Z-Tech's Product

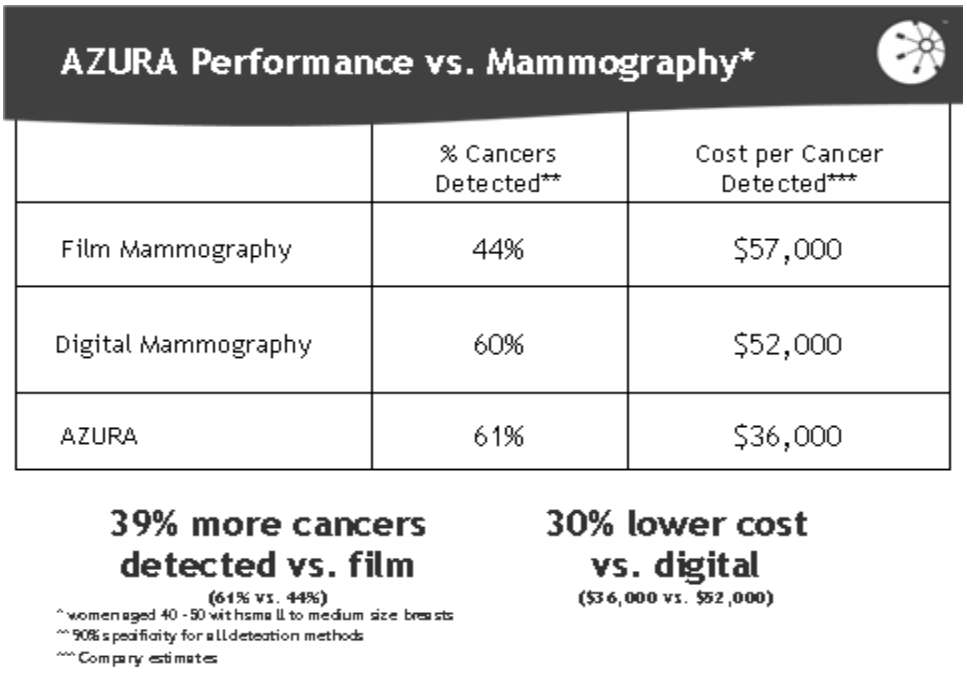
Breast Cancer and Breast Cancer Screening

Breast cancer is the most common form of cancer in women in North America, accounting for 20% of all cancer deaths. One in eight women will ultimately be diagnosed with breast cancer and early detection is the only current means to improve survival. The American Cancer Society estimates that 180,000 new cases of breast cancer will be diagnosed each year in the United States. Worldwide, the new case incidence reaches 1.3 million. As well, nearly 41,000 deaths are expected annually due to breast cancer in the United States. Worldwide, there are over 465,000 deaths annually attributed to breast cancer. Early detection has proven to be the most effective impact on reducing the costs associated with breast cancer. Five year survival rates for the detection of localized breast cancer are reported at 98% as compared to 26% if the cancer has metastasized. Large, randomized clinical trials have demonstrated that screening mammography leads to a reduction in breast cancer mortality of 29% to 40%, especially for women between 50-69 years old, and up to 13% for women aged 40-49.

Film mammography is the established diagnostic "standard of care"; however, mammography has many significant drawbacks. Data reported in the September 2005 New England Journal of Medicine for the Digital Mammographic Imaging Screening Trial ("DMIST") reported that film mammography, with a false positive rate of 10%, identifies only 44% of cancers in women 40-50 years of age. Major factors that hinder the detection of breast cancer by film mammography include the patient's age, cancer type, location and density of breast tissue, which can vary with genetic factors, hormone status and diet. Many cancers are missed with screening film mammography.

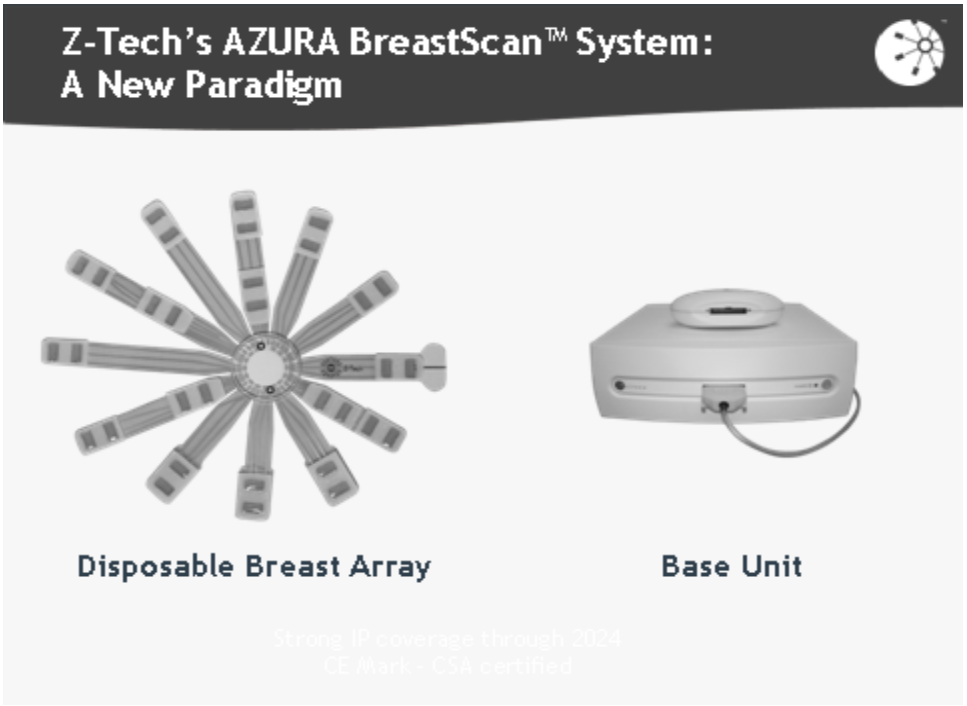
Recently, digital mammography has been introduced with reports of improved cancer detection for women in the 40-50 age group. Data from the DMIST suggests that digital mammography may detect up to 60% of cancers in women at a 10% false positive rate.

Z-Tech's proof of concept data for the Azura BreastScan™ System suggests cancer detection rates of 61% at a 10% false positive rate, comparable to digital mammography, and superior to film mammography detection rates of 44%. Based upon payer costs and the reported cancer detection rates for Azura BreastScan™ System from the proof of concept study and reported detection rates for film and digital mammography reported in DMIST, Z-Tech estimates the cost per cancer detected by Azura BreastScan™ System may be 30% less than digital and 37% less than film mammography in women 40-50 years of age. See also "Superior Economics". Additionally Azura BreastScan™ System does not require painful breast compression, exposure to radiation, high capital and operating costs and inconvenience that are hallmarks of mammographic technologies. Azura BreastScan™ System is portable and its results are available to the healthcare provider immediately without further interpretation by licensed professionals.



The Azura BreastScan™ System

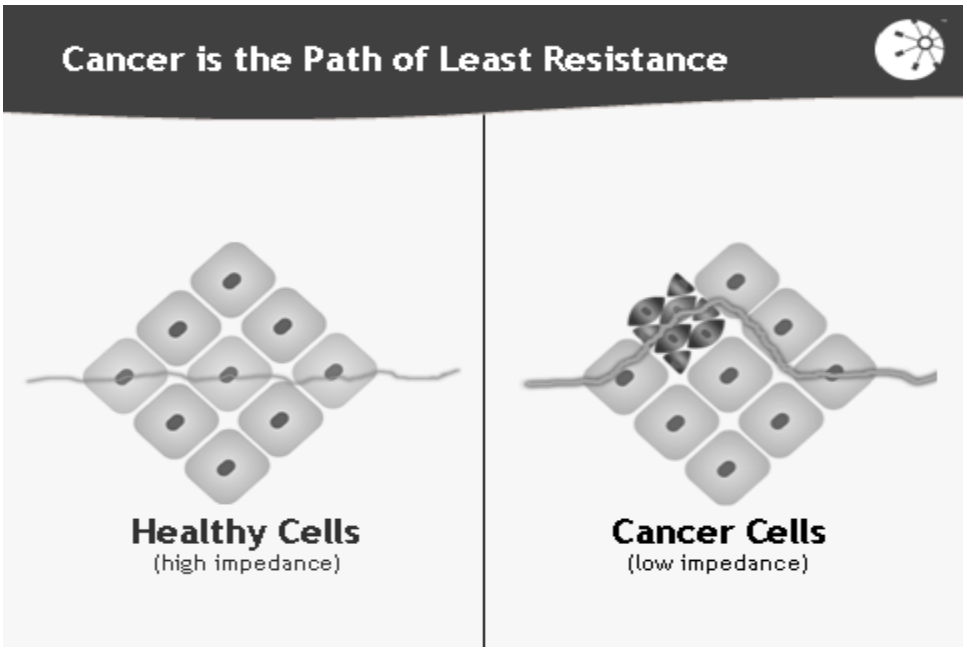
Azura BreastScan™ System initially targets the breast cancer screening market of women aged 40-50 with small to medium breasts, where screening mammography has diminished ability to accurately detect breast cancer. Since inception, Z-Tech's main activities have centred on the research and development of the Azura BreastScan™ System.



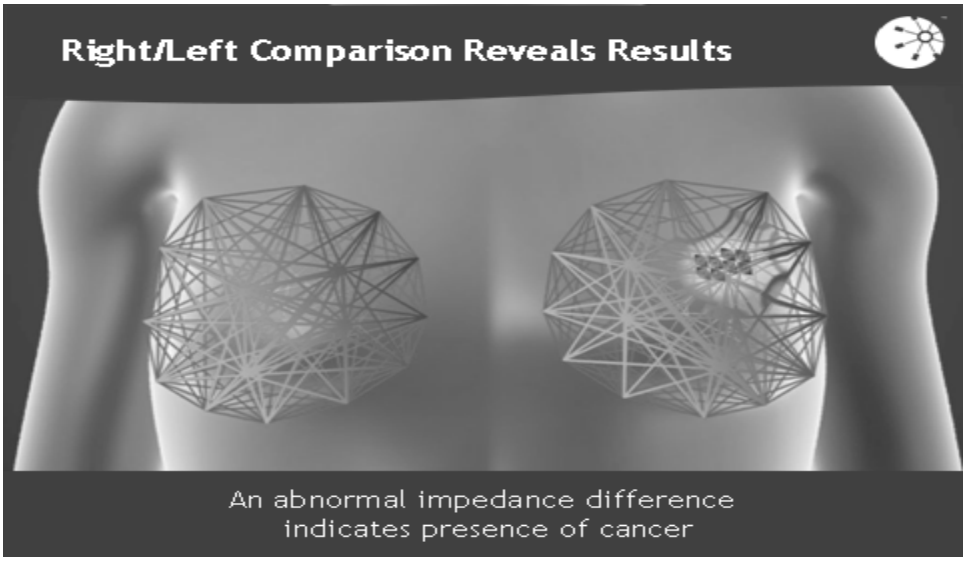
The Azura BreastScan™ Electrode Array (left) and the Azura BreastScan™ System (right)

Z-Tech's Technology

It is well documented that the electrical characteristics of cancerous tissue are different from those of normal tissue. Cancerous tissue tends to be more porous, vascular and fluid filled and conducts electrical current more easily compared to normal tissue.



Z-Tech's technology is based on the differences in these electrical characteristics and its ability to detect and measure these differences. Azura BreastScan™ System employs a proprietary technology comprised of the Azura BreastScan™ System and the disposable Azura BreastScan™ Electrode Array that, together, detect and measure small differences in electrical signals (reactance and resistance or impedance) between a women's breasts that is then used to identify potential cancerous tissue. The basic feature of Z-Tech's technology is the use of a side-to-side breast impedance comparison of numerous identical small regions of the two breasts and to compare the results of these measurements. Differences in impedance measurements between the two breasts indicate the possibility of different tissue and the potential for cancerous tissue.

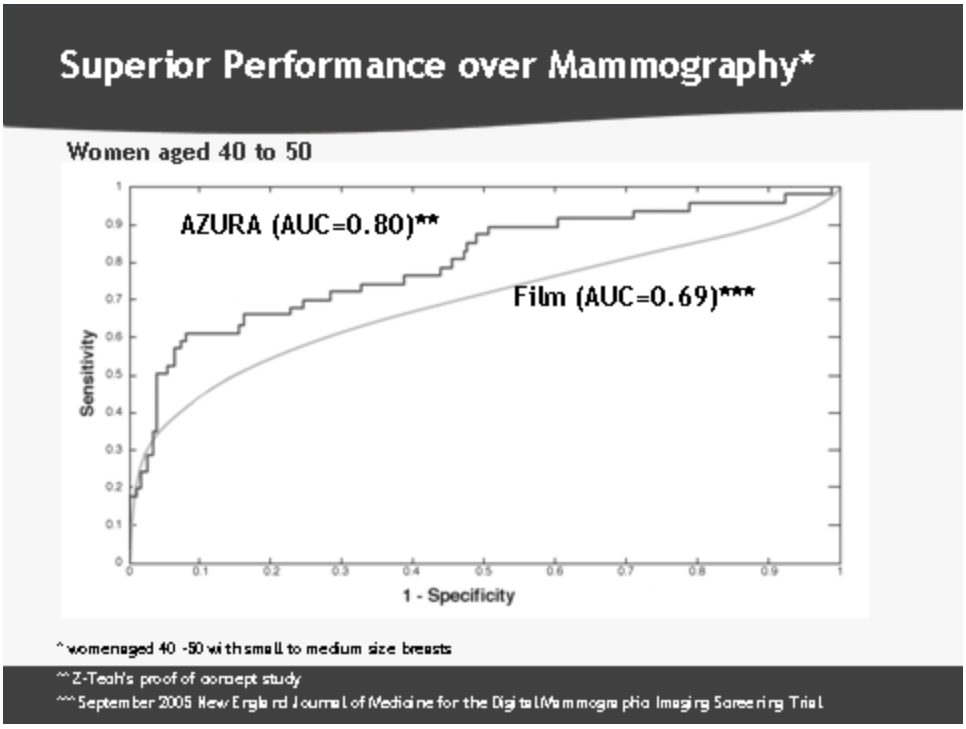


Z-Tech's Clinical Data and Strategy

Z-Tech's initial proof of concept study was completed in 2007 on more than 3,500 women. The proof of concept study was conducted at 28 clinical sites in the United States, Canada and Europe. Study sites included such prestigious institutions such as the Massachusetts General Hospital (Boston, MA); Beth Israel Medical Center (New York, NY) and Mount Sinai Hospital (Toronto, ON). The study included data from 2,300 screening subjects and 1,200 biopsy subjects producing 200 cancers for analysis to develop and refine the Azura BreastScan™ System technology as well as to derive its target indicator. Included within this trial was a subset of approximately 392 women aged 40–50 with small to medium breasts that yielded cancers that were evaluated on the optimized algorithm and device. Of these 392 women, 209, including 42 cancers, were selected for inclusion in the study analysis. This study was completed in 2007.

Results from the proof of concept study for women aged 40-50 with small and medium breasts indicate that Azura BreastScan™ System detects 61% of cancers in women at a 10% false positive operating point. These results were compared to data reported in the September 2005 New England Journal of Medicine on digital mammography results. That study, the Digital Mammographic Imaging Screening Trial ("DMIST"), obtained results for over 14,000 women studied in the same age population. In this study, film mammography's cancer detection rate was reported to be 44% at a 10% false positive operating point. Based upon these studies Azura BreastScan™ System reported 39% (61% vs. 44%) more cancers than the current standard of care for this population group.

Another important measure of device performance is the area under the curve, or AUC, which compares the diagnostic accuracy of a device over multiple operating points. Using the AUC measure, a perfect device would have an AUC of 1.00, detecting 100% of cancers with 0% false positives. Less than perfect devices report AUC's less than 1.00. The higher the AUC of a device, the better the device performs. The AUC for Azura BreastScan™ System from the proof of concept study in women aged 40-50 with small to medium breasts is 0.80. The AUC for film mammography as reported in the DMIST is 0.69. The AUC values for the two devices is reported in the graph below.



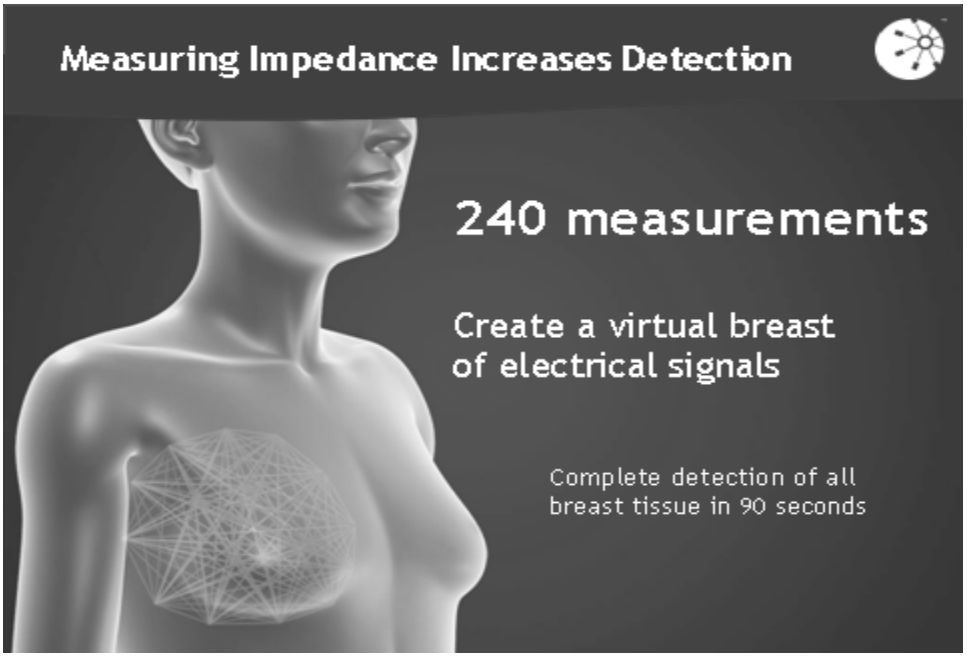
Based upon the performance of Azura BreastScan™ System in the proof of concept study Z-Tech has commenced its pivotal trial with the objective to demonstrate the effectiveness and safety of Azura BreastScan™ System as a screening tool for breast cancer. In order for a screening test such as Azura BreastScan™ System to obtain approval for marketing and sale in the U.S., test results must demonstrate diagnostic non-inferiority to screening film mammography when both are used independently in the study.

Azura BreastScan™ System is a Class 3 medical device requiring clinical data supporting its safety and effectiveness and requiring a PMA before commercial sale in the United States. A PMA application is a regulatory review to evaluate the safety and effectiveness of Class 3 medical devices. According to the Center for Devices and Radiological Health, Class 3 devices are "those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury".

Z-Tech's goal is to obtain study results that demonstrate diagnostic non-inferiority of its product as compared to screening film mammography when both are used in the study. The target population is women with small to medium breasts between the ages of 40-50. Z-Tech expects the study will be conducted at up to 35 sites in North America and will include 1,500 women having received an Azura BreastScan™ System screen and a film screening mammogram. The study is expected to yield 100 confirmed malignancies from 700 biopsies and 800 screening mammography subjects. Z-Tech expects that patient recruitment will be completed in late 2008 or early 2009.

Z-Tech's System

The Azura BreastScan™ System consists of a detection and analysis instrument, a single-use, pair of disposable Azura BreastScan™ Electrode Arrays, and breast preparation supplies. The breast electrode arrays are applied to the skin and held in place by self-adhesive pads on each arm of the array. The detection and analysis instrument produces a very small, imperceptible current between selected electrode pairs, scanning the interior of the breast from its surface and seeking electrical evidence of malignant change. An electrical current is sent from each electrode to all other 15 electrodes. The Azura BreastScan™ System measures impedance across 120 separate pathways using two different frequencies, thus collecting 240 individual measurements. Complete detection of all breast tissue occurs in less than 90 seconds. The measurements of each breast are compared and an abnormally low impedance (or increased current flow) difference indicates the potential presence of a malignancy.



Z-Tech believes that its product will enable women at younger ages to undergo breast cancer screening with less fear, less discomfort, and better cancer detection rates. Z-Tech's system is painless, fast and cost effective. The patient is not exposed to any radiation, and the procedure does not require a radiologist or specialized facilities. Z-Tech believes there is significant unmet clinical need and market opportunity for a more accurate and cost-effective method of breast cancer screening.

Market and Competitive Position

The current standard of care for breast cancer screening is mammography. Mammography may be either digital or film. Globally, the mammography installed base remains predominantly film-based mammography systems. According to the Mammography Quality Standards Act Facility Scorecard, film mammography accounts for approximately 65% of the available mammography systems in the U.S. The balance of the U.S. market has converted to full field digital mammography. According to Mammography World Markets, Trimark Report (2005), digital mammography represents only about 6% of all mammography systems outside of North America.

The current suppliers of digital mammography systems include Hologic Inc., General Electric Healthcare, Siemens Healthcare and Fischer Imaging Corporation. Hologic Inc., currently the largest supplier of full field digital mammography equipment, reports almost 1700 digital systems installed or approximately 46% of the total digital mammography systems in the U.S. General Electric Healthcare is the second largest supplier of digital mammography systems. Siemens Healthcare and Fischer Imaging Corporation account for the balance of the digital mammography systems in the U.S.

While Z-Tech believes that the replacement of film mammography systems with digital mammography systems will continue especially in North America, it should be noted that digital mammography also does not address many of the imperfections that exist with mammography as a screening technology. Breast compression, radiation exposure and extended wait times will continue to affect patient compliance rates. Additionally, the provider will continue to be pressured by low reimbursement, lack of qualified technicians and radiologists, the need for specialized facilities and high malpractice insurance costs.

For women 40–50 years of age, cancer detection rates for film mammography have been reported at only 44% and digital at 60%, both at a 10% false positive rate. A separate mammography appointment, in addition to the patient's regular medical examinations, is also required. Mammography readings take time to compile, are subjective, and create patient stress while waiting for results.

Z-Tech believes that this combination of pain from breast compression, radiation exposure, poor detection and inconvenience contribute significantly to the low mammography compliance rates experienced in the U.S. and elsewhere. The American Cancer Society reports that only 55% of women in the US aged 40-50, receive their annual recommended breast cancer screen. These compliance statistics have also shown a consistent decline over recent years. Z-Tech believes that the Azura BreastScan™ System has the possibility to improve screening compliance rates as it removes many of the imperfections and limitations that currently exist with the screening mammography procedure. Z-Tech believes improved compliance coupled with increased detection and reduced cost will have an impact on the cost of identifying and treating breast cancers in the healthcare setting.

Other Breast Cancer Screening Technologies

In addition to mammography, there exists a number of other technologies that have the ability or potential to screen for breast cancer but because of cost and/or performance limitations have not, to date, been adopted as screening alternatives.

Ultrasound

Ultrasound is currently used as an adjunctive technology usually after a screening mammogram is performed. The procedure is used to verify or add information to an inconclusive reading of the original screening mammogram. A skilled sonographer is required to correctly image the suspicious mass and a skilled radiologist that possesses ultrasound expertise is required to interpret the scan. As a primary screening tool, ultrasound is highly sonographer and radiologist dependent and is most effective only on certain fluid filled masses.

Magnetic Resonance Imaging

Magnetic Resonance Imaging ("MRI") requires a contrast agent to be injected into the patient and is very expensive and time consuming. MRI is currently used as an adjunctive modality again after a screening mammogram to confirm a mass and the likelihood of malignancy. The high cost, invasive nature and time per procedure limit MRI's capability to screen large populations of women effectively.

Thermography

Thermography uses the increased heat generated from cancer cells to detect the presence of cancer. This technology has not proven effective as a screening device since detection appears to be limited to larger cancers and palpable masses. Companies utilizing infrared technology are currently collecting clinical data for adjunctive use after a screening mammogram provides inconclusive results. At least one company has left the breast cancer detection market after their device failed to find a clinical adjunctive niche.

Optical Imaging

Optical imaging uses laser technology. The laser based systems are large, expensive and have limited clinical evidence behind them especially in the area of screening for breast cancer. Scanning times are slow and the systems have had limited acceptance after years in third world markets.

Ductal Lavage

Ductal lavage collects cells from milk ducts that are analyzed in a testing facility. The presence of atypical cells usually do not develop into breast cancer and a study appearing in the October 2004 issue of the Journal of the National Cancer Institute found that ductal lavage was ineffective at detecting breast cancer among women who had already been diagnosed with the disease. While presently a possible research tool, ductal lavage is not a screening technology for the early detection of breast cancer.

Blood Screening

Blood markers provide some information of the level of cancer cells in the body relative to a previous reading but blood markers have not proven effective or accurate as a screening technique.

Marketing Plans and Strategy

Z-Tech estimates the worldwide opportunity for the Azura BreastScan™ System based solely on the initial indication (breast cancer) and target population (small to medium breasted women aged 40 to 50) to be more than $1.5 billion annually, of which $750 million is estimated from the North American market.

Customers

Hospital and medical center-based radiologists are likely to be centrally important customers of Z-Tech's system as an alternative to mammography for screening their patients. In addition, family, internal medicine and gynaecologic practices are expected to be significant new markets. Z-Tech believes that Azura BreastScan™ System can be placed in these point-of-care settings, providing patient convenience, better screening performance, and, potentially, added practice revenue.

Gynaecologists are likely to be one of the first medical specialties to provide this new service after an initial adoption period. Gynaecologists are accustomed to purchasing or leasing capital equipment, tend to be more entrepreneurial with regards to reimbursable procedures, and provide medical services to women in the appropriate age group. This procedure may be covered under their current malpractice insurance, adding no additional cost to their practice.

Z-Tech believes patients will be strong influencers in the selection of the device to be used to detect potential breast cancer. Patients are becoming more educated consumers of healthcare services and are increasingly concerned with the physical discomfort and radiation received from a mammography procedure. Patient interviews regarding Azura BreastScan™ System have confirmed very high patient acceptance and preference of Azura BreastScan™ System over mammography if cancer detection rates are comparable.

Z-Tech believes that the Azura BreastScan™ System would enable primary care facilities to screen younger patients at lower cost, without radiation exposure, and with greater comfort and convenience. The Azura BreastScan™ System would make breast cancer screening more accessible to patients, by utilizing the Azura BreastScan™ System in the primary care setting.

Superior Economics

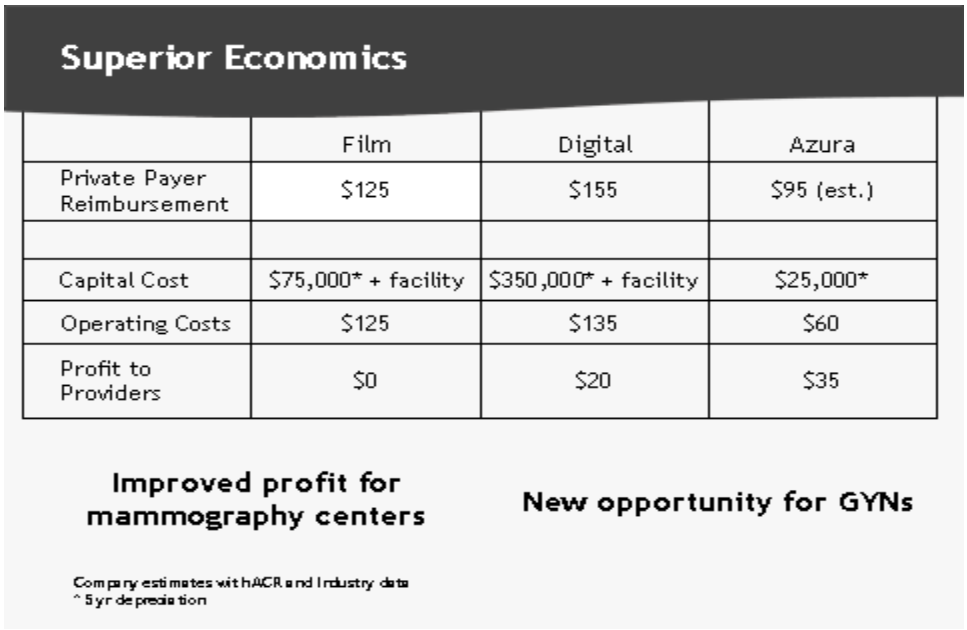
Azura BreastScan™ System's cost is expected to also be an important factor in its adoption. Z-Tech estimates the cost to private payers for a mammogram to be $125 – $155 depending on whether the mammogram screen film or digital. This compares to an estimated $95 Azura BreastScan™ System test. Based upon these payer costs and the reported cancer detection rates for Azura BreastScan™ System from the proof of concept study and reported detection rates for film and digital mammography reported in the DMIST, Z-Tech estimates that the cost per cancer detected of the different technologies to be as follows:

	Cancer Detection Rate based on 10% False Positive Rates	**Cost per Cancer Detected**
Film Mammography	44%	$57,000
Digital Mammography	60%	$52,000
Azura BreastScan™ System	61%	$36,000

Based on these estimates, the cost of per cancer detected by Azura BreastScan™ System is expected to be 37% and 30% respectively less than the film and digital alternatives. See also "Z-Tech's Product - Breast Cancer and Breast Cancer Screening". The capital cost of mammogram equipment ranges from $75,000, in the case of film, to over $350,000, in the case of digital. Additionally, specialized lead lined facilities are required for mammography procedures. Z-Tech estimates the capital cost of an Azura BreastScan™ System to be approximately $25,000 with no specialized facility requirement.

Operating costs reported by the International Medical News Group, the American College of Radiology and other industry data have estimated average film mammography costs at approximately US$125 per patient. Additionally, when the cost of digital equipment is amortized over a 5 year period, the company estimates the cost of digital mammography to be approximately $135 per patient. With film private payer reimbursement at approximately US$125 and digital reimbursement at US$155, few film sites make money on the procedure and digital sites make approximately US$20 per patient. The Azura BreastScan™ System is estimated to have an operating cost of approximately US$60 or less than half the cost associated with mammography. Reimbursement for the Azura BreastScan™ System procedure with private payers is estimated at US$95. At that level of reimbursement, the Azura BreastScan™ System procedure is 39% less than digital mammography, the hospital or clinic would realize a profit of approximately US$35 per patient or US$15 more than digital mammography.

Z-Tech believes the combination of superior cancer detection to film mammography, a superior patient diagnostic experience (no painful breast compression, no exposure to radiation, and no inconvenience) and superior economics to both film and digital mammography will provide a strong foundation for user, provider and payer interest in Azura BreastScan™ System.



Sales and Distribution

North American distribution is expected to be handled with the assistance of strategic partners. Z-Tech anticipates developing a focused team of sales specialists to augment and support the sales effort of its partner to provide the appropriate mix of sales coverage and product knowledge. Z-Tech anticipates that one partner will focus on radiologists with another developing the gynaecology market opportunity. A direct marketing awareness campaign is also envisioned to educate potential mammography patients of the Azura BreastScan™ System alternative.

Z-Tech's strategy is to initially pursue market/clinical research and a limited launch of the Azura BreastScan™ System in Asia to address what it believes is a $350 million market opportunity. Asia is a market ideally suited for the technology due to a high prevalence of women with small to medium dense breasts, a growing awareness and funding of breast cancer screening programs, and regulatory requirements that can be met in the near-term. By gaining commercialization experience and generating additional clinical data in this market and endorsement from key opinion leaders, Z-Tech will be better prepared to support the launch of the Azura BreastScan™ System in Europe and in the U.S. in late 2009.

Z-Tech intends to support the Asian market research efforts through a network of local distributors. Upon PMA approval, strategic partners would be utilized for the broader introduction of the Azura BreastScan™ System. Z-Tech estimates that North America and E.U. markets will add $1.1 billion to the market potential for the Azura BreastScan™ System.

Z-Tech has entered into distribution agreements with three distributors in Asia to initially assist in market development and support of Azura BreastScan™ Systems for evaluation purposes. These agreements cover Singapore, Hong Kong, Thailand, Malaysia, Macau, Indonesia, and the Philippines. After obtaining evaluation experience and feedback Z-Tech will assess next steps with respect to further commercialization in these markets.

Proprietary Protection

Z-Tech believes it has a strong intellectual property portfolio including four issued patents: three in the United States and one in Canada; and 55 patents pending, including 19 in the U.S., 12 in Canada, and 24 internationally, including in China and Japan. Z-Tech's patents and applications broadly cover Azura BreastScan™ System's methodology and apparatus, as well as improvements to the apparatus and the data analysis methodology. Z-Tech believes that these patents thoroughly covers Azura BreastScan™ System's methodology, array design and apparatus design, and provides Z-Tech with freedom to operate and the ability to effectively block competitors.

The three issued U.S. patents are:

- 6.122.544 – expiry April 2019 (subject to payment of maintenance fees): "Electrical Impedance Method and Apparatus for Detecting and Diagnosing Diseases" is related to the first-generation of Z-Tech's technology. It covers a method and apparatus for screening, sensing, or diagnosing disease states by obtaining many electrical impedance data measurements in organized patterns from two anatomically homologous body regions, one of which may be affected by disease. This patent has also been issued in Canada.

- 6.768.921 – expiry May 2021 (subject to payment of maintenance fees): "Improved Electrical Impedance Method and Apparatus for Detecting and Diagnosing Diseases" is related to the second-generation of Z-Tech's technology. It covers an improved method and apparatus for detecting and diagnosing disease states in a living organism by using many electrical impedance measurements. In particular, the invention provides for an improved electrode array for diagnosing the presence of a disease state in a human breast.

- 7.212.852 – expiry October 2024 (subject to payment of maintenance fees): "Bioimpedance measurement using controller-switched current injection and multiplexer selected electrode connection" is related to the second generation of Z-Tech's technology. It covers instrumentation that enables novel measurements used to assess electrode contact and post measurement fidelity.

U.S. trademarks have been registered for the Z-Tech name and logo. U.S. trademarks are pending for a new company logo. Trademarks for the logos and the Z-Tech and Z-Tech Medical names are pending in Canada, and an application for the logo is pending in the European Union.

In 2007 Z-Tech obtained CSA and CE Mark approvals for the Azura BreastScan™ System.

Z-Tech is an ISO certified company.

Operations and Manufacturing

Z-Tech expects that the Azura BreastScan™ System subassemblies, including printed circuit boards, cables and housing will be manufactured at vendors specially selected and qualified to manufacture devices in an ISO quality system environment. Z-Tech expects that final assembly and testing of the device will initially be handled by an in-house manufacturing staff located at its Toronto location. Z-Tech's arrays are manufactured by an outside vendor.

Z-Tech currently leases its facilities in Toronto and Westford and has 25 employees.

Z-Tech leases 2,400 sq. ft. of commercial space at its facility in Westford, Massachusetts on a month to month basis at a rate of US$3,500 per month. In addition, Z-Tech leases 5,400 sq. ft. of commercial space at its

Toronto, Ontario location. Z-Tech's lease expires on November 30, 2008, and is automatically renewed on an annual basis. The current annual rent is $158,000 per year.

Regulatory Requirements

Z-Tech's Azura BreastScan™ System is a "medical device". Before Z-Tech can market and sell Azura BreastScan™ System in a specific country, it must receive approval from the governmental authority in that country to do so. The requirements for approval vary from country to country. The following sets out, in general terms, the requirements for approval in Canada, the United States and Europe.

Canada

In Canada, applications for approval of a medical device are processed by the medical device group of the Therapeutic Products Directorate of Health Canada. Medical devices are classified into one of four classes, depending on Health Canada's assessment of the risk the medical device poses to humans:

- Class I devices (low risk) are not subject to any regulatory review, however, manufacturers are required to obtain an establishment licence if they do not import or distribute through another entity that already holds an establishment licence.

- Class II to IV (high risk) devices require a medical device licence. An importer or distributor of these devices is required to hold an establishment licence. In addition to the items identified for Class I, the licence holder must also attest that the establishment has documented procedures in place for handling, storage, delivery, installation, corrective action, and servicing of medical devices.

An application for a medical device license includes one or more of the following, depending on the medical device classifications:

  - Attestation by an official of the manufacturer of objective evidence to establish that the device meets safety and effectiveness requirements.

  - Manufacturer must submit a summary of all studies on which the manufacturer relies to ensure the device meets safety and effectiveness requirements.

  - Manufacturer must provide detailed information on all studies on which the manufacturer relies to ensure the device meets safety and effectiveness requirements, including preclinical and clinical studies, process validation studies, if appropriate software validation studies, literature studies plus a summary of all these studies.

In addition, manufacturers are required to demonstrate their quality systems are certified to ISO 13488 (for Class II devices) or ISO13485 (for Class III and IV devices).

Azura BreastScan™ System is considered a Class III device in Canada based on an indication of screening for breast cancer in women 40 to 50 years of age with transverse breast measurements of 9.5 inches or less (C cup) and who would normally undergo film mammography for breast cancer screening. Under this classification, Z-Tech must submit a summary of all studies on which the manufacturer relies to ensure the device meets safety and effectiveness requirements. Health Canada typically takes three to five months to review submissions for this type of medical device.

Z-Tech filed an application for a Class III Canadian Medical Device License in October 2007 for Azura BreastScan™ System. Z-Tech was informed by Health Canada in November 2007 that the submission would not be accepted for review due to deficiencies in the application. Z-Tech has been in contact with Health Canada and is in the process of reviewing these deficiencies.

United States

In the United States, medical devices are regulated by the Center for Devices and Radiological Health ("CDRH") division of the FDA. The Office of Device Evaluation within CDRH is responsible for reviewing and approving medical device applications.

Azura BreastScan™ System is considered to be a Class 3 medical device requiring Pre-Market Approval from the FDA.

Pre-Market Approval

A Pre-Market Approval ("PMA") application is a regulatory review to evaluate the safety and effectiveness of Class 3 medical devices. Class 3 devices are defined as "those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury".

The FDA's statutory review time is 180 days to make a determination on a PMA submission. In addition, the FDA may request an expert advisory committee meeting to review the PMA and provide a recommendation, which can delay the approval date. If a PMA lacks the required elements listed in an administrative checklist, the FDA can refuse to file the submission and will not proceed with the review.

The technical parts of the PMA submission contain data and information which allows the FDA to determine the safety and effectiveness of the device and whether to approve or disapprove the application. These technical sections are usually divided into:

- Non-clinical laboratory studies, which include information on microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life and other laboratory and animal tests; and,

- Clinical investigation studies, which include study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all individual subjects, and results of statistical analyses.

Z-Tech has periodically been in communication with the FDA CDRH over the last three plus years to discuss the development, design and structure of the proof of concept and pivotal trials. Although the pivotal trial is considered by FDA requirements and opinion to be a "non-significant risk" clinical study not requiring an Investigational Device Exemption ("IDE") submission and in turn, not requiring review and approval by the FDA, Z-Tech nonetheless has submitted the pivotal trial protocol to seek FDA's input and advice. Based on FDA's review, Z-Tech has made adjustments to the protocol that it believes have addressed FDA's major concerns. More recently, Z-Tech has been in discussions with FDA on the Modular Pre-Market Approval (PMA) Shell which is the outline of those sections that will be necessary to complete the PMA. A description of all modules is needed to support filing and approval of the Azura BreastScan™ device.

Z-Tech also underwent an FDA establishment inspection of its premises at 234 Littleton Road, Westford, Massachusetts on October 29, 2007. The inspection covered Corrective & Preventive Actions and Management Controls. No objectionable conditions were noted and no FDA 483 was issued. The Agency has communicated to Z-Tech that this inspection is "closed", which means no further actions are required by Z-Tech.

European Regulatory Approval System

The European system for gaining approval of a medical device is known as "CE Marking". This system provides a manufacturer with approval in the 25 member states of the European Union plus three European Free Trade Association members. The 25 countries are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, Netherlands, Portugal, Spain, Sweden, United Kingdom Great Britain, Estonia, Latvia, Lithuania, Poland, Czech Republic, Slovakia, Hungary, Slovenia, Malta, and Cyprus.

"CE" is an abbreviation of the French term "Conformité Européene", indicating that a manufacturer has conformed to all the regulatory obligations required by European legislation.

There are seven steps required to obtain CE Marking:

- determine which directives apply to the product;
- determine the extent to which a product complies with the essential requirements for design and manufacturing in the applicable directives;
- choose the conformity assessment procedure from the options available from the directive;
- select the applicable product standards and test methods and select an independent lab (i.e., Notified Body) if product testing is done externally;
- establish an authorized representative for regulatory affairs in the European Union for the product;
- prepare a declaration of conformity that includes a list of standards and directives to which the product conforms. Obtain Notified Body Declaration of Conformity, if required; and,
- apply CE Marking to the product.

The European Council Medical Device Directive provides details regarding the approval of medical devices in Europe.

European Device Classifications

Europe has a four-stage classification system for medical devices "based on the vulnerability of the human body, taking account of the potential risks associated with the technical design and manufacture of the devices":

- Class I – Low risk, conformity assessment procedures are carried out by the manufacturer – e.g., non-active (unpowered) devices that do not penetrate the body;
- Class IIa – Intervention of a Notified Body is compulsory at the production stage – e.g., diagnostic instruments, surgically invasive devices for transient and short term use;
- Class IIb – High-risk potential. Inspection by a Notified Body is required for design and manufacturer of devices – e.g., surgically invasive devices for short-term use, radiotherapy devices, and long-term use or implantable devices; and
- Class III – Critical devices for which explicit prior authorization with regard to conformity is required for them to be placed on the market – e.g., device contacts the central nervous system or heart or is absorbed by the body.

Notified Bodies

Europe has established a system of Notified Bodies which are nationally accredited bodies that certify products on behalf of the European Union ("EU"). Notified Bodies are independent, private, "for profit" companies. They are authorized by the legal health authority or Competent Authority of EU countries to serve as independent test labs and perform the steps required by the product directives for devices that are not self-certified by a manufacturer.

Declaration of Conformity

A declaration of conformity is a procedure whereby the manufacturer fulfills the obligations and declares a product meets the provisions of the appropriate directives. A manufacturer must also file an application for an assessment of its quality system with a Notified Body. The Notified Body audits a manufacturer's quality system prior to granting a declaration of conformity.

A Notified Body examines a product's design to determine if it complies with a directive, and this may require further testing. Once a certificate is granted, it states the conclusions of examination, the conditions under which it is valid, the data required for identification of the approved design, and sometimes a description of the intended purpose of the product.

Once a single Notified Body approves the device, it can be marketed in any of the 25 countries. Once on the market, state agencies, called "competent authorities" – departments of health or health-related agencies, similar to the FDA – monitor manufacturer advertising and investigate safety, quality and performance issues that may arise about a particular CE-marked device. If necessary, the competent authority can order the withdrawal of a device from the market and notify other competent authorities and the European Commission of its actions.

Z-Tech received ISO13485 quality standard and Canadian Medical Devices Conformity Assessment System ("CMDCAS") certification in 2006 by its Notified Body Intertek Semko AB. In November of 2007, the Azura BreastScan™ System received a CE Mark Certificate per the European Council Directive 93/42/EEC on Medical Devices (MDD) as a Class IIb medical device by Intertek Semko AB.

Asia

Z-Tech intends to perform market/clinical research and a limited launch of the Azura BreastScan™ System in Asia through entering into distribution agreements with distributors in those countries it has identified as having a potential market for its product. As each country in Asia has specific regulatory requirements Z-Tech expects that the terms of the distribution agreements will require the local distributor to obtain government approval on its behalf for the sale and marketing of the system in specific countries.

Typically the information required to sell and market a medical device in Asia includes:

- Government certificate of clearance and free sale/ registration approval of the product from the country of origin issued by Health Authority and duly authenticated by the respective territorial consulate.

- Government certificate attesting to the status of the manufacturer, competency and reliability of the personnel and facilities and duly authenticated by the respective territorial consulate and / or valid ISO certificate for imported product.

- Certificate of agreement between the manufacturer and trader/ distributor / importer regarding the product involved.

Selected Consolidated Financial Information and Management's Discussion and Analysis of Z-Tech

SELECTED ANNUAL INFORMATION

Selected Statement of Loss Information

	9 months ended September 30, 2007 ($)	9 months ended September 30, 2006 ($)	Year ended December 31, 2006 ($)	Year ended December 31, 2005 ($)	Year ended December 31, 2004 ($)
Research & development [2]	1,300,838	2,399,321	2,134,851	4,459,369	4,321,542
Selling, general & administrative	1,646,253	1,130,119	1,710,646	1,311,183	1,010,891
Amortization	46,914	46,394	59,282	106,473	107,433
Interest & other income	(163,870)	(144,581)	(170,508)	(162,337)	(105,622)
Financing costs related to MMV Financial Inc. loan and warrant life extension	309,288	454,659	631,230	1,023,589	-
Income tax expense	33,371	10,622	17,340	32,700	16,315
Loss before financing expenses on convertible securities[1]	**3,172,794**	**3,896,534**	**4,382,841**	**6,770,977**	5,350,559
Financing expense convertible securities[1]	6,214,227	3,430,374	4,693,895	3,766,588	1,851,229
Loss for the period	**9,387,021**	**7,326,908**	**9,076,736**	**10,537,565**	7,201,788

Notes:

(1) Financing expenses on convertible securities include expenses charged to the statement of loss related to Z-Tech Debentures, Z-Tech Class B Shares and Z-Tech B Warrants. Such expenses include (i) interest expense; (ii) accretion expense (which is the difference between the initial recorded value of the instrument and its face value at maturity); (iii) dividends; (iv) Part VI.1 tax on the dividends; (v) fair value adjustments related to the Z-Tech Warrants; and (vi) other financing costs. (Details are included in Note 16 of the consolidated financial statements of Z-Tech included elsewhere in the document.)

(2) Research and development is net of assessed scientific and experimental development refundable investment tax credits of: $788,727 (September 2007), $781,398 (September 2006), $1,693,469 (December 2006), $1,343,948 (December 2005), nil (December 2004).

Selected Balance Sheet Information

	As at September 30, 2007 ($)	As at December 31, 2006 ($)	As at December 31, 2005 ($)
Balance Sheet			
Assets			
Cash	4,194,480	1,529,738	7,573,359
Restricted cash	-	906,344	-
Other working capital assets	394,773	261,655	69,421
Capital & other assets	189,244	398,581	662,550
Total assets	**4,778,497**	**3,096,318**	**8,305,330**
Liabilities			
Working capital liabilities (excluding convertible securities classified as current liabilities)	1,610,377	326,040	521,478
Long-term loan	408,654	2,757,686	3,279,660
Convertible securities (includes convertible debt, Z-Tech Class B Shares, Z-Tech B Warrants and the related interest and dividends payable and future tax liability)	41,065,222	26,910,493	22,433,052
Total liabilities	**43,084,253**	**29,994,219**	**26,234,190**
Total shareholders' deficiency	**(38,305,756)**	**(26,897,901)**	**(17,928,860)**

Results of Operations

Nine Months Ended September 30, 2007 Compared To Nine Months Ended September 30, 2006

For the nine months ended September 30, 2007, Z-Tech recorded a net loss of $9.4 million ($6.26 per share) compared to a net loss of $7.3 million ($4.88 per share) for the nine months ended September 30, 2006.

Z-Tech's loss before financing expenses on convertible securities for the nine months ended September 30, 2007, was $3.2 million, representing a decrease of $0.7 million, or 18%, compared to a loss of $3.9 million for the nine months ended September 30, 2006 on a comparable basis.