



## **AirXpanders Announces European CE Mark Approval for AeroForm™ Patient-Controlled Tissue Expander for Patients Undergoing Breast Reconstruction**

PALO ALTO, Calif. (Oct 25, 2012) – AirXpanders Inc., a company developing novel technology for women who require tissue expansion for breast reconstruction following a mastectomy, today announced that it has received European CE Mark approval for AeroForm™, a needle-free, patient-controlled tissue expansion system.

The CE Mark enables AirXpanders to commercialize the AeroForm system in Europe and other select markets around the world. The company plans to work with leading plastic surgeons across the European Union to generate post market clinical data on European patients to support widespread commercialization in the region.

"We are extremely pleased that the AeroForm has received this important regulatory milestone that will give women outside of the United States access to a patient-friendly option for tissue expansion when undergoing breast reconstruction after a mastectomy," said Scott Dodson, AirXpanders President and Chief Executive Officer. The company will begin the formalization of its International distribution plan over the next few months while we simultaneously complete our ongoing IDE trial in the United States.

AeroForm allows women to complete their expansion at home, without needles and at their own pace based on their level of comfort.

A current method of breast reconstruction involves tissue expansion followed by placement of a breast implant. In the traditional method for expansion, a surgeon places a saline tissue expander under the skin and pectoral muscle following the mastectomy. During subsequent office visits, the surgeon inserts a needle through the skin and muscle into a magnetic port to inject a bolus of saline into the expander to the level tolerated by the patient. The series of saline inflations needed to fill the expander, can take up to six months while the AeroForm has been shown to achieve full expansion in as little as 14 days, according to a study published in Plastic and Reconstructive Surgery in October of 2011.

### **About AirXpanders**

AirXpanders Inc. ([www.airxpanders.com](http://www.airxpanders.com)), is a tissue-expansion company focused on the area of breast cancer reconstruction. By employing a revolutionary patient-controlled expander, activated by a wireless remote control, the often painful process of reclaiming one's body after cancer can potentially be eased with this needle-free technology. This technology is easy to use and may enable the patient to proceed to a permanent implant much faster than the current standard-of-care. At this time, AirXpanders' products are not cleared or approved for sale. AirXpanders is backed by Vivo Ventures, GBS Venture Partners, Prolog Ventures, Heron Capital, Shalon Ventures, Correlation Ventures and Western Technology Investments.

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