



10 July 2019

AirXpanders Receives Notice of Proposal to Suspend AeroForm Devices from the Australian Device Register from TGA

AirXpanders, Inc. (the “**Company**” or “**AirXpanders**”) has received a Notice of Proposal to Suspend (“**Notice**”) the AeroForm Patent Controlled Tissue Expander (“**AeroForm**”) from the Australian Register of Therapeutic Goods (the “**Register**”). Suspension of AeroForm from the Register would result in the cessation of sales and distribution of AeroForm in Australia for a period of six months. The Australian Therapeutic Goods Administration (the “**TGA**”) has notified Emergo Australia, AirXpanders’ sponsor in the Australian market, of this Notice.

The Notice is the result of a TGA review of all textured breast implants included in the Register. The review involved laboratory testing of relevant breast implants, along with statistical and clinical analysis concerning the incidence of breast implant associated anaplastic large cell lymphoma (BIA-ALCL), and the implants associated with those BIA-ALCL cases. Although the Notice outlines that there have been no cases of BIA-ALCL associated with AeroForm, the TGA considers that there are grounds to conclude that the potential risk of BIA-ALCL associated with the device outweighs any benefits of the device.

The Notice provides Emergo Australia and AirXpanders with an opportunity to make submissions in response to the Notice on or before 24 July 2019. After that date, the TGA will make a decision on the suspension, which may require the sponsor to recall the products and remove all remaining products from the market. Such a recall would only apply to product that is awaiting to be implanted, and there is not a recommendation to remove implanted products. It is important to note that the suspension outlined in the Notice is *proposed*. No decision has been made by the TGA to suspend or cancel the entry of AeroForm on the Register at this time.

“We are very disappointed to see this Notice,” stated Frank Grillo, CEO of AirXpanders. “There have been zero cases of BIA-ALCL associated with the AeroForm device, which is indicated for implantation for no more than six months. According to literature reviews, the median time of implantation of a breast implant and the onset of BIA-ALCL is eight years. Due to the limited history of AeroForm in Australia, TGA has preliminarily concluded that any link between the device and BIA-ALCL is yet to be seen in Australia.”

“We will carefully evaluate the Notice and the accompanying test reports and literature reviews provided by the TGA,” continued Mr. Grillo. “We believe the AeroForm Tissue Expander is safe, effective, and provides a level of convenience highly desired by patients and their surgeons. In addition, due to the much shorter implantation time, we do not believe a tissue expander should be evaluated in the same manner as a permanent breast implant.”

“Regardless of the outcome of the Notice, AirXpanders continues to work diligently to bring AeroForm Smooth Shell to the market as expeditiously as possible. This product will no longer have a textured shell. We expect FDA clearance in the US shortly, and we aim to



achieve CE mark later this year. We will update the market as we progress our regulatory clearances for this new product.”

About AirXpanders:

Founded in 2005, AirXpanders, Inc. (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. Previously, the Company announced it has retained Cowen as an independent financial advisor to assist in exploring financial and strategic alternatives. With Cowen’s assistance, the Company is continuing to evaluate opportunities to explore a wide range of financial and strategic alternatives, that could enhance stockholder value and enable the Company to continue serving patients and physicians.

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 to regulatory clearances, product developments, new products, 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 covenant violations under our loan agreement, our ability to consummate any particular financing or strategic transaction on favourable 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 Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission on May 15, 2019 (US 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.

- ENDS -