Nanox Receives FDA Clearance for HealthFLD, an Advanced AI-Based Software Empowering Clinicians in Assessment of Fatty Liver

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Nanox's HealthFLD is pioneering the use of a fully automated AI software for liver attenuation analysis from CT scans that has received FDA 510(k) clearance for use in general population

Expands Nanox's offering in AI solutions, marking third product in Nanox AI's suite of population health solutions to become commercially available

PETACH TIKVA, Israel, Feb. 13, 2024 (GLOBE NEWSWIRE) -- ("Nanox" or the "Company," Nasdaq: NNOX), an innovative medical imaging technology company, today announced that its deep-learning medical imaging analytics subsidiary, Nanox AI Ltd., received 510(k) clearance by the U.S. Food and Drug Administration (FDA) for HealthFLD, an artificial intelligence (AI) software that provides automated qualitative and quantitative analysis of liver attenuation from routine contrast and non-contrast chest and abdomen CT scans in patients between the ages of 18 to 75. HealthFLD is intended to support clinicians in the detection of fatty liver, correlated with hepatic steatosis, an early sign of metabolic dysfunction-associated steatotic liver disease (MASLD), formerly referred to as non-alcoholic fatty liver disease (NAFLD).

An estimated 24% of U.S. adults are living with MASLD or NAFLD[i], a metabolic disease linked to obesity, cardiovascular disease and type 2 diabetes, all of which pose significant public health concerns. Adults with MASLD are not only at risk of developing severe liver complications, such as cirrhosis and metabolic dysfunction-associated steatohepatitis (MASH), but are also at risk of cardiovascular disease, which is the leading cause of death in people living with MASLD[ii]. MASLD is commonly asymptomatic until it progresses to advanced liver fibrosis, and the current gold standard for diagnosis is a liver biopsy, which is invasive and costly. As such, early diagnosis of MASLD could benefit patients and the healthcare system.

While AI assessment of medical imaging offers a reliable, non-invasive, large-scale approach to support clinicians in the assessment of hepatic steatosis (fatty liver), it has traditionally been difficult to assess liver attenuation on contrast-enhanced scans – which make up a large proportion of CT scans – limiting the ability of clinicians to detect non-severe cases of MASLD[iii]. HealthFLD was designed to help clinicians in the assessment and analysis of fatty liver in the general population from routine CT scans.

Amidst rising obesity rates, the prevalence of liver-related disease is growing, and the need for an approved treatment for MASH has yet to be met. With several late-stage drug candidates for MASH in development and the availability of GLP-1 drugs for the management of type 2 diabetes and other metabolic diseases, identification of liver steatosis is especially relevant.

"We are proud to offer HealthFLD as the third product of Nanox AI's suite of cutting-edge, AI-powered population health solutions designed to confront chronic diseases of great public health concern head-on and potentially improve health outcomes," said Erez Meltzer, Chief Executive Officer of Nanox. "Furthermore, we believe that AI innovative solutions, and specifically HealthFLD, may deliver substantial advantages to the biopharmaceutical industry to streamline the identification of candidates for clinical trials of much-needed therapies for liver diseases including MASH. This regulatory decision solidifies our leadership as a developer of automated AI software medical devices."

In a retrospective 2023 study of 2,917 patients, published in the *American Journal of Roentgenology (AJR),* the HealthFLD AI software demonstrated high performance in the detection of at least moderate hepatic steatosis in contrast-enhanced CT scans, with a sensitivity of 77.8% and specificity of 93.2% at less than 80 HU. Medical imaging offers the only reliable noninvasive method for quantifying liver fat. Integrating HealthFLD with widely used standard CT scans offers clinicians the potential to opportunistically screen for liver steatosis and possible signs of MASLD on a population level. "In recent years, automated, deep learning tools have offered an efficient, low-cost tool used to detect diseases in earlier stages," said Perry J. Pickhardt, MD, of the University of Wisconsin School of Medicine & Public Health, and lead author of the AJR study. "We are now at a watershed moment when metabolic diseases are growing in prevalence and more effective treatment options are becoming available. It's promising to have a liver solution available that may help evaluate early signs of illness from routine imaging."

The HealthFLD clearance is the third product across the Nanox AI suite of population health solutions to receive FDA clearance. The FDA previously cleared HealthCCSng, a solution that detects coronary artery calcium (CAC) that presents a risk for coronary artery disease, and HealthOST, a solution that assesses vertebral compression fractures and bone mineral density to support clinicians in the evaluation and assessment of musculoskeletal disease of the spine (such as osteoporosis).

About Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)

Metabolic dysfunction-associated steatotic liver disease (MASLD), formerly referred to as non-alcoholic fatty liver disease (NAFLD), refers to a group of metabolic conditions linked to obesity, cardiovascular disease and type 2 diabetes. An estimated 30% of the adult population globally has MASLD,[iv] a major risk factor for chronic liver disease and for cardiovascular disease, which is the leading cause of mortality in this patient population.[v]

About Nanox AI

Nanox AI is the deep-learning medical imaging analytics subsidiary of Nanox. Nanox.AI solutions are developed to target highly prevalent chronic and acute diseases affecting large populations around the world. Leveraging AI technology, Nanox AI helps clinicians extract valuable and actionable clinical insights from routine medical imaging that otherwise may go unnoticed, potentially initiating further medical assessment to establish individual preventative care pathways for patients. For more information, please visit https://www.nanox.vision/ai.

About Nanox

Nanox (NASDAQ: NNOX) is focused on applying its 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.

Forward-Looking Statements

This press release contains historical information and forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 with respect to the business, financial condition and results of operations of Nanox. 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 the words "will," "believe," "expect," "intend," "plan," "should," "estimate", "might", "may", "should", "anticipate", "expect", "predict"' "potential" and similar expressions which are intended to identify forward-looking statements. 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, 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.

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