

24 August 2021

Company Announcements Office  
Australian Securities Exchange

## Nanosonics 2021 full year financial results

### HIGHLIGHTS

- Full year revenue of \$103.1 million, up 3.0% on prior corresponding period (up 12% in constant currency<sup>1</sup>) with significant recovery in H2 with revenue of \$60.0 million, up 39% compared with H1 (up 50% in constant currency).
- Global installed base up 13% (3,030 units) to 26,750. H2 new installed base up 20% compared with H1 with 1,650 units installed.
- Full year consumables and service revenue of \$76.4 million, up 9% on prior corresponding period.
  - H2 consumables and service revenue of \$42.7 million, up 27% compared with H1 as ultrasound procedure volumes continue to recover towards pre-COVID-19 levels.
- Full year capital revenue of \$26.7 million, down 11% on prior corresponding period.
  - H2 capital revenue of \$17.3 million, up 84% compared with H1 as installed base growth recovered and GE Healthcare's capital purchases increased.
- Significant increase in trophon<sup>®</sup> opportunity in North America resulting from increased estimate of Total Addressable Market, revised up to 60,000 units from 40,000 units, reflecting growth in the ultrasound market over the last eight years.
- Continued investment in strategic growth agenda with operating expenses up 12% to \$70.8 million. Operating expenses increased in H2 compared with H1 as market conditions improved, with Q4 expenses of \$20.3 million reflecting a return to intended investment run rate.
- Operating profit before tax of \$11.0 million, compared with \$12.4 million in prior corresponding period. H2 profit before tax of \$10.8 million as total revenue increased 39% in H2 compared with H1.
- Free cash flow for the year of \$5.9 million, with H2 free cash flow of \$8.3 million offsetting net cash outflow of \$2.4 million in H1.
- Cash and cash equivalents up \$4.2 million to \$96.0 million, providing ongoing strong foundation for continued investment in growth. The Company has no debt.
- Continued investment in product expansion strategy with R&D investment of \$17.2 million, increasing in line with revenue growth and directed across multiple projects.
- Positive progress with new instrument reprocessing product platform, Nanosonics Coris<sup>®</sup>, aimed at transforming the cleaning of flexible endoscopes.
- Launched new digital product platform, Nanosonics AuditPro<sup>™</sup>, delivering a unique new digital workflow compliance management system with potential applicability across a range of medical instruments.

Nanosonics (ASX: NAN), a leader in infection prevention solutions, today announced its Appendix 4E Full Year Report for year ended 30 June 2021.

“The 2021 financial year was an important year of progress where the Company successfully adapted to the global challenges associated with COVID-19. Despite varying constraints and disruptions, the Nanosonics team continued to progress many aspects of our strategic growth agenda. Significant growth was achieved in the second half of the year as market conditions improved. This saw total revenue growing 39% compared with the first half resulting from strong growth in the installed base as well as ultrasound procedures trending back towards pre-COVID-19 levels”, said Michael Kavanagh, Nanosonics’ Chief Executive Officer and President.

“I would like to thank each Nanosonics employee around the world for their resilience, flexibility, dedication and customer focus during an unprecedented year. I also acknowledge all the infection preventionists and frontline workers globally for their tireless efforts in managing the COVID-19 pandemic. As an infection prevention company, we are acutely aware of the risks of cross contamination and the devastating impacts of infection. Now more than ever, infection prevention is of paramount importance not just within the medical community but the community at large; which strengthens our resolve to continue to execute on our strategic growth agenda to truly deliver on our mission.

“During the year, we continued to grow our investment across our key strategic priorities. Despite significant COVID-19 related constraints, we continued to increase our investments in infrastructure growth and market expansion across the Europe and Middle East region. Together with the strengthening fundamentals for adoption of trophon throughout the region, this saw the installed base in the region increase by 35% and total revenue increase by 38% for the year.

“In North America, the implementation of a new sales infrastructure including the integration of clinical applications specialists into the existing sales team resulted in a growing awareness and appreciation of the requirement for high-level disinfection across over 150 different types of ultrasound procedures. This saw trophon units being adopted across an increasing number of departments within hospitals.

“In addition, a review was undertaken to better understand the Total Addressable Market in the USA for trophon units in light of the significant growth in ultrasound over the eight years since the last review was conducted. This resulted in the estimated TAM for trophon devices in North America increasing by 50% to 60,000 units<sup>2</sup> underpinning the significant opportunity for further growth in this important market.

“In Asia Pacific, work continued on strengthening the fundamentals for adoption in Japan. Despite the challenges associated with Japan being in a state of emergency for the majority of the year, we continued our market development work with virtual education and training with relevant specialists, societies and our distributors. In addition, we expanded our local infrastructure to support ongoing market development activities in partnership with our distributors including GE Healthcare.

“We are currently finalising the registration of a Wholly Owned Foreign Enterprise in China (纳安诺医疗设备（上海）有限公司), and are now preparing for regulatory submission to approve trophon2 for commercialisation in that market.

“Throughout the year our manufacturing and logistics teams managed one of the most complex business environments for supply chain and freight management ever experienced to ensure continuity of supply was maintained across all regions and all customer orders were delivered in full and on time.

“Increased investments were made in R&D where significant progress was made across our R&D program. We released our first discrete data, traceability and compliance management system, Nanosonics AuditPro. The Company made positive progress in the development of our new instrument reprocessing platform that is focussed on one of the most significant issues in instrument reprocessing today – flexible endoscope reprocessing (de-contamination).

Throughout the year we continued to expand our capacity and capability with the total number of employees increasing 9% to 339. Diversity and inclusion is recognised as an important driver of our growth and a core aspect of the Nanosonics culture. The Nanosonics workforce now represents approximately 29 different nationalities with 41% of employees being female. 38% of senior management positions in the organisations are also held by females.

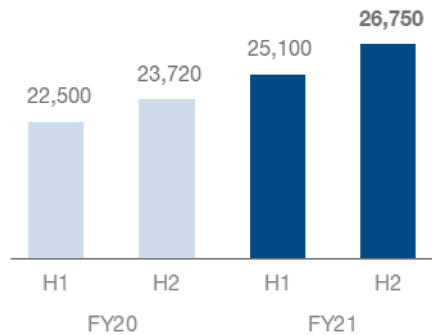
Importantly, at the centre of all our activities during the year was a focus on our customers ensuring they had the necessary support. It has been a challenging year for the infection prevention community with the demands related to COVID19. We acknowledge and recognise their tireless efforts and those of all frontline workers throughout the year.

### INSTALLED BASE GROWTH

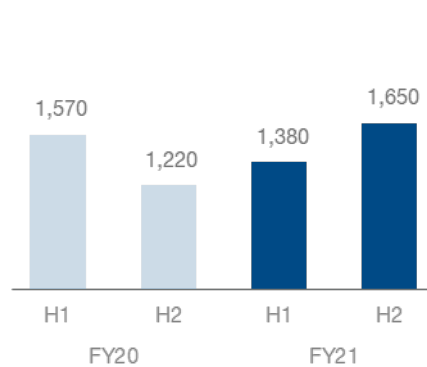
“Despite the impacts of COVID-19, the global installed base increased 13% to 26,750 units, an increase of 3,030 units for the year, with all regions performing well.

“Importantly, the second half of the year saw a significant recovery in new installed base adoption as market conditions improved, with 1,650 new units installed growing 20% compared with the first half.

Cumulative Global Installed Base (units)



Global Installed Base Growth by Half (units)



- FY21 cumulative installed base up 13% vs. FY20
- FY21 H2 new units up 20% vs. FY21 H1

“In North America, the installed base increased 12% or 2,490 units for the year with 23,480 units now installed across over 5,000 institutions. A significant recovery was experienced in H2 as market conditions improved, with new installed base growing by 1,360 units, up 28% compared with the prior corresponding period and up 20% compared with H1 FY21.

“Importantly the estimated Total Addressable Market for trophon units in North America has been revised up from 40,000 units to 60,000 units, taking into account the growth in the ultrasound market over the last eight years in USA, which further increases the opportunity for trophon as we continue expanding our North American operations.

“In the Europe and Middle East region, despite COVID-19 related restrictions prevailing for the full financial year, the installed base grew 35% or 390 units for the year, with 1,510 units now installed across the region. This growth reflects the strengthening fundamentals for adoption of trophon across the region as our geographical footprint expands, guidelines supporting automated high level disinfection continue to emerge and the increased investment in our infrastructure across the region. Both halves of the year demonstrated significant growth compared with prior corresponding periods with H1 up 54% compared with the prior corresponding period and H2 up 73% compared with the prior corresponding period.

“In Asia Pacific the installed base grew 9% or 150 units for the year with 1,760 units now installed in the region. The majority of the growth was experienced in ANZ as Japan was effectively in lockdown for the majority of the year. The number of new units installed in H2 was up 100% compared with

both the prior corresponding period and the first half, demonstrating a strong recovery in ANZ”, said Mr Kavanagh.

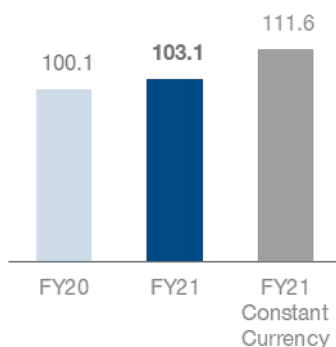
## FINANCIAL RESULTS

\$ million	FY21	FY20	Change%
<b>Revenue</b>	<b>103.1</b>	<b>100.1</b>	<b>▲ 3%</b> <b>▲ 12% cc*</b>
<b>Gross profit</b>	<b>80.4</b>	<b>75.5</b>	<b>▲ 6%</b>
%	78.0	75.4	
<b>Operating expenses</b>			
Selling, general and administration	(53.6)	(47.6)	▲ 13%
Research and development	(17.2)	(15.6)	▲ 11%
Other income	0.2	0.0	
Other gains/(losses) (net)	1.0	(0.7)	
<b>Earnings before interest and tax</b>	<b>10.8</b>	<b>11.6</b>	<b>▼ 7%</b>
Finance income (net)	0.2	0.8	▼ 75%
<b>Profit before income tax</b>	<b>11.0</b>	<b>12.4</b>	<b>▼ 11%</b>
Income tax expense	(2.4)	(2.3)	
<b>Profit after income tax</b>	<b>8.6</b>	<b>10.1</b>	<b>▼ 15%</b>

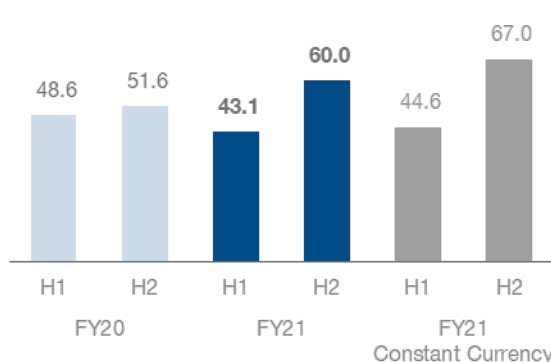
\*Constant Currency

Total revenue for the year was \$103.1 million, up 3% compared with the prior corresponding period. In constant currency, total revenue was up 12% compared with the prior corresponding period. Importantly, H2 saw a significant recovery as market conditions improved resulting in total revenue of \$60.0 million, up 39% compared with H1. In constant currency terms, H2 revenue was up 50% compared with H1.

**Global Revenue**  
(\$ million)



**Global Revenue by Half**  
(\$ million)

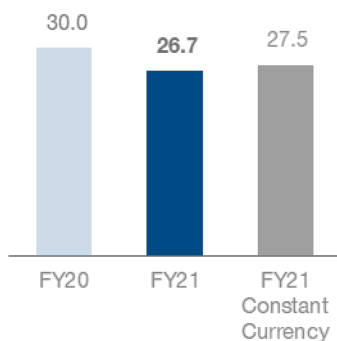


- FY21 up 3% vs. FY20 (up 12% in constant currency)
- FY21 H2 up 39% vs. FY21 H1 (up 50% in constant currency)
- FY21 H2 up 16% vs. prior corresponding period

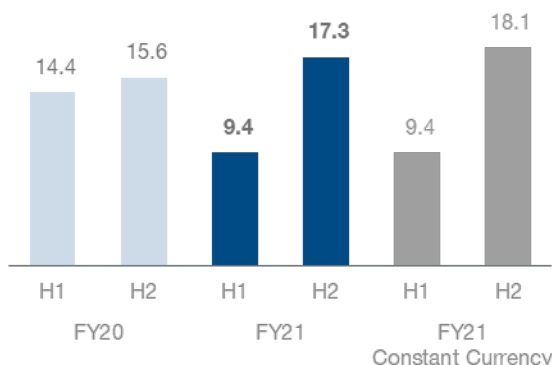
## Capital revenue

Despite a 13% increase in new installed base, capital revenue for the year was down 11% to \$26.7 million (down 8% in constant currency). This reduction was primarily associated with a reduction in the number of units sold to GE Healthcare (GE) in the first half of FY21. This was due to a decrease in installed base growth as a result of COVID-19, particularly in Q4 of FY20 and Q1 of FY21 and the corresponding impact on GE’s inventory levels. Importantly, capital revenue increased 84% in H2 compared with H1 as market conditions improved, installed base growth recovered and GE resumed normal capital purchasing patterns.

**Capital Revenue**  
(\$ million)



**Capital Revenue by Half**  
(\$ million)

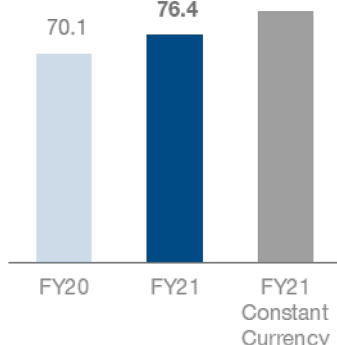


- FY21 down 11% vs. FY20 (down 8% in constant currency)
- FY21 H2 up 84% vs. FY21 H1 (up 92% in constant currency)
- FY21 H2 up 11% vs. prior corresponding period

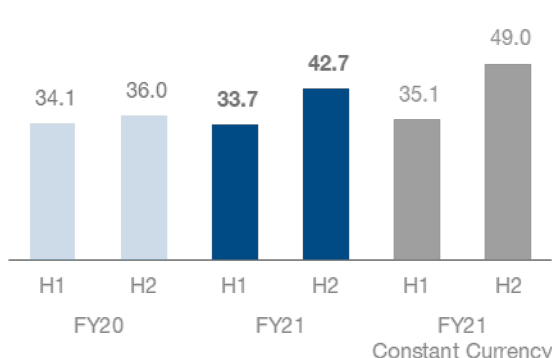
## Consumables and service revenue

Revenue from consumables and service increased 9% to \$76.4 million (up 20% in constant currency). First half consumables sales were reduced due to the impacts of COVID-19 on ultrasound procedure volumes. However, H2 saw a positive trend towards pre-COVID-19 procedure levels with revenue from consumables and service up 27% (up 39% in constant currency) in H2 compared with H1. Importantly, towards the end of FY21 all indications were that ultrasound procedure volumes were approaching pre-COVID-19 levels across most markets.

**Consumables/Service Revenue**  
(\$ million)



**Consumables/Service Revenue by Half**  
(\$ million)



- FY21 up 9% vs. FY20 (up 20% in constant currency)
- FY21 H2 up 27% vs. FY21 H1 (up 39% in constant currency)
- FY21 H2 up 19% vs. prior corresponding period

## Regional financial performance

### North America

Total revenue for the year of \$89.2 million was down 1% compared with the prior corresponding period (up 8% in constant currency). This reduction in revenue was primarily associated with a significant reduction in capital revenue in H1 of FY21 compared with H2 of FY20 of 49%. As explained above, this reduction was primarily associated with the impacts of COVID-19 on new installed base growth in Q4 of FY20 and Q1 of FY21 resulting in GE's capital inventory being higher than anticipated at the end of FY20.

As market conditions improved in the second half of the year, total revenue improved significantly and was up 42% compared with H1. Capital revenue in H2 increased 96% compared with H1 as new installed base grew and GE resumed purchasing capital equipment.

Consumables and service revenue increased 8% for the year. In H2, as ultrasound procedure volumes trended back to pre-COVID-19 levels, so did the recovery of revenue from consumables and service, increasing 29% in H2 compared with H1.

## **Europe and Middle East**

Despite COVID-19 restrictions prevailing throughout Europe and the Middle East for the full year, total revenue in the region was up 38% to \$7.2 million (43% in constant currency). This is a positive indication of the growing opportunity in the region as the fundamentals for adoption for trophon continue to strengthen with new guidelines continuing to emerge. The Company continued to invest in the region's infrastructure and market expansion activities throughout the year.

Both halves of the year delivered strong growth compared with prior corresponding periods with H1 up 50% and H2 up 29% compared with the prior corresponding periods.

Total capital revenue for the year was up 91% to \$2.7 million. Importantly, as the majority of units placed in the UK (the largest market in the region) are under the managed equipment service model where no capital revenue is recognised, this increase in capital revenue reflects the growth in the markets outside of the UK.

Consumables and service revenue increased 18% compared with the prior corresponding period. As in North America, an increase in consumables revenue was achieved in H2 compared with H1 as ultrasound procedure volumes continued to trend back towards pre-COVID-19 levels.

## **Asia Pacific**

Total revenue in the Asia Pacific region was up 42% to \$6.7 million. The majority of the growth was recorded in ANZ as the installed base continued to grow by 9% and trophon upgrades commenced.

Total capital revenue for the year was up 143% to \$2.7 million and was up 36% excluding revenue from upgrades. Consumables and service revenue increased 12% compared with the prior corresponding period with H2 revenue up 11% compared with H1 as the installed base grew and ultrasound procedure volumes returned to pre-COVID-19 levels.

## **Other financial results**

The Company continued to increase its investments in its strategic growth agenda throughout the year reflecting the significant growth opportunity for trophon globally as well as major opportunities for growth in the broader infection prevention market through product expansion.

Operating expenses for the year increased 12% to \$70.8 million. In particular, expenditure increased in H2, up 15% compared with H1 as market conditions improved. Operating expenses in Q4 represented 29% (\$20.3 million) of the total year as the Company returned to its intended investment run rate for the year.

Profit before tax for the year was \$11.0 million. Of the \$11.0 million, \$10.8 million was achieved in the second half as revenue grew 39% in H2 compared with H1.

Total free cash flow for the year was \$5.9 million, with H2 free cash flow of \$8.3 million offsetting net cash outflow of \$2.4 million in the first half.

Cash and cash equivalents increased 4.6% to \$96.0 million. The Company has no debt and reviews its capital management strategy regularly. In light of an increasing global focus on infection prevention and the opportunities this presents for Nanosonics, investment in the broader strategic growth agenda of the Company is planned to continue actively and the capital reserves of the Company provide strong support for this.



## NEW PRODUCTS

### Research and development

During the year, Nanosonics continued to invest in its product expansion strategy. R&D investment increased 11% to \$17.2 million directed across multiple projects. Nanosonics' R&D interests span five key areas of infection prevention:

- Instrument cleaning;
- Instrument disinfection;
- Environmental decontamination;
- Digital solutions for traceability and compliance; and
- Storage solutions.

### **New Product Platform – Nanosonics Coris<sup>®</sup>, transforming the cleaning of flexible endoscopes**

The R&D team achieved a number of important milestones across a number of projects with a focus on our new technology platform which is directed at addressing one of the most significant issues in instrument reprocessing today – flexible endoscope cleaning. Indeed, more healthcare-associated outbreaks have been linked to contaminated endoscopes than any other medical device<sup>3,4</sup>.

Reusable flexible endoscopes are highly sophisticated medical devices designed to enable advanced diagnostic and therapeutic interventions to diagnose and treat cancers and other life-threatening conditions. They incorporate advanced technology that gives physicians a sophisticated level of control in carrying out complex, minimally-invasive procedures and navigating challenging anatomical situations to deliver the highest level of patient care.

There are many different types of flexible endoscopes including colonoscopes, gastroscopes, duodenoscopes, bronchoscopes, urological scopes and ENT scopes, in addition to other specialty scopes.

The potential to address the challenges of contaminated endoscopes represents a significant opportunity for Nanosonics with over 60 million flexible endoscopy procedures being conducted across the United States and the largest five markets in Europe alone every year and growing at 6% per annum.<sup>5</sup>

The cleaning stage of the reprocessing process is a critical step and has significant implications for the outcomes of the subsequent high level disinfection stage of the process. Challenges associated with manual cleaning, combined with reports of persistent contamination from biofilm despite routine cleaning, represents a significant unmet need which has been recognised by regulators and customers. This technical challenge has existed for many years and is a complex one to address.

The Nanosonics R&D team have focussed on these significant technical challenges for a number of years with the aim of developing a novel automated technology designed to revolutionise the cleaning process of flexible endoscopes. The new Nanosonics Coris platform technology, like trophon, will comprise both capital equipment and consumables with the expectation that the system will benefit from intellectual property protection.

In testing to date, this new automated platform technology has demonstrated the potential to deliver significant superiority in cleaning efficacy over the requirements of the current standards. In addition, testing demonstrates superior efficacy over manual cleaning against difficult biofilm contamination, including in the smallest channels of an endoscope.

Work continues to progress positively with the product development including the integration of a number of enhancements to the new platform. This work will be followed by external clinical assessment to support the regulatory submission. Nanosonics continues to engage with the US FDA

to determine the necessary requirements to support a successful regulatory submission. The timing for commercial launch previously indicated is being revised and will be determined in due course dependent on the necessary technical, regulatory and operational milestones being met with the Company currently targeting the first commercial launch to occur in calendar 2023. Updates will be provided as material new information becomes available. The Company remains confident both in the ongoing progress of the development project, and importantly in the overall commercial opportunity for this transformational technology platform which it believes has the potential to become a new standard of care for endoscope cleaning<sup>6</sup>.

### **Launch of Nanosonics AuditPro™**

In June 2021, Nanosonics AuditPro was launched at the Association for Professionals in Infection Control (APIC) conference in the United States, with plans for launch into other key markets throughout FY22.

AuditPro is the result of a number of years of research and development and opens up a significant opportunity to market a unique solution that integrates infection prevention decision making, track and trace and compliance into a single digital solution. AuditPro delivers real time access to a broad range of compliance and traceability data for customers which is an important aspect of infection prevention to ensure medical instruments have been appropriately disinfected in accordance with relevant standards.

The new AuditPro digital solution comprises of a mobile scanning device coupled with a subscription to a browser-based application for users. The first application focuses on ultrasound procedures, with the new handheld scanning device designed to be coupled with every ultrasound console at point of care. With approximately 271,000 ultrasound units in the USA alone<sup>7</sup>, AuditPro represents a significant new opportunity for Nanosonics. Being a platform technology, AuditPro presents the opportunity to grow beyond ultrasound and be applied to other medical instruments.

While AuditPro is a discrete new product platform, it's application for ultrasound and connectivity with trophon2 further enhances the trophon2 value proposition as well as competitive advantage. This further supports the leading position and ongoing adoption of trophon2 as well as the potential to support upgrades from trophon EPR to trophon2. In addition, through its education platform to guide clinicians on which ultrasound procedures require high level disinfection of the probe, there is the potential that this could lead to increased usage of trophon devices.

### **BUSINESS OUTLOOK – FY22**

The second half of FY21 reflected a significant recovery as market conditions improved. This recovery demonstrates the strength of the underlying fundamentals of the business. Despite the inherent risks and uncertainties associated with COVID-19, in particular those emerging with different strains of the virus, Nanosonics remains optimistic that the improved market conditions will continue as vaccination numbers increase across all major markets.

Assuming the positive market recovery trends continue, the Company anticipates a return to double digit growth in total revenue in FY22, driven by an ongoing increase in installed base globally and increased usage of consumables across all regions as ultrasound procedures return to pre-COVID-19 levels. In addition, it is anticipated that a growth in upgrades from trophon EPR to trophon2 will occur in FY22. Taking into account the anticipated increase in capital from new installed base growth and upgrades, the mix between capital revenue and consumables will likely change which will result in a lower gross profit margin compared with FY21. However, it is anticipated that the Company's gross profit margin will remain above 75%.

Nanosonics' infrastructure, people, capability, and cash balance provide a strong foundation for the future. With the growing opportunities for the trophon franchise as well as further opportunities in the broader infection prevention market, the Company maintains its commitment to continue to invest in its long-term strategic growth agenda with an emphasis on continuing investment growth in our



regional operations and R&D. Operating expenses for the fourth quarter of FY21 were \$20.3 million as the business returned to its intended investment run rate. It is expected that there will be growth in this run rate into FY22 with total operating expenses for the year expected to be approximately \$90 million.

## BEYOND FY22

Nanosonics' forward-looking growth agenda remains very much intact with significant opportunities for growth of the trophon franchise as well as significant opportunities from the planned expanded product portfolio. Beyond FY22, Nanosonics is targeting:

- Continued growth in the trophon installed base and associated ecosystem across all regions;
- Growth in upgrades of trophon EPR to trophon2;
- Japan to become an important contributor to global installed base growth as well as further expansion into Asia Pacific, including China;
- New source of revenue opportunity associated with the global launch of AuditPro as well as further new product launches;
- Ongoing expansion of the product portfolio through internal product development and opportunities for strategic acquisitions and product licensing across key vectors of infection; and
- Ongoing investment in R&D, infrastructure, people and capability to continue to drive the Company's global growth strategy with the aim of establishing Nanosonics as a global leader in infection prevention.

**Michael Kavanagh**  
CEO / President

### Notes

1. Constant currency (CC) removes the impact of foreign exchange rate movements to facilitate comparability of operational performance. This is done by converting the current period sales of entities that use currencies other than Australian dollars at the rates that were applicable in the prior period. The average exchange rate used for the Company's major foreign currency (USD) for the 12 months to June 2021 was 0.7492 (2020: 0.6715).
2. Nanosonics analysis based on updated ultrasound information commissioned by Nanosonics and an estimated trophon to ultrasound attachment rate. The North America market has been the focus of the TAM analysis undertaken. Similar data is not readily available for the Asia Pacific and EMEA regions. However, the Company's expectation is that the ultrasound market will have also grown in those two regions in the years since the Company last analysed the TAM in those markets.
3. Guideline for Disinfection and Sterilization in Healthcare Facilities, U.S. CDC, Update: May 2019.
4. Top 10 Health Technology Hazards for 2018, ECRI Institute, 2018.
5. Frost & Sullivan, Endoscope Reprocessing Systems and Software Solutions Market Assessment (US, W. Europe, Australia), 2018.
6. All research and new product development programs involve inherent risks and uncertainties which can impact commercialisation timelines.
7. Nanosonics analysis of U.S. ultrasound market based on third party data.

Authorised for lodgement by the Board of Directors of Nanosonics Limited

### Investor conference call

Investors are invited to join a conference call on Tuesday 24 August 2021 at 11:00am (AEST) hosted by Nanosonics CEO & President, Michael Kavanagh, and Mr McGregor Grant, CFO.

To join the conference, simply dial the number and passcode followed by your PIN, and you will join the conference instantly.

You can obtain your dial-in number, passcode, and PIN by registering through this link:  
<https://s1.c-conf.com/diamondpass/10015697-hs8mc7.html>

### For more information please contact:

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