

# **DOBI Global, LLC**

*Advanced Angiogenesis Imaging  
For  
Improved Disease Detection & Treatment*

**Business Plan Executive Summary**  
April 2012

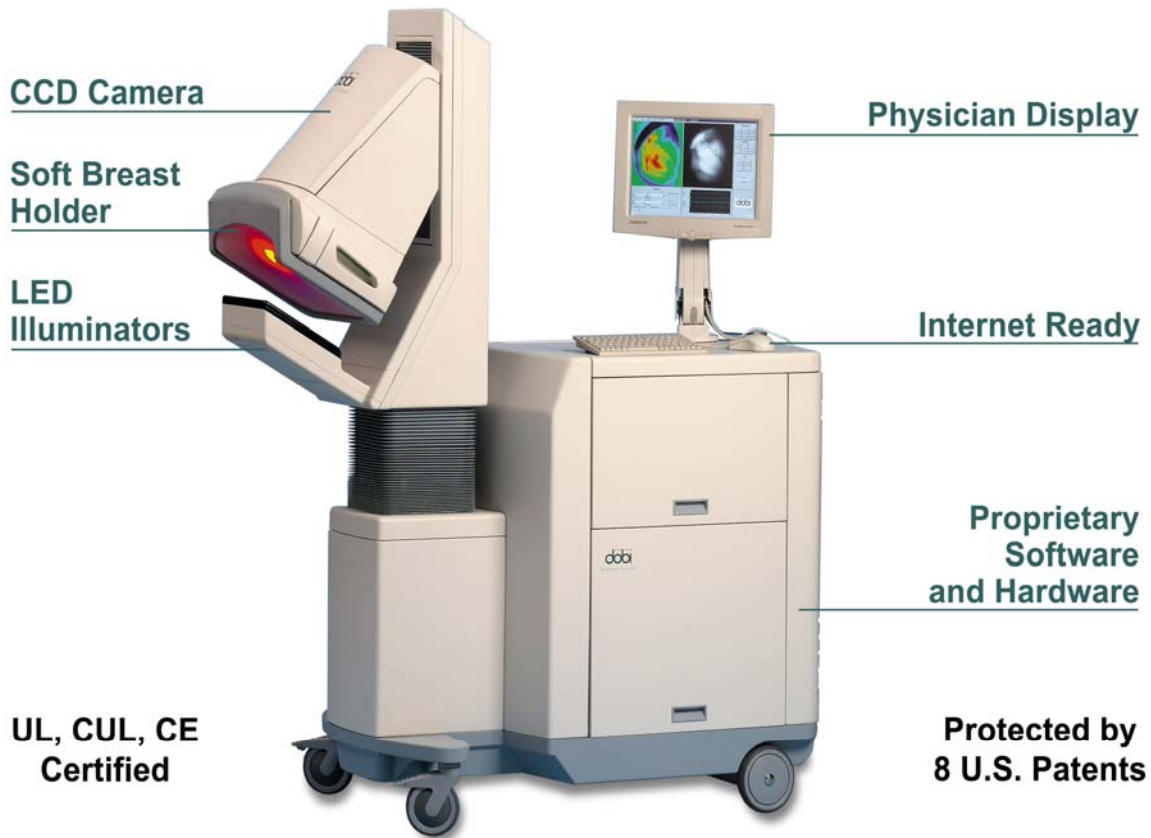
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**Small, Portable, And Inexpensive, The DOBI System “Sees”  
Vascular Developments Associated With Cancers**

*Sophisticated Technology, Simply Implemented  
(Actual Photo)*

**Dynamic Optical Breast Imaging System**

**User and Patient Friendly**



# EXECUTIVE SUMMARY

## THE COMPANY

DOBI Global, headquartered in Southborough, Massachusetts, is a technology based medical device company that continues the development and manufacture of a well developed, unique, accurate and potentially lifesaving means for the improved detection of breast cancer at early stage. At its founding, the Company acquired all the intellectual property, rights, title and interest in an advanced breast imaging system known as the — DOBI ComfortScan System. The ComfortScan system was developed over an eight year period before 2000 wherein nearly \$45MM was spent on product development and clinical testing, and its marketing development was over an six year period from 2000 to 2006 wherein nearly 38MM was spend. ComfortScan's medical benefit is the detection of angiogenesis in the breast which is often a natural biomarker for the presence of a malignant tumor starting from the early stage. The initial use of the ComfortScan systems is as an important adjunctive tool to diagnostic mammography and ultrasound for improved breast cancer diagnosis by providing physiological information. Additional uses of the ComfortScan system will include implementation alone or in tandem with other common imaging modalities, such as ultrasound and mammography, as both a broad based cancer-screening tool and the non-invasive monitoring of anti-angiogenesis based cancer therapy treatments for millions of patients worldwide. Furthermore, laboratory research usage within the scientific and pharmaceutical industries is also expected.

## THE TECHNOLOGY

The medical and scientific foundation of the DOBI Global technology is the unique ability to image, quickly, inexpensively, and painlessly, the body's creation of new blood vessels (neovascularization) to support and sustain cancer development. This process, known as **angiogenesis**, is a vital element in the development and growth of virtually all cancers and over 70 other human diseases. Today, the ability for medical and scientific professionals to accurately and cost effectively image angiogenesis in the human body is virtually non-existent. Anti-angiogenesis treatments for cancer treatment are becoming more common, although imaging techniques to monitor the effectiveness of these drugs is also limited.

In the case of breast cancer detection, mammographic x-ray is the industry standard, even though it is well known to be limited in its capabilities. In particular, mammographic x-ray is often painful, irradiates the patient, and, most importantly, is limited in its ability to identify breast cancer in its early stages (i.e., below 4~5mm in size) along with little capability to accurately differentiate malignant from benign masses. More importantly, industry estimates are that as many as 1,000,000 women

in the United States alone have breast cancer and do not know it. This is due in part to poor detection by current screening technologies as well as a lack of participation by many women in regular breast cancer screening.

In November 2009, U.S. Preventive Services Task Force (USPSTF) recommends against routine screening mammography in women aged 40 to 49 years, and biennial screening mammography for women between the ages of 50 and 74 years after examining the evidence on the efficacy of 5 screening modalities in reducing mortality from breast cancer by comparing the expected health outcomes of mammography screening at different ages.

In March 2001, these and other limitations led the U.S. National Academy of Sciences' Institute of Medicine to issue a call to action to science and technology for improvement in breast-imaging techniques. With its non-invasive, accurate and cost-effective imaging system, DOBI Global's new, patented technology is a response to this call.

## **REVENUES AND PROFITS**

Based on its current stage of development and progress in marketing and selling current DOBI Breast Imaging System ("ComfortScan") product worldwide, the Company anticipates incremental revenue generation from international customers and potential the States. Gradually growing profitability is expected to be achieved in following years. The revenue projection is \$5, \$22, \$63, \$138.5 and \$245.5 millions with respect to following five years, 2012, 2013, 2014, 2015 and 2016.

## **MARKET OPPORTUNITY**

According to most industry reports, the worldwide healthcare industry is considered to be a high-growth investment area over the next decade. Within this market, the medical imaging industry was over \$6.6 billions in 2004 and will grow 7.6 percent annually from 2008 to 2013. The U.S. market in biomedical segment, which includes diagnostic imaging equipment, is expected to generate sales of over \$5.5 billion in 2010, including sales of about \$1 billion in oncology-related imaging equipment (Medical Data International). The diagnostic imaging equipment market in emerging countries (China, India & Brazil) is expected to grow at a Compounded Annual Growth Rate (CAGR) of 7.3% over 2009~2016 to reach \$3.5 billion by 2016. The diagnostic imaging equipment market in emerging countries gains most of its revenues from the Chinese market. In 2009, China accounted for 62% of the diagnostic imaging market revenues from emerging economies. Recently introduced healthcare reforms in China are expected to drive the market. The reforms are aimed at improving the healthcare infrastructure across China. These will encompass the upgrading of existing healthcare facilities as well as the establishment of new healthcare facilities. Diagnostic imaging procedures being the precursor for the diagnosis of many diseases and disorders, is expected to gain maximum patient volume. Use of diagnostic imaging

equipment is expected to rise due to the expansion of healthcare infrastructure in China after the reforms. The global market for diagnostic imaging equipment for oncology reached more than \$11.6 billion in 2010 and, despite the global recession, is forecast to grow to about \$14.8 billion by 2015, an overall compound annual growth rate (CAGR) of 5% for 2010 through 2015. The X-ray systems include CR, DR, fluoroscopy, and full-field digital mammography (FFDM).

Sales of mammography equipment in Diagnostic segment, besides screening and monitoring segments, is forecast to reach 3913 units, and US\$925 million by the year 2015 globally. The U.S. breast imaging and mammography markets are expected to reach more than \$1 billion by 2017, according to a new report by iData Research. Life Science Intelligence (LSI) reports that Breast Disease Diagnosis and Therapy Markets, 2007, finds that the \$550 million U.S. digital mammography segment is expected to grow more than 50% annually during the next 3 years as digital technology replaces analog. European Women's Healthcare Imaging Markets finds that the total market comprising mammography, bone densitometry, breast MRI, breast and ob/gyn ultrasound earned revenues of \$1,224.5 million in 2009 and estimates this to reach \$1,655.6 million in 2016. In 2008, China mammography tendering purchased over 50 units for nearly \$30 million at 8.62% annual growth rate.

The Company, DOBI Global, is positioned within the biomedical market as an advanced medical imaging company with proprietary software and hardware technology for imaging angiogenesis wherever it is found in the human body and as the angiogenesis-imaging leader in the market with specific applications, i.e. early breast cancer detecting.

Breast cancer has the highest prevalence of any cancer, was newly diagnosed in over 1.5 million women each year and that 500,000 women worldwide died of this disease in 2010. The chance of developing invasive breast cancer at some time in a woman's life is about 1 in 8 (12%). In 2009, an estimated 192,370 new cases of invasive breast cancer was diagnosed among women in the United States. In addition to invasive breast cancer, there were about 62,280 new cases of carcinoma in situ (CIS) in 2009. CIS is non-invasive and is the earliest form of breast cancer. In 2008, the incident of breast cancer in Europe was 332,771, 103.7/100,000, and 89,797, 23.9/100,000, died of breast cancer. The report by China Health Ministry also shows that urban women are more likely to get breast cancer - the incidence being 49 per 100,000. In Shanghai, 55 out of every 100,000 women have breast cancer, a 31 percent increase since 1997, the China Daily reported. About 45 out of every 100,000 women in Beijing have the disease, a 23 percent increase over 10 years. In 2005, China had 142,732 new cases and, sadly, 40,134 women died. According to several articles, between 170,000 – 200,000 women are diagnosed with breast cancer in China each year. Since an average almost “10 years younger than in the West is found, as a result, experts are advising Chinese women to begin cancer screening starting as early as 36 year of age.

According to ACS, breast cancer is the leading cause of cancer death among women ages 40 to 55. The fact that mammography is particularly limited in this age group further highlights the need for improved diagnostic methods. Today, X-ray mammography is regarded as the current gold standard for breast cancer screening and diagnosis throughout the world. An estimated 75 million mammograms, utilizing an installed base of approximately 45,000 units, are performed annually worldwide. About 39 million women undergo mammograms each year in the United States, costing the health-care system more than \$5 billion. However, despite its extensive use, mammography is limited in its ability to differentiate between benign and cancerous lesions while exposing women to cumulating amounts of ionizing radiation. Furthermore, mammography is widely considered to be ineffectual for premenopausal women due to the inability of x-rays to penetrate dense breast tissue. For many women, mammography is often painful, and most importantly, is limited in its ability to identify breast cancer in its early stages (i.e., below 4~5mm in size).

Federal panel recommends reducing number of mammograms. Women in their 40s should stop routinely having annual mammograms and older women should cut back to one scheduled exam every other year, an influential federal task force has concluded, challenging the use of one of the most common medical tests. The new guidelines also recommend against teaching women to do regular self-exams and concluded that there is insufficient evidence to recommend that doctors do the exams or to continue routine mammograms beyond age 74.

Due to inherent limitations, current mammographic techniques often result in a need for patients to undergo additional downstream testing. At least 10% undergo invasive surgical biopsies to differentiate malignant from benign tumors. Due largely in part to these limitations, 80% of these 2,500,000 costly biopsies are later determined to be benign and therefore potentially avoidable. More importantly, industry estimates are that as many as 1,000,000 women in the United States alone have breast cancer and do not know it. This is due in part to poor detection by current screening technologies as well as a lack of participation by many women in regular breast cancer screening.

Due to these and many other concerns, the Company's angiogenesis based imaging technology represents an entirely new and improved means for early, non-invasive breast cancer detection. The DOBI Breast Imaging System is designed to accurately confirm the presence of cancer and differentiate cancer from benign lesions by displaying the contrast between areas of malignancy versus normal tissue within the breast. Unlike comparably priced systems in use today, this non-invasive, all-digital process is fast, exerts very mild and gentle pressure on the breast, uses no ionizing radiation, and is effective for women of all ages.

The many advantages of the DOBI ComfortScan System over current available imaging modalities will make it extremely attractive to healthcare providers and payers, as well as to women themselves. Based on feedback from previous physicians, technicians and women studies and recent market and installations, the Company anticipates ready market acceptance continuously and increase the sales gradually —

the DOBI System's accuracy and low cost combined with its comfort, convenience and safety.

## **SALES**

The DOBI System's accuracy and low cost combined with its comfort, convenience and safety will generate considerable enthusiasm among women and breast cancer advocates.

To accelerate revenue generation and demonstrate market acceptance, international sales activities have begun. The Company has begun to enter into distribution arrangements and strategic partnerships in select countries in Latin America, Europe, Asia-Pacific, and the Middle East. In 2008 and 2010, only China and Italy installation sites have increased from zero to over forty, and additional fifty (50) orders from both countries are secured for year 2012.

The Company will build a rapid and sustainable revenue stream by making the DOBI System available either as an outright purchase or on a "pay-per-use" basis. The DOBI System's low manufacturing cost allows attractive pricing flexibility that will enhance its early adoption. Once full production levels are attained, the Company anticipates gross margins of approximately 70% after discounts to distributors.

## **MARKETING**

The Company has also created a comprehensive marketing plan to systematically enhance awareness abroad and lay the groundwork for next generation in the U.S. after FDA approval. A full-scale, multi-faceted market awareness campaign will be rolled out to support sales. Marketing and public relations efforts will address scientists (thought leaders in angiogenesis, breast cancer and radiology), physicians (such as oncologists and OB-GYN's), third-party payers (public and private insurers), service providers (radiology practices), breast cancer advocacy groups (which carry monumental influence) and patients (the women who will benefit). Further, the Company has begun the process of obtaining a medical reimbursement (CPT) code, using experts in the areas of private, Federal, and State agencies familiar with such programs worldwide.

## **PRICING ADVANTAGES**

The Company currently anticipates the base price of the DOBI System to be less than \$150,000. This price is competitive with the cost of virtually all other diagnostic imaging devices addressing the breast imaging market, which range in price from \$100,000 to over \$450,000. Given the lower up-front cost and minimal overhead required to operate the DOBI System, the "per procedure" costs of an examination using the DOBI System will be competitive with the current costs of diagnostic mammography and ultrasound.

## **COMPETITION**

Medical Data International estimates that the installed base of x-ray mammography units worldwide is approximately 50,000. Traditional units generally sell for \$100,000 - \$150,000 (not including facility improvements, etc.) and the newest digital units are between \$450,000 and \$600,000. Due to the high capital costs associated and the specialized training and facilities necessary to operate equipment and read the images, mammography is typically available only at hospitals, imaging centers, or specialty breast clinics.

Once a mammogram has identified a mass, ultrasound is the most widely used secondary screening detection method short of a biopsy to distinguish cysts from solid masses. If a cyst is identified, it is generally aspirated. However, if a solid mass is found, ultrasound offers no capability to determine if it is a malignancy.

The DOBI System can differentiate between benign and malignant lesions at a cost on par with an ultrasound procedure and has the potential to rapidly become the tool of choice due to its accuracy, speed, comfort, safety, convenience, digital format, low cost and ease of use.

The breast cancer imaging market is largely composed of well-established players such as Fischer Imaging, GE Medical, Lorad, Kodak, Philips, Siemens and Toshiba. These companies are likely strategic partners or potential acquirers of DOBI technology. There are optical imaging systems being commercially developed by companies such as Imaging Diagnostic Systems, Inc. (IMDS; Plantation, Florida) and Advanced Research and Technology, Inc. (ART; Montreal, Canada). Both companies use laser-based technologies to assess various optical properties of breast abnormalities. Computerized Thermal Imaging (CTI; Layton, Utah) manufactures equipment that analyzes breast tissue using heat waves/caloric output and the technology has concluded the clinical testing phase. A hand-held electrical impedance device manufactured by TranScan Research and Development, Ltd. is not widely sold.

## **MANUFACTURING**

The Company uses contract manufacturers to produce the major sub-systems for the DOBI units and most electronic components and raw materials required are readily available from a variety of suppliers. DOBI Global has contracted two OEM manufactures to be the final assembly, test, QA/QC, warehouse and shipping operation after the full marketing and sales. This approach will allow the Company to establish and maintain a limited in-house final assembly and test capability, including better inventory and quality control, resulting in lower overhead costs and improved gross profit margins.

## **SERVICE**

The Company has been providing a variety of service capabilities to support the DOBI System in the field. The DOBI System has been designed in modular units to facilitate



easy diagnosis and repair. The soft membrane breast holder is the item most susceptible to normal replacement, which can easily be done in the field. If a unit fails to function properly at a customer's site, the Company plans to provide 24/7 on-line support or toll-free telephone access during business hours.

In situations where Resellers will be providing on-site support to customers, each Reseller will have been trained and certified by the Company in the proper maintenance to the DOBI System. Reseller agreements shall include provisions to provide qualified service and parts on a 24/7 basis to users of the DOBI System.

## **USE OF FUNDS**

The Company intends to raise three (\$3) million US dollars to continue marketing development of DOBI product, ComfortScan, the development of DOBI technology and its next generation, ComfortScreen, for woman screening at all ages worldwide in 2012.

To industrialize the ComfortScreen and international market development, Approvals, of the ComfortScreen, the Company plans to raise additional three (\$3) million US dollars in 2013 before market development, FDA Approvals, in the United States.

The most likely exit strategy for shareholders is a sale of the Company to a large imaging firm such as GE Medical, Siemens, Kodak or Hitachi because the non-invasive detection of breast cancer at early stage will make DOBI Global an especially attractive acquisition. Alternatively, the Company will consider an IPO with a leading investment banking firm, as market conditions allow.

## **MANAGEMENT**

A highly experienced and skilled management team is lead by Dr. G. John Zhang, co-founder and CEO. The team has excellent technical, financial, clinical, sales, marketing, and manufacturing expertise. Additionally, a number of highly regarded outside physicians and scientists advise the Company.

## **CONCLUSION**

There is an obvious and growing need for a technological shift toward marked improvement in the diagnostic imaging of breast cancer. DOBI Global is perfectly positioned to provide the much-needed next level of improvement in accuracy, speed, comfort, safety, convenience and cost effectiveness. The management team is strong, the technology works and has additional future expansion, patents are in place, and sales are starting.