

# AirXpanders Inc.

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**Summary:** Women who undergo mastectomy for breast cancer may soon be able to play a more active role in their recovery. An implanted tissue expansion system from AirXpanders Inc. uses compressed carbon dioxide to stretch existing tissue in preparation for a permanent breast implant. The patient is also given an external handheld dose controller that releases small amounts of CO2 into the tissue expander, up to three times daily for about two weeks.

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**Article begins on the next page . . .**

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## **AirXpanders Inc.**

### **Compressed CO2 expands tissue for breast reconstruction**

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Web Site: [www.airxpanders.com](http://www.airxpanders.com)

Contact: Scott Dodson, President & CEO

Industry Segment: Tissue Expansion

Business: Tissue expansion technology

Founded: March 2005

Founders: Barry Cheskin, Chairman; Dan Jacobs, MD, CMO; Teddy Shalon (Shalon Ventures)

Employees: 14

Financing to Date: \$12.1 million

Investors: GBS Venture Partners Ltd.; Heron Capital; Prolog Ventures

Board of Directors: Barry Cheskin; Teddy Shalon; Brigitte Smith (GBS Venture Partners); Brian Clevinger, PhD (Prolog Ventures)

Scientific Advisory Board: Dan Jacobs; Robert Menard, MD (Stanford University Medical Center); Jane Weston, MD (Stanford University Medical Center)

Women who undergo mastectomy for breast cancer may soon be able to play a more active role in their recovery. An implanted tissue expansion system from **AirXpanders Inc.** uses compressed carbon dioxide (CO2) to stretch existing tissue in preparation for a permanent breast implant. The patient is also given an external, handheld dose controller to release small amounts of CO2 into the tissue expander, up to three times daily for about two weeks.

"This represents the first major breakthrough in breast construction surgery in over 30 years," says company president and CEO Scott Dodson, referring to previously developed acellular dermal matrix (ADM) materials used in conjunction with conventional saline expanders to support devices and permanent implants. Two of the largest drawbacks of existing technology are patient pain from having to endure weekly bolus injections of saline and the lengthy treatment protocol of up to five months. "In our feasibility study, the physician received far fewer pain comments from patients, presumably due to the incremental daily expansion verses weekly bolus injections," Dodson says.

Of the approximately 250,000 cases of breast cancer diagnosed yearly in the US, about 85,000 result in reconstruction, representing a monetary opportunity in the \$300 to \$330 million range. Globally, the breast cancer reconstruction space is easily a \$500 million dollar opportunity. "However, the number of

reconstruction procedures should actually be about twice that number because patients are not particularly well informed about the options available to them," Dodson notes.

Co-founder Dan Jacobs, a plastic surgeon at Kaiser Permanente in San Jose, CA, has believed for many years now that tissue expansion should be more convenient for the patient. CO<sub>2</sub> was chosen because of its proven track record in medical applications, foremost in laparoscopic procedures. "CO<sub>2</sub> is readily absorbed by the body and it is deemed safe," Dodson says. The biggest challenge, though, was developing a system that would deliver precise doses of CO<sub>2</sub> to the implant.

Dodson, who in September assumed the role of president and CEO at AirXpanders, most recently served as president and CEO of Avantis Medical Systems Inc. (imaging technology for colonoscopy) from 2008 to 2010. He has also held executive management positions at Boston Scientific Corp. (endoscopy), Orthofix International NV (orthopedics) and Barrx Medical Inc. (GI cancer).

AirXpanders has eight pending patents (none issued) and licenses some of its intellectual property from one of the inventors of the device, Teddy Shalon, who is a managing partner of Shalon Ventures, a San Francisco Bay Area health care investment group.

The tissue expansion system has two main components: the expander implant itself that contains a reservoir of compressed CO<sub>2</sub> and an external dose controller that activates the implant. The implant is an anatomically shaped expander made of silicone, whereas the internal reservoir is made of stainless steel.

Prior to the outpatient or inpatient procedure that takes about one hour under general anesthesia, the patient is trained on how to use the dose controller.

Intraoperatively, the plastic or breast surgeon makes an incision under the pectoral muscle and creates a breast pocket through dissection. After the expander is placed in the pocket, the wound is closed. The surgeon then activates the expander by pressing a button on the wireless, battery-operated controller, which transmits radiofrequency energy to an internal antenna on the implant that triggers the release of precise doses of CO<sub>2</sub> to form a breast mound.

Typically, the patient is sent home – without the dose controller – for two weeks for wound healing. She then returns to the physician's office for an assessment of her healing process and additional expansion with the dose controller. The patient is then released with the controller so that she can administer further expansion by herself in the convenience of her own home.

At home, patients can dose up to three times a day, with each dose releasing 10 milliliters of CO<sub>2</sub>. However, for safety, there is a programmed three-hour lockout between doses and a programmed 24-hour lockout from the first to the fourth dose. "Much like pain pumps, the patient is unable to dose continually throughout the day," Dodson explains.

It usually takes the patient a few days to observe a change in breast shape during the two-week at-home expansion cycle. Permanent implant exchange surgery is then scheduled about two months later.

A human clinical trial of seven patients (10 implants) conducted in Australia in 2010 found successful expansion to the point of permanent implant exchange. There were also no reported device-related complications or significant adverse events with the tissue expansion system.

Traditional saline expanders from **Allergan Inc.** ( *CUI*) and **Johnson & Johnson's Mentor Corp.** ( *Contour Profile*) require weekly saline injections to inflate their devices. "The bolus inflation process can be excruciatingly painful to patients," Dodson states. Typically, injections occur weekly over a three- to five-month period, as opposed to normally just two follow-up office visits with the AirXpanders device. The

pain associated with competing devices and the number of office visits required also decrease patient compliance. In fact, online blogs reveal that many women "would never have agreed to the expansion process if they knew in advance just how painful it was going to be," Dodson says.

Additionally, the results with the AirXpanders system "are very consistent because our device has a predetermined anatomical shape," Dodson says. "The CO2 seeks that shape, unlike traditional saline expanders that act more like a standard balloon. The more medium you place in these saline expanders, the more the breast may appear misshapen."

AirXpanders expects its tissue expansion device to receive CE mark in 2011, followed shortly thereafter by 510(k) clearance.

Sales of the AirXpanders system are expected to start in select European countries and Australia in 2011 through a network of distributors, and soon after in the US, initially through a direct sales organization. "As in the US, reimbursement is federally mandated in many international markets," Dodson says. "This is a tremendous advantage because many other medical devices are limited in their adoption due to lack of reimbursement."

AirXpanders has raised \$12.1 million to date. A \$5.6 million Series A round led by Heron Capital and Prolog Ventures closed in 2005, a \$1.5 million Series B round in 2007 was financed by inside participants, and a \$5 million Series C round that closed in April 2010 and was solely capitalized by GBS Venture Partners Ltd. A Series D round from a combination of VC firms and insiders will be initiated sometime in 2012 to carry the company to profitability.

Currently, AirXpanders has no strategic partnerships, but is seeking European and other international distribution partners. Besides breast cancer/breast tissue expansion, two other potential substantial markets are burn and pediatrics by offering skin grafting and creating skin through expansion.

Meanwhile, AirXpanders expects a rapid adoption of its relatively painless technology for breast reconstruction. "I believe patients will undoubtedly play a big role," Dodson says. "This is one of the most informed patient groups in medical devices." – Bob Kronemyer