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ASX ANNOUNCEMENT

AirXpanders submits FDA 510(k) filing for AeroForm®

PALO ALTO, CA, United States, 1 September 2015: AirXpanders Inc. (ASX:AXP) a medical device company focused on the design, manufacture, sale and distribution of the AeroForm® tissue expander, announces it has filed its 510(k) submission with the US Food and Drug Administration (FDA).

AirXpanders CEO, Mr Scott Dodson, said: "I am delighted to announce that AirXpanders has submitted a 510(k) notification to the FDA for the AeroForm® tissue expander. This is a very important milestone for the Company as we continue to commercialize our device in Australia and prepare for entry into the US market. I believe AirXpanders is well-positioned to capitalise on the significant opportunities that lie ahead for the Company".

In August 2015, AirXpanders announced its pivotal XPAND study had met its primary endpoint in patients that have undergone a mastectomy: the subjects in the study arm achieved successful exchange to a permanent implant with the equivalent safety profile as saline tissue expanders. The detailed final trial results have been submitted to the FDA as part of the Company's 510(k) filing, and will be presented at the American Society of Plastic Surgery Meeting on Sunday 18 October in Boston, Massachusetts.

AirXpanders estimates that the current US market for tissue expanders is approximately 120,000 units per year, with a total addressable US market of approximately 350,000 units per year. The Company believes its commercialisation efforts will benefit from existing reimbursement covering breast reconstruction procedures in the US, as well as federal laws such as the Women's Healthcare Act of 1998 which mandates reimbursement coverage for reconstructive procedures with a diagnosis of breast cancer.

The AeroForm® device uses a controlled delivery of small amounts of carbon dioxide (CO_2) to achieve the tissue expansion usually required for the placement of a permanent breast implant. It gives patients the ability to control the expansion process themselves, and its needle-free design allows for less painful tissue expansion at a significantly faster rate, with fewer visits to their physician, than is achieved using traditional expanders.

-ENDS-

For more information

AirXpanders

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About AirXpanders

Founded in 2005, AirXpanders (ASX:AXP) is a medical device company focused on the design, manufacture, sale and distribution of its AeroForm® tissue expander used in patients undergoing breast reconstruction following mastectomy. AeroForm® uses controlled delivery of small amounts of gas (CO_2) to achieve tissue expansion prior to the placement of a permanent breast implant. AeroForm® successfully eliminates the need for needle-based expansion required by traditional saline tissue expanders and provides a faster and less painful breast reconstruction journey.

AeroForm® has CE Mark and TGA approval and is covered by the Australian reimbursement regime. It is cleared for commercialisation in Europe and Australia. AirXpanders devices are not cleared or approved for use in the United States and are considered for investigational use only. To date, AeroForm® has been successfully implanted more than 500 times in women in Australia and the United States. For more information, refer to the Company's website at www.airxpanders.com.