



Nanox Receives FDA Clearance for General Use of New Imaging System, Nanox.ARC X

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- *First FDA clearance for Nanox.ARC X to produce tomographic images for general use, including musculoskeletal, pulmonary, intra-abdominal and paranasal indications*
- *Enhanced imaging system features sleek design with smaller footprint; simplified 'plug and play' installation process*
- *System design enables software upgrades and new capabilities to be added remotely following future regulatory clearances*

PETACH TIKVA, Israel, April 17, 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 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Nanox.ARC X, its new multi-source digital tomosynthesis system. The FDA 510(k) clearance was received in less than 30 days from the date of submission and covers the production of tomographic images for general use, including the human musculoskeletal system and pulmonary, intra-abdominal and paranasal sinus indications, adjunctive to conventional radiography on adult patients.

The Nanox.ARC X maintains the Nanox.ARC's proprietary digital Nanox.SOURCE and advanced tomosynthesis technology with a cold cathode, which enables it to create a more comprehensive, sliced three-dimensional view of the body, enhance visualization with multiple layers of images, and reduce the super-imposition of structures often seen in 2D X-rays. The Nanox.ARC X introduces a fully integrated, single-unit system with a streamlined design that significantly reduces the physical footprint. The system features 'plug and play' one-day installation capability, making advanced tomosynthesis technology more accessible to diverse healthcare settings with space constraints.

"The FDA clearance of the Nanox.ARC X marks an important evolution in our imaging technology," said Erez Meltzer, Chief Executive Officer and Acting Chairman of Nanox. "By integrating our proprietary digital technology in this new imaging system, we're making it easier for healthcare providers to adopt digital 3D imaging. This milestone advances our mission to expand access to essential medical imaging technology to more patients, regardless of their location. We look forward to introducing further capabilities to the Nanox.ARC X in the future and making them available through remote and immediate upgrades."

The Nanox.ARC X is designed to be installed in any standard X-ray shielded room with minimal infrastructure requirements. The system operates on standard power (110v/230v 16A) and features a cables-free design for enhanced user and patient safety, ease of cleaning, and maintenance.

Nanox will offer the Nanox.ARC X system, later this year, alongside the current Nanox.ARC, expanding the Company's product portfolio to meet diverse customer needs and use cases.

For more information about Nanox's complete suite of medical imaging solutions, please visit www.nanox.vision.

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 and Nanox.ARC X – a multi-source digital tomosynthesis system that is cost-effective and user-friendly; Nanox AI Ltd. – with 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 and/or the Nanox.ARC X, 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," "should," "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/or the Nanox.ARC X 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 and/or the Nanox.ARC X; (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, 2024, 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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