

ASX ANNOUNCEMENT

AirXpanders issues Shareholder Newsletter

PALO ALTO, CA, United States, 17 December 2015: AirXpanders Ltd (ASX:AXP) a medical device company focused on the design, manufacture, sale and distribution of the AeroForm® tissue expander, has lodged its Shareholder Newsletter with the ASX today.

The company will be distributing future issues of the newsletter in digital-only format. Those interested in receiving Company news each quarter should register at www.airxpanders.com/contact-us/.

- ENDS -

<i>Company</i>	<i>Investor relations</i>
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About AirXpanders:

Founded in 2005, AirXpanders is a medical devices company focused on the design, manufacture, sale and distribution of its AeroForm® tissue expander used in patients undergoing breast reconstruction following mastectomy. It considers that its AeroForm® device is the best innovation in expander technology in 50 years. AeroForm® uses controlled delivery of small amounts of gas (CO₂) to achieve tissue expansion prior to the placement of a permanent breast implant. AeroForm® successfully eliminates the need for needle-based expansion required for traditional saline tissue expanders and provides a faster, less painful and less stressful breast reconstruction journey. The Company has CE Mark and TGA approval for AeroForm® and is fully reimbursed under Australian Medicare. To date, AeroForm® has been successfully implanted in over 400 patients worldwide. AirXpanders devices are not cleared or approved for use in the United States and are considered for investigational use only. AirXpanders is cleared for commercialization in Europe and in Australia.

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



Scott Dodson **CEO**

Highlights

- **FDA *de novo* application completed and submitted**
- **Early Australian uptake momentum - 70+ surgeons trained to date**
- **Received the top presentation award at the American Society of Plastic Surgeon's Meeting, the world's largest speciality plastic surgery organization**
- **Continuing strong patient and surgeon advocacy**
- **Continued build-out of US sales and marketing capability through key new hires in anticipation of US approval and launch next year**

Sign up to receive our quarterly e-news

AirXpanders is moving to digital-only news. Visit www.airxpanders.com/contact-us/ and register to receive news and updates from AirXpanders each quarter.

A message from the CEO

Dear Shareholders,

I am writing this e-news update as we wrap a productive trip to Australia. It has been a great chance to meet with some of our newly trained surgeons across Sydney, Melbourne and Brisbane and speak to existing and prospective investors on both our progress in the Australian market and the preparations we are making for a commercial launch in the US.

As we reported recently, AirXpanders received advice from the FDA in Nov 2015 regarding our 510(k) submission, and indicated it would instead proceed with a *de novo* submission. This is a pathway for novel devices, of low to moderate risk, and required us to reorient the existing submission to the required template to highlight the technical differences between the AeroForm and saline tissue expanders. We indicated that this would be completed within a few weeks, and I am pleased to report the *de novo* application has now been submitted. Dialogue between the Company and the FDA will be ongoing, with a formal review of the application expected in the second quarter of 2016. In the mean time we continue to prepare for a US commercial launch having made some recent high calibre, key hires in addition to commencing the manufacturing transfer process to our automated facility with a contract manufacturer in Costa Rica.

In Australia, I have been very pleased with the progress that our Australian sales team has made under the

leadership of our National Business Manager, Kirsty Amland. Since our last update, we have trained an additional 20 surgeons, bringing the total to 70 and our sales have significantly increased on a quarter to quarter basis. We continue to see a positive trend in sales, uptake and continued interest in making the AeroForm the device of choice for women looking to under reconstruction following mastectomy.

We are receiving positive feedback from patients and surgeons who have used the device and encourage you to read the testimonials and quotes provided in this e-news update.

In addition to all of the excellent progress being made in Australia, we presented our final data from the XPAND trial on October 19 at the American Society of Plastic Surgery Meeting in Boston, the world's largest plastic surgery conference. This presentation was made to a standing room only crowd at the conference and received the top presentation award for the entire conference.

On behalf of the AirXpanders Board and Management, we greatly appreciate the support of our shareholders and hope that you find this update of value. Feel free to drop me a line with any feedback at sdodson@airxpanders.com

Yours sincerely,

Scott Dodson
Chief Executive Officer
AirXpanders Inc



Events

31 January

Quarterly financial results

Appendix 4C cash flow report and investor conference call

25 February

Full Year Results



Australian Launch Highlights and Sales Team Focus

The national launch of AeroForm is now well underway in Australia. As we approach six months in the market, close to 70 surgeons have been trained. We are seeing a positive quarterly trend emerge, as a result of the efforts of our strong sales team in Australia and the strong demand from plastic surgeons in the market.

Our strategy of focusing on top tier surgeons, on-board their relevant facilities and provide support on the ground (before expanding further), has proven highly effective. Overall the experience has been very positive, for both surgeons and patients, and with the first exchanges now starting to occur, we are receiving repeat orders for the next round of procedures.

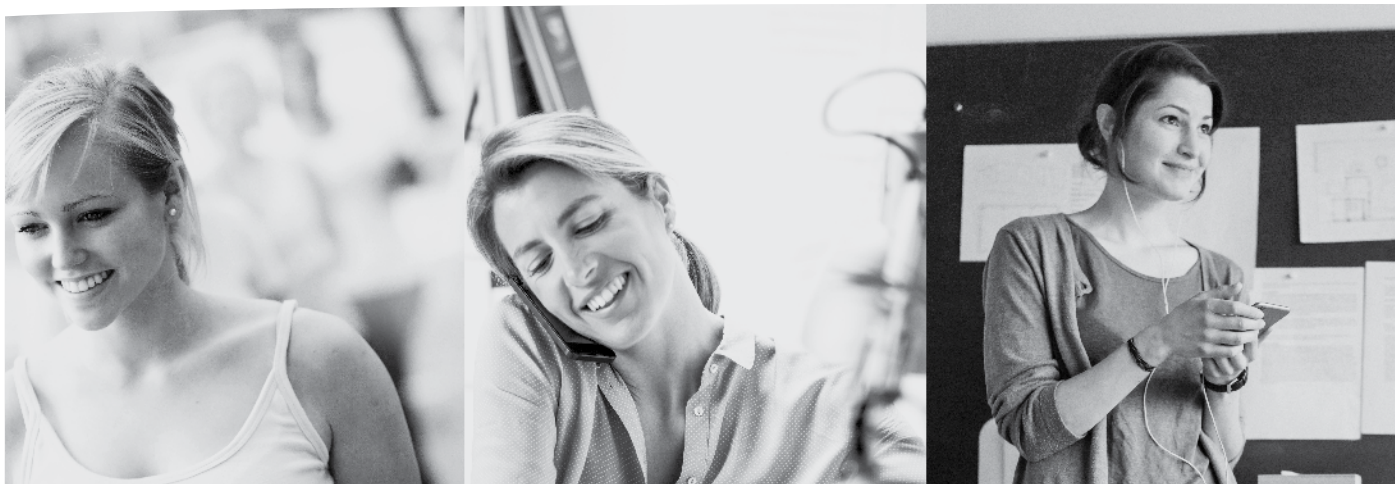
We will continue to host our Early User Forums, in conjunction with our clinical

trial investigator, Dr Tony Connell and other top users. These events have proven highly effective in driving utilisation with 80% of attendees either booking procedures or indicating their intent to use AeroForm after attending. These events have been hosted in Brisbane, Melbourne and Sydney.

Our sales team is in high demand, with appointments booked out for the next few months as we follow up our initial surgeons, and commence meeting with a wider range of plastic and reconstructive surgeons across the country.

We are also very focused on raising awareness through patient groups, conferences and PR. Some initiatives underway include:

- Partnership with Reclaim Your Curves at www.reclaimyourcurves.com.au, a local breast reconstruction patient awareness group, associated with the Breast Cancer Network Australia. This partnership enables AirXpanders access to more women through the group's network and increase patient and physician awareness of the AeroForm product.
- Sponsorship and presentations at several state and national Plastic and Breast Surgery meetings including the Victorian Breast Surgeon Journal Club and the Australasian Society for Breast Disease. These sponsorships have effectively driven increased awareness of the AeroForm device and its advantages over traditional expanders within the surgeon community.



Patient and Surgeon Feedback

What is it that patients and surgeons like about AeroForm? These testimonials collected in the field provide some insights to our point of difference in the market and positive impact on patients.



"Aeroform offers a number of advantages over the traditional method of implant reconstruction such as greater patient control of the process, quicker expansion rates and a reduced risk of infection, as no needles are used." – **Dr Fred Clarke, NSW**

"I find the Aeroform so easy to use, for both myself and my patients' – **Surgeon, VIC**

"Yes, I will offer this option to all my patients. I know which one they will choose!" – **Surgeon, VIC**

"It is great to literally hold control during a time where I've had no control of anything." – **Patient NSW**

"The remote controlled expansion may reduce the risk of infection, psychological barrier, pain, discomfort and sheer inconvenience traditional needle injections can bring."

– **Surgeon NSW**

"I had thoroughly researched my reconstruction options and had spoken to a number of surgeons as well as women who had undergone the various procedures available, but it wasn't until I heard about AirXpanders that I felt that this was the option for me. It seems much less invasive and a much quicker option and I like the fact that I can control the process."

– **Patient NSW**



News and Analyst Coverage

Canaccord Research Report

AirXpanders files for US approval

1 September 2015

Body and Soul magazine

Breast Cancer Special: Reconstruction – What's the Latest?

27 September 2015

Bioshares

Three Short Term Plays Before Christmas – Highlights the upcoming milestone of the release of our US Expand Trial data in October

28 September 2015

News.com.au

What Australian women don't know about breast reconstruction

23 October 2015

Canaccord Research Report

FDA recommends 510k de novo path for AeroForm

13 November 2015

AirXpanders: Expanding our Team

Following the filing of our de novo application with the FDA, we are focused on building a sales and marketing team in the US in anticipation of approval and commercial launch next year. On that note, AirXpanders is pleased to announce the appointment of **Anthony Carnemolla to the position of Vice President, US Sales**. Anthony has a strong track record of building, motivating and developing Operating Room based sales organizations to deliver best in class results in a highly competitive surgical environment. Over the last 24 years, Anthony has led organizations such as Invuity, Volcano Corporation, Inamed, Steris and Johnson & Johnson in their efforts to develop markets, break new ground and establish new technologies as the gold standard for the medical device industry. Most recently, Anthony led the Invuity Corporation in establishing their lighted retractor line into the fiercely competitive surgical theatre environment while building a sales organization from the ground up. During this five year period, Invuity saw their revenue rates grow over 400% vs. their annual forecast for their premium product offering.

We have also appointed a **Senior Director of Global Marketing, Jennie Kim**, who brings 15 years of experience in healthcare marketing and public relations. Prior to joining AirXpanders, Jennie held

a number of leadership roles in marketing and public affairs at Abbott Vascular. In her most recent role at Abbott, she led global branding and positioning efforts for Absorb, the world's first fully bioresorbable coronary scaffold. She has experience in medical device marketing targeting both healthcare professionals and consumers. Jennie began her career in women's reproductive health, and worked extensively with patient advocacy groups. Jennie received her Masters of Health Sciences degree from the Johns Hopkins University School of Public Health and her Bachelor of Arts degree from Pomona College in Claremont, CA.

To manage our customer service efforts and sales analytics, we have appointed **Gary Jones as Director of Customer Fulfilment** who will be managing the implementation of an ERP system to help the company input and track orders on a much larger scale.

Gary has built and led customer service organizations for over 35 years. During this time, Gary has managed this function in seven medical device start-ups who went on to commercial success and has developed a keen ability to work across different regions of the world to insure that customers are satisfied and their patients are treated effectively.

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