

Synapse Biomedical Fact Sheet

THE COMPANY: 300 Artino Street
Oberlin, Ohio 44074
Phone: 440-774-2488
Fax: 440-774-2572
www.synapsebiomedical.com

Co-Founder, CEO & President: Anthony Ignagni
Chief Operating Officer: Moustapha Diop

HISTORY: Synapse Biomedical was founded in September 2002 in Oberlin, Ohio, to commercialize the NeuRx[®] platform for treating a number of severe breathing problems with minimally invasive neurostimulation technology. The NeuRx Diaphragm Pacing System (DPS)[®] was developed by physicians and engineers at Case Western Reserve University, University Hospitals and Louis Stokes VA Medical Center, all in Cleveland, Ohio.

NeuRx DPS[®]
STATUS:

- FDA Humanitarian Device Exemption (HDE) marketing approval #H100006 for Humanitarian Use Device (HUD) (10-0242) in September 2011, for treating chronic hypoventilation related to amyotrophic lateral sclerosis (ALS), aka Lou Gehrig's disease.
- Cleveland Clinic's Medical Innovations Summit award for the Top 10 Medical Innovations of 2009. The system ranked third at the prestigious competition.
- FDA HDE approval on June 17, 2008, for treating ventilator dependency as a result of spinal cord injury (SCI).
- CE Mark (CE Registration #518356) in November 2007, for treating patients with diaphragm dysfunction in the European Union.

WHAT WE DO: Synapse Biomedical is focused on the commercialization of NeuRx DPS[®], a life-transforming neurostimulation platform technology, to treat people with respiratory insufficiency. NeuRx DPS[®] allows people with high spinal cord injuries that affect their respiratory muscles and nerves, to breathe without ventilators.

More than 400 SCI and ALS patients, including late actor Christopher Reeve, have been treated at leading centers around the world with the NeuRx DPS[®] technology. A list of spinal cord injury treatment centers can be found at

www.synapsebiomedical.com/products/us_sci.shtml .

In ALS, the NeuRx DPS[®] delays the need for mechanical ventilation and tracheostomy. Treatment centers are being currently established within the existing SCI treatment network and in cooperation with the ALS Association and MDA ALS clinic network. A list of treatment ALS centers can be found at www.synapsebiomedical.com/als/usneurx-centers.shtml

TODAY & BEYOND:

In September 2011, Synapse received FDA approval to expand the indications for use for NeuRx DPS[®] to treat ALS patients. The findings indicate benefits to prolong and improve quality of life in patients treated in a multicenter clinical trial that enrolled 144 ALS patients.

Synapse continues work on expanding indications for use of the NeuRx[®] platform technology. Initial studies for use of NeuRx DPS[®] to wean intensive care patients off of mechanical ventilators have begun. This is as an alternate or assist for mechanical ventilation which is the #1 charged procedure in the U.S. and has an aggregate “national bill” to healthcare exceeding \$61 billion (2008, U.S. DHHS HCUP Nationwide Inpatient Sample statistics). In 2012, Synapse plans to begin discussion with FDA on our clinical trial design for the NeuRx[®] platform use in surgical intensive care.

FOR MORE INFO:

Contact Steven Annunziato SVP Marketing & Sales at 440-787-0187 or email sa1@synapsebiomedcal.com