

Investor Relations | Hologic

R2 Technology Receives FDA Approval for Computer-Aided Detection on Hologic's Digital Mammography System

CAD Technology Could Benefit Millions of Women in the Fight Against Breast Cancer

PRNewswire-FirstCall

BEDFORD, Mass. and SUNNYVALE, Calif.

BEDFORD, Mass., Apr. 13, 2004 / [PRNewswire-FirstCall](#)/ -- Hologic, Inc., (NASDAQ: HOLX), a leading provider of women's diagnostic imaging systems and state-of-the-art digital radiology systems, and R2 Technology, Inc., a pioneer in computer-aided detection (CAD) technology, today announced R2 has received U.S. Food and Drug Administration (FDA) approval for the use of R2's ImageChecker® CAD technology customized for Hologic's Selenia™ full field digital mammography (FFDM) system.

CAD is used by an increasing number of radiologists as "a second pair of eyes" when reading a woman's mammogram. Analogous to a "spellchecker" system on a personal computer, CAD technology has the potential to detect findings that might otherwise be overlooked during the review process, thus increasing cancer detection. CAD technology also is especially effective in identifying calcifications, some of which can be cancerous.

"Receiving FDA approval finalizes the commitment of both companies to merge our premier technologies together in a package that we believe will provide one of the most powerful tools in assisting physicians in the early detection of breast cancer," said Jack Cumming, Hologic's Chairman and CEO. "At present rates, breast cancer will affect one out of every eight women. If found and treated early while localized to the breast, the five-year survival rate is over 90 percent. I am personally committed to raising awareness for women's health issues and emphasize the importance for all women to have regular mammograms and checkups."

The Hologic Selenia produces digital x-ray images captured without film and is designed to generate digital mammographic images that can be used for screening and diagnosis of breast cancer. Hologic believes over one-half of all Selenia FFDM systems sold will be equipped with CAD technology.

"We are very pleased to be able to offer a customized ImageChecker solution for Hologic's FFDM Selenia," said Michael S. Klein, president and CEO of R2 Technology. "Hologic is a recognized leader in mammography and is well known for its extensive experience in providing innovative and cutting-edge technology focused on the early detection of breast cancer. Hologic's established base of screen-film mammography customers and its growing base of digital customers presents a very exciting pathway for us to make this customized CAD product available to a larger number of users."

Under the terms of an agreement with R2 signed in July 2003, Hologic has exclusive worldwide distribution rights to sell the R2 customized product in combination with its Selenia system. In addition, Hologic has distribution rights for R2 CAD products for use with conventional film-based mammography systems that are able to be upgraded to digital mammography systems. The agreement is for an initial term of five years.

R2's ImageChecker® system was originally approved by the FDA in 1998 for use with film-based screening mammography to assist radiologists in minimizing false negative readings, and in 2001 the FDA expanded its approval to include use with diagnostic mammograms. To date, R2 has shipped more than 1,200 film and digital-based systems worldwide and more than 6.8 million women have had their mammograms interpreted with the aid of an ImageChecker CAD system.

About Hologic

Hologic Inc. is a leading developer, manufacturer and supplier of medical imaging systems dedicated to serving the healthcare needs of women, and a leading developer of state-of-the-art digital imaging technology for general radiography and mammography applications. Hologic's core business units are focused on osteoporosis assessment, mammography and breast biopsy, direct-to-digital X-ray for general radiography applications and mini C-arm imaging for orthopedic applications.

About R2 Technology, Inc.

R2 Technology, Inc., headquartered in Sunnyvale, Calif., is a recognized leader in the development and commercialization of computer-aided detection (CAD), an innovative technology that assists radiologists in the early detection of breast cancer, lung nodules and other lung abnormalities. R2's ImageChecker CAD mammography system with OmniCAD™ technology is being used successfully by hospitals and imaging centers as an aid to radiologists for the early detection of breast cancer. As a medical software company, R2 is developing CAD systems for a variety of imaging modalities and disease states. R2 recently received an "A" rating from MD Buyline and was given the 2003 Frost and Sullivan Product Leadership Award. For information, visit www.r2tech.com.

Forward Looking Disclaimer

This News Release contains forward-looking information that involves risks and uncertainties, including statements about Hologic's plans, objectives, expectations and intentions. Such statements include, without limitation, statements regarding the relationship and anticipated benefits from Hologic's agreement with R2 and the anticipated performance of the customized systems developed under the agreement with R2. These forward-looking statements are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those anticipated. Factors that could cause actual results to materially differ include, without limitation, Hologic's and R2's limited experience in working together; the risk that newly introduced products may contain undetected errors or defects or otherwise not perform as anticipated; the early stage of market development for digital X-ray products; Hologic's ability to predict accurately the demand for its products and to develop strategies to address its markets successfully; risks relating to Hologic's reliance on a single source of supply for some key components of its products; the need to comply with especially high standards in the manufacture of digital X-ray products; Hologic's ongoing ability to satisfy financial and other covenants in its credit and lease agreements; technical innovations that could render products marketed or under development by Hologic obsolete; competition; and reimbursement policies for the use of Hologic's products. Other factors that could adversely affect Hologic's business and prospects are described in Hologic's filings with the Securities and Exchange Commission. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements to reflect any change in Hologic's expectations or any change in events, conditions or circumstances on which any such statement is based.

ImageChecker is a registered trademark and OmniCAD is a trademark of R2 Technology, Inc. Hologic and HTC are registered trademarks and Selenia is a trademark of Hologic, Inc.

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