Thermatome Corporation

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BUSINESS PLAN – NOVEMBER 2015

SUMMARY:

Thermatome will have measurable impact on the lives of millions of women and their families. We fill a need in the marketplace and have a clear path to commercialization.

Thermatome is developing patented medical devices that have the potential to save millions of women with breast cancer, and their families, significant time and cost (financial, economic, physical, emotional and psychological).

Our product is a heated balloon catheter system to treat residual cancer following breast cancer lumpectomy surgery, providing women with an alternative to weeks of costly, and potentially harmful, daily radiation treatments following surgery.

Thermatome addresses a large and growing segment of the breast cancer treatment market, both domestically and globally, with a high gross margin disposable balloon catheter device that should provide attractive growth, revenue, net income and investor returns.

PROBLEM:

One of every eight women in the US will be diagnosed with breast cancer in their lifetime. A majority will be eligible for Breast-Conserving Therapy (BCT), consisting of lumpectomy surgery to remove the tumor, leaving the breast intact, followed by radiation to treat residual cancer.

Radiation therapy requires daily treatments for up to six weeks following surgery, causing significant time away from family and work. Radiation also has potential toxic and harmful side-effects including pain, burning, deformity and fatigue, as well as possible long term effects on the heart, lung and ribs, and costs payers up to $40K per patient.

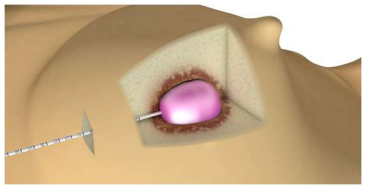
Over and above treatment costs, there is a minimum annual economic burden of $200 million in the US, resulting from radiation therapy, due to time away from work and family, travel, day care and other expenses. In addition to patients, this burden falls heavily on working women whose mothers, or other relatives, require assistance getting to and from daily radiation treatments.

As many as 20% of women discontinue their radiation treatment plan before completion, increasing their risk of cancer recurrence.

There is a 25% re-excision rate for lumpectomy, resulting from unclear surgical margins found in pathology post-surgery, requiring the patient to return for re-surgery. Re-surgery results in more time away from work and family, in addition to the potential emotional and psychological effects of re-surgery, and places a financial burden on providers, who absorb the additional cost treatment.

SOLUTION:

Thermatome addresses these issues with a balloon-catheter and control unit system. A one-time, 20 minute procedure, performed by surgeons immediately following lumpectomy. The balloon is placed in the lumpectomy cavity and filled with saline fluid, conforming to fit the irregular shape of the cavity. The fluid is heated to uniformly raise tissue temperature in a uniform 1cm zone around the balloon, necrotizing the tissue and destroying residual cancer cells. The fluid is then drained and the device is removed.



Heated balloon catheter destroys residual cancer cells

With this treatment, women will avoid radiation therapy and the associated costs, side effects and time away from family and work.

MARKET:

There are 295K new breast cancer diagnoses annually in US, 180K are eligible for BCT. Total annual breast cancer diagnoses are expected to be 440K by 2030, with much of the growth coming in early stage cancers (BCT candidates). The annual addressable market for Thermatome devices in the US is $450M. Worldwide there are more than 1.7 billion breast cancer diagnoses annually. Assuming that 50% of these women are eligible for breast conserving lumpectomy surgery, this represents 850,000 procedures each year worldwide where Thermatome devices could be utilized; a potential addressable annual global market for Thermatome devices of $2 Billion.

As early detection techniques continue to improve and to be utilized more broadly, the worldwide use of lumpectomy, followed by treatment of residual cancer, can be expected to increase.

Thermatome has identified patient populations that are likely early adopters including those patients who had previous BCT, and have local cancer recurrence (these patients can't be re-treated with radiation in same breast, and face mastectomy as their only surgical option), and BCT eligible patients, who currently choose mastectomy to avoid cost, travel and/or side effects of radiation.

REGULATORY:

A regulatory assessment of Thermatome devices has been completed by EdgeOne Medical, a Chicago regulatory consulting firm.

The results of the assessment indicate that Thermatome's technology does not currently have an associated FDA regulation and product code necessary to determine a predicate device required for FDA 510K clearance. However, because 1) the general intended use (soft tissue ablation) of the Thermatome devices is considered moderate risk, 2) the temperatures and time durations of use are equivalent to other class II thermal ablation devices, and 3) thermal ablation is well understood by the FDA, a class II clearance through the FDA's the *de novo* process is the pathway to FDA clearance for Thermatome. Initial informal discussions with FDA have validated this assessment.

Early in the next product development phase, a pre-submission package will be submitted to FDA to solicit guidance and feedback on the proposed de novo submission plan, indication for use, animal testing plans and on the likely regulatory controls necessary to provide a reasonable assurance of safety and effectiveness.

Thermatome plans to submit for FDA de novo clearance as a Class II medical device, with general intended use of soft tissue ablation (cell destruction), in 2016. FDA de novo clearance will be followed by limited product launch and clinical trials to support FDA 510(k) clearance with specific intended use to treat lumpectomy margins.

PROVEN FEASIBILITY:

Thermatome has developed prototype systems and demonstrated feasibility with published animal tests and a human case study.

The animal tests, performed on goats, demonstrated our ability to necrotize tissue in mammary glands in a controlled and uniform manner.

The multiple patient human case study showed that Thermatome's thermal therapy system can generate uniform zones of tissue necrosis of ~1cm, around irregularly shaped lumpectomy cavities, as verified by MRI and biopsy, and that controlled clinical trials to fully demonstrate safety and efficacy are warranted.

COMPETITION:

Whole breast radiation is the current standard of care for treating residual cancer following lumpectomy surgery. It consists of an external beam to deliver radiation to the entire breast and requires the patient to visit the radiation clinic five days per week for up to 6 weeks. Patients who undergo whole breast radiation may experience side effects as a result of radiation exposure to healthy tissue, as well as the skin, ribs, heart and lungs. Approximately 85% of U.S. lumpectomy surgeries are followed by whole breast radiation.

Brachytherapy devices, such as Hologic's Mammosite and Cianna's SAVI, localize radiation at the lumpectomy site. A device with an external port is placed in the lumpectomy cavity at the time of surgery, or within a few days after surgery. The device remains in the breast during the course of treatment. The patient then returns to the radiation clinic twice daily for 5-7 days to have irradiated seeds placed in the device through the external port. The seeds are in the breast for up to 30 minutes, and the seeds are then removed. The brachytherapy device is surgically removed after the course of treatment is completed. Approximately 15% of U.S. lumpectomy surgeries are followed by brachytherapy treatment. Side effects include infection at and around the site of the external port.

Intraoperative Radiation Therapy (IORT) has been used in the US for a small number of patients. IORT applies radiation beam treatment directly to the surgical margins at the time of surgery. It requires a large capital outlay for the equipment, special shielding and special power.

Thermatome is less expensive, more convenient for the patient with fewer side effects, and is equally as effective as whole breast and brachytherapy radiation.

There are ongoing clinical trials investigating the use of radio frequency (RF) energy as a method of heating and ablating tissue in the margins of a lumpectomy cavity. The trials are being conducted with a device used for liver ablation, which heats tissue to equivalent temperatures, for equivalent time durations, as Thermatome's balloon catheter, to ablate tissue in a zone of 1 cm around the lumpectomy cavity. The results thus far have been positive, which bodes well for Thermatome. The key to tissue ablation and necrotization is temperature and time duration, so results of these trials, with respect to tissue necrotization, cancer cell destruction and local recurrence of breast cancer, can be viewed as a surrogate for Thermatome's performance. Thermatome's device is designed specifically to treat the lumpectomy cavity, and will be simpler, easier to use and less costly than the liver cancer device used in these trials.

Thermatome is aware of one early stage company that is developing a device to use RF to ablate tissue in the margins of lumpectomy. This device will be more costly than Thermatome's balloon catheter device, and is not likely to be as effective as Thermatome's flexible, fluid-filled and heated balloon for treating a uniform zone of tissue around an irregular shaped lumpectomy cavity.

There are other device therapies being investigated to treat the breast cancer tumors with minimally invasive surgical procedures. While clinical trials are on-going, none have been cleared by FDA for breast cancer treatment. These include RF, cryotherapy, laser, microwave and high frequency ultrasound devices. These trials are addressing small tumors of ≤ 2cm, and most require post-procedure radiation to address residual cancer. Because breast cancer tumors are surgically accessible without impacting bone, muscle or other organs, and because surgical removal of breast cancer tumors has a high success rate in long term patient survival, lumpectomy surgery, with follow up treatment of the surgical margins to address residual cancer, is likely to remain the treatment of choice for early stage breast cancer.

INTELLECTUAL PROPERTY:

Thermatome owns the patent (High Temperature Thermal Therapy of Breast Cancer. U.S. Patent No. 8,486,127, issued 7/16/13) which includes the key claim: A method to kill cells surrounding a cavity with heated fluid using a balloon catheter, wherein the cavity is caused by the removal of an undesirable growth and wherein the cavity may have various shapes.

This patent has broad application to any surgical cavity, and lumpectomy is our first application

REIMBURSEMENT:

Reimbursement codes exist for general soft tissue ablation procedures using RF and other energy producing devices. There are also reimbursement codes for the surgical placement and removal of brachytherapy radiation devices, and for the daily brachytherapy treatments. Thermatome may be able to leverage existing codes, but will likely need new or modified codes that recognize Thermatome as a standard of care for post lumpectomy treatment. Thermatome has partnered with RCRI (Minneapolis) to develop and execute a reimbursement strategy, including the clinical trial planning to support the strategy.

TEAM:

Tom Ryan, CEO. Mr. Ryan joined the Thermatome team in early 2015. He has 20 years of leadership experience in general management, product development and commercialization, for equipment and consumables, in the medical device and biotech industries, including start-up and early stage companies and successful exits.

Dr. Kambiz Dowlatshahi, Founder, Chief Medical Officer. Dr. Dowlatshahi was a world renowned breast surgeon at Rush University. He has developed many minimally invasive techniques pushing the boundaries of breast cancer surgery. His contributions include stereotactic needle biopsy, sentinel node biopsy, in-situ laser therapy and, most recently, Thermatome Thermal Therapy.

Chris Valadez, Product Development Director. Mr. Valadez joined Dr. Dowlatshahi over 15 years ago and brought many advanced surgical techniques from the lab to clinical settings. His oversight over clinical trials and technical experience was integral in the success of many research initiatives while at Rush University with Dr. Dowlatshahi.

Thermatome is building a team of advisors that includes Key Opinion Leaders, breast cancer specialists and medical device experts, and we have partnered with third party industry experts in regulatory (EdgeOne Medical, Chicago), pre-clinical testing and clinical trials (NAMSA, Ohio/MN), reimbursement (RCRI, Minneapolis) and product development/manufacturing (Medical Murray, Chicago).

SALES AND MARKETING PLAN:

With a high gross margin (> 80%) disposable balloon catheter, and our control unit, which will be provided to users at low or no cost, Thermatome fits the razor/razor blade sales model.

We plan to market and distribute the devices through a network of independent sales representatives. A key hire as we approach commercialization with be a VP of Sales and Marketing with medical device industry experience building, managing and incentivizing an independent rep sales force, as well as experience selling new surgical devices to hospitals and surgery centers.

We will leverage our founder's relationships with key opinion leaders, and other breast cancer surgeons, who will support Thermatome with clinical trials and publications.

PRODUCT DEVELOPMENT PLAN:

Thermatome's prototype balloon catheter and control unit devices, which were used in animal and human testing, were developed to near final form with respect to functional performance, materials and mechanical and electrical design. They require additional development and testing under design control procedures to ready them for FDA clearance and commercialization, as well as to address user requirements for ergonomics, human factors and user interfaces.

Thermatome has partnered with experienced medical device contract product developers/manufactures to complete the product development of the balloon catheter and the control unit. These firms have the quality systems and procedures in place to meet FDA requirements for Design Control. Additionally, they are FDA Good Manufacturing Practices (GMP) certified and have the manufacturing, supply chain and logistics expertise to build and warehouse Thermatome products, as well as to drop ship directly to Thermatome customers.

To determine the requirements for user interface, ergonomics and other human factors elements of the devices, Thermatome will meet with potential clinical users of the devices to solicit their input and feedback on the usability of Thermatome designs, and will incorporate that information into user requirements that will become a part of the basis for product development.

A major component of the testing that will be required for FDA clearance of Thermatome devices will be additional animal testing under Good Laboratory Practices (GLP) controls. Depending on FDA guidance, this animal testing could include demonstrating the safety and efficacy of Thermatome devices on up to three different tissue types with many as 36 animals.

Thermatome will contract with an experienced GLP testing facility, who will develop the procedures and controls for the animal testing, complete the testing and write the reports needed for FDA submission.

CLINICAL TRIAL PLANNING:

Following initial FDA clearance as a general soft tissue ablation device, human clinical trials will be performed to provide data to support 1) subsequent submissions to FDA for 510(k) clearances with specific indications for treating residual cancer following lumpectomy surgery, 2) applications for new and/or modified reimbursement codes 3) publications to show patients and the medical community that Thermatome can be a standard of care for treating residual cancer post-lumpectomy.

The funds from this round of fundraising will support clinical trial planning, but the funds that will be required to perform clinical trials will be raised in a subsequent fundraising round following initial FDA clearance of devices.

FUNDING/TIMELINE: Thermatome is currently raising $750K, to fund: 1) design, build and testing of our first generation commercial devices, 2) FDA pre-submission, 3) operations. We plan to raise $1.5million in 2016 to fund: 1) full-scale product development to FDA standards, 2) animal testing, 3) FDA de novo submission and clearance, 4) clinical trial planning, 5) operations. Development and testing to date has been completed with $250K of founder funds and grants.

Additional funding: $6-7 Million in 2017 for clinical trials, additional FDA submissions and commercialization. Upon successful clinical trials, significant market penetration could begin as early as Q2 2019, with up to 10% market penetration by 2021.

EXIT: With greater than 80% gross margins for the disposable balloon-catheter, and the potential for significant market penetration, Thermatome will be an attractive acquisition target for strategic medical device consolidators. We have had preliminary contact with potential strategics, and substantive strategic discussions will likely begin upon generation of test data required for FDA de novo submission. Opportunities for exit could occur as early as FDA de novo clearance.

FINANCIAL PROJECTIONS ($ Millions):