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Nimbic Systems Receives NIH Grant to Study Device for Prevention of Implant Infections

HOUSTON (September 15, 2014) – Nimbic Systems, an early stage medical device company based in the Houston area and focused on technologies to reduce prosthesis-related infections, announced today that it has been awarded a $1.5 million grant from the National Institutes of Health to further study its FDA-cleared Air Barrier System device in a pivotal, multi-center clinical trial.

Post-operative infection following implant surgery is a serious complication occurring in approximately 2-3% of orthopedic joint arthroplasty cases and accounting for an estimated $1.2 billion in additional treatment costs annually. The infection rate after spine implant procedures is estimated at 3-10% according to recent peer-reviewed publications. Prosthesis infection may be caused by skin bacteria that deposit into a surgical wound and on to the implant at the time of surgery. Research published in peer-reviewed journals indicates that a primary source of these bacteria is skin cells shed by operating room personnel into the airborne environment that settle onto the surgical field.

Nimbic Systems has developed the Air Barrier System (ABS), a portable, inexpensive device that shields surgical sites from bacteria present in the operating room by creating a localized clean-air field over the surgery site that prevents airborne microorganisms from entering the incision. Currently, the ABS is cleared for use in hip arthroplasty and posterior spine surgery. In a clinical study funded by an SBIR Phase I grant from National Sciences Foundation and published in the August 2011 issue of *Journal of Arthoplasty*, the ABS reduced the presence of airborne bacteria at incision sites during hip surgery by up to 84%.

Based on a history of promising clinical research to-date, NIH awarded Nimbic Systems a $1.5 million SBIR Phase IIB award to study the ABS in a multi-center prospective randomized clinical trial in hip arthroplasty, spine fusion, acetabular reconstruction, and vascular bypass graft procedures. The company has partnered with Baylor College of Medicine (Houston) and the University of Texas Medical Branch (Galveston) to conduct the research at the Michael E. DeBakey Veterans Affairs Medical Center (VAMC), Ben Taub General, and UTMB TDCJ hospitals.

Nimbic Systems also expects to publish the results of its current NIH-sponsored Phase II clinical trial of the device in at the Houston VAMC in April 2015. This Phase II study is a prospective randomized clinical trial that examines the ability of the ABS device to reduce the

clinical rate of prostheses-related infection in 300 patients undergoing hip, spine, and certain vascular implant procedures.

For more information about Nimbic Systems, visit www.nimbicsystems.com

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