

FOR IMMEDIATE RELEASE

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KCBioMediX[®] Announces FDA 510(k) Approval for New Neonatal Medical Device System, the “NTrainer System[®]”

Shawnee, KS, JUNE 16, 2008 – KCBioMediX, Inc. (“KCBioMediX[®]”), a local medical device company that specializes in the care and treatment of high-risk infants born prematurely, announced today that it has received 510(k) “Clearance to Market” letter from the *Federal Drug Administration* (“FDA”) for its flagship product, the “NTrainer System[®]” a medical device system.

The NTrainer System[®] Technology

“I believe NTrainer will revolutionize our way of managing both preterm and term infants who have feeding issues.” Dongli Song, MD, PhD, Division of Neonatology, Santa Clara Valley Medical Center, CA.

Premature infants (born prior to the 37th week of gestation) typically confront a variety of health issues, central of which is difficulty coordinating breathing, swallowing, and sucking in order to feed. The ability to coordinate these fundamental building blocks of development, known as Non-Nutritive Suck (“NNS”), allows an infant to oral feed independently. Most premature infants are born before this ability has developed. Without the ability of the NNS, a premature infant that is already under-weight lacks the capability to nourish itself in order to gain weight. Further, the lack of NNS results in slow or stunted development, can lead to other neurological and physiological conditions, and in extreme cases, aspiration and even death. NNS is currently assessed and monitored by a clinician inserting a gloved finger into the infant’s mouth and subjectively determining a premature infant’s NNS development. This non-quantifiable method has the potential to result in inaccurate or erroneous determinations of a premature infant’s NNS capabilities, and does little to promote or speed proper development of NNS.

“Huge implications for length of stay and cost of care for NICU patients.” Jonathan NedreLOW, MD, Cook Children’s Hospital, Texas.

The NTrainer System[®], a breakthrough medical device system based on technology developed at the University of Kansas, consists of both sophisticated hardware and innovative software that monitors and trains premature infants to convert their disorganized and dysfunctional NNS motions into normal NNS patterns. The NTrainer System[®] objectively assesses and quantifies the patterns of NNS early in the care and treatment of premature infants, and then quickly and

effectively helps establish the correct sucking patterns. Developing normal NNS patterns early allows an infant to independent oral feed sooner and more effectively.

The conclusion of a recent study completed by Dr. Steven Barlow and submitted to *ACTA Paediatrica* in January, 2008, the NTrainer System[®] was that the NTrainer patterned therapy accelerates non – nutritive suck development and oral feeding success in preterm infants who are at risk for oromotor dysfunction. Further, in a joint research study conducted by *Stormont-Vail Medical Center* and *KU Medical Center*, the NTrainer System[®] technology was shown the ability to entrain the NNS, as well as, to accelerate the move of premature infants to independent oral feed in some cases, in as little as six days. According to Nicole Ickes, Pediatric Supervisor of the Orlando Hospital, Orlando, FL, “the NTrainer[®] assesses the non-nutritive suck sooner, at less risk to the baby and with more certainty than any of the other methods available.”

FDA 510(k) Clearance to Market Approval

KCBioMediX[®] announced today that it received approval and a *Clearance to Market Letter* from the FDA (the regulatory arm of the medical industry) on February 1, 2008 for its 510(k) application for the NTrainer System[®]. The FDA mandates new medical devices must go through a rigorous application and approval process before the owner of the device can make specific claims as to that device’s efficacy, and before the device can be commercially distributed in the United States. This approval process requires: (1) submission of a *Pre-market Notification 510(k) for Class II Medical Devices*; and (2) issuance a letter of substantial equivalence (owner must demonstrate that the device is substantially equivalent to one legally in commercial distribution in the United States). This FDA approval allows the NTrainer System[®] to be commercially distributed in the United States, and allows KCBioMediX[®] to make specific claims as to the NTrainer System’s[®] efficacy and proven results from premature infants that have been administered the NTrainer[®] therapy in initial research studies at *Stormont-Vail Medical Center* and *KU Medical Center* conducted in 2005.

The announcement of the NTrainer’s[®] 510(k) Clearance to Market represents an important milestone in KCBioMediX’s[®] business development. According to Mike Litscher, CEO of KCBioMediX[®], “we couldn’t be happier; this approval brings us one step closer to providing a break-through technology in the area of critical care of premature babies and ultimately, positively impacting the lives of these patients and their families.” KCBioMediX[®] is currently building enhanced prototypes for expanded clinical trials and plans to begin offering commercial-ready NTrainer Systems[®] to NICU’s [*Neonatal Intensive Care Units*] in the U.S. by early spring, 2009.

Expanded Clinical Trials

KCBioMediX[®] is currently aggressively pursuing expanded research trials in order to amend its original 510(k) to broaden and strengthen the initial claims approved by the FDA in its Clearance to Market letter. Currently, KCBioMediX[®] is conducting research trials at *Overland Park Regional Medical Center (Sunflower Neonatology Associates)* in Overland Park, Kansas (trials began in October, 2007), and *Wake Forest Medical Health & Hospital* in Raleigh, North Carolina (trials began in January, 2008). KCBioMediX[®] anticipates these trials will allow them to substantiate further claims discovered during its initial research trials. According to Litscher,

“we are confident the expanded clinical trials at OPRMC and Wake-Med will establish and validate broadened claims as to the significant results that the NTrainer System[®] brings to high-risk neonate lives.

About KCBioMediX[®], Inc.

KCBioMediX[®] is a neonatal intensive care medical device company that was established to commercialize technologies developed at the University of Kansas that measure develop and monitor the Non-Nutritive Suck (“NNS”) of premature infants. The foundation of KCBioMediX’s[®] technologies leverage over fifteen years of research led by Dr. Steven Barlow, the support of \$2,400,000 in grants from the *National Institutes of Health*, and extensive collaboration between numerous industry and medical experts, clinicians, and outside research institutions. In addition to the NTrainer[®] technology, KCBioMediX[®] anticipates expanding its product line into other related areas of clinical complication where relearning nutritive sucking patterns or other patterns of organized brain activity are necessary.

KCBioMediX[®] has partnered with the *Lawrence Regional Technology Center* (“LRTC”), a Lawrence, KS-based high-tech business incubator, as its premier technology commercialization, business development, and early-stage investment capital - strategist. KCBioMediX[®] is privately funded and is currently seeking an undisclosed sum of private investment in order to continue with the NTrainer’s[®] market launch, in addition to, continued development of its follow-on technologies and products.

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