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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health



National Institutes of Health Commercialization Assistance Program
(NIH-CAP)

Company Overview

Industry Sector: Medical Devices

Company Overview: We are developing and commercializing a platform of innovative, patient friendly dedicated breast CT scanners designed to detect the presence of breast cancer much earlier than current technologies on the market. In more than 15% of women being screened, breast cancer will be present in spite of a normal mammogram. Conversely, more than 80% of biopsies performed because of a suspicious mammogram turn out to be normal. This leaves much room for improvement. Preliminary breast CT studies have shown that much smaller tumors can be detected than with screening mammography, especially in women with dense breasts. This is accomplished without breast compression, a fact that could result in increased participation. Significantly improved breast cancer detection is the focus of the company.

Target Market(s): Private and hospital based mammography clinics worldwide.

Key Value Drivers

Technology*: Zumatek's 3D dedicated breast scanners provide fully 3D information about the breast to deliver more accurate and earlier diagnosis of breast cancer, leading to improved patient survival. A full 3D scan of the breast, chest wall, and axilla is performed within a 30 second or less procedure at doses equal to or lower than conventional screening mammography. 3D information also allows for more accurate therapy monitoring and biopsy guidance.

Competitive Advantage: The Zumatek breast CT scanner is the only 3D dedicated breast scanner capable of the complex motion necessary to acquire the full breast, chest wall, and axilla, essential elements for breast screening. We are also the only provider of multi-modality dedicated breast scanners, combining SPECT-CT and PET-CT for more accurate diagnosis. Through a proprietary filtering method, we can acquire these scans at significantly lower doses than competitors.

Plan & Strategy: seeking a strategic partner and outside investment

*Technology funded by the NCI and being commercialized under the NIH-CAP

Management

Leadership:

Randolph L McKinley, PhD, President and CEO – doctorate in Biomedical Engineering and original developer of the breast CT system
Sheila Mikhail, JD, Chief Counsel – founder and managing member of Life Sciences Law, founder and former CEO of Asklepios BioPharmaceutical
Martin Tornai, PhD, Board of Directors – doctorate in Biomedical Physics, co-founder, and associate professor, Department of Radiology, Duke University
Steve Just, Director of Engineering – 15 years management of medical device design, development, and manufacturing

Scientific Advisory Board:

Etta Pisano, MD – Kenan Professor of Radiology, University of North Carolina, and Director of the UNC Biomedical Imaging Research Center. World renowned leader in breast imaging, 20+ years medical device development, founder of NextRay, Inc.

Product Development

A clinic ready breast CT scanner capable of routine breast screening is the first product being developed by Zumatek. It is also the primary result of the current SBIR Phase II award. Subsequent products will include the combination of molecular imaging techniques with breast CT for dedicated breast imaging dual modality solutions including breast SPECT-CT and breast PET-CT. This is expected to provide improved tools for detection, diagnosis, and staging of breast cancer.

Milestones include:

1. Placement of next generation clinic-ready scanner at UNC Cancer Hospital for pilot patient studies – July 2010
2. Additional 4 scanners placed at leading clinics in U.S. for FDA trials – December 2010
3. Completion of FDA approval – December 2012
4. Product market launch – December 2012
5. Initiation of dual modality product development of SPECT-CT and PET-CT – March 2011