

# Nanosonics Limited

2016 Half Year Results  
Investor Presentation

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# Corporate Mission



We improve the safety of patients, clinics, their staff and the environment by transforming the way infection prevention practices are understood and conducted, and introducing innovative technologies that deliver improved standards of care.

# Corporate objectives

## Customer Experience

Establish our offerings as new standards of care globally and provide customers a convenient, seamless and consistent experience with both product and brand.

## Product Innovation

Create and bring to market a portfolio of innovative and quality products that address unmet customer needs providing higher standards of safety, efficiency and patient care.

## Operational Excellence

Develop an agile operation with scalable, compliant and performance focussed processes, designed to deliver a positive experience for our customers.

## People Engagement

Build an organisation that attracts and retains the best people and engages and empowers them to take appropriate initiative and be accountable for our core objectives.

## Value Creation

Create sustainable shareholder value, delivering high growth and strong returns , while making a significant contribution to social good.

# Company Overview

- Proprietary automated technology for low temperature, high level disinfection
- First product, trophon® EPR, for high level disinfection of ultrasound probes
- Approved for sale in most major markets including: US/Canada, ANZ, Europe, Singapore, HK, South Korea, Japan
- 130 Staff across Australia, US, UK, Germany and France
- Sold through direct sales and distributors including leading brands: GE Healthcare, Toshiba and Miele Professional
- Active R&D program targeting expansion of product portfolio for Infection Prevention market

Key Corporate Data	
Share price*	\$1.87
Shares on issue*	283.51 million
Market capitalisation*	\$530 million
Liquidity (30 day avg)	535,000 shares
Cash (31 Dec 15)	\$42.6 million
Share register breakdown	Founders/Related Parties 20% Institutions 42% Private 38%

\* As at 23 Feb 2016



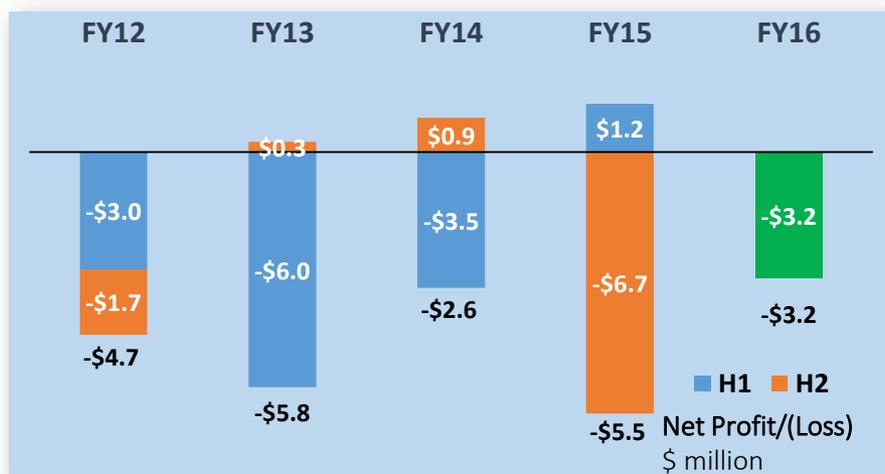
# 2016 H1 Highlights

- First full half under new North American direct operations delivers record sales of \$15.5 million.
- Installed base in North America increased by over 1,700 units in half with total installed base now in excess of 6,700 units.
- Publication of HPV study demonstrating trophon as only system proven to kill cancer causing HPV.
- Established strategic partnership with APIC (Association for Professional in Infection Prevention and Epidemiology) in United States.
- Market fundamentals continue to strengthen with FDA and CDC issuing alert emphasising importance for healthcare institutions to review decontamination practices due to proven risks of cross contamination.
- R&D program progressing to develop next generation trophon and identify a number of new portfolio expansion opportunities.

# 2016 H1 Financial Results



- Record sales of \$15.6 million under first full half operating with new North American business model.
- No trophon unit sales to GE Healthcare in North America in period (note: GEHC recommencing unit purchases from Q3 FY16).



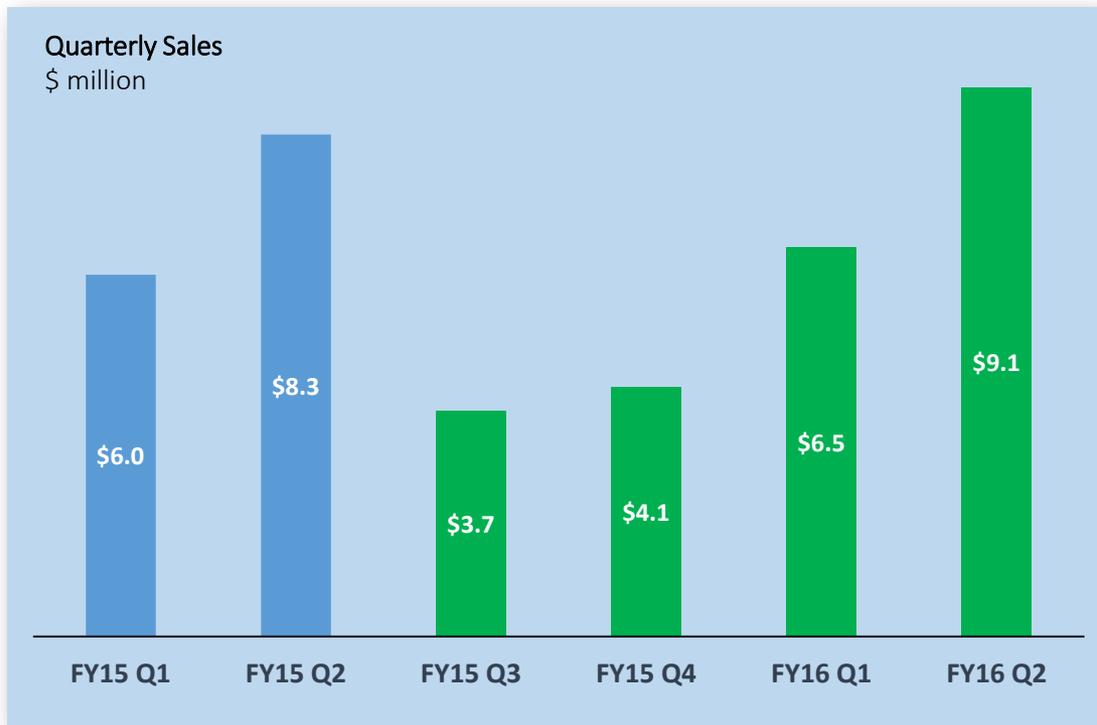
- Net loss of \$3.2 million reflecting investment in new North American direct operations plus increased R&D investment.

# 2016 Financial Results

	FY16		FY15		FY14		
\$ million	H1	H1	H2	FY15	H1	H2	FY14
<b>Sales Revenue</b>	<b>15.6</b>	<b>14.3</b>	<b>7.9</b>	<b>22.2</b>	<b>9.7</b>	<b>11.8</b>	<b>21.5</b>
<b>Gross Profit</b>	<b>12.6</b>	<b>9.2</b>	<b>6.1</b>	<b>15.3</b>	<b>6.0</b>	<b>7.9</b>	<b>13.9</b>
%	81%	64%	77%	69%	62%	67%	65%
Other Income/expense	0.3	1.6	0.7	2.3	0.8	2.6	3.4
Operating expenses	(16.4)	(9.6)	(13.8)	(23.4)	(10.3)	(9.8)	(20.1)
<b>EBIT</b>	<b>(3.5)</b>	<b>1.2</b>	<b>(7.0)</b>	<b>(5.8)</b>	<b>(3.6)</b>	<b>0.8</b>	<b>(2.8)</b>
Interest (net)	0.3	-	0.3	0.3	0.1	0.1	0.2
<b>Pre-tax loss / profit</b>	<b>(3.2)</b>	<b>1.2</b>	<b>(6.7)</b>	<b>(5.5)</b>	<b>(3.5)</b>	<b>0.8</b>	<b>(2.6)</b>
<b>Net loss / profit</b>	<b>(3.2)</b>	<b>1.2</b>	<b>(6.7)</b>	<b>(5.5)</b>	<b>(3.5)</b>	<b>0.9</b>	<b>(2.6)</b>
<b>Cash Balance</b>	<b>42.6</b>			<b>45.7</b>			<b>21.2</b>

- Sales up 8.6% to \$15.6 million
  - In line with plan as North American direct sales fully operational
- Gross Profit up \$3.4 million to \$12.6 million
- GP% 81% vs pcp 64% mainly due to:
  - Increase proportion of direct sales at higher margins
  - Increased proportion of higher margin consumables and spare parts
  - Favourable impact of exchange
- Operating expense up \$3.3 million:
  - Increased investment associated with the establishment of the direct North American operations
  - Increased marketing investment to drive awareness and adoption
  - Increased R&D expenditure as the organisation progresses its R&D pipeline strategy
  - Lower production overhead recoveries resulting from lower production volumes mainly associated with no purchases of trophon units by GE Healthcare
- Other income down \$1.37 million:
  - No reimbursement of US costs as a result of direct operation
  - Lower FX gains
- Cash balance of \$42.6 million

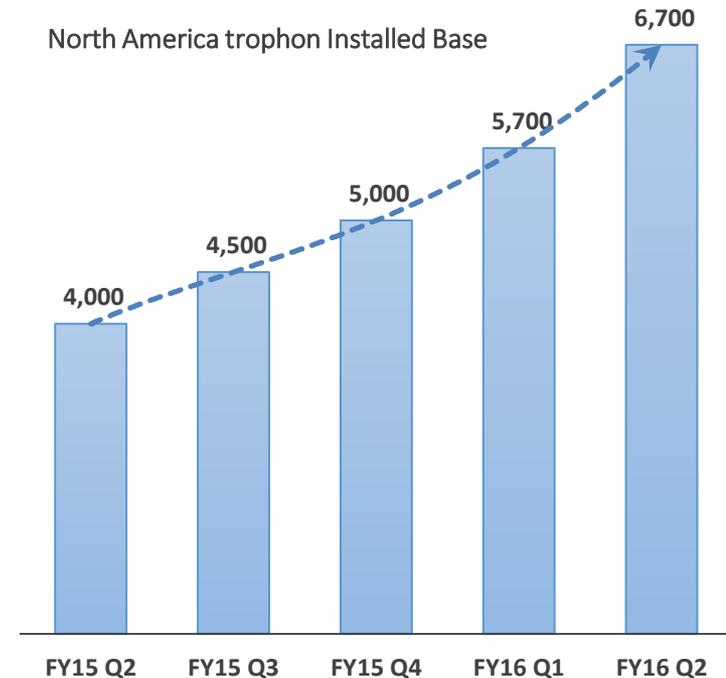
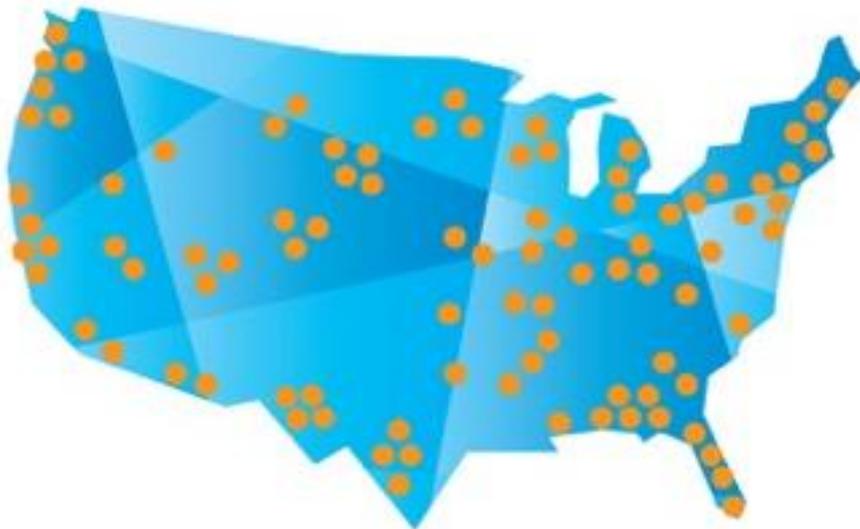
# Excellent growth momentum under new North American business model



- Steady growth over the past four quarters following the announcement of North American direct operations
  - FY15 Q3 – Announced new business model
  - FY15 Q3 / Q4 – Established North American operations and commenced building pipeline
  - FY16 Q1 / Q2 – Direct sales momentum in North America and continue building pipeline.

# Trophon becoming standard of care in North America

- Installed base increased by over 1,700 units in H1 FY16
- There are now more than 6,700 trophon EPR systems in operation across 2,000 facilities including 44 of top 50 hospitals
- Estimated market opportunity in excess of 40,000 systems



# Regional Highlights



## Europe

- UK awaiting guidelines from England and Scotland (expected Q4). Pipeline growing strongly in anticipation of guidelines.
- 25 NHS trusts (46 hospitals) already adopted trophon. 9 of the 25 have followed up initial purchase with additional units
- Welsh guidelines released and effective in driving adoption
- In Germany two major University hospitals of the federal state of Schleswig-Holstein (UKSH) - Kiel and Lubeck adopt trophon. Excellent reference sites for rest of country. Awareness and education ongoing
- Guidelines under review in France

## Australia/NZ

- Trophon as standard of care with >1000 units installed and growing off a high base – approx. 60% market penetrated
- Excellent demonstration of what is possible when fundamentals for adoption strong

## Rest of World

- Commercialisation strategy for Japan and Korea under development
- JSUM in Japan developing new set of guidelines for decontamination of probes – expect market entry FY17
- Tenders in place in KSA and Qatar and plans for UAE actively being developed

# Fundamentals for adoption continue to strengthen.



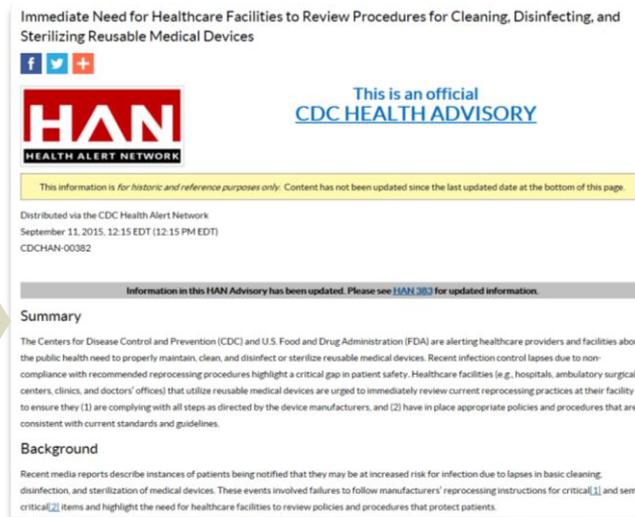
The Hospital-Acquired Condition (HAC) Reduction Program<sup>1</sup>



The Joint Commission Non compliance with infection control standards associated with medical equipment & devices is one of the top 5 findings by The Joint Commission<sup>2</sup>

CDC

Health Advisory - public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices<sup>3</sup>



1. Electronically accessed: cms.gov. 2 Nov 2015.
2. Electronically accessed: thejointcommission.org. May 2014. Issue Two. Improperly sterilized or high-level disinfected equipment.
3. Electronically accessed: emergency.cdc.gov. Sep 2015

# HPV – A real risk of cross contamination through ultrasound examination - For patients AND staff



- “a considerable number of ultrasound probes contaminated with human and HR-HPV DNA, despite LLD disinfection and probe cover”<sup>1</sup>
- A substantial persistence of microorganisms observed on disinfected probes: **HPV DNA found on 13% of samples**<sup>2</sup>
- “HPVs are very stable viruses, able to survive on fomites and surfaces for days”<sup>3</sup>

1. Casalegno et. Al.: High Risk HPV Contamination of Endocavity Vaginal Ultrasound Probes: An Underestimated Route of Nosocomial Infection?, PLOS ONE, Oct 2012, Volume 7, Issue 10
2. M'Zali et al. Persistence of microbial contamination on transvaginal ultrasound probes despite low-level disinfection procedure. PLoS One 2014;9:e93368.
3. Ryndock EJ, Meyers C., A risk for non-sexual transmission of human papilloma virus? Expert Rev. Anti Infect. Ther. 12(10), 1165-1170 (2014).

# trophon EPR first and only system to kill HPV

- 2014 study showed disinfectants commonly used on ultrasound probes not effective against human papillomavirus (HPV)<sup>1</sup>
- Second study demonstrated that trophon EPR is the first and only system proven to kill high-risk, cancer-causing strains of HPV<sup>2</sup>



HPV accounts for 5% of all cancers worldwide<sup>4</sup>



High risk types of HPV cause 99.7% of cervical cancer cases<sup>5</sup>

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J Antimicrob Chemother  
doi:10.1093/acitru/dkt006

**Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants**

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(Present address) Present address: Received 7 October 2013; Accepted 10 November 2013

**Objectives:** Little is understood about the ability of commonly used disinfectants to inactivate high-risk HPV. While several disinfectants are used in clinical practice, their effectiveness against HPV is not well understood.

**Methods:** Using a recently developed, sensitive, quantitative PCR (qPCR) assay, the ability of 10 disinfectants to inactivate high-risk HPV16 and HPV18 was tested. Native HPV16 and HPV18 viruses were generated in organotypic epithelial raft cultures. Viral titers were determined by qPCR. Efficacy tests were performed against the automated device at 30% and 31.5% H<sub>2</sub>O<sub>2</sub> and 0.55% OPA in quadruplicate with matched input, neutralization, and cytotoxicity controls. Hypochlorite was included as a positive control. Infectivity was determined by the abundance of RT-PCR of the split-end E7/E8 transcript in infected recipient cells. The automated HLD device showed excellent efficacy against HPV16 and HPV18 (1.5-log<sub>10</sub> reductions in infectivity) whereas OPA showed minimal efficacy (0.58 log<sub>10</sub> reductions). While HPV is highly resistant to OPA, ionized hydrogen peroxide offers an effective disinfection solution for ultrasound probes. Disinfection methods that are effective against HPV should be adopted where possible.

**J. Med. Virol.** (2014) 86, 100–104. doi:10.1093/acitru/dkt006

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**Keywords:** hospital sterilants, HPV, trophon EPR, ortho-phthalaldehyde, virucidal

**Introduction**

Due to the specific life cycle of virus (HPV), infectious virus has been shown to be resistant to some high-level disinfectants (HLDs). This study compared efficacy of two leading ultrasound probe HLD methods: liquid ortho-phthalaldehyde (Cidex<sup>®</sup> OPA) and an automated device using ionized hydrogen peroxide (trophon<sup>®</sup> EPR) against HPV16 and HPV18 in a hard-surface carrier test. Native HPV16 and HPV18 viruses were generated in organotypic epithelial raft cultures. Viral titers were determined by qPCR with a 5% (w/v) protein soil. Efficacy tests were performed against the automated device at 30% and 31.5% H<sub>2</sub>O<sub>2</sub> and 0.55% OPA in quadruplicate with matched input, neutralization, and cytotoxicity controls. Hypochlorite was included as a positive control. Infectivity was determined by the abundance of RT-PCR of the split-end E7/E8 transcript in infected recipient cells. The automated HLD device showed excellent efficacy against HPV16 and HPV18 (1.5-log<sub>10</sub> reductions in infectivity) whereas OPA showed minimal efficacy (0.58 log<sub>10</sub> reductions). While HPV is highly resistant to OPA, ionized hydrogen peroxide offers an effective disinfection solution for ultrasound probes. Disinfection methods that are effective against HPV should be adopted where possible.

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Journal of Antimicrobial Chemotherapy

**Susceptibility of HPV16 and 18 to High Level Disinfectants Indicated for Semi-Critical Ultrasound Probes**

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Ultrasound probes used in endocavitary procedures have been shown to be contaminated with high-risk HPV after routine use and HPV is also known to be resistant to some high-level disinfectants (HLDs). This study compared efficacy of two leading ultrasound probe HLD methods: liquid ortho-phthalaldehyde (Cidex<sup>®</sup> OPA) and an automated device using ionized hydrogen peroxide (trophon<sup>®</sup> EPR) against HPV16 and HPV18 in a hard-surface carrier test. Native HPV16 and HPV18 viruses were generated in organotypic epithelial raft cultures. Viral titers were determined by qPCR with a 5% (w/v) protein soil. Efficacy tests were performed against the automated device at 30% and 31.5% H<sub>2</sub>O<sub>2</sub> and 0.55% OPA in quadruplicate with matched input, neutralization, and cytotoxicity controls. Hypochlorite was included as a positive control. Infectivity was determined by the abundance of RT-PCR of the split-end E7/E8 transcript in infected recipient cells. The automated HLD device showed excellent efficacy against HPV16 and HPV18 (1.5-log<sub>10</sub> reductions in infectivity) whereas OPA showed minimal efficacy (0.58 log<sub>10</sub> reductions). While HPV is highly resistant to OPA, ionized hydrogen peroxide offers an effective disinfection solution for ultrasound probes. Disinfection methods that are effective against HPV should be adopted where possible.

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**KEY WORDS:** high level disinfection (HLD), trophon EPR, ortho-phthalaldehyde, virucidal

Grant sponsor: Nanosonics Ltd  
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E-mail: cme1@psu.edu  
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Published online in Wiley Online Library (wileyonlinelibrary.com).

**INTRODUCTION**

High risk human papillomavirus (HPV) is the causative agent of cervical cancer and plays an important role in oropharyngeal and esophageal malignancies.

1. Meyers, J., et al., Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. *J Antimicrob Chemother*, 2014  
 2. Ryndock E, Robison R, Meyers C. Susceptibility of HPV16 and 18 to high level disinfectants indicated for semi-critical ultrasound probes. *J Med Virol*, 2015

# Why is trophon<sup>®</sup> being adopted as Standard of Care?



## Reduces the risk of ultrasound HAIs

- Extensive clinical validation
- Only system proven to kill HPV
- Simpler to use with consistent results



## Creates a safer environment for patients & staff

- No exposure to harmful chemicals or fumes
- Easy to HLD probes between patients
- Water & Oxygen by-products



## Reduce reprocessing risks & costs

- Easier to comply with audit & accreditation requirements
- Flexible, low cost installation options (inc. POC)
- Reduced:
  - Risk of probe damage
  - Waste
  - Protective equipment

# Compatible with more than 950 ultrasound transducer models

- Covers all world's leading manufacturers
- Includes both intracavitary and surface probes



# R&D investment

- \$3.3 million in half invested in R&D activities across mechanical, electrical and software engineering, microbiology and chemistry
- Active programs underway on:
  - Next generation trophon
  - New decontamination devices
  - New disinfectant chemistries



# Business Outlook – Positive momentum continues

- Direct North American sales operations in place and delivering encouraging results.
- Becoming standard of care in North America with >6700 units installed.
- New supporting guidelines expected in UK, France and Japan
- Expansion into new territories being planned.
- Market fundamentals for standard of care strengthening with highly relevant clinical data.
- Active R&D program to diversify portfolio.

The logo graphic consists of two white, curved lines that form a partial circle or loop around the word "nanosonics". One line starts above the 'n' and curves down to the right, while the other starts below the 'n' and curves up to the right, meeting the first line.

**nanosonics**  
Infection Prevention. For Life.