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Hologic Receives Approvable Letter from the FDA for the LORAD® Full Field Digital Mammography System

PRNewswire
BEDFORD, Mass.

Hologic, Inc. (NASDAQ: HOLX), a leading provider of specialized medical imaging equipment for women's health and general radiographic applications, today announced it received an approvable letter from the Food and Drug Administration (FDA) for the Company's Lorad® Full Field Digital Mammography System. The Lorad division of Hologic is an industry leader in the production of high quality and technically advanced mammography and breast biopsy systems. The Pre-market Application submission for this system was based on three years of clinical data gathered and analyzed at some of the world's leading medical institutions.

The Lorad Full Field Digital Mammography System, utilizing CCD-based technology, is designed to generate digital mammographic images that can be used for the screening and diagnosis of breast cancer. The American Cancer Society estimates that in 2001, approximately 192,000 new cases of breast cancer will be diagnosed among women in the United States and 40,000 women will die of breast cancer.

Commenting on the approvable letter, Jack Cumming, Hologic's President and CEO stated, "We are pleased with the FDA's finding and look forward to working with them in the final phase of the review process. The FDA's forthright cooperation and responsiveness through this extensive PMA review process has enabled the Company to achieve this first, and very important, milestone in our digital mammography development program. We have undertaken a product development strategy dedicated to bringing the best digital mammography system to market in the shortest time possible. This Full Field Digital Mammography System will serve as the foundation for additional revolutionary advances in breast cancer detection."

Final marketing clearance for the Lorad Full Field Digital Mammography System is subject to labeling discussions, the agreement on criteria on the use of the product and successful completion of a Good Manufacturing Practices (GMP) audit by the FDA of Hologic's manufacturing facility in Bedford Massachusetts. The Company will continue to work with the FDA in this final phase of the Pre-market Application review process.

Mr. Cumming also indicated that the Company is in the advanced stages of development of a second-generation digital mammography system that incorporates its proprietary amorphous selenium DirectRay® direct-to-digital technology. The Company believes this amorphous selenium-based full-field digital mammography system will be superior in performance to other modalities currently available due to its enhanced image quality and dose utilization characteristics. This system will require additional regulatory review by the FDA. The Company expects to work closely with the FDA to bring this second- generation system to market as expeditiously as possible.

Pete Kershaw, Vice President and General Manager of Lorad said, "Our TEAM of scientists, engineers, regulatory and manufacturing personnel should be commended on their contributions to the development of the Lorad Full Field Digital Mammography System. The name Lorad has long been synonymous with the best in mammographic imaging systems and breast biopsy devices. We believe that the migration into digital imaging will solidify our leadership in the field. With recent studies indicating the five-year survival rate is almost 100% when breast cancer in detected at an early stage, the need to broaden the access to mammography screening services has never been greater. This new system is a first step in addressing this need. From a business opportunity standpoint, market studies estimate that the x-ray mammography market is expected to double to $567.2 million by 2007, driven by the emergence of full- field digital mammography. Our Full Field Digital Mammography System positions us well to benefit from this anticipated growth."

About Hologic, Inc.

Hologic, Inc. is dedicated to developing and delivering proprietary X-ray and ultrasound systems that incorporate direct-to-digital radiographic imaging technology for both women's health and general radiographic applications. Hologic's business divisions include: the Hologic Radiographic Systems division encompassing general and digital radiography systems; Direct Radiography Corp., a wholly owned subsidiary and manufacturer of state-of-the- art proprietary flat panel technology called DirectRay®; the Hologic Bone Densitometry division; the Lorad division, specializing in state-of-the-art breast imaging and minimally invasive breast biopsy systems; and Fluoroscan Imaging, a wholly owned subsidiary, manufacturing and marketing state-of-the- art, low intensity, real time X-ray imaging devices. For more information on Hologic and Lorad, please visit their respective websites at http://www.hologic.com/ and http://www.loradmedical.com/.

This News Release contains forward-looking information that involves risks and uncertainties, including statements about the Company's plans, objectives, expectations and intentions. Such statements include, without limitation, statements regarding the anticipated performance of the LORAD Full Field Digital Mammography System, the Company's ability to

obtain FDA PMA approval for that product, the Company's marketing plans and the anticipated market for the product, the Company's ability to market the product successfully, if and when approved, and the Company's ongoing research and development plans for digital mammography including its plans for the development of a second- generation digital mammography system. These forward-looking statements are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those anticipated. The Company cannot assure that the FDA will approve the Company's PMA for the LORAD Full Field Digital Mammography System on a timely basis, if at all, that the product, if and when approved, will be commercially successful, or that the product will serve as a foundation for further Hologic developments in digital mammography. Factors that could cause actual results to materially differ include, without limitation, uncertainty of FDA PMA approval; Hologic's continuing losses and ability to fund those losses as well as other working capital requirements; Hologic's ability to predict accurately the demand for its products and to develop strategies to address its markets successfully; uncertainties inherent in the development of new products and the enhancement of existing products, including technical and regulatory risks, cost overruns and delays; the early stage of market development for digital X-ray products; risks relating to the Company'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, risks related to ongoing litigation; 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 the Company's expectations or any change in events, conditions or circumstances on which any such statement is based.

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SOURCE: Hologic, Inc.

Contact: Glenn P. Muir, Executive Vice President & CFO, or Marianne E. Ritchie, Manager, Investor Relations, +1-781-999-7300

Web site: http://www.hologic.com/
