



Nanox Announces FDA 510(k) Submission for First Version of Multi-Source Nanox.ARC

June 17, 2021

510(K) Class II FDA submission seeks clearance of the first version of company's multi-source 3-D digital tomosynthesis system as the next step in its U.S. regulatory process

NEVE ILAN, Israel, June 17, 2021 (GLOBE NEWSWIRE) -- NANOX IMAGING LTD (NASDAQ: NNOX) ("**Nanox**" or the "**Company**"), an innovative medical imaging technology company, announced today that the Company has submitted a 510(k) premarket notification application to the U.S. Food and Drug Administration (FDA) for the first version of its multi-source Nanox.ARC 3-D digital tomosynthesis system.

"The 510(k) submission for the first version of our multi-source Nanox.ARC is an important achievement," stated Ran Poliakine, Chairman and Chief Executive Officer of Nanox. "There exists a significant unmet medical need globally for a more accessible and cost-effective medical imaging solution. If cleared by the FDA, we believe our Nanox.ARC 3-D digital tomosynthesis can address this need."

The first version of the multi-source Nanox.ARC will be followed by future Nanox.ARC versions. Nanox.ARC is a 3-D tomosynthesis imaging system that produces scans of a human body part. The system is being designed for easy setup and operation with multiple alternately-switched X-ray tubes arranged around the patient.

"We are excited to take this next step in our regulatory process as we move toward future versions of the multi-source Nanox.ARC, which will fulfill current and future contracts with service providers and collaboration agreements and allow us to achieve our global vision," added Mr. Poliakine.

Nanox received FDA clearance of its single source Nanox Cart X-Ray System in April 2021.

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," "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

NANO-X

Source: Nano-X Imaging