

## Synapse Biomedical Fact Sheet

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Co-Founder, CEO & President: Anthony Ignagni  
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**HISTORY:** Synapse Biomedical was founded in September 2002 in Oberlin, Ohio to commercialize the NeuRx Diaphragm Pacing System (DPS)™. The NeuRx DPS™ was developed through a joint effort of physicians and engineers at Case Western Reserve University, University Hospitals of Cleveland, and the Veterans Administration Medical Center.

The NeuRx DPS™ received:

- CE Mark (CE Registration #518356) in November 2007, for treating patients with diaphragm dysfunction in the European Union.
- FDA Humanitarian Device Exemption (HDE) approval on June 17<sup>th</sup> 2008, for treating vent dependency as a result of spinal cord injury (SCI).
- FDA IDE #G040142 in October 2005, for use in a clinical trial for amyotrophic lateral sclerosis (ALS).
- FDA Humanitarian Use Device (HUD) designation on June 11<sup>th</sup> 2009 for chronic hypoventilation related to ALS, aka Lou Gehrig's disease, which is the first step in obtaining ALS HDE marketing approval.
- Cleveland Clinic's Medical Innovations Summit award for the Top 10 Medical Innovations of 2009. The system ranked 3<sup>rd</sup> at the prestigious competition.

**WHAT THEY DO:** Synapse Biomedical is focused on the commercialization of the NeuRx DPS™, a life-transforming neurostimulation platform technology, to treat people with respiratory insufficiency. The NeuRx DPS™ allows people with high spinal cord injuries affecting their respiratory muscles and nerves to breathe without a ventilator.

Over 150 SCI patients, including Christopher Reeve, have been treated at leading centers around the US with the NeuRx DPS™ technology. A list of treatment centers can be found at [www.synapsebiomedical.com/products/us\\_sci.shtml](http://www.synapsebiomedical.com/products/us_sci.shtml).

In 2009, Synapse submitted to the FDA their 88 patient clinical trial data for treating chronic hypoventilation in ALS. Approximately 30,000 people in the US live with ALS. Of the estimated 5600 new cases diagnosed each year, 2400 have both chronic hypoventilation and intact phrenic nerves. It is this patient population that Synapse has applied for approval to treat with the NeuRx DPS™. Synapse continues to work on expanding the NeuRx DPS™ indications beyond SCI and ALS.

**FOR MORE INFO** Contact Steven Annunziato at 440-787-0187 or email [sa1@synapsebiomedcal.com](mailto:sa1@synapsebiomedcal.com)