Company Backgrounder

Cianna Medical, Inc.

Cianna Medical, Inc. is a medical device company focused on women’s health and dedicated to the innovative treatment of early-stage breast cancer. The company manufactures and markets the SAVI® breast brachytherapy applicator for the delivery of radiation therapy after lumpectomy surgery.

The company’s core technology, which delivers a shortened, five-day course of high-dose radiation therapy, represents the next generation of accelerated partial breast irradiation (APBI). With its unique ability to customize the radiation dose to the anatomy of the patient, the SAVI applicator enables more women to benefit from APBI.

Cianna Medical launched in 2007, when its SAVI technology was spun out from BioLucent, Inc. concurrent with BioLucent’s acquisition by Hologic Inc. The SAVI applicator received FDA 510 (k) clearance in 2006. In 2010, Cianna Medical successfully completed the ISO 13485 registration process and the company’s products were approved to apply the CE Mark.

Cianna Medical benefits from the expertise of several leading medical device innovators, plus a management team with a proven record of success in the breast health market. President and CEO Jill Anderson draws upon more than 20 years as a healthcare industry executive. With her experience in both the management of healthcare delivery in oncology services and as a medical device executive in breast health, she is uniquely qualified to lead Cianna Medical and oversee the development of SAVI as the next generation in radiation therapy.

The Evolution of Breast Conservation Therapy

Twenty years ago, the standard treatment for women diagnosed with breast cancer was a mastectomy. Since then, research has shown that breast conservation therapy (BCT), which consists of lumpectomy followed by radiation therapy, is as effective as mastectomy in decreasing the risk of local recurrence.

The current standard of care for radiation as part of BCT is whole breast radiation, which uses an external beam to deliver radiation to the entire breast and requires 6-7 weeks of daily treatments. However, this extended treatment schedule can significantly disrupt a woman’s life, whether it is interference with family, the cost of missed work, or the difficulty of traveling to a medical facility every day for several weeks.
These difficulties have been cited as reasons why nearly 20% of women fail to receive follow-up radiation after their lumpectomies. Unfortunately, eliminating the radiation portion of BCT triples the risk of recurrence.

APBI was developed to address the limitations of whole breast irradiation. With APBI, a full course of treatment can be delivered in just five days. In addition, internal APBI (also known as “breast brachytherapy”) delivers less radiation to healthy tissue and organs than external radiation treatment. Though the efficacy of APBI compared to whole breast irradiation has not been established, early results are promising. The definitive study comparing the two forms of treatment is currently underway by the National Surgical Breast and Bowel Project (NSABP), and initial results are expected by 2013.

The two earliest forms of breast brachytherapy were interstitial and intracavitary (“balloon”) brachytherapy. Interstitial, a technically challenging procedure, places multiple catheters into the breast, with multiple entry and exit points, providing the doctor flexibility on where to deliver the radiation dose. With the intracavitary “balloon,” a physician inserts a single balloon catheter into the lumpectomy site. However, the use of only one catheter prevents physicians from having the ability to customize treatment based on the patient’s anatomy. Restrictions, such as the tumor being located too close to the skin or chest wall, limits the number of women who can benefit from this approach.

The Next Generation: Targeting Radiation Treatment with SAVI

SAVI offers a hybrid approach to APBI, by combining the single-entry ease of balloon brachytherapy with the multi-catheter precision of interstitial brachytherapy. The strut-based, open architecture design allows physicians to sculpt radiation based on patient-specific anatomy, which increases the number of women who can benefit from APBI. Clinical studies show that by providing targeted radiation where it is needed most, the risks of toxicity and cosmetic side effects are reduced.

Clinical studies on SAVI have been authored by internationally known radiation oncology experts such as Robert Kuske, M.D., and by researchers from institutions such as MD Anderson Cancer Center and UC San Diego Moores Cancer Center. These studies show multi-catheter radiation treatment with SAVI makes the benefits of APBI available to twice as many women, as well as results in better outcomes, including less skin toxicity, reduced risk of infection and improved cosmesis. SAVI is positioned to grow the market by substantially increasing the number of women who are eligible for APBI.

In April 2010, the SAVI applicator was named a winner in the 2010 Medical Design Excellence Awards (MDEA) competition, the only awards program that exclusively recognizes contributions and advances in the design of medical products.

Board of Directors
Heath Lukatch, Ph.D.
Dr. Lukatch, the Chairman of Cianna Medical, is a Partner in Novo Ventures, Novo A/S. He is also Chairman of the Board of Inogen, Inc. and NeuroTherapeutics Pharma, Inc. Mr. Lukatch was previously responsible for biotech venture investments as a Managing Director for Piper Jaffray Ventures and SightLine Partners. He also founded and was CEO of AutoMate Scientific, Inc., a biotechnology instrumentation company.

Nancy Olson
Ms. Olson is the Managing Partner of Fog City Fund, a venture fund that invests in life science and medical companies. She was previously a General Partner at St. Paul Venture Capital, specializing in healthcare and medical technology. Ms. Olson also serves as a Trustee of the University of California.

Paul McCormick
Mr. McCormick has more than 27 years of experience in the medical device industry, including serving as President and Chief Executive Officer of Endologix from 2003 to 2008. He is also the Chairman of the Board of Cardiogenesis Inc. (CGCP) and Embrella Cardiovascular (private).

Zack Scott, MD
Dr. Scott joined Saints Capital in 2008, where he is currently a Vice President. Prior to his tenure at Saints Capital, Dr. Scott was at Burrill & Co., specializing in healthcare investments. He has invested in the areas of medical devices, healthcare services, diagnostics and biopharmaceuticals.

Tiba Aynechi, Ph.D.
Dr. Aynechi is a Principal in Novo Ventures, Novo A/S. Prior to joining Novo A/S, Dr. Aynechi was a Director with Burrill & Company where she completed regional and cross-border M&A, licensing, and financing transactions for biotechnology and large pharmaceutical companies.

Jill Anderson – President and CEO
Ms. Anderson has more than two decades of experience as a medical device and healthcare industry executive. She previously served as President of BioLucent, Inc. until the company’s acquisition by Hologic, Inc. Her prior experience includes serving as Vice President, Oncology Services for Lehigh Valley Hospital and Health Network, and Vice President of Salick Health Care.

Chris Serocke – Chief Operating Officer
Mr. Serocke served as BioLucent’s COO from the company’s inception in 2001 until its acquisition by Hologic. He has extensive experience in manufacturing operations and worldwide sales/distribution. He was previously General Manager of Bentley Laboratories, a division of Baxter Healthcare.
Management Team

Jill Anderson – President and CEO

Chris Serocke – Chief Operating Officer

Gordon Busenbark – Chief Financial Officer
Mr. Busenbark has over 30 years of global experience in the life sciences industry, including experience with companies involved in biologics, pharmaceuticals and medical devices. He worked for Baxter Healthcare for 23 years, in a variety of positions in finance and accounting, operations and general management.

Eduardo Chi Sing – Vice President of Research & Development
Mr. Chi Sing has more than 20 years of engineering and operations experience in the medical device industry. He led the development and commercialization of the SAVI applicator platform technology at BioLucent, Inc.

Gary Mocnik – Vice President of Quality Assurance/Regulatory Affairs
Mr. Mocnik has more than 20 years of experience in quality assurance and regulatory affairs in the medical device, diagnostic and pharmaceutical industries. He held senior management positions at Birtcher Medical Systems and Allergan Medical Optics.

Charles Bracken – Vice President of Sales
Mr. Bracken directed the highly successful BioLucent sales team. He was previously National Retail Sales Manager of Wyeth Consumer Healthcare.

Mike Numamoto – Vice President of Marketing
Mr. Numamoto has over 25 years of medical device marketing experience. He previously served as Vice President of Marketing for Uptake Medical, a start-up medical device company, and Vice President of Marketing at Edwards Lifesciences.

Marie Shaw – Senior Director, Strategic Communications
Ms. Shaw was a marketing and business development consultant with BioLucent. Previously, she served as Director of Marketing and Women Health Services at Lehigh Valley Hospital and Health Network.

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