

July 16, 2019

## **AirXpanders® Receives FDA 510(k) Clearance for a Smooth Shell Version of the AeroForm® Tissue Expander System**

**San Jose, CA, United States – AirXpanders, Inc. (ASX: AXP)**, a medical device company focused on the design, manufacture, sale and distribution of the AeroForm® Tissue Expander System, today announced that the Company has received U.S. Food and Drug Administration (FDA) 510(k) clearance to market a smooth shell version of the AeroForm Tissue Expander.

“We are very pleased to receive FDA 510(k) clearance for the smooth shell AeroForm tissue expander,” said Frank Grillo, President and CEO of AirXpanders. “The plastic surgery community has embraced the textured version of our tissue expander, and they have also been asking us to provide a smooth, untextured version of AeroForm. This clearance enables market release in the U.S., and we have already submitted our regulatory application for CE mark approval.”

Previously, the Company announced it has retained Cowen as an independent financial advisor to assist in exploring financial and strategic alternatives that could enhance stockholder value and enable the Company to continue serving patients and physicians. As AirXpanders explores these alternatives, it will also evaluate U.S. launch plans and timing for the AeroForm Smooth products.

### **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 AeroForm Tissue Expander System, is used in patients undergoing two-stage breast reconstruction following mastectomy. Headquartered in San Jose, California, 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 publicly listed Company on the Australian Securities Exchange under the symbol "AXP." AeroForm was granted U.S. FDA de novo marketing authorization in 2016, subsequent U.S. market clearance in 2017, 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, including those related actual and anticipated covenant breaches under our loan agreement, strategic alternatives, the use of proceeds, cash forecasts and anticipated growth of the Company's business, are forward-looking statements. These include, without limitation, risks and uncertainties related to our ability to obtain a waiver of the covenant violations under the loan agreement from Oxford, our ability to consummate any particular financing or strategic transaction on favorable terms or at all, our ability to enhance stockholder value and/or to provide our products and services to patients and physicians, and additional business risks included in the Company's periodic reports filed with the SEC. Management believes that these forward-looking statements are reasonable when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. AirXpanders may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements. For additional information and considerations regarding the risks faced by AirXpanders that could cause actual results to differ materially, see its most recent Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on February 28, 2019 (AUS time). AirXpanders disclaims any obligation to update information contained in any forward-looking statement, except as required by law. For more information, refer to the Company's website at [www.airxpanders.com](http://www.airxpanders.com).

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