

**5 January 2017****AirXpanders releases investor presentation**

**PALO ALTO, CA, United States — AirXpanders, Inc. (ASX: AXP) (AirXpanders or Company)**, a medical device company focused on the design, manufacture, sale and distribution of the AeroForm® Tissue Expander System, today released a copy of its investor presentation, following receipt of its *de novo* clearance from the United States Food and Drug Administration for AeroForm in late December 2016.

Please see below for a copy of the investor presentation.

-ENDS-

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**About AirXpanders:**

Founded in 2005, AirXpanders, Inc. ([www.airxpanders.com](http://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. AeroForm received U.S. FDA *de novo* clearance in 2016, first CE mark in Europe in 2012 and is currently licensed for sale in 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 commercialize our products; our ability to develop and commercialize new products including our ability to obtain reimbursement for our products; our expectations with respect to our regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position. 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](http://www.airxpanders.com).



# AirXpanders®

Investor Presentation

January 2017



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# ABOUT AIRXPANDERS



We believe the best innovation in tissue expansion in decades

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US\$800m+ addressable market in U.S.

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FDA clearance achieved; AU and U.S. reimbursement in place

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Strong and sustained market share in AU

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U.S. launch commencing Jan 2017

# Overview of Breast Cancer Reconstruction

## Current breast surgical treatments

- Mastectomy – Most frequently performed treatment in the U.S. (250,000 p.a.)
- Lumpectomy – removing a portion of the breast

## Reconstruction surgery types

- Two stage surgery with tissue expanders (~72%)
- Microsurgical tissue flaps & direct to implant (~28%)

## Most U.S. women choose reconstruction if offered

- Currently, only 1/3 of U.S. women are informed about their reconstruction options
- The Breast Cancer Patient Education Act of 2015 now mandates all breast cancer patients are educated about their reconstruction options



**1 in 8 women will develop  
breast cancer**

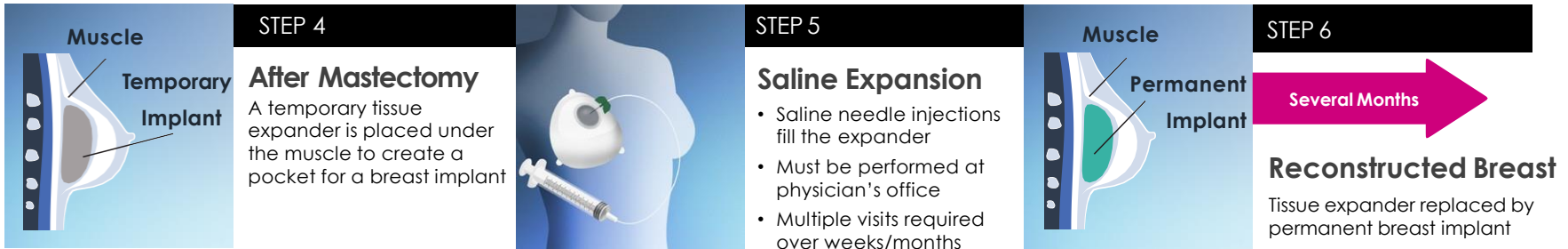
# Mastectomy and Traditional Breast Reconstruction

Following a mastectomy there is typically insufficient skin to accommodate a breast implant

## Phase 1



## Phase 2



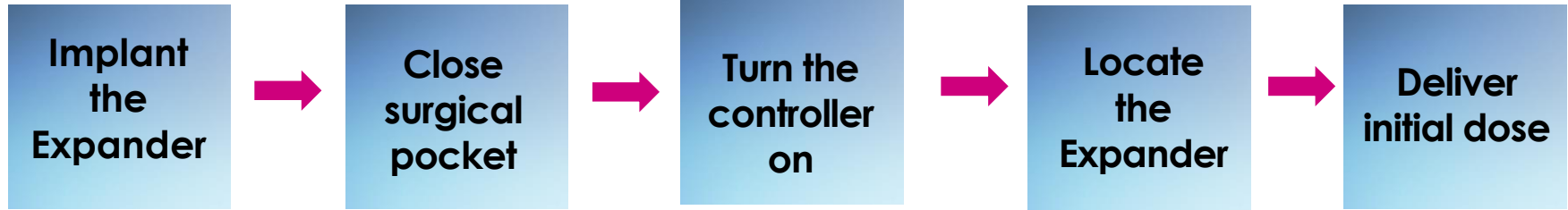
# Features of AeroForm® Tissue Expander System

- Needle-free
- Patient-controlled expansion
- Wireless dose controller
- CO<sub>2</sub> canister inside tissue expander

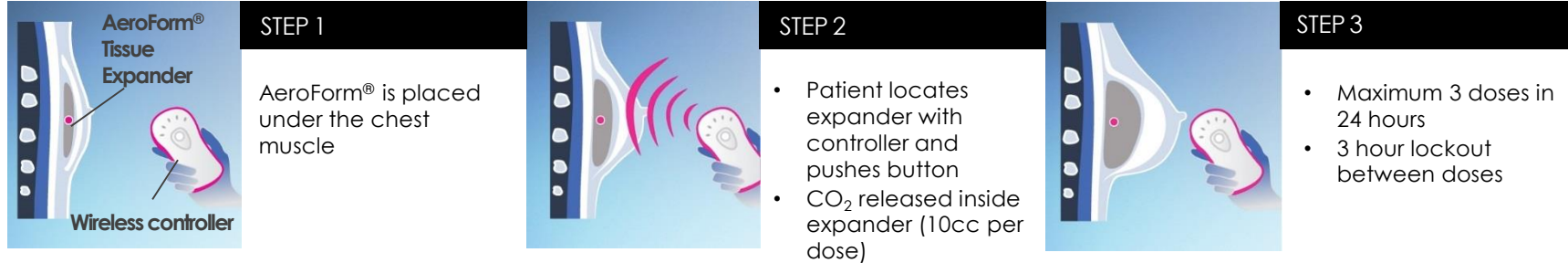


# How the AeroForm® Tissue Expander System Works

## Easy for the surgeon



## Easy for the patient





# Advantages of AeroForm<sup>®</sup> Tissue Expander System

## AeroForm<sup>®</sup> Tissue Expander System

- No needles / needle anxiety
- Patient controls expansion at own pace and environment
- Faster expansion
- Fewer office visits
- True anatomical shape
- Less infection risk



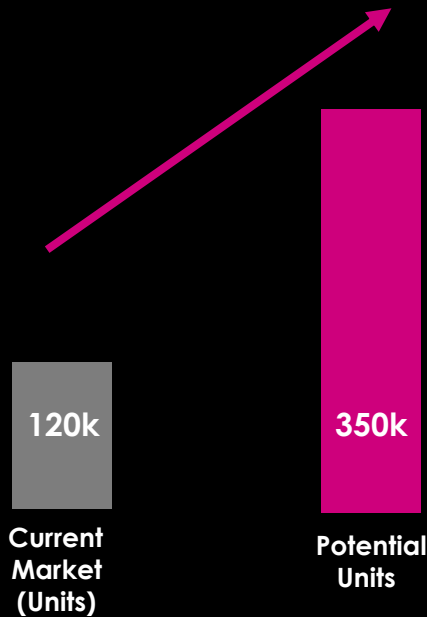
## Saline Tissue Expander

- Needles / needle anxiety
- Lengthy, time consuming
- Requires multiple visits to doctor's office
- Sub-optimal cosmetic result
- Decreased productivity for surgeons and hospitals

**U.S. Addressable Market**

**=**

**US\$800m +**



## Market Opportunity

### U.S. Market Opportunity

- 300,000 breast cancer diagnoses
- 72%+ use tissue expanders
- 60% bilateral operations
- 350,000 potential units

### Growth drivers

- Only 1/3 women are aware of their options today
- U.S. Breast Cancer Patient Education Act
- Most women choose reconstruction if offered
- A large latent pool of women haven't undertaken reconstruction

### Rest of World

- 1.4 million breast cancer diagnoses annually



# AIRXPANDERS MILESTONES



**"The pure simplicity of the patient  
controlled expansion is the strength of  
the device."**

Damien Grinsell  
(MBBS FRACS Plas)  
Member of Royal Australian College of  
Surgeons and Australian Society of  
Plastic Surgeons

# Milestones

## 2015

**Jun** Listed on ASX and launch in Australia

**Oct** Successful XPAND pivotal trial data

**Dec** FDA *de novo* submission for AeroForm®

## Upcoming

Initiate commercial launch in U.S.

Obtain 510k clearance for film enhancement

Accelerate U.S. Sales and Marketing expansion

## 2016

**Feb** ~20% market share in Australia (run rate)

**Jun** A\$20M private placement

**Sep** Further progress on increasing manufacturing capacity

**Sep** Increased quarterly unit sales by 25% vs Q2 2016

**Dec** US IDE Trial Publication

**Dec** FDA *de novo* clearance



# U.S. COMMERCIALISATION


**“AeroForm® represents the first major change in breast tissue expansion in 40 years. It’s a real game-changer. It’s super-easy to use. You just press a button and that’s it.”**

Jeffrey Ascherman, M.D.  
Site Chief, Division of Plastic Surgery  
Professor of Surgery  
Columbia University Medical Center



# AeroForm® Enters U.S. Market in a Strong Position

- High level of awareness among surgeons for AeroForm®
- Exceptional clinical results in 2 U.S. and 3 AUS trials
- More than 13 peer-reviewed publications
- Presented at major U.S. industry conferences and events for past 5 years
- Strong patient advocacy awareness via patient support groups and social media
- 17 major hospitals involved in clinical trials
- Significant pent-up demand for AeroForm® in the U.S.
- Received consistent inbound surgeon enquiries



**“I hope that the AeroForm® becomes the standard of care for all breast cancer survivors in the very near future. No woman who has to face this illness should be denied this easier path to reconstruction... Having so much control over the expansion process enabled me to keep living fully during treatment.”**

– Sofia Q, patient



# U.S. Sales and Launch Strategy

## U.S. commercial launch in January 2017

### 1H 2017

- Targeted release to 12+ major hospitals, clinical users of AeroForm® in XPAND pivotal and continued access trial
  - High volume academic and community hospitals
- Secure majority share from existing clinical surgeons
- Build deep presence at initial sites by recruiting and training additional surgeons and establishing routine use
- File traditional 510k for enhanced film

### 2H 2017

- Full commercial release\*
- Additional direct and indirect sales force to target new hospitals and regions
  - 120+ preselected customers
- Expand around established commercial sites to create competitive hospital bidding

\*Pending FDA clearance of new film

# U.S. Sales Force Buildout Underway

## Hybrid sales force: Direct and Commission Only Reps

- Targeted hiring schedule vs recruiting schedule

	Direct reps	Indirect reps
1Q 2017	7	
2Q 2017	3	6
3Q 2017		3
4Q 2017		3
<b>Total</b>	<b>10</b>	<b>12</b>

- 19 sales reps already recruited for hiring



Sales Representatives across the U.S.

# Reimbursement and Pricing in U.S. Market

- Women's Health and Cancer Rights Act of 1998 - mandatory reimbursement for breast reconstruction
- Rates of reimbursement increasing since 2010
- Breast Cancer Patient Education Act of 2015 – all patients must be informed of breast reconstruction options
- Procedure covered by U.S. CPT Category 1 Code





## Increasing manufacturing capacity

- Adding manufacturing capability in high-tech, low-cost MedTech manufacturing hub in Costa Rica
- Decreased manufacturing costs and increased production volume will drive greater margins
- First new line installed in Costa Rica
  - Fully validated and operating in early 2017
  - Capacity of 15,000 – 20,000 units per year
- Second line installation to commence 2H 2017
  - Additional 15,000 – 20,000 units per year
- Maintain manufacturing capacity in California (3,000-4,000 units per year)



# INTERNATIONAL OPPORTUNITIES



Continue to expand the market in Australia

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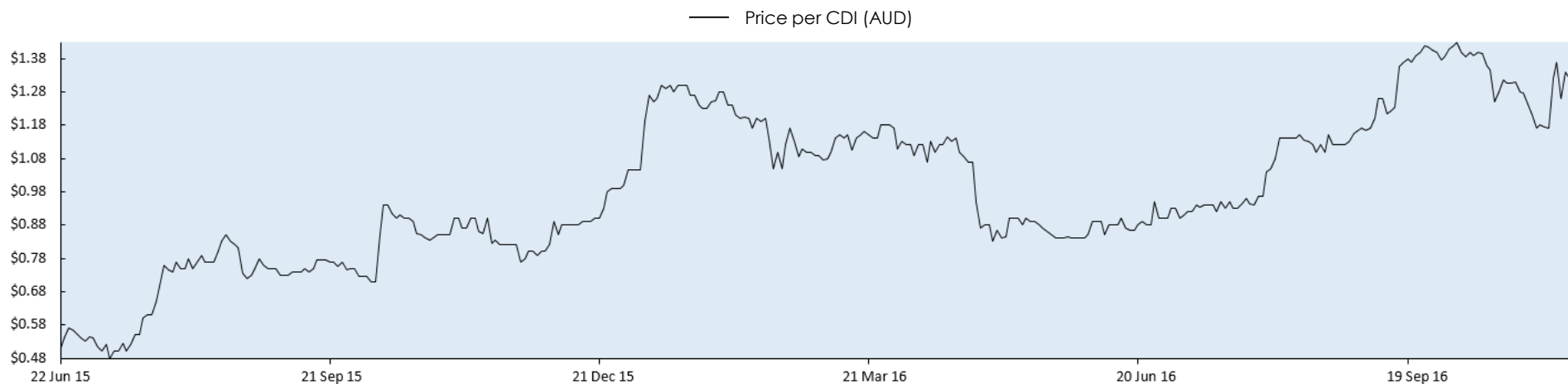
Conduct Key Opinion Leader evaluation in Europe  
and assess target countries

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Identify regulatory pathways into targeted AP markets

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# Corporate Snapshot



**Market Cap:** A\$268M (as of 2 Dec 2016)

**Shares issued:** 79.20M

**CDI issued:** 237.6M (assuming all shares are held as CDIs)

**Cash position:** US\$17.7M (as of 30 Sep 2016)

## Major shareholders:

- GBS Ventures
- Prolog Ventures
- Heron Capital
- Vivo Ventures
- Correlation
- Regal Funds Management

## Summary

- We believe the best innovation in tissue expansion in decades
- US\$800m addressable market in U.S.
- Strong and sustained market share achieved in Australia
- FDA clearance achieved
- U.S. launch commencing Jan 2017



**“AeroForm® allows them [patients] to do the reconstruction with their schedule, their timing and giving that power back to them is really empowering in a time where that is taken away.”**

Khashayar Moheballi, M.D.  
Moheballi Plastic Surgery, California



**Thank you**

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## Appendix

### Clinical Data



## Clinical Data – Australian Trials

- 3 trials on 61 trial patients
- 105 devices implanted
- 98% success rate
- 18 days average expansion time
- No device-related adverse events
- Positive Australian results enabled:
  - CE Mark
  - TGA approval
  - FDA approval for pivotal U.S. trial

	PACE 1	PACE2	ASPIRE
Patients enrolled	7	33	21
Implanted AeroForm®	10	61	34
Average expansion time (days)	15	17	22
Overall patient & surgeon satisfaction	100%	98%	95%

XPAND trial	Results
Patients enrolled	150
Implanted AeroForm®	168
Device-related adverse events	7
Average expansion time (days)	21

## Clinical Data

### - U.S. XPAND Pivotal Trial

- FDA pivotal study
- 150 patients
- 2:1 randomisation
- Average expansion time cut in half vs. saline expanders
- 98% of patients found AeroForm® easy to use
- 93% of patients found AeroForm® convenient



## **U.S. Clinical Data - Continued Access Trial**

- Allowed existing investigators continued access to AeroForm® during FDA review process
- 50 patients treated
- 86 devices
- 72% bilateral rate
- Interim results as per pivotal clinical trial