



Nanox Announces FDA Clearance of 510(k) for Single Source Nanox.ARC Digital X-Ray

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NEVE ILAN, Israel, April 02, 2021 (GLOBE NEWSWIRE) -- NANO-X IMAGING LTD (NASDAQ: NNOX) (“**Nanox**” or the “**Company**”), an innovative medical imaging technology company, announced today that its single-source Nanox.ARC digital x-ray technology has received 510(k) clearance from the US Food and Drug Administration (the “**FDA**”).

“Obtaining 510(k) clearance from the FDA for our single-source Nanox.ARC digital x-ray is a significant step forward along our US regulatory pathway,” stated Ran Poliakine, Chairman and Chief Executive Officer of Nanox. “We remain on track to commence system shipments in the fourth quarter of 2021 and the first quarter of 2022 with the goal of finalizing deployment of the initial 15,000 Nanox.ARC systems by the end of 2024.”

“We believe we are well positioned to achieve our goal of democratizing medical imaging and expanding the market to the roughly two-thirds of the world’s population who currently have limited or no meaningful access to imaging or the preventative screening that it offers,” Mr. Poliakine concluded.

The Company remains on track and expects to submit a 510(k) application to the FDA for its multi-source Nanox.ARC and the Nanox.CLOUD in 2021. If cleared, the multi-source Nanox.ARC will be the Company’s commercial imaging system that it expects to deploy broadly across the globe.

About Nanox:

Nanox, founded by the serial entrepreneur Ran Poliakine, is an Israeli corporation that is developing a commercial-grade digital X-ray source designed to be used in real-world medical imaging applications. Nanox believes that its novel technology could significantly reduce the costs of medical imaging systems and plans to seek collaborations with world-leading healthcare organizations and companies to provide affordable, early detection imaging service for all. 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 Nanox’s research and development, manufacturing and commercialization activities with respect to its X-ray source technology and the Nanox.Arc. 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 Nanox 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 business interruptions resulting from the COVID-19 pandemic or similar public health crises could cause a disruption of the development, deployment or regulatory clearance of the Nanox System and adversely impact our business; Nanox’s ability to successfully demonstrate the feasibility of its technology for commercial applications; Nanox’s expectations regarding the necessity of, timing of filing for, and receipt and maintenance of, regulatory clearances or approvals regarding its X-ray source technology and the Nanox.Arc from regulatory agencies worldwide and its ongoing compliance with applicable quality standards and regulatory requirements; Nanox’s ability to enter into and maintain commercially reasonable arrangements with third-party manufacturers and suppliers to manufacture the Nanox.Arc; the market acceptance of the Nanox.Arc and the proposed pay-per-scan business model; Nanox’s expectations regarding collaborations with third-parties and their potential benefits; and Nanox’s ability to conduct business globally, among others. 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 Nanox’s expectations.

Contacts:

Investors

Itzhak Maayan
Nanox Imaging
IR@nanox.vision

Bob Yedid
LifeSci Advisors
646-597-6989
bob@lifesciadvisors.com

Media

Alona Stein
ReBlonde for Nanox
alona@reblonde.com



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