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## Pivotal Trial Data for AirXpanders<sup>®</sup> AeroForm<sup>®</sup> Tissue Expander System for Breast Reconstruction Published in *Plastic and Reconstructive Surgery*<sup>®</sup>

Results show women undergoing reconstructive surgery following mastectomy who received AeroForm able to complete expansion and reconstruction faster than women who received traditional saline-based expanders

**PALO ALTO, Calif., November 29, 2016:** <u>AirXpanders, Inc.</u>, **(ASX: AXP) (AirXpanders** or **Company**), a medical device company focused on the design, manufacture, sale and distribution of the AeroForm Tissue Expander System, announced that pivotal trial data from its XPAND study on AeroForm was published in the December issue of *Plastic and Reconstructive Surgery*, the official journal of the American Society of Plastic Surgeons. AeroForm is currently available in Australia and under review with the U.S. Food and Drug Administration.

AeroForm is designed to offer women who choose reconstructive surgery following a mastectomy a needle-free alternative for tissue expansion. AeroForm is activated by a handheld wireless controller that administers small amounts of carbon dioxide ( $CO_2$ ) up to three times a day, to gradually stretch the tissue to prepare for reconstruction. With the push of a button from a remote controller, the programmed amount of  $CO_2$  is delivered in seconds, allowing the patient to continue with her daily activities while preparing for reconstruction.

The XPAND study evaluated AirXpanders' AeroForm Tissue Expander System compared to traditional saline expanders in a randomized, controlled trial that included 150 patients across 17 sites in the U.S. Study data demonstrated that with AeroForm, patients were able to complete tissue expansion in an average of 21 days, compared to an average of 46 days for the saline group. The study also demonstrated that both study groups achieved successful exchange to an implant with similar safety profiles. AirXpanders submitted the results of the XPAND study to the U.S. Food and Drug Administration (FDA) as part of the Company's *de novo* dossier, submitted late last year.

"Fear of a time-consuming and potentially uncomfortable medical process can deter women who have undergone mastectomy from having reconstruction," said Jeffrey Ascherman, M.D., site chief of the Division of Plastic Surgery NewYork-Presbyterian/Columbia University Medical Center and principal investigator for AirXpanders' U.S. XPAND study. "This study is further evidence that AeroForm could improve the standard of care for reconstruction, enabling women to complete reconstruction faster and with greater control over the process."

"Publication of the XPAND data validates AeroForm and its potential to provide plastic surgeons and patients with what we believe is one of the first major advancements in twostage breast reconstruction in more than 40 years," said Scott Dodson, president and CEO, AirXpanders. "We look forward to working with FDA to bring this revolutionary technology to surgeons and women in the U.S. and continuing our efforts to expand access to AeroForm globally."

An abstract of the XPAND data published in the journal is available from the following link: http://journals.lww.com/plasreconsurg/Abstract/2016/12000/Carbon\_Dioxide\_Based\_versus\_ Saline\_Tissue.5.aspx

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## About AirXpanders:

Founded in 2005, AirXpanders, Inc. (www.airxpanders.com) designs, manufactures and markets innovative medical devices to improve breast reconstruction. The company's flagship product, the AeroForm Tissue Expander System, is used in patients undergoing two-stage breast reconstruction following mastectomy. Headquartered in Palo Alto, California, AirXpanders is committed to providing patients and surgeons with best-in-class products that are made under strict design and quality standards. AirXpanders' vision is to be the global leader in reconstructive surgery products and to become the standard of care in two-stage breast reconstruction. AirXpanders is a publically listed company on the Australian Stock Exchange under the symbol AXP. The AeroForm Tissue Expander System is not cleared or approved for use in the United States and is for investigational use only. AeroForm is cleared for commercialization in Europe and Australia

## **Forward-Looking Statements**

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to obtain FDA approval for our product; to commercialize our product; our ability to obtain reimbursement for our product; therapeutic advantages of our product, and market opportunity for our product. Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. AirXpanders does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. AirXpanders may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

For more information, refer to the Company's website at www.airxpanders.com.