Investor Relations | Hologic

Hologic Receives FDA Marketing Clearance for Lorad Affinity Mammography System

PRNewswire
BEDFORD, Mass.

Hologic, Inc. (NASDAQ: HOLX), a leading provider of specialized medical imaging equipment for women's health and digital radiographic applications, today announced receipt of marketing clearance from the Food and Drug Administration (FDA) for its Lorad Affinity Mammography System. Lorad, a division of Hologic located in Danbury, Connecticut, is an industry leader in the production of innovative mammography and minimally invasive breast biopsy systems.

The Lorad Affinity is a high performance screen-film mammography system specifically developed to fill a market need for a cost-effective product, with performance characteristics similar to high-end systems. The Affinity System will be marketed globally and will be available in configurations utilizing Lorad innovations to improve mammographic image quality, including its award winning High Transmission Cellular (HTC™) Grid technology and exclusive Fully Automatic Self-adjusting Tilt (F.A.S.T.) compression paddle.

According to Jack W. Cumming, CEO and President of Hologic, "Receiving FDA marketing clearance for the Affinity is one more step in our ongoing initiative to provide the highest quality breast imaging products to meet the needs of every facet of the market. The Affinity product line will help strengthen Hologic's overall leadership position in breast imaging by providing expanded product offerings for cost-sensitive segments of the international and domestic marketplace. Development of the Affinity, combined with our recent advances in digital mammography, our demonstrated expertise in premier screen-film mammography systems and our strength in stereotactic biopsy systems provides a strong foundation for technological superiority in every breast imaging product line."

Commenting on the FDA action, Pete Kershaw, Vice President and General Manager of Lorad said, "We are pleased to receive confirmation of marketing clearance from the FDA for the Affinity Mammography System. We believe this system provides a highly effective solution for value-driven customers seeking a quality product to meet their mammography needs. The introduction of this versatile system to the mammography community provides effective, expanded choices for this market niche and advances Lorad's commitment to improving women's healthcare by producing high-quality products for the early detection of breast cancer."

The Company expects full commercial production of the Affinity to begin in the first quarter of 2002.

About Hologic

Hologic, Inc. is dedicated to developing and delivering proprietary X-ray systems that incorporate direct-to-digital radiographic imaging technology for both women's health and general radiographic applications. Hologic's business divisions include Hologic Osteoporosis Assessment, a provider of premier bone densitometry systems, Hologic Radiographic Systems, encompassing general and digital radiography systems, and the wholly-owned subsidiaries: Direct Radiography Corp., a manufacturer of state-of-the-art proprietary flat panel technology called DirectRay®; Fluoroscan Imaging, a manufacturer of low intensity, real time X-ray imaging devices; and Lorad, specializing in innovative mammography and minimally invasive breast biopsy systems.

For more information, please visit http://www.hologic.com/.

Forward Looking Disclaimer

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 Affinity System, the Company's marketing plans, the anticipated market for the product, and the Company's ability to market the product successfully. 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 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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