'ROVER' MOBILE MEDICAL X-RAY RECEIVES US FDA 510(K) CLEARANCE

Regulatory clearance of the Rover in only 5 weeks - Micro-X's second commercial product for the US market

Adelaide, Australia, 20th July 2020: Australian hi-tech company Micro-X Ltd (ASX:MX1) (**Micro-X** or the **Company**), a leader in cold cathode x-ray technology for health and security markets globally, is pleased to announce it has received 510(k) clearance from the United States Food and Drug Administration (**FDA**) for its 'Rover' mobile X-ray product which is designed for deployed military medical facilities.

FDA 510(k) clearance received as a Class II Medical Device

On 10th June 2020 Micro-X received confirmation of lodgement from the FDA of its 510(k) submission for the Rover, a Class II medical device, filed by Micro-X as manufacturer seeking approval for the sale of this device in the United States. The FDA advertises a nominal 90 calendar day review period for submissions so the receipt of this 510(k) clearance in only five weeks is recognition of the quality of the submission by Micro-X's regulatory team and advisers.

Commercialisation of Rover

The concept for the Rover product was originally developed under a contract from the Australian Department of Defence to prove that Micro-X's technology could fulfil an unmet need for a full-performance, digital, medical x-ray imager, light enough to be used in deployed medical facilities. Defence forces all over the world which deploy temporary medical facilities in support of combat or humanitarian aid operations share a problem that, until now, the weight limits for deployable equipment restricted their choice of mobile x-ray to very low-powered units originally intended for small-animal veterinary use. Now the Rover, at only 95kg, will offer the higher power needed for trauma imaging previously only available from conventional technology units more than five times that weight. The Rover also embodies a number of enhancements in ruggedisation, increased ground clearance and battery endurance which have been purpose-designed for military operations.

This FDA clearance represents a significant step forward in Micro-X's commercialisation plan of its second product as it enables commercial launch to begin in the United States. With the world's largest defence budget, the United States represents the single largest market for the Rover and Micro-X has been engaged in active discussions with the US Army Medical Materiel Agency regarding Rover for some time.

Rover's commercialisation is planned to be conducted through the Company's direct sales channel which will allow for greater control of the sales process and superior product revenues and margins by not using distributors. The direct sales model will focus initially on the United States, Australia, the United Kingdom and other NATO countries with an addressable market size exceeding $170 million.

The Company plans to also seek CE Mark and TGA registration within the next 12 months to enable commercial access to the European Union and Australia.

Micro-X's Managing Director, Peter Rowland, commented:

"Securing FDA clearance for the Rover is a hugely exciting milestone for us as we can now start full marketing and demonstration activities of this unique product to the US Army, Navy and Air Force. As the only deployable product with this full x-ray performance our focus is now on ramping up sales and commercialisation activities in the US to convert the interest into sales. I would like to make a special commendation of our regulatory team who, in its first FDA submission, has secured this approval in a fraction of the normal timescale."

This ASX Announcement is authorised by the Board of Micro-X

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About Micro-X

Micro-X Limited (the **Company**) is an ASX listed hi-tech company developing and commercialising a range of innovative products for global health and security markets, based on proprietary cold cathode, carbon nanotube emitter technology. The electronic control of emitters with this technology enables X-ray products with significant reduction in size, weight and power requirements, enabling greater mobility and ease of use in existing x-ray markets and a range of new and unique security and defence applications. The Company has its core R&D, engineering and production capability at its facility in Adelaide, Australia.

The Company's first product, marketed as the *Carestream DRX Revolution Nano*, is an ultra-lightweight digital medical X-ray system for the rapidly expanding mobile X-ray market in hospitals and healthcare. The *Nano* holds 510(k) and CE Mark certifications and is sold commercially in a number of global markets by the Company's exclusive distributor. The second product, the Rover mobile X-ray for deployed military medical facilities, will be commercially launched in 2020. The Company has a portfolio of innovative products in development, aimed at customer solutions where there is little or no competition. This includes the Mobile Backscatter Imager or MBI which will image Improvised Explosive Devices for defence and counter-terrorism applications. The MBI is being jointly developed in partnership with Thales, a global supplier of defence and security technology systems, who are providing technical support and $10 million of funding.

CONTACTS

Micro-X Limited	Investor Enquiries
Peter Rowland Managing Director Tel: +61 8 7099 3966 E: admin@micro-x.com	**David Allen / John Granger** Hawkesbury Partners Tel: +61 2 9103 9494 E: dallen@hawkesburypartners.com jgranger@hawkesburypartners.com