

Innovative Breast Conserving Therapy Technologies



Jill Anderson
President & CEO

“Ultimately, it’s the company’s service promise that distinguishes a great company. Cianna Medical has earned a reputation for delivering exceptional customer service to all its stakeholders – patients, physicians, allied health professionals and hospital administrators. At Cianna Medical we follow a “Code of Honor” that begins with Patients First – Always. Adhering to a patient focused philosophy gives the entire organization the freedom to make good choices in all that we do – from developing new technologies to offering patient and family support during procedures.” - Jill Anderson

CEOCFO: Ms. Anderson, what is the concept behind Cianna Medical?

Ms. Anderson: Cianna Medical is focused on developing innovative technologies for breast conserving therapies. For women who choose to have a lumpectomy instead of a mastectomy; they will likely require surgery and radiation therapy. We have invented two technologies – the SAVI breast brachytherapy applicator and SAVI SCOUT surgical guidance system. Both products can be used to support a treatment program that is unique to each woman.

CEOCFO: Would you please explain the “unique to them” aspect?

Ms. Anderson: Twenty or so years ago, results of a pivotal clinical trial showed that many women did not need to have a mastectomy. They could have a lumpectomy (removal of the cancerous tissue) followed by a brief period of radiation therapy and receive the same or similar survival benefit. About 70% of cancers are diagnosed at a very early staging, meaning they can choose to save their natural breast. Our flagship product is the SAVI® breast brachytherapy applicator. Brachytherapy is faster and more precise approach to delivering radiation therapy. Historically, radiation therapy is provided to the entire breast. Brachytherapy reduces the amount of radiation that is being received by healthy tissue and also allows us to accelerate the treatment schedule. Therefore, women can complete their course of radiation in five days verses a more traditional six week course of treatment. What is

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unique about the SAVI applicator is that it can deliver a very personalized dose of radiation based, spare healthy tissue from unnecessary radiation and reduce radiation-induced side effects.

CEOCFO: *Are women generally comfortable ruling out a mastectomy? Do you find it a changing landscape?*

Ms. Anderson: The published data tells us that about 65 to 70 percent of women will choose breast conservation or lumpectomy instead of a mastectomy. Those percentages have been holding pretty true over the last several years. More recently, there has been discussion about an increase in the number of women choosing to have a mastectomy with breast reconstruction. However this increase is not consistent across the nation; probably because doctors agree there is little, if any, survival benefit for most women.

CEOCFO: *Would you tell us about SAVI SCOUT®?*

Ms. Anderson: The SAVI SCOUT surgical guidance system is our newest technology, invented to give surgeons a better approach to locate and remove breast lesions. If you go back to the days when ladies were undergoing mastectomies, there really was not a need to identify the exact location of the tumor, because all the breast tissue was being removed. Precisely locating the breast tumor is critical in performing lumpectomy procedures. The surgical goal is to remove all the tumor cells, but also remove as little health tissue as possible to give women the best cosmetic outcome.

A method called wire localization was developed thirty years ago to help doctors find the tumor during surgery. A radiologist will implant this wire on the morning of surgery using either mammographic or ultrasound guidance. The most common challenges reported with this localization technique are scheduling and workflow, surgical planning and guidance, high re-excision rates and a sub-optimal patient experience.

The SAVI SCOUT surgical guidance system is an FDA cleared, technological advance in tumor localization. The system uses a non-radioactive electromagnetic wave technology to detect a reflector that is placed in the tissue up to seven days prior to surgery. The system uses real-time audible and visual indicators to give surgeons a precise way to target tissue for removal. This approach offers several benefits over current localization methods including simplified scheduling, optimal surgical planning and guidance, and enhanced patient satisfaction.

CEOCFO: *What were the challenges in creating SAVI SCOUT?*

Ms. Anderson: Developing a non-imaging technology that could precisely detect an object in human tissue was the greatest challenge. Cianna Medical's research and development team, led by Eduardo Chi Sing, devoted years to creating this technology and insuring it worked in a manner that would be clinically appropriate for breast surgery.

CEOCFO: *There was recent FDA approval. What is the plan now? How do we get SAVI SCOUT into the hands of everyone who should have it?*

Ms. Anderson: Our approach is to validate the system's performance and reliability in a real-life clinical environment before a national launch. Dr. Charles Cox, MD, University of Florida, initiated a clinical trial at his institution to do just that. Pat Whitworth, MD, Nashville Breast Center joined his efforts as our second clinical site. Their preliminary results have been discussed in a poster presentation at the San Antonio Breast

Cancer Symposia in December, 2014; and just recently at the 32nd Annual Miami Breast Cancer Conference. Final results will be released at The American Society of Breast Surgeons 16th Annual Meeting to be held in Orlando, Florida, April 29-May 3, 2015. We expect to release SAVI SCOUT initially in New York, New Jersey, Pennsylvania, Delaware, Florida, Texas, Southern California and Arizona as early as June, 2015. A broader, national launch is planned for October, 2015.

CEOCFO: *What do you understand about the challenges of gaining acceptance and about the marketing procedure that will ease the process?*

Ms. Anderson: This team has been involved in developing and marketing medical devices specific to breast cancer for nearly two decades, giving us a deep understanding of unmet clinical needs and market dynamics. The most important principle in new technology adoption is to be sure it addresses a significant unmet need. We know that SAVI SCOUT addresses a significant unmet need, because our customers have told us so. More than 93% of surgeons interviewed told us they need a better approach to localizing breast tumors. Proving a new technology works in a clinical setting, supporting investigator-initiated clinical trials, and publication of results in peer-reviewed literature is very helpful to gaining acceptance. Also, the ability to articulate new product benefits in terms that are meaningful to hospital administrators who continue in their tireless efforts to improve operating efficiencies and clinical outcomes is imperative in today's health care economic environment.

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CEOCFO: *Are you funded for the next steps? Will you be seeking partnerships?*

Ms. Anderson: We have sufficient funding to commercialization of SAVI SCOUT. We are continuously looking at companies and talking to people that might be interested in strategic allegiances. We are open to opportunities that will create value for our employees and investors.

CEOCFO: *Is there something similar to SAVI SCOUT? Are there other new approved approaches that you are aware of in the works that might ultimately be competition?*

Ms. Anderson: There currently is an alternative to wire localization that began a number of years back called radioactive seed localization, or RSL for short. The way it works is quite similar to what SAVI SCOUT is able to do, except physicians implant a low dose radioactive seed at the tumor site. Then they use a gamma counter to locate the radioactive seed during surgery. SAVI SCOUT is non-radioactive which is very important for technology adoption. Hospitals and physicians find it challenging, to implement state and federal regulatory requirements for safe handling radioactive materials for this type of indication. Therefore having a non-radioactive alternative is beneficial.

CEOFCO: *Would you tell us about SAVI Sisters®?*

Ms. Anderson: SAVI Sisters is a terrific community of women who have had breast cancer and their caregivers. It is an internet based community of women who can share their stories about their cancer and their treatments; particularly about their treatments using either SAVI products. We make this available to our physicians, so as they are talking to women about their options, they can send them to this website to learn more about brachytherapy, and connect with women who have had these experiences. The SAVI Sisters Facebook page is very active with over 40,000 followers.

CEOFCO: *Do many people come to you looking for a SAVI doctor? Is that fairly common?*

Ms. Anderson: It is quite common. We receive phone calls from women who are looking for physicians who offer SAVI technologies because they have been told about them by friends, or they are seeking alternatives to treatments that have been offered. Both the Cianna Medical and SAVI Sister websites have a searchable database of SAVI physicians.

CEOFCO: *What are your plans over the next year or two?*

Ms. Anderson: For the next year or two we will focus on making SAVI SCOUT available throughout the United States. We will continue to innovate and improve on this great technology. I believe surgical guidance is one of those areas that needs improvement; not only for operational and efficiency reason, but also to reduce re-excision rates. Published data tells us that about 30 percent of women who have a lumpectomy will need to have a second surgery because tumor cells were left behind. We are hopeful that providing a better guidance tool will reduce the number of repeat lumpectomy procedures.

CEOFCO: *That certainly sounds like it cannot hurt!*

Ms. Anderson: It just makes sense, doesn't it? We also want women to know about their post-surgery radiation treatment choices. In spite of published clinical data and medical society guidelines supporting brachytherapy as an alternative treatment to whole breast radiation, the majority of physicians do not offer brachytherapy as a treatment option.

CEOFCO: *What surprised you in your role as President and CEO of Cianna Medical?*

Ms. Anderson: What astonishes me the most are the results my team can achieve in this dynamic and fluid healthcare environment. Their successes are a testament to their commitment to our mission, respect for one another and passion for improving patient care. It's not often one can build a team of such talented people who truly like working together.

CEOFCO: *Why is Cianna Medical a company to notice?*

Ms. Anderson: One in eight women in their lifetime will have a breast cancer diagnosis. That is over 200,000 women today, and I have seen reports stating that by the year 2020 over 400,000 women every year will have a breast cancer diagnosis. Cianna Medical is focused on developing products and technologies that make breast cancer therapies and treatments easier for these women.

Interview conducted by: Lynn Fosse, Senior Editor, CEOFCO Magazine
