23 August 2022

Company Announcements Office
Australian Securities Exchange

Nanosonics 2022 full year financial results

HIGHLIGHTS

- **Revenue of $120.3 million, up 17% on prior corresponding period.**
- **Global installed base up 12% (3,100 units) to 29,850 units. New units installed in H2 FY22 up 20% on H1 FY22.**
- **Capital revenue of $37.7 million up 41% on prior corresponding period.**
- **Global upgrades of 1,000 trophon EPR devices up 133% compared with prior corresponding period, with H2 FY22 upgrade units up 50% compared with H1 FY22.**
- **Consumables and service revenue of $82.6 million up 8% on prior corresponding period.**
- **Gross profit margin of 76.4% compared with 78% in prior corresponding period reflecting increased freight costs. The gross profit margin was ahead of the guidance provided in February 2022 mainly due to favourable pricing outcomes in North America.**
- **Continued investment in growth strategy with operating expenses up 28% to $90.5 million which was below the February 2022 guidance. Operating expenses includes $22.3 million associated with R&D, up 30% compared with prior corresponding period.**
- **Profit before tax of $1.6 million compared with $11.0 million in prior corresponding period. This reflects the increased investment in the Company's strategic growth agenda as well as the foreshadowed one-off impact in H2 FY22 on revenue in North America associated with the move to a largely direct sales model.**
- **Cash and cash equivalents of $94.5 million at 30 June, providing ongoing strong foundation for continued investment in growth. The Company has no debt.**
- **Transition to revised largely direct North American sales model successfully implemented.**
- **Positive progress with Nanosonics CORIS across development activities, clinical / regulatory planning and manufacturing preparation of new endoscope instrument reprocessing platform.**

Nanosonics (ASX: NAN), a leader in infection prevention solutions, today announced its Appendix 4E Full Year Report for the year ended 30 June 2022.

"The 2022 financial year was an important year in the ongoing growth of the organisation through the successful implementation of a number of key strategic priorities", said Michael Kavanagh, Nanosonics' Chief Executive Officer & President. Central to these was the successful evolution of our sales model in North America to an expanded and largely direct model. Nanosonics now manages all trophon customers directly for the ongoing provision of consumables. This largely direct sales model aims to capture the full market opportunity for trophon in North America as well as prepare for future product expansion plans.

"In addition, we continued to invest in Europe and Asia Pacific to further expand our local infrastructure. With the total installed base continuing to grow and market fundamentals continuing to strengthen, we expect these investments to be further leveraged in FY23 with improved market access conditions after prolonged periods of COVID-19 related disruption.

“Importantly our product diversification plans also progressed through increased investment in R&D across our ultrasound reprocessing, endoscopy reprocessing and cloud solution platforms as well as investments in chemistry and biosciences. Positive progress continued in the development activities, clinical and regulatory planning and preparation for manufacturing of the new endoscope reprocessing platform, Nanosonics CORIS®.[1]

“It was very pleasing to have the FDA recently accept CORIS into the FDA Safer Technologies Program (STeP). Products accepted into this program are reasonably expected to significantly improve the safety of currently available treatments. Through the program the FDA aims to provide additional review resources facilitating more interactive and timely communication through the submission review process.

“The organisation also significantly increased its capabilities and capacity through the move to new corporate headquarters including expanded manufacturing and R&D facilities. This positions Nanosonics well to expand its participation as a leading infection prevention company in the multi-billion-dollar global infection prevention market. The move to the new global headquarters is supported by the NSW Government’s Jobs Plus Program, facilitated through Investment NSW.

“Total revenue for the year grew 17% to $120.3 million resulting from continued growth in new installed base, upgrades and consumables/service. This was a very pleasing result taking into consideration the foreshadowed one-off revenue impact in H2 associated with the transition to a largely direct sales model in North America. As a result of this revised sales model, GE Healthcare ran down their capital and consumable inventory and transitioned to a non-stocking capital reseller extending their agreement by a further 12 months to 30 June 2023.

“Gross profit margin for the year was 76.4% delivering a gross profit of $91.9 million. Consistent with our investment for growth strategy, our investments across R&D, the revised North American sales model, geographical expansion and broad capability and capacity expansion saw operating expenses increase to $90.5 million. Pleasingly, profit before tax for the year was $1.6 million, which was ahead of recent expectations, despite the complex operating environment experienced during the year and the foreshadowed one-off impact in H2 FY22 on revenue in North America associated with the move to a largely direct sales model.

“Throughout the year our manufacturing and logistics teams continued to manage a challenging and complex supply chain. This required an 91% increase in inventory holding to mitigate risks in supply to customers. Effective management saw continuity of supply maintained across all regions and all customers orders delivered in full.

REVISED NORTH AMERICAN SALES MODEL

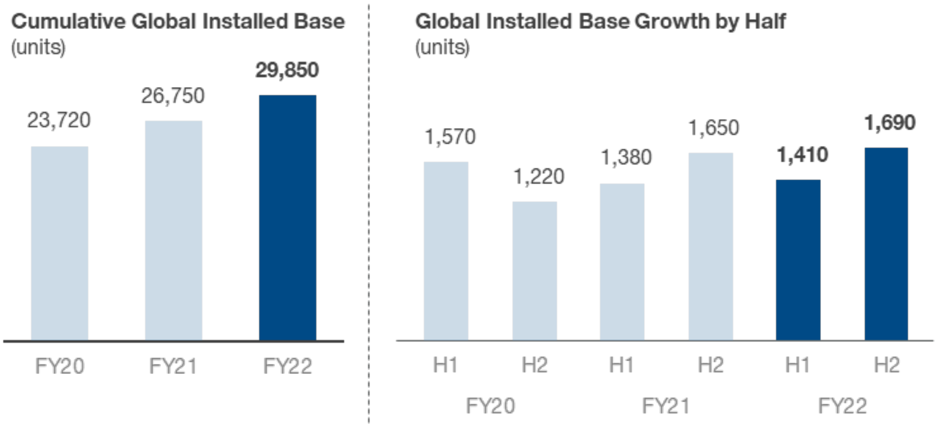
“As foreshadowed in our 8 February 2022 announcement, Nanosonics and GE Healthcare revised the North American sales model to a largely direct Nanosonics sales model. Through this change, GE have transferred all its trophon customers to Nanosonics for the ongoing provision of all consumables. In addition, through an expansion of the Nanosonics direct team, Nanosonics are now responsible for the majority of all capital sales moving forward, with GE still having access to capital equipment as a non-stocking capital reseller. This evolution of the North American sales strategy to a largely direct sales model with OEM capital reseller partners represented another significant milestone in the ongoing growth of the organisation bringing many benefits to Nanosonics and trophon customers.

“The transition to the largely direct sales model is now complete. The expanded North American team is in place and includes the hiring of a number of members of the former GE high level disinfection team. Shipping volumes through the Nanosonics logistics facility in Indianapolis are up over 100% in the last three months with no disruption in supply to customers and sufficient capacity in place to support expected future growth. The team has also executed over 30 new enterprise agreements with strategic accounts / Integrated Delivery Networks with many more due to be completed in the coming months. Nanosonics has also established the necessary partnerships to enable selling to US Federal Government accounts where GE previously represented 80% of the sales to those accounts.

"Our North American team is now well positioned to manage the overall growth strategy associated with new installed base, upgrade adoption and consumables usage. The business performance in Q4 FY22 saw many of these benefits start to come to fruition. In that quarter the Nanosonics team were responsible for 91% of the new installed base together with 86% of upgrade sales. The resulting deeper customer relationships with the majority of North American hospitals and our corresponding infrastructure expansion also supports planned product expansion beyond trophon", said Mr Kavanagh.

INSTALLED BASE GROWTH

The global installed base increased 12% to 29,850 units, an increase of 3,100 units for the year. The installed base increased 1,690 units in H2, up 20% compared with H1.



In North America, the installed base increased 2,650 units for the year to 26,130 representing an 11% increase. Hospital access continued to improve throughout the year and the installed base increased by 1,450 units in H2, up 21% compared with H1. The North American installed base now represents approximately 44% of the estimated total addressable market of 60,000 units where trophon is in use in over 5,000 institutions, further consolidating its position as standard of care. The overall ultrasound market continues to grow with new innovations in the market such as wireless hand-held probes being released. The Nanosonics R&D team has developed an accessory to enable wireless probes to be decontaminated in trophon with the first of such accessories due to launch in Q2 FY23.

During FY22, the Company also progressed the launch of AuditPro in North America with a focus on a number of key reference sites. In parallel, the Company advanced preparations for ISO27001 accreditation, the internationally accepted standard for the management of information security, which will further streamline customer security assessment requests as part of AuditPro implementation.

In the Europe and Middle East region, the installed base increased 310 units for the year, with the total installed base increasing by 21% to 1,820 units. Notwithstanding the impact of COVID-19 related market restrictions during the year, and other factors such as the sanctions on Russia, the number of new installed base units in H2 was 170 units, up 21% compared with H1. The Company continued its investment in the Europe and Middle East region in FY22 in particular in the UK and Germany. With market restrictions and hospital access now markedly improved it is expected that FY23 will see the first full year since 2020 where the investments in this region can be fully leveraged.

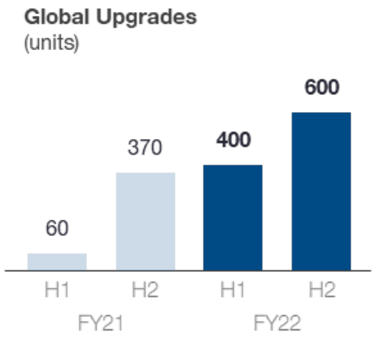
In Asia Pacific, the installed base increased 140 units for the year with the total installed base increasing 8% to 1,900 units. The number of units installed in H2 was equivalent to H1 reflecting the COVID-19 restrictions that prevailed during the year.

In Japan, the Company expanded its local team and medical affairs activities as we worked with local authorities on the establishment of local guidelines. In China, the registration of our Wholly Owned Foreign Enterprise was completed. Further, after significant delays due to COVID-19 related lockdowns, required local testing of the trophon device and consumables by the relevant State authorities has now commenced as part of our product registration plans.

trophon2 UPGRADES

There is a significant opportunity for upgrades from the first-generation trophon EPR to trophon2, where approximately 9,000 trophon EPR units are now at least seven years of age.

Globally 1,000 trophon EPR devices were upgraded in FY22 up 133% compared with FY21. Upgrade momentum continued into H2 with upgrades of 600 units, up 50% compared with H1.



In North America, where the majority of the upgrade opportunity exists, 880 upgrade units were sold during the year up 283% compared with FY21. Good growth momentum was also achieved in H2 over H1, with 500 upgrade units in H2 up 32% compared with H1. Importantly, 63% of the upgrade units sold in North America in H2 were sold in Q4 during the transition to the largely direct sales model with Nanosonics responsible for 86% of those sales. This result demonstrates the opportunity for Nanosonics to further drive the upgrade strategy with its direct access to all trophon customers.

In Australia / New Zealand, 100 upgrades were sold with 80% of those in H2.

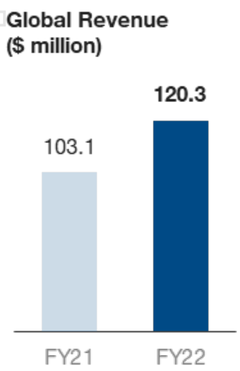
FINANCIAL RESULTS

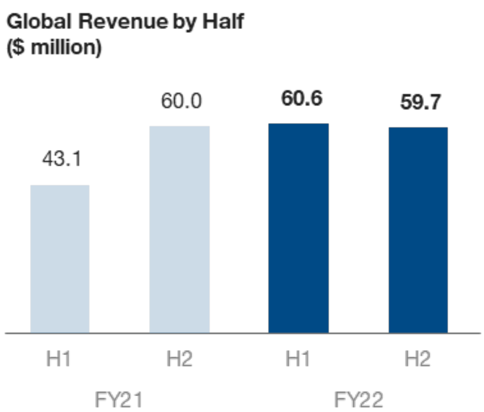
$ million	FY22	FY22	Change %
Capital revenue	37.7	26.7	▲ 41%
Consumable / service revenue	82.6	76.4	▲ 8%
Total revenue	**120.3**	**103.1**	▲ 17%
Gross profit	**91.9**	**80.4**	▲ 14%
%	76.4%	78.0%	
Operating expenses			
Selling and general	(47.9)	(37.6)	▲ 27%
Administration	(20.3)	(16.0)	▲ 27%
Research and development	(22.3)	(17.2)	▲ 30%
Other income	0.5	0.2	
Other (losses) / gains - net	(0.1)	1.0	
Earnings before interest and tax	**1.8**	**10.8**	▼ -83%
Finance (expense) / income (net)	(0.2)	0.2	
Operating income before income tax	**1.6**	**11.0**	▼ -85%
Income tax benefit / (expense)	2.1	(2.4)	
Profit after income tax	**3.7**	**8.6**	▼ -57%

Total revenue

Total revenue for the year was $120.3 million, up 17% (15% in constant currency[2]) on prior corresponding period. Revenue in H2 FY22 was $59.7 million, down 2% compared with H1 FY22 of $60.6 million.

The growth in revenue associated with both capital and consumables in H2 was impacted by the transition to the largely direct sales model in North America. As part of that transition, GE ran down their capital and consumable inventory with no replenishment as they transitioned to a non-stocking capital reseller by 30 June 2022.

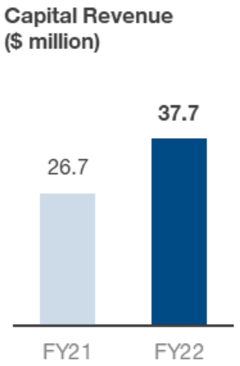


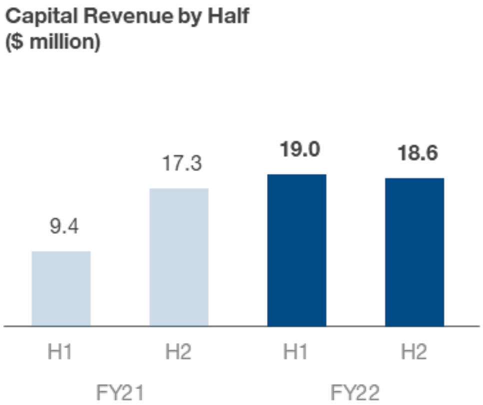


Capital revenue

Total capital revenue for the year was $37.7 million, up 41% on prior corresponding period. This increase reflects the recovery from the significant reduction in capital revenue experienced in H1 FY21 in North America associated with the reduction in the number of units sold to GE Healthcare in that period as a result of the negative impact of COVID-19 on new installed base growth.

While new installed base and upgrade capital units increased in H2, capital revenue of $18.6 million in H2 was down 2% compared with H1. This was primarily due to the impact of the revised North American sales model and GE Healthcare destocking as they transitioned to a non-stocking capital reseller.

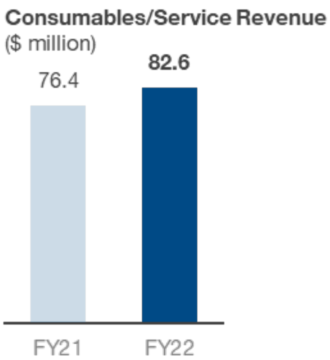


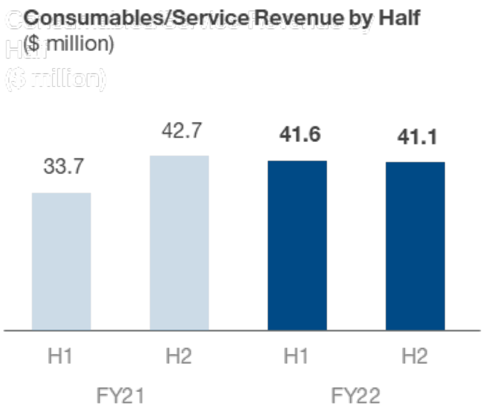


Consumables and service revenue

As COVID-19 restrictions eased during the year, market access conditions improved resulting in ultrasound procedure volumes returning to near pre-COVID levels. Consumables and service revenue represented 69% of total revenue highlighting the attractive annuity revenue nature of the business.

Total consumables and service revenue for the year was $82.6 million, up 8% on prior corresponding period. Revenue of $41.1 million in H2 FY22 was down 1% compared with H1 FY22 again reflecting the impact of the revised North American sales model with GE Healthcare consuming their inventory. There was no impact in the continuity of supply of consumables to customers during the transition.





Regional financial performance

North America

Total revenue for the year in North America was $106.9 million, up 20% on prior corresponding period.

Capital revenue was $33.6 million, up 58% on prior corresponding period.

While installed base and upgrade units sold in H2 FY22 increased, capital revenue in H2 of $16.3 million was down 6% compared with H1, primarily due to the impact of the revised North American sales model and GE Healthcare destocking.

Consumables and service revenue was $73.3 million, up 8% on prior corresponding period. In H2 FY22 consumables and service revenue was $36.3 million, down 2% compared with H1 FY22 again reflecting the impact of GE Healthcare's destocking.

Europe and Middle East

Total revenue for the year in the Europe and Middle East region was $7.5 million, up 4% on prior corresponding period. H2 FY22 revenue was $4.1 million, up 21% compared with H1 FY22.

Capital revenue was $2.1 million, down 22% on prior corresponding period. The reduction in revenue reflects the delayed easing of COVID-19 related market restrictions coupled with other factors including impact of sanctions on Russia. It is important to note that 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.

Consumables and service revenue was $5.4 million, up 20% compared with prior corresponding period. Consumables and service revenue in H2 FY22 was $2.8 million, up 8% compared with H1 FY22 as ultrasound procedure volumes returned to near pre-COVID levels.

Asia Pacific

Total revenue for the year was $5.9 million, down 12% compared with the prior corresponding period. H2 FY22 revenue was $3.0 million, up 3% compared with H1 FY22. Importantly, FY21 included a one-off upgrade deal of 200 units with I-MED Radiology Network, the largest customer in Australia.

Capital revenue was $1.9m, down 30% compared with the prior corresponding period, mainly as a result of the upgrade deal with I-MED in FY21. H2 FY22 revenue was up 11% compared with H1 FY22.

Consumables and service revenue of $4.0 million was the same as the prior corresponding period. While revenue growth in FY22 was impacted by the timing of shipments to distributors, sales of consumables (NanoNebulant) to end customers increased in FY22 compared with FY21.

Other financial results

Gross profit

Gross profit margin for the year was 76.4% compared with 78% in prior corresponding period. This reduction was primarily attributable to increased freight costs driven by global shortages in transport capacity. An increase in freight costs in Q4 FY22 were also attributable to the transition to the largely direct sales model in North America (amounting to approximately $0.3 million). The gross profit margin was ahead of the February 2022 guidance mainly due to favourable pricing outcomes in North America.

Investing for growth – Operating expenses

In line with the Company's deliberate strategy to continue to invest for growth in the multi-billion-dollar global infection prevention market, operating expenses for the year increased 28% to $90.5 million.

Attractive returns from these investments are expected over time as demonstrated by the Company's performance in North America, its largest and most developed business, where operating margins have been in the range of 55%-60%.[3]

Of the total operating expenses in FY22 approximately:

- 43% was associated with market development activities. The increase in these costs included the additional investment in Q4 of approximately $0.8 million to expand the Company's North American operations;
- 25% of total operating expenses in FY22 was associated with the Company's product innovation programs across the new Nanosonics CORIS technology as well as ongoing programs in ultrasound reprocessing and cloud solutions; and
- 32% of total operating expenses in FY22 relate to the Company's infrastructure including, manufacturing and other headquarter support costs.

In FY22, the Company incurred additional costs of approximately $1.5 million as a result of its relocation to its new global headquarter facility, increasing the organisation's capabilities and capacity for future growth.

Operating expenses increased to $47.8 million in H2, up 12% compared with H1 and in Q4 FY22 operating expenses were $24.6 million or 27% of the total year.

Other income and profit before tax

Other income for the year was $0.5 million, up $0.3 million compared with prior corresponding period. The increase in other income was mainly attributable to the NSW State Government funding received from the Jobs Plus Program.

Profit before tax for the year was $1.6 million reflecting the increased investment in the Company's strategic growth agenda as well as the foreshadowed impact in H2 on revenue in North America associated with the move to a largely direct sales model.

Working capital

Free cash flow for the year was a net outflow of $0.2 million driven mainly by capital expenditure associated with the new corporate headquarters and the increase in the Company's inventory holding. Free cash flow in H2 FY22 was a net inflow of $3.6 million, offsetting the net outflow in H1 of $3.8 million. The Company expects to receive at least $1.6 million cash in FY23 relating to infrastructure rebate claims in respect of FY22 under the NSW Jobs Plus Program.

Cash and cash equivalents were $94.5 million at 30 June, providing a strong foundation for continued investment in growth. The Company has no debt and continues to regularly review its capital management strategy.

During the year the Company increased its inventory holding by 91% to $22.6 million. This increase was driven by the need to carry more safety inventory in response to increased supply chain risks caused by the COVID-19 pandemic and the Company's transition to a largely direct sales model in North America. Of the total increase, 55% was associated with finished goods and the balance related to raw materials. As a result of the Company's COVID-19 pandemic inventory policy, there were no supply disruptions to customers. The Company expects it will maintain inventory at a similar level throughout FY23 reflecting the ongoing complexities with the global supply chain and the move to a largely direct model in North America. It is anticipated that once the supply chain risks reduce the Company's inventory holding requirements will also reduce.

R&D / NEW PRODUCTS

Research and development is a corner stone of the future growth of Company. In FY22 the Company invested $22.3 million in R&D up 30% compared with FY21. Through these investments, which are all expensed, the Company has expanded its capacity and capabilities programs across ultrasound reprocessing, endoscope reprocessing, data through cloud solutions as well as chemistry and bioscience. The Company also increased its capacity to add new innovation programs to its R&D program through the establishment of expanded R&D facilities as part of its corporate headquarters move. These important investments position the Company well to further expand its participation as a leading infection prevention company in the significant global infection prevention market.

Nanosonics CORIS – transforming the cleaning of flexible endoscopes

In the United States, CORIS represents a disruptive innovation. As such, there is no existing predicate device like it on the market. As a completely novel technology platform, CORIS will be subject to the FDA de novo clearance pathway thus setting a new benchmark and creating an entirely new category for endoscope cleaning.

Recently, the Nanosonics CORIS technology was accepted into the FDA Safer Technologies Program (STeP). Products accepted into this program are reasonably expected to significantly improve the safety of currently available treatments. The goal of STeP is to provide patients and healthcare providers with timely access to these medical devices by expediting their development, assessment and review while preserving the statutory standards for approval. Through the program the FDA provides sponsors of devices with additional review resources, facilitating more interactive and timely communication through the submission review process.

The new CORIS platform aims to deliver a solution to one of the biggest unmet needs in instrument reprocessing – reprocessing failures of flexible endoscopes due to current limitations of manual cleaning resulting in an increased risk of cross-contamination.

The potential to address the challenges of contaminated endoscopes represents a significant opportunity for Nanosonics in a growing market with over 60 million flexible endoscopy procedures per annum being conducted across major Western markets including the United States, Canada, Australia and key European markets every year. Similar to trophon (which comprises a range of business models) CORIS will include capital equipment together with an annuity revenue stream associated with consumables used for every cleaning cycle. Studies have shown that the cost of the full manual cleaning stage for a single flexible endoscope today can be between US$11 - $37.[4] CORIS aims to automate a significant proportion of the current manual cleaning including the complex channel cleaning and deliver significantly superior cleaning outcomes compared to what can be achieved today.

CORIS is being designed as a global solution ultimately to be used across all channeled flexible endoscope types. The CORIS technology continues to advance with the Company targeting progressive market introductions aligned with regulatory approvals, with the first introduction targeted for calendar 2023 and likely to be in Australia and/or Europe.

Further details on CORIS can be found in the Company's 2022 Full Year Results Investor Presentation.

BUSINESS OUTLOOK – FY23

Nanosonics is well positioned to continue to invest in its longer-term strategic growth agenda and expand its participation as a leading infection prevention company in the multi-billion-dollar global infection prevention market.

While the threat of further COVID-19 related disruptions exist through growing rates of infection or the emergence of new variants, our expectation is that current improved market conditions will prevail throughout FY23.

FY23 will also be the first full year of the largely direct sales model in North America and is anticipated to be the first full year since 2020 in which the Company will be able to fully leverage its investments in geographical expansion, especially in the Europe and Middle East region.

Targets for FY23 include:

- Total revenue growth of 20-25%.
- Gross margin of between 75-76%, reflecting:
    - an increase in the proportion of capital revenue resulting from growth in the sales of both new installed base units (which drives growth in high margin consumable revenue over time) and upgrade units;
    - ongoing increased freight costs; and
    - increased component costs.
- Operating expenses to grow between 15-18%. It is expected that the overall proportion of operating expenses associated with infrastructure will decrease. Accordingly, the significant majority of the increase in operating expenses in FY23 is expected to be weighted towards:
    - market development activities; and
    - ongoing product innovation across ultrasound reprocessing, endoscope reprocessing, data through cloud solutions as well as chemistry and bioscience.

All guidance is subject to ongoing uncertainty in relation to variability in market access conditions should COVID-19 pandemic related measures change in relevant markets and broader economic and geopolitical uncertainty.

Recognising the increasing global focus on infection prevention and the opportunities this presents for Nanosonics, the Company will also continue to work on identifying M&A opportunities to expand its product portfolio.

BEYOND FY23

In addition to the targeted growth in FY23, beyond FY23 Nanosonics is targeting:

- Continued expansion of the trophon franchise across all regions including growth in installed base, consumables usage, service business and trophon upgrades.
- Japan to become an important contributor to the global trophon installed base as well as further expansion across the Asia Pacific region including China.
- Growth in our participation in the infection prevention data and analytics field through the AuditPro platform.
- Ongoing expansion of the product portfolio introducing the new CORIS endoscope reprocessing platform across multiple markets and broader indications. In addition, opportunities for strategic acquisitions will continue to be identified and assessed.
- Ongoing investment in R&D, infrastructure, people and capability to continue driving 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. All research and new product development programs involve inherent risks and uncertainties which can impact commercialisation timelines.
2. 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 30 June 2022 was 0.7231 (2021: 0.7492).
3. Before any HQ costs are allocated to the region.
4. Ofstead, C.L., Quick, M.R., Eiland, J.E. and Adams, S.J., 2017. A glimpse at the true cost of reprocessing endoscopes. International Association of Healthcare Central Service Material Management.

This announcement has been authorised by the Board of Directors of Nanosonics.

Investor conference call
Investors are invited to join a conference call on Tuesday 23 August 2022 at 11:00am (AEST) hosted by Nanosonics CEO & President, Michael Kavanagh, and 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/10023678-dh3ms1.html

For more information, please contact:
Michael Kavanagh, CEO & President or McGregor Grant, CFO on (02) 8063 1600