration.

Mission

Ehmet Health will become the standard to treat the number one disease in women: breast cancer. We will achieve this with our initial devices by delivering superior clinical solutions specific to this anatomy isolating critical organs from unnecessary radiation and dramatically reducing unwanted whole-body dose at the lowest price point in the industry. In addition, to the potential for defined better cosmetic outcomes, which according to 90% of women surveyed is a key consideration when deciding care, our technology will address the financial needs of our customers and shareholders, and account for current and future reimbursement practices. Following successful commercialization of the breast radiotherapy device, we intend to apply our platform technology to develop other self-shielded devices for general-purpose radiotherapy.

Summary

While there are areas of innovation that evolve quickly such as evidenced in other areas of technology, others barely move. The treatment of breast cancer with radiation is one. As recently as earlier this year, one of the most effective ways recommended by clinicians to reduce secondary complications is known as deep breath hold. In this day of artificial intelligence, self-driving vehicles and DNA-specific therapeutics, if the best we can do for women is ask them to hold their breath during radiation treatment, what have we as innovators really given them? Ehmet Health believes there is a better way and the Mammoknife is that solution.

Ehmet Health will deliver a precision radiotherapy device dedicated to the treatment of breast cancer that will reduce secondary complications, and potentially greatly improve cosmetic outcomes. The ability to deploy these units without the need for a vault or excessive shielding creates a new paradigm in the delivery of care, defining it as the new standard. Our team is currently working with an NCI cancer center and their leading breast specialist identifying the best methods and techniques that will be required in order to reach the hundreds of thousands of patients worldwide. When matched with the only available system for radiation therapy to be administered in a mobile setting, we have the potential to create a global brand, a true differentiator that academics will use for new research, community hospitals and clinics to attract new patients, and that providers in emerging markets will need to serve a rapidly growing population.

"Mammoknife is not just a product, it is a movement that will create a global brand by bringing life-saving technology to women in segments, both demographically and geographically, that were neglected before. The ability to address these needs and save lives will allow the Mammoknife to build a strong social media presence; a true product and company differentiator in the healthcare vertical today." Michael Teicher CEO for Ehmet.