



Nanox Receives FDA 510(k) Clearance for TAP2D New Image Enhancement Capability for Nanox.ARC and Nanox.ARC X Systems

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This clearance enables the next phase of development aimed ultimately at removing the adjunct use in the US

The newly cleared capability provides radiologists with a 2D image generated directly from the tomosynthesis scan, enabling both 3D and 2D views from a single scan, without exposing the patient to any additional radiation

PETACH TIKVA, Israel – February 3 – [NANO-X IMAGING LTD](#) ("Nanox" or the "Company") today announced that the United States Food and Drug Administration (FDA) has granted 510(k) clearance for TAP2D, a new cloud enabled image enhancement capability for the Nanox.ARC and Nanox.ARC X digital tomosynthesis systems. This clearance marks an important step in Nanox's regulatory strategy to position its tomosynthesis systems as primary diagnostic solutions and advances the Company's commitment to increased access to innovative medical imaging solutions.

The newly cleared enhancement capability provides radiologists with an additional, clear 2D view, generated from the digital tomosynthesis scan. The feature is designed to support evaluation while maintaining a smooth workflow for users. The additional view is automatically delivered within the existing clinical environment without adding complexity for clinicians or operators.

The [Nanox.ARC](#) and [Nanox.ARC X](#) are FDA cleared, multi-source digital tomosynthesis systems that utilize advanced 3D imaging technology to provide enhanced diagnostic capabilities at a lower cost and radiation dose than traditional systems.

The Nanox.ARC systems' software upgrades and new capabilities, such as TAP2D, can be added remotely to the Nanox.ARC systems, following this and future regulatory clearances.

"We are pleased to receive FDA clearance for TAP2D," said Erez Meltzer, Chief Executive Officer and Acting Chairman of Nanox. "This clearance provides important regulatory insights as we work toward our goal of removing the adjunctive use in the United States, which would allow the Nanox.ARC to serve as a standalone primary imaging solution as it already does in Europe under our CE Mark certification. We remain focused on delivering innovations that elevate patient care and broaden access to high quality imaging around the world."

Nanox plans to make the newly cleared enhancement software available to existing installations as part of its ongoing rollout of imaging improvements.

About Nanox

Nanox (NASDAQ: NNOX) is focused on driving the world's transition to preventive health care by delivering an integrated, end-to-end medical imaging and healthcare services platform.

Nanox combines affordable imaging hardware, advanced AI-based solutions, cloud-based software, access to remote radiology, health IT solutions, and a marketplace to enable earlier detection, improved clinical efficiency, and broader access to care.

Nanox's vision is to expand the reach of medical imaging both within and beyond traditional hospital settings by providing a seamless solution from scan to interpretation and beyond. By leveraging proprietary digital X-ray technology, AI-driven analytics, and a clinically driven approach, Nanox aims to enhance the efficiency of routine imaging workflows, support early detection of disease, and improve patient outcomes.

The Nanox ecosystem includes **Nanox.ARC**, a cost-effective, 3D multi-source digital tomosynthesis imaging system designed for ease of use and scalability; **Nanox.AI**, a suite of AI-based algorithms that augment the interpretation of routine CT imaging to identify early signs often associated with chronic disease; **Nanox.CLOUD**, a cloud-based platform for secure data management, storage, and advanced imaging analytics; **Nanox.MARKETPLACE** and **USARAD Holdings**, which provide access to remote radiology and cardiology experts and comprehensive teleradiology services; and **Nanox Health IT**, which combines deep healthcare IT expertise with leading technology partners to deliver RIS, PACS, AI, dictation, and secure infrastructure solutions that streamline workflows and support safer, more efficient care delivery.

By integrating imaging technology, AI, cloud infrastructure, clinical expertise, a marketplace, and health information technology, Nanox seeks to lower barriers to adoption, improve utilization, and advance preventive care 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, 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.

Contacts

Media Contact:

Ben Shannon
ICR Healthcare
NanoxPR@icrinc.com

Investor Contact:

Mike Cavanaugh
ICR Healthcare
mike.cavanaugh@icrhealthcare.com