Zynex Medical - Investor Relations

Zynex Submits FDA Application for Its NiCO Laser Pulse Oximeter

ENGLEWOOD, Colo., May 12, 2025 /PRNewswire/ -- Zynex, Inc. (NASDAQ: ZYXI), an innovative medical technology company specializing in the manufacture and sale of non-invasive medical devices for pain management, rehabilitation, and patient monitoring, today announced it has submitted a 510(k) application to the U.S. Food and Drug Administration ("FDA") for its NiCO™, Noninvasive CO-Oximeter device.

This submission marks a historic milestone in the evolution of pulse oximetry and a major breakthrough for the Company in its mission to improve the quality of care and patient outcomes through its patient monitoring products. Pulse oximetry is one of the world's largest medical device markets and current devices on the market have long been under scrutiny for their inaccuracy and limitations. Zynex's laser technology enables oxygen levels to be measured accurately for patients with dark skin. In cases of carbon monoxide (CO) poisoning, not only are the measurements non-invasive and results instantaneous, but both oxygen and CO are measured accurately, potentially reducing the need for taking blood samples and having to wait for the lab results.

Clinical studies following the COVID-19 pandemic highlighted a long-standing problem with traditional LED-based pulse oximeters dangerously misinterpreting oxygenation levels in individuals with darker skin pigmentation, and in patient populations that suffer from low oxygen perfusion[1,2]. In response to this pressing public health issue, the FDA issued updated pulse oximetry device recommendations earlier this year urging device manufacturers to address this issue in both existing and new technologies with expanded testing guidelines and higher overall accuracy standards.

Highly precise laser technology directly measures fractional blood oxygenation levels, rather than the current LED technology which estimates functional oxygen saturation (SpO_2), giving clinicians a more complete, reliable and accurate overview of the patient's real-time oxygenation status. Unlike current LED-based pulse oximeters, laser-based pulse oximetry performance is not skewed by pigments such as melanin or nail polish, resulting in highly trustworthy measurements and eliminating harmful pigmentation bias problems. The NiCO is expected to be the first product to accurately and continuously measure all four primary hemoglobin species via patented laser pulse oximetry technology, to enable earlier and more accurate detection of hypoxia and hyperoxia.

Furthermore, in addition to oxygenated hemoglobin, the NiCO pulse oximeter measures the level of reduced hemoglobin, as well as dysfunctional hemoglobins (dyshemoglobins), specifically carboxyhemoglobin and methemoglobin. Dyshemoglobins can result from the ingestion of various poisons, use of various prescription medications, or due to carbon monoxide poisoning. They are unable to bind oxygen and transport it throughout the body, which is essential for life. The ability to non-invasively measure dyshemoglobins is a game changing event.

"We believe NiCO is a distinct market disrupting technology and can provide significant improvements to patient care for hospital and non-hospital providers in numerous medical settings," said Donald Gregg, President of Zynex Monitoring Solutions. "Clinical studies have shown the Zynex NiCO Laser Pulse Oximeter is groundbreaking in providing more reliable, comprehensive, and accurate information about a patient's oxygen status by continuously measuring all four primary hemoglobin species. The real-time display of oxygenated hemoglobin, reduced hemoglobin, carboxyhemoglobin and methemoglobin will assist clinicians in earlier and more accurate detection of hypoxia and hyperoxia, which can save lives, lower costs, and enhance overall patient care efficiency."

This FDA 510(k) application submission represents a major milestone in Zynex's commitment to delivering cutting-edge medical devices, demonstrating the Company's dedication to ensuring patients and doctors have access to the latest innovations in medical technology. The estimated accessible market for pulse oximetry monitoring is over $2.8 billion today, growing to $4.3 billion in 2027[3]. Pulse oximeters are currently used in nearly every clinical care area in hospital and non-hospital settings.

"This 510(k) submission marks a major breakthrough on the path to changing the landscape of patient monitoring," said Thomas Sandgaard, Zynex Founder and CEO. "Enormous thanks are owed to the tireless work of our tremendous Zynex

Monitoring team, and the day we see NiCO in clinical care is approaching at an exciting pace." Laser pulse oximetry has the promise to revolutionize not only oxygen saturation measurements, but also the total hemoglobin testing market which is another $2-3[4] billion market opportunity that Zynex can pursue with laser-based technology. The NiCO submission is an exciting first step in creating a new standard for patient monitoring.

[1] Sjoding MW, et al. Racial Bias in Pulse Oximetry Measurement. N Engl J Med. 2020; 383:2477-8.
[2] Gudelunas MK, et al. Low Perfusion and Missed Diagnosis of Hypoxemia by Pulse Oximetry in Darkly Pigmented Skin: A Prospective Study. Anesthesia and Analgesia. 2024;138(3):552-561.
[3] Markets and Markets: Pulse Oximeter Global Forecast 2022.
[4] Verified Market Research, GLOBAL HEMOGLOBIN MONITOR MARKET 2022-2031, and The Business Research Company, Hemoglobin Testing Global Market Report 2025.

About Zynex, Inc.

Zynex, founded in 1996, develops, manufactures, markets, and sells medical devices used for pain management and rehabilitation as well as non-invasive fluid, sepsis, and laser-based pulse oximetry monitoring systems for use in hospitals. For additional information, please visit: www.zynex.com.

Safe Harbor Statement

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, as amended. our results of operations and the plans, strategies and objectives for future operations; the timing and scope of any potential stock repurchase; and other similar statements.

Words such as "anticipate," "believe," "continue," "could," "designed," "endeavor," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "target," "preliminary," "will," "would" and similar expressions are intended to identify forward-looking statements. The express or implied forward-looking statements included in this press release are only predictions and are subject to a number of risks, uncertainties and assumptions. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. The Company makes no express or implied representation or warranty as to the completeness of forward-looking statements or, in the case of projections, as to their attainability or the accuracy and completeness of the assumptions from which they are derived. Factors that could cause actual results to materially differ from forward-looking statements include, but are not limited to, the need to obtain CE marking of new products; the acceptance of new products as well as existing products by doctors and hospitals, larger competitors with greater financial resources; the need to keep pace with technological changes; our dependence on the reimbursement for our products from health insurance companies; our dependence on first party manufacturers to produce our products on time and to our specifications' implementation of our sales strategy including a strong direct sales force, the impact of COVID-19 on the global economy; market conditions; the timing, scope and possibility that the repurchase program may be suspended or discontinued; economic factors, such as interest rate fluctuations; and other risks described in our filings with the Securities and Exchange Commission.

These and other risks are described in our filings with the Securities and Exchange Commission including but not limited to, our Annual Report on Form 10-K for the year ended December 31, 2024, as well as our quarterly reports on Form 10-Q and current reports on Form 8-K. Any forward-looking statements contained in this press release represent Zynex's views only as of today and should not be relied upon as representing its views as of any subsequent date. Zynex explicitly disclaims any obligation to update any forward-looking statements, except to the extent required by law.

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