

Investor Relations | Hologic

Hologic Receives FDA Approval for First 3-D Digital Mammography (Breast Tomosynthesis) System

Selenia Dimensions 3-D technology addresses many of the limitations of conventional mammography

PR Newswire
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BEDFORD, Mass., Feb. 11, 2011 /PRNewswire/ -- Hologic, Inc. (Hologic or the Company) (Nasdaq: HOLX), a leading developer, manufacturer and supplier of premium diagnostic products, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, today announced the Company received approval from the U.S. Food and Drug Administration (FDA) for its Selenia Dimensions digital breast tomosynthesis system (Dimensions 3-D).

Mammography systems using conventional 2-D imaging have limitations caused by tissue overlapping tissue in the breast that may hide lesions or cause benign areas to appear suspicious. Clinical trials using Hologic's Dimensions 3-D system showed measurable improvement in clinical performance over conventional mammography. These trials also showed significant gains in specificity -- the confidence to rule out cancer without recalling the patient for further study -- and other benefits including improved lesion and margin visibility and the ability to accurately localize structures in the breast. The combination of measurable improvements in accuracy and detection, and improved sensitivity, makes the Dimensions 3-D system a superior system vs. conventional digital mammography systems.

"We are extremely proud to be the first company to receive FDA approval of a 3-D digital mammography system and to offer women this ground-breaking, superior imaging technology," said Rob Cascella, President and Chief Executive Officer. "Our Dimensions 3-D takes advantage of all of the benefits of digital mammography and quite simply makes it better with the combination of fast, high quality 3-D breast imaging. We believe tomosynthesis has the potential to change how screening and diagnostic mammography is performed, and over time will prove invaluable to the earliest possible detection of breast cancer and in the reduction of unnecessary diagnostic interventions."

According to Jay Stein, PhD, Hologic co-founder and Chief Technology Officer, "Tomosynthesis scans can be performed quickly with Dimensions. This means enhanced performance not just for diagnostic problem solving, but in everyday routine screening. Over the next several years we view Dimensions as a platform technology for other imaging modalities to aid in the fight against breast cancer."

Hologic's Dimensions 3-D system is available commercially in more than 40 countries including countries in Europe, Latin America and Asia. In North America, commercial systems are already installed in Canada and Mexico.

About Breast Cancer

One in eight American women will develop breast cancer sometime in her lifetime.⁽¹⁾ In 2009, an estimated 192,370 new cases of invasive breast cancer were diagnosed among American women, as well as an estimated 62,280 additional cases of in situ breast cancer.⁽²⁾ Over 40,000 American women died from breast cancer in 2009.⁽³⁾ Only lung cancer accounts for more cancer deaths in American women. The stage at which breast cancer is detected influences a woman's chance of survival. If detected early, the five-year survival rate is 98 percent.⁽⁴⁾ At this time, there is no sure way to prevent breast cancer, which is why regular mammograms starting for most women at age 40 are so important.⁽⁵⁾

About the Dimensions 3-D System

The Company's Dimensions 3-D mammography system is a new method for breast cancer screening and diagnosis. Unlike prior-generation mammography systems which generate two-dimensional images, breast tomosynthesis produces three-dimensional images which are intended to reveal the inner architecture of the breast, free from the distortion typically caused by tissue shadowing or density. Tomosynthesis images are acquired with the breast held briefly in compression. The examination, which includes a 3-D tomosynthesis image in combination with a 2-D image, takes only seconds longer than a conventional 2-D digital mammogram at a total exam dose within current FDA guidelines. The 3-D scan results in a stack of thin high-resolution image slices intended to provide clear rendition of structures in the breast and their spatial relationship with the surrounding breast tissue. The images are displayed on a standard diagnostic workstation for review by the radiologist.

Dimensions 3-D software is a purchasable option on existing Selenia Dimensions 2-D systems. Enabling the 3-D capability on a Dimensions 2-D system involves a software key and adjusting a PC-board setting. There is no need for new hardware. Upright stereotactic biopsy and computer-aided detection are already cleared for use on the Company's 2-D Dimensions systems.

⁽¹⁾ National Cancer Institute Fact Sheet: "Probability of Breast Cancer in American Women"

(2) American Cancer Society: Breast Cancer Facts and Figures 2009-2010. Table 2, page 4

(3) American Cancer Society, Breast Cancer Facts and Figures 2009-2010. Table 2, page 4

(4) American Cancer Society, Breast Cancer Facts and Figures 2009-2010. Table 7, page 9

(5) www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-detection

About Hologic, Inc.

Hologic, Inc. is a leading developer, manufacturer and supplier of premium diagnostics products, medical imaging systems and surgical products dedicated to serving the healthcare needs of women. Hologic's core business units are focused on breast health, diagnostics, GYN surgical, and skeletal health. Hologic provides a comprehensive suite of technologies with products for mammography and breast biopsy, breast magnetic resonance imaging, radiation treatment for early-stage breast cancer, cervical cancer screening, treatment for menorrhagia and uterine fibroids, permanent contraception, osteoporosis assessment, preterm birth risk assessment, mini C-arm for extremity imaging and molecular diagnostic products including HPV and reagents for a variety of DNA and RNA analysis applications. For more information, visit www.hologic.com.

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Forward Looking Disclaimer

This News Release contains forward-looking information that involves known and unknown risks and uncertainties, including statements about Hologic's Dimensions 3-D mammography system, including the anticipated benefits of that system. The Company cannot assure that the system will achieve the anticipated benefits described herein, or that such benefits will be replicated in any particular manner with respect to an individual patient as the actual effect of the use of the system can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. Among other things, newly introduced products may contain undetected errors or defects or otherwise not perform as anticipated. The risks and uncertainties included above are not exhaustive. Other factors that could adversely affect the Company's business and prospects are described in the Company's filings with the Securities and Exchange Commission. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to the data or statements presented herein to reflect any change in the Company's expectations or any change in events, conditions or circumstances on which any such data or statements are based.

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