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## **Company Backgrounder**

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 inside the breast after lumpectomy surgery.

SAVI represents the next generation of accelerated partial breast irradiation (APBI), following years of research on the most effective delivery of radiation treatment. With its unique ability to conform the radiation dose to the anatomy of the patient, the SAVI applicator provides greater potential for more women to benefit from APBI.

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.

Steve Gex, as Chairman of Cianna Medical, brings extensive experience in the successful development of medical device technologies and companies. A co-founder of BioLucent, Inc., he served the company as Chairman and CEO. Prior to BioLucent, Gex co-founded and served as CEO of Biopsys Medical, Inc., which developed the Mammotome breast biopsy device. Dr. Thomas Fogarty, a member of Cianna Medical's Board of Directors, is a world-renowned medical inventor who has been instrumental in the founding of more than 30 medical device companies.

### **The Evolution of Breast Conservation Therapy, Including APBI**

The SAVI applicator provides physicians with an alternative method to deliver radiation to the breast that may extend the benefits of APBI to a larger group of women. Its unique design enables physicians to contour the radiation dose and reduce exposure of healthy tissue such as the heart, lung, skin and ribs. This allows physicians to treat patients who otherwise would have been eliminated as candidates for breast brachytherapy.

Prior to breast conservation therapy (BCT), the standard of care was mastectomy, in which the entire breast was removed. As research showed that lumpectomy and radiation of the entire breast were just as effective at reducing recurrence, whole breast radiation became the standard of care for early-stage breast cancer.

However, whole breast radiation is not without its disadvantages. The lengthy treatment time can significantly disrupt a woman's life. In fact, interference with family, the cost of missed work, and the difficulty of traveling to a medical facility every day for six-to-seven weeks 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).

The two earliest forms of 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.

### **SAVI – The Next Generation**

The SAVI applicator represents an important alternative for delivering partial breast irradiation. SAVI offers a hybrid approach to APBI, by combining the single-entry ease of balloon brachytherapy with the multi-catheter precision of interstitial brachytherapy. With this refined approach to radiation delivery, physicians are no longer limited by the size, shape or location of the cavity.

SAVI is the only single-entry APBI applicator that can contour the radiation dose to the size and shape of the cavity bed and a woman's anatomy. It allows physicians to precisely target radiation to the area that needs it most. Without the technical limitations of balloon brachytherapy, SAVI is positioned to grow the market by substantially increasing the number of women who are eligible for APBI.

## **Cianna Medical Board of Directors**

### *Steve Gex*

Mr. Gex was the co-founder and CEO of BioLucent, makers of the MammoPad breast cushion for a softer mammogram, until the company's acquisition by Hologic in 2007. He co-founded and served as the President & CEO of Biopsys Medical, Inc., which developed the Mammotome breast biopsy device and was acquired by Ethicon Endo-Surgery (Johnson & Johnson). Mr. Gex also serves on a number of private company boards of directors.

### *Thomas Fogarty, M.D.*

Dr. Fogarty is Professor of Surgery at Stanford University. He has been instrumental in the founding of more than 30 medical device companies, including Biopsys Medical, BioLucent, and Cianna Medical. Dr. Fogarty has shown a particular dedication to the field of breast health care. In 2000, he received the Scientific Leadership Award, presented by the National Breast Cancer Coalition, for his role in pioneering the Mammotome breast biopsy device.

### *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 serves on a number of private company boards, is a Trustee of the University of California, and is involved with a number of non-profit and performing arts organizations.

### *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. in 2007. Her prior experience includes serving as Vice President, Oncology Services for Lehigh Valley Hospital and Health Network, and Vice President of Salick Health Care.

## **Management Team**

### *Jill Anderson – President and CEO*

See information above.

### *Chris Serocke – Chief Operating Officer*

Mr. Serocke served as BioLucent's COO from the company's inception in 2001 until its acquisition by Hologic, Inc. in 2007. Mr. Serocke has extensive experience in manufacturing operations and worldwide sales/distribution. He was previously General Manager of Bentley Laboratories, a division of Baxter Healthcare.

*Hugh Neuharth – Chief Financial Officer*

Formerly CFO of BioLucent and Finance Director of the Australia region for Smith & Nephew, Mr. Neuharth has also been a consultant to medical device organizations on strategy, operations, fund-raising, and financial and organization structure/management issues.

*James Stubbs, Ph.D. – Chief Science Officer*

Dr. Stubbs has extensive experience with research, product development and clinical applications in the brachytherapy field. Prior to joining Cianna, he spent 10 years at Proxima Therapeutics, Inc., eventually becoming Chief Research Scientist of Cytoc Surgical Products following Proxima's acquisition by Cytoc in 2005.

*Vicki Clements – Vice President, Marketing*

Formerly President of a strategic marketing and consulting firm that focused on small-technology applications, Ms. Clements has extensive experience with medical device development. She also served as COO of Irvine Scientific, where she oversaw the company's Sales, Marketing and Operations divisions.

*Charles Bracken – Vice President, Sales*

Mr. Bracken directed the highly successful BioLucent sales team for several years, prior to the company's acquisition by Hologic. He was previously National Retail Sales Manager of Wyeth Consumer Healthcare.

*Gary Mocnik – Vice President, Quality Assurance/Regulatory Affairs*

Mr. Mocnik has over 20 years of experience in quality assurance and regulatory affairs in the medical device, diagnostic and pharmaceutical industries. He has held senior management positions at several major medical device companies, including Birtcher Medical Systems and Allergan Medical Optics.

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