Nanox.ARC Imaging System Receives FDA Clearance, Pioneering a New Era in Medical Imaging

May 1, 2023

- *Nanox.ARC presents high powered digital X-ray tubes for 3D tomosynthesis imaging*
- *Nanox.ARC could help expand the availability of medical imaging*

NEVE ILAN, Israel, May 01, 2023 (GLOBE NEWSWIRE) -- NANO-X IMAGING LTD ("Nanox" or the "Company," Nasdaq: NNOX), an innovative medical imaging technology company, today announced that it has received a 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market the multi-source Nanox.ARC, including the Nanox.CLOUD, its accompanying cloud-based infrastructure. Nanox.ARC is a stationary X-ray system intended to produce tomographic images of the human musculoskeletal system adjunctive to conventional radiography on adult patients. Representing a major advancement in X-ray technology, Nanox.ARC is a multi-source digital 3D tomosynthesis system that utilizes novel, cold cathode X-ray tubes, which the Company intends to offer using an innovative pay-per-scan business model.

Nanox.ARC

Image of the Nanox ARC

The FDA cleared Nanox.ARC for use in professional healthcare facilities or radiological environments, such as hospitals, clinics, imaging centers, and other medical practices by trained radiographers, radiologists, and physicians, and has the potential to increase availability to medical imaging around the world, once approved by local regulatory authorities and deployed at scale.

The Company received 510(k) clearance to market its single-source X-ray device, known as the Nanox Cart X-Ray System, in April 2021. The multi-source Nanox.ARC has the ability to reconstruct a series of 2D projection images into a stack of tomograms (or slices) of the imaged object, forming a 3D visualization. This visualization reduces the effect of overlying structures and provides in-depth information on structures of interest.

Nanox.ARC

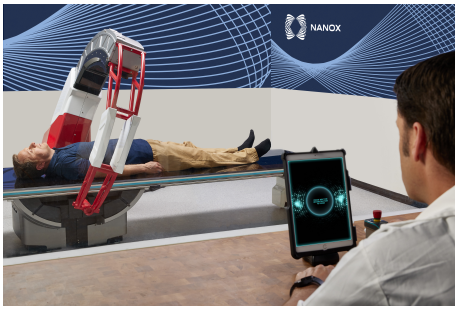

Image of the Nanox ARC

"Today's milestone is a significant achievement as part of our commitment to make state-of-the-art medical imaging technology available for use in a wide array of professional healthcare facilities and other medical practices," said Erez Meltzer, Chief Executive Officer of Nanox. "Our vision is that Nanox's innovative technology and approach not only have the potential to increase access to medical imaging, but also to shift healthcare from reactive to proactive—enabling early detection and prevention of diseases."

Following this clearance, Nanox will continue to work with the FDA to pursue additional regulatory clearances and intends to expand clinical indications. The U.S. regulatory clearance also paves the way for Nanox.ARC to be approved in other countries that are FDA-clearance-based markets. Other applications will be available in other markets per local regulatory approvals.

Medical imaging systems are an important early detection tool that are key to initiating early treatment, improving health outcomes, and ultimately saving lives. Approximately two-thirds of the world's population does not have access to medical imaging systems, according to the World Health Organization (WHO),[1] while many people with access face substantial wait times for scanning, potentially delaying diagnoses. By introducing an innovative pay-per-scan business model, Nanox offers an opportunity to help expand these resources to more healthcare settings.

While access to medical imaging is relatively high in the U.S. compared to many other countries, medical imaging can still be limited in certain areas, particularly in rural or low-income areas where facilities and equipment may be scarce. For example, compared with patients at urban hospitals, emergency department patients in rural hospitals are 7% less likely to receive advanced imaging, while patients at critical access hospitals are 18% less likely to have advanced imaging.[2]

"The FDA clearance of Nanox.ARC represents an important breakthrough and represents an opportunity to increase the availability and accessibility of medical imaging in the United States and worldwide," said Geoffrey Rubin, MD, MBA, Professor and Chairman of the Department of Medical Imaging at the University of Arizona and a member of Nanox's Advisory Board. "Medical imaging is essential for detecting, diagnosing, and managing disease, guiding treatment decisions for improved health outcomes. Nanox.ARC has the potential to be a cost-effective and scalable imaging solution in healthcare settings that would otherwise be unable to deploy traditional medical imaging equipment."

EDITOR'S NOTE: *Photographs and video of Nanox.ARC are available upon request. Please contact NanoxPR@icrinc.com.*

About Nanox

We, NANO-X IMAGING LTD or Nanox (Nasdaq: NNOX), are focused on applying our proprietary medical imaging technology and solutions to make diagnostic medicine more accessible and affordable across the globe.

Nanox's vision is to increase access, reduce costs and enhance the efficiency of routine medical imaging technology and processes, in order to improve early detection and treatment, which Nanox believes is key to helping people achieve better health outcomes, and, ultimately, to save lives.

The Nanox ecosystem includes Nanox.ARC - a multi-source Digital Tomosynthesis system that is cost-effective, and user-friendly; an AI-based suite of algorithms that augment the readings of routine CT imaging to highlight early signs often related to chronic disease, (Nanox.AI); a cloud-based infrastructure (Nanox.CLOUD); and 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 (Nanox.MARKETPLACE).

Together, Nanox's products and services create a worldwide, innovative, and comprehensive solution that connects medical imaging solutions, from scan to diagnosis. For more information, please visit www.nanox.vision.

[1] Pan American Health Organization and World Health Organization ("WHO"), 2012

[2] Hanna TN, Friedberg E, Dequesada IM, Chaves L, Pyatt R, Duszak R, Jr, Hughes DR. Disparities in the Use of Emergency Department Advanced Imaging in Medicare Beneficiaries. *Am J Roentgenol*. 2021; 216(2): 519–5215

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 continue to develop of the Nanox imaging 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 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 imaging system and the proposed pay-per-scan business model; (vii) Nanox's expectations regarding collaborations with third-parties and their potential benefits; and (viii) Nanox's ability to conduct business globally; (ix) changes in global, political, economic, business, competitive, market and regulatory forces; and (x) risks related to business interruptions resulting from the COVID-19 pandemic or similar public health crises, among other things.

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, 2022, 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:
Rachael Roselli
ICR Westwicke
NanoxPR@icrinc.com

Investor Contact:
Mike Cavanaugh
ICR Westwicke
mike.cavanaugh@westwicke.com

Photos accompanying this announcement are available at

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