

The logo for Micro-X Ltd, featuring the word "MICRO-X" in a bold, black, sans-serif font, with a green "X". To the right of "MICRO-X" is the word "Ltd" in a smaller, black, sans-serif font.

**MICRO-X** Ltd

ACN 153 273 735

## Nano – Preparing for Production & Sales

Investor Update

by

**Peter Rowland** Managing Director, Micro-X Ltd.

23<sup>rd</sup> March, 2017

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**MICRO-X**

Commercial-in-Confidence

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# Company Quality Accreditation :

## ISO 13485 Accreditation Recommended 3<sup>rd</sup> March 2017.

- BSI Stage Two Audit successful - Certificate expected shortly
- Company-wide Quality Management System is recognised to meet Medical Device Directorate standards for all company processes operating in
  - Design
  - Manufacturing
  - Quality
  - Supply chain management
- Necessary for CE Marking

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## Regulatory Approvals:

'K' Number received from FDA: 15<sup>th</sup> March 2017.

- FDA acknowledge receipt of a complete & valid 510(k) submission
- Product marketing can now commence
- Approval time normally 90 days
  
- Health Canada Licence Application submitted to Therapeutic Products Directorate
  
- Declaration of Conformity (for CE Marking) data preparation well advanced

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# Reliability Growth Testing:

Achieved RG Target 8<sup>th</sup> March 2017.

- Normal Operation:
- 60 x-ray shots/day = 22,000 per annum
- Target for Mean Time Between Failures is 11,000 cycles
  
- RGT Program
- 3 carts, 50 circuits/shift, 3 shifts/day
  
- Reliability Target set at 130,000 cycles
- **Currently at 180,000 cycles (8 years life)**
- Continuing to add 1500 cycles per day



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# Generating Strong Market Interest

- Enthusiastic customer interest shown at recent Trade Shows
- Carestream regional sales offices requesting additional units for demo/sale
- **Pre-launch stocking order now planned for 2.5x earlier guidance with increasing momentum**



European Congress of Radiology,  
Vienna, 2<sup>nd</sup> March 2017



Arab Health,  
Dubai, 30<sup>th</sup> January 2017

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## Pathway to Launch :

- Service Training under way at Carestream HQ
- Hospital Trade Trials in Canada on receipt of TPD Licence
- Nano featured in more major Trade Shows:
  - Genoa, Italy, 6<sup>th</sup> April
  - Sao Paulo, Brazil, 4<sup>th</sup> May
  - Leipzig, Germany, 24<sup>th</sup> May
  - Manchester, UK, 12<sup>th</sup> June
- Nano production rate increases for Carestream:
  - Reliability demonstration
  - International Service & End-User Training
  - QA Evaluation
  - Internal Trials
  - Market Development
- Regulatory Approvals



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**Thank You; Any questions?**