Nanox.ARC Imaging System Receives FDA Clearance for General Use, Including Pulmonary Indication

December 5, 2024

- *Nanox.ARC receives additional FDA clearance to produce tomographic images for general use, including pulmonary, intra-abdominal and paranasal indications, in addition to its previously cleared indication for the musculoskeletal system*
- *Nanox.ARC uses high voltage powered digital X-ray tubes for 3D tomosynthesis imaging that could help expand availability of medical imaging*
- *Nanox.ARC now deployed at healthcare facilities across seven states in the U.S.*

PETACH TIKVA, Israel, Dec. 05, 2024 (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 its Nanox.ARC, a stationary X-ray system intended to produce tomographic images for general use including human musculoskeletal system, pulmonary, intra-abdominal, and paranasal sinus indications, adjunctive to conventional radiography, on adult patients.

The Nanox.ARC features a proprietary digital X-ray source, representing a significant advancement in X-ray technology. The Nanox.ARC 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.

"With this FDA clearance, we can now offer U.S. healthcare providers significantly broader imaging capabilities that are akin to commonly used traditional X-ray devices," said Erez Meltzer, Nanox Chief Executive Officer and Acting Chairman. "Our mission is to provide healthcare practices with a transformative imaging advantage with the Nanox.ARC – an accessible, cost-effective solution that not only provides advanced diagnostic imaging capabilities but also elevates overall patient care. We look forward to bringing this technology to more healthcare facilities throughout the country."

The Company believes the new FDA-cleared indications will help broaden Nanox. ARC's commercial expansion in the U.S., where it is currently deployed at multiple healthcare facilities across seven states. Worldwide, there are a few dozen units in various stages of shipments and deployments for both commercial and clinical uses.

"The installation of the Nanox.ARC at our facility marks a significant leap forward in our diagnostic capabilities," said Sherri Donaldson, COO at Diagnostic Radiology Institute of Kansas City, located in Mission, Kansas. "This technology allows us to provide our patients with advanced imaging services, potentially reducing wait times and improving the overall patient experience. We're excited to be at the forefront of this technological advancement in medical imaging."

The 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 operated by trained radiographers, radiologists and physicians. It is designed to allow easy and efficient integration into current clinical workflows. The Nanox.ARC has the potential benefits of reducing patient wait times, enabling faster care and more efficient diagnosis, while also potentially reducing the need to visit a separate imaging facility.

"Digital tomosynthesis provides added value in certain clinical situations. Musculoskeletal, thoracic and abdominal imaging all have use cases that may be best served by digital tomosynthesis compared to CT or radiography," said Greg Kicska M.D., Ph.D, Assistant Professor at Harborview Medical Center and Nanox Advisory Board Member. "The Nanox system is also unique in that it doesn't have as large a footprint as traditional X-ray machines, doesn't require as much power and utilizes a matrix pattern that blurs out structural noise, making images more clean."

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 novel digital 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 for smarter diagnostics 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 – 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," "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 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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