



Nanox.ARC Imaging System Receives CE Mark, Expanding Medical Imaging Offering in European Market

February 25, 2025

- *CE Mark is the first major regulatory milestone for Nanox.ARC Imaging System in the European market; follows recent general use FDA clearance in the U.S.*
- *New clinical data supporting use of Nanox.ARC to be presented at European Congress of Radiology (ECR) 2025.*
- *Nanox.ARC is an FDA, CE Marked, digital multi-source 3D tomosynthesis imaging system, providing advanced radiographic visualization.*
- *Nanox.ARC unlocks significant value for medical practices, providers, and their patients.*

PETACH TIKVA, Israel, Feb. 25, 2025 (GLOBE NEWSWIRE) -- [NANO-X IMAGING LTD](#) ("Nanox" or the "Company," Nasdaq: NNOX), an innovative medical imaging technology company, today announced that it has received CE (Conformité Européenne) mark certification to market the multi-source Nanox.ARC system, including the Nanox.CLOUD, its accompanying cloud-based infrastructure. Nanox.ARC is a stationary X-ray system, intended to generate tomographic images of human anatomy from a single tomographic sweep performed in recumbent positions of adult patients.

The Nanox.ARC features a proprietary digital X-ray source, representing a significant advancement in X-ray technology. The system utilizes advanced tomosynthesis technology with a cold cathode to create a more comprehensive, sliced three-dimensional view of the body, enhancing visualization with multiple layers of images and reducing the super-imposition of structures often seen in 2D X-rays.

"Receiving the CE mark represents a significant milestone in our global expansion effort, building on the Nanox.ARC's [recent FDA clearance for general use](#)," said Erez Meltzer, Nanox Chief Executive Officer and Acting Chairman. "This certification for whole-body imaging in Europe, combined with our existing distributors and ongoing pursuit of strategic partnerships, positions us to accelerate the Nanox.ARC's commercial introduction across the region."

The Company believes the CE Mark may help broaden Nanox.ARC's commercial expansion globally and specifically in Europe, where worldwide, there are a few dozen units in various stages of shipments and deployments for both commercial and clinical uses.

Nanox.ARC is intended for use in professional healthcare facilities or radiological environments, such as hospitals, clinics, imaging centers and other medical practices, and is intended to be operated by qualified personnel with the necessary knowledge and expertise to operate X-ray equipment, such as radiographers, physicians, and physicists, in accordance with the relevant country-specific regulations. It is designed to allow easy and efficient integration into current clinical workflows.

Nanox.ARC's advanced tomosynthesis system is designed to support better patient care. It bridges the gap between standard X-rays and CT scans, offering advanced clinical imaging, increasing clinicians' diagnostic confidence by allowing new clinical insights not available in conventional X-ray with only a fraction of the radiation exposure of a CT scan.

Nanox is conducting clinical trials featuring the Nanox.ARC at multiple sites and has published data demonstrating its visualization capabilities allowing clinicians utilizing the Nanox.ARC system to detect [occult lesions](#) and [fractures](#) which were not detected on conventional radiography.

Nanox will present new data further supporting the use of the Nanox.ARC at the [European Congress of Radiology \(ECR\) 2025](#).

About Nanox

Nanox (NASDAQ: NNOX) is focused on driving the world's transition to preventive health care by bringing a full solution of affordable medical imaging technologies based on advanced AI and proprietary digital X-ray source.

Nanox's vision encompasses expanding the reach of Nanox technology both within and beyond hospital settings, providing a seamless end-to-end solution from scan to diagnosis, leveraging AI to enhance the efficiency of routine medical imaging technology and processes, in order to improve early detection and treatment and maintaining a clinically driven approach. The Nanox ecosystem includes Nanox.ARC – a multi-source digital tomosynthesis system that is cost-effective and user-friendly; Nanox.AI LTD, a subsidiary of Nanox Imaging, an AI-based suite of algorithms that augment the readings of routine CT imaging to highlight early signs often related to chronic diseases; Nanox.CLOUD – a cloud-based software platform that manages and stores data collected by Nanox devices, and provides users with tools for in-depth imaging analysis; Nanox.MARKETPLACE – a proprietary decentralized marketplace through Nanox's subsidiary, USARAD Holdings Inc., that provides remote access to radiology and cardiology experts, and a comprehensive teleradiology services platform. By improving early detection and treatment, Nanox aims to enhance better health outcomes worldwide. For more information, please visit www.nanox.vision

Forward-Looking Statements

This press release may contain forward-looking statements that are subject to risks and uncertainties. All statements that are not historical facts contained in this press release are forward-looking statements. Such statements include, but are not limited to, any statements relating to the initiation, timing, progress and results of the Company's research and development, manufacturing, and commercialization activities with respect to its X-ray source technology and the Nanox.ARC, the ability to realize the expected benefits of its recent acquisitions and the projected business prospects of the Company and the acquired companies. In some cases, you can identify forward-looking statements by terminology such as "can," "might," "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "could," "expect," "predict," "potential," or the negative of these

terms or other similar expressions. Forward-looking statements are based on information the Company has when those statements are made or management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Factors that could cause actual results to differ materially from those currently anticipated include: risks related to (i) Nanox's ability to complete development of the Nanox System; (ii) Nanox's ability to successfully demonstrate the feasibility of its technology for commercial applications; (iii) Nanox's expectations regarding the necessity of, timing of filing for, and receipt and maintenance of, regulatory clearances or approvals regarding its technology, the Nanox.ARC and Nanox.CLOUD from regulatory agencies worldwide and its ongoing compliance with applicable quality standards and regulatory requirements; (iv) Nanox's ability to realize the anticipated benefits of the acquisitions, which may be affected by, among other things, competition, brand recognition, the ability of the acquired companies to grow and manage growth profitably and retain their key employees; (v) Nanox's ability to enter into and maintain commercially reasonable arrangements with third-party manufacturers and suppliers to manufacture the Nanox.ARC; (vi) the market acceptance of the Nanox System and the proposed pay-per-scan business model; (vii) Nanox's expectations regarding collaborations with third-parties and their potential benefits; (viii) Nanox's ability to conduct business globally; (ix) changes in global, political, economic, business, competitive, market and regulatory forces; (x) risks related to the current war between Israel and Hamas and any worsening of the situation in Israel; (xi) risks related to business interruptions resulting from the COVID-19 pandemic or similar public health crises, among other things; and (xii) potential litigation associated with our transactions.

For a discussion of other risks and uncertainties, and other important factors, any of which could cause Nanox's actual results to differ from those contained in the Forward-Looking Statements, see the section titled "Risk Factors" in Nanox's Annual Report on Form 20-F for the year ended December 31, 2023, and subsequent filings with the U.S. Securities and Exchange Commission. The reader should not place undue reliance on any forward-looking statements included in this press release. Except as required by law, Nanox undertakes no obligation to update publicly any forward-looking statements after the date of this press release to conform these statements to actual results or to changes in the Company's expectations.

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