

## Blood-oxygenating device to get human trials

### Respiratory assist support system could mean big things for small South Side company

Tuesday, January 05, 2010

By Steve Twedt, Pittsburgh Post-Gazette



Michel Sauret/Post-Gazette

Pete DeComo, chief executive officer, and Nick Kuhn, chief operating officer of ALung, show off their HemoLung respiratory-assist device that works as an artificial lung for medical patients.

Nick Kuhn, chief operating officer of ALung Technologies Inc., expects to receive a phone call within the next few weeks that could signal big things for the small South Side company.

The call may come from the Artemis Health Institute in Gurgaon, India, or one of five hospitals in Germany where doctors are preparing to use ALung's HemoLung respiratory assist device on a human patient for the first time.

If all goes well, ALung could be selling HemoLung to hospitals throughout Europe a year from now, and in the United States by late 2012.

The HemoLung does for patients with chronic respiratory problems what

hemodialysis does for patients with kidney disease, intervening to support a patient through a possibly life-threatening infection without the need for a ventilator.

Through a catheter inserted in either the femoral or jugular vein, Hemolung simultaneously extracts carbon dioxide and administers oxygen using a patented cylinder design with specially coated fibers that allow the gas exchange.

Functionally, it is the same idea as the highly specialized treatment known as Extracorporeal Membrane Oxygenation, only its developers say Hemolung is safer, faster, more efficient and cheaper - and can be used at any hospital that is capable of doing dialysis.

Where ECMO requires two large catheters, Hemolung has one small catheter, reducing the risk of an infection. With ECMO, 40 percent to 50 percent of the patient's blood may be circulating outside the body at any given minute, so the procedure requires close supervision; with Hemolung, it's 5 percent to 8 percent. Even if the machine completely shuts down unexpectedly, patients should not be in any immediate danger.

Also, ECMO requires maintenance as frequently as every six hours to prevent clotting. Because of its design, Hemolung has gone eight days in animal trials without any clotting problems.

Currently, a ventilator can end up being the best option for someone with chronic obstructive pulmonary disorder who develops an infection and requires help breathing - patients who are "living on the edge," said ALung Chairman and CEO Pete DeComo, a respiratory therapist by training who was director of respiratory care services at UPMC Shadyside from 1979 to 1985.

But, while saving lives, ventilators can damage the lungs, are uncomfortable and leave a patient unable to talk or eat by mouth.

Also, weaning a patient off a ventilator may take four to five days, while Mr. DeComo says a patient may be weaned from Hemolung in a matter of hours, all while allowing the patient to eat and talk.

Work has progressed on Hemolung, despite the unexpected death last year of

medical director Dr. Brack Hattler, co-inventor and co-director of ALung. Dr. Hattler drowned while competing in a minitriathlon in New Jersey. In addition to missing him, said Mr. Kuhn, "it would have been nice to have him around to talk to people in the medical community."

Chemical engineer William Federspiel is the other inventor and director of ALung.

ALung recently announced an infusion of \$2.5 million from current investors to move ahead with the clinical trials, giving the company a total of \$16 million in investor funding and \$12 million in federal grants.

ALung has 11 full-time employees but will be hiring four more engineers and a technician in coming weeks, Mr. DeComo said. It also is looking to expand its 6,000-square-foot office space at the Riverwalk Corporate Center.

The idea behind Hemolung emerged nine years ago from research being done at the University of Pittsburgh's artificial lung program. Actual work started on the first Hemolung prototype four years ago; the current incarnation is a 4-foot-tall, 150-pound machine with a cylinder seated with magnets on top that spins at 1,000 rpm.

ALung has studied Hemolung's performance in sheep and pigs, leading up to the human trials. They're starting clinical trials in India and Europe first because the approval process is faster, said Mr. DeComo. They may get approval in Germany after studying Hemolung's effectiveness in only 20 patients, he said, which can lead to regulatory approval for all of Europe.

In the United States, they expect it will take 200 patients and a year's time to gain approval from the Food and Drug Administration. The American clinical trials are expected to begin in early 2011.

But word is getting out here already, said Mr. Kuhn, and, "there's a lot of excitement" about using Hemolung as a bridge to keeping patients alive while they await a lung transplant - though that market is very small. The goal, he said, is to have Hemolung available at "every community hospital in the country."

They have designed Hemolung to use a catheter similar in size to those used in dialysis, so frontline clinicians will feel comfortable using it.

"We didn't want to change the way clinicians practice medicine," said Mr. DeComo, reasoning that hospital staff would be less likely to use a device that was radically different from what they're familiar with.

"The smaller it is, the less daunting it is to use," said Mr. Kuhn.

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First published on January 5, 2010 at 12:00 am



