22 August 2023

Company Announcements Office
Australian Securities Exchange

Nanosonics 2023 full year financial results

HIGHLIGHTS

- **Revenue of $166.0 million, up 38% on prior corresponding period (30% in constant currency[1]).**
  - **Capital revenue of $54.2 million, up 44% on prior corresponding period.**
  - **Consumables and service revenue of $111.8 million, up 35% on prior corresponding period.**
- **Total trophon2® units placed of 4,410, up 8% on prior corresponding period.**
  - **Global installed base up 9% (2,600 units) on prior corresponding period to 32,450 units.**
  - **trophon2 upgrades of 1,810 units, up 81% on prior corresponding period.**
- **Gross profit margin of 78.7% compared with 76.4% in prior corresponding period, reflecting favourable capital and consumables pricing in North America associated with the transition to direct sales model and favourable foreign exchange.**
- **Continued investment in growth strategy with operating expenses of $114.2 million up 26% on prior corresponding period. Operating expenses includes $29.5 million associated with R&D.**
- **Operating profit before tax of $21.6 million compared with $1.6 million in prior corresponding period.**
- **Free cash flow for the year of $19.8 million, with cash and cash equivalents of $112.2 million at 30 June 2023.**
- **New CORIS technology progressed against key milestones. Recent FDA input has provided early notice that certain testing originally scheduled to be conducted in Australia is now required to be completed in the USA. This will add to the timeline for the FDA submission date likely moving it into Q3 FY24.**

Nanosonics (ASX: NAN), a leader in infection prevention solutions, today announced its Appendix 4E Full Year Report for year ended 30 June 2023.

“The 2023 financial year has been another year of significant achievement. The trophon business continued to expand globally, delivering excellent sales growth and profitability. Our commitment to ongoing investment in the drivers of future growth through geographical expansion and Research and Development also continued, with the Company successfully executing several key strategic priorities throughout the year”, said Michael Kavanagh, Nanosonics’ Chief Executive Officer and President.

Central to these was the first full year operating under the new largely direct sales model in North America.

Progress was also made with our geographical expansion plans. In Japan, the Company continues its investment in market development efforts to establish local high level disinfection guidelines for

[1] Constant currency removes the impact of foreign exchange rate movements to facilitate comparability of operational performance. This is done by converting the current year sales of entities that use currencies other than Australian dollars at the average rates that were applicable in the prior year. The average exchange rate used for the Company's major foreign currency (USD) for the year was 0.6731 (2022:0.7283).

the reprocessing of ultrasound transducers. A new infection control management bundle[2] for ultrasound probe reprocessing in Obstetrics and Gynaecology was recently published by an advisory committee on infection control in Obstetrics and Gynaecology. This was recently presented at the Japanese Society of Infection Prevention and Control (JSIPC).

In China, the necessary documentation for regulatory approval to market and sell trophon2 is now under review with the Chinese regulatory authorities.

R&D continues to be a cornerstone of future growth for the Company. Through its R&D investments, the Company has built depth in its capacity and capabilities.

Our next transformational product, CORIS, is being designed to address one of the most recognised unmet needs in medical instrument reprocessing, endoscope cleaning. It was recently presented at the Association for Professionals in Infection Control and Epidemiology (APIC) conference in the USA with further presentations planned throughout FY24. Recent FDA input through the STeP program gave early notice that certain testing originally scheduled to be conducted in Australia is now required to be completed in the USA. This will likely move the date of the FDA submission into Q3 FY24. The other CORIS clinical trial activities will be conducted in parallel in Australia as planned. Given FDA submission is the key priority, there will be an impact on timing for commercialisation plans in other markets including Australia and Europe, which will be clearer once the FDA de novo submission is made.[3]

Growth momentum continued and total global installed base grew 9% for the year with 32,450 trophon units now in operation around the world. While the pipeline for new installed base grew throughout the year, due to a range of adverse market conditions, new installed base growth declined 16% compared to prior corresponding period. Much of the new pipeline generated during the year is now forecasted for sale in FY24. Importantly, 32,450 trophon units in operation means over 26 million patients are protected annually from the risk of ultrasound probe cross contamination.

The number of customers upgrading from the first generation trophon EPR device to trophon2 is now growing significantly, with over 1,800 upgrade units placed in FY23, up 81% compared with FY22. These upgrades bring significant benefits to customers in terms of usability, traceability and digitisation compared to other available solutions. Significantly, in addition to the ongoing annuity revenue from consumables associated with each upgrade, upgrades also represent an opportunity for increased annuity revenue in the form of service revenue.

Importantly, throughout the year our manufacturing and logistics teams continued to manage a challenging and complex supply chain. There was an approximately 3-fold increase in the number of shipments to customers in North America from our direct operations as a result of the transition to a largely direct model. Continuity of supply was maintained across all regions with all customers' orders being delivered in full and on time.

Total revenue for the year grew 38% to $166.0 million, with capital revenue up 44% to $54.2 million and consumable and service revenue up 35% to $111.8 million.

Gross profit margin for the year was 78.7% delivering a gross profit of $130.6 million. Consistent with our commitment to invest for future growth, operating expenses for the business grew 26% to $114.2 million. This included $29.5 million invested in R&D, including all costs associated with our new endoscope reprocessing technology platform, CORIS.
Profit before tax for the year was $21.6 million, up from $1.6 million in FY22.

[2] "Infection control management bundle for ultrasound probe reprocessing in ObGyn". A bundle is a set of evidence-based practices that when performed collectively and reliably have been proven to improve patient outcomes. It is a structured way of improving the processes of care for specific conditions or situations. https://usipbundle.jp

[3] All research and new product development programs involve inherent risks and uncertainties which can impact commercialisation timelines.

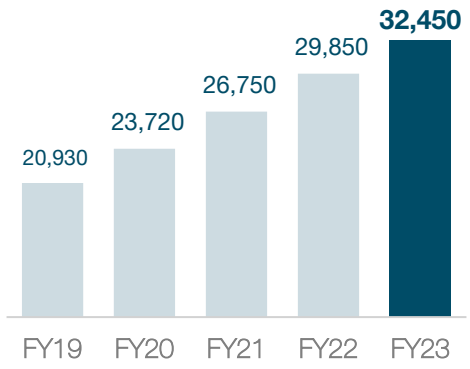
Excluding the investments in our long-term growth strategy, in particular those associated with future product expansion, the trophon business alone delivers significant earnings with operating profit before tax of approximately $44.0 million[4] and return on equity of 22%.[5] This return is inclusive of investments being made in emerging markets for trophon that are not currently contributing significantly to revenue today but have the potential to do so in the future.

trophon2 UNITS

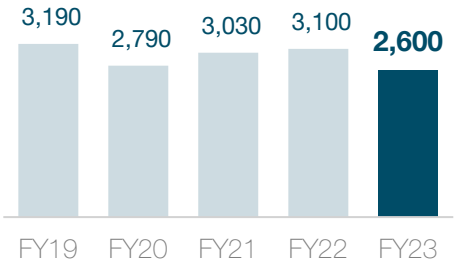
New installed base

The global installed base increased 9% to 32,450 units, an increase of 2,600 units for the year. While the pipeline remains strong for new installed base, delays in purchase orders were experienced as capital budgets in certain hospitals were restricted, in particular in H2 FY23. This resulted in new installed base for the year being down 16% on prior corresponding period with much of the new installed base pipeline generated in FY23 now forecasted for sale in FY24.

Global Total Installed Base



New Installed Base

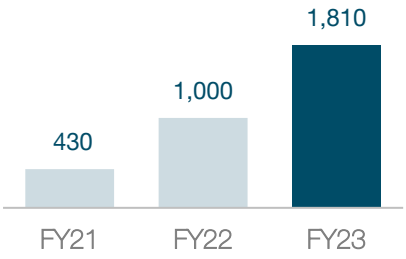


Upgrades

Upgrades represent a significant growth opportunity in new capital revenue, ongoing consumables annuity revenue, and also new annuity revenue through the sale of technical service contracts. Approximately 35% of the global installed base is 7 years of age or older.

Global upgrades grew 81% compared with prior corresponding period with 1,810 upgrade units installed.

Upgrades

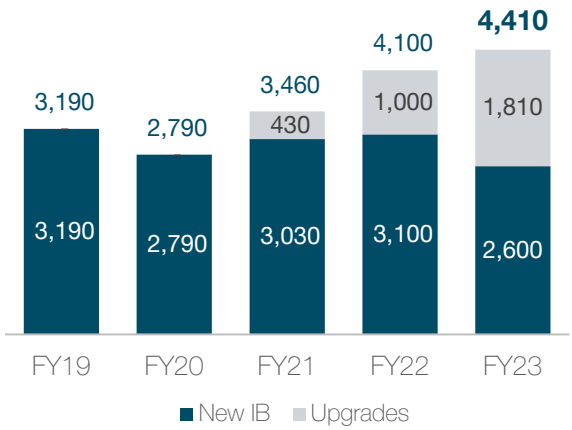


[4] The pro forma profit before tax for the trophon business is unaudited and has been prepared by management to reflect total Company results less operating costs associated with new product development and commercialisation. Operating costs reflect management allocation estimates where resources are shared between trophon and new products development and commercialisation. The pro forma profit and loss statement also includes income received from the Jobs Plus Program.

[5] Return on equity is calculated based on the pro forma profit after income tax of the trophon business divided by the average equity for FY23.

Total units

Global total trophon2 units[6] grew 8% on prior corresponding period with 4,410 units placed in the year.



Regional unit review

In North America, the total installed base increased by 2,260 units for the year to 28,390 units, representing a 9% increase.

The pipeline for new installed base continued to grow throughout the year, however, restrictions on certain hospital capital budgets delayed the dates of purchase which are now forecasted for FY24. This was most pronounced in H2 of FY23. These delays resulted in the growth in new installed base for the year being down 15% compared to prior corresponding period.

With trophon represented in over 5,000 institutions, a large percentage of the new installed base in FY23 were installed in new departments within the same hospital. This demonstrates a growing standardisation across all departments within a hospital for the use of trophon as their standard of care for the high-level disinfection of ultrasound transducers.

trophon2 upgrades in North America continued to grow strongly throughout the year with 1,390 upgrades placed, up 58% over prior corresponding period.

Overall, total units placed in North America grew 3% for the year with 3,650 units installed.

In Europe and Middle East (**EMEA**), the market challenges experienced in the first half of the year relating to ongoing COVID-19 and budgetary pressures experienced by the hospital systems continued into the second half.

While new installed base grew 38% in the second half over the first with 110 units installed in H2 of FY23, overall new installed base was down 39% on prior year. Upgrades for the year were up 900% compared to FY22 with 200 upgrades installed.

Total units installed in EMEA grew 18% for the year with 390 units installed.

In Asia Pacific, new installed base grew 7% for the year with 150 units installed further consolidating the market leading position for trophon in ANZ. Upgrade units for the year grew 120% with 220 upgrades installed.

[6] Units comprises new installed base units and upgrades including UK MES units.

Total units in Asia Pacific grew 54% for the year with 370 units installed.

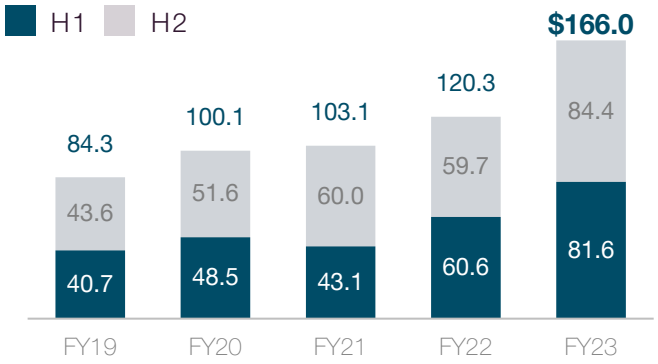
FINANCIAL RESULTS

$ millions	FY23	FY22	Change %
Capital revenue	54.2	37.7	▲ 44%
Consumable/service revenue	111.8	82.6	▲ 35%
Total revenue	**166.0**	**120.3**	▲ 38%
Gross profit	**130.6**	**91.9**	▲ 42%
%	78.7%	76.4%	
Operating expenses			
Selling and general	(60.9)	(47.9)	▲ 27%
Administration	(23.7)	(20.3)	▲ 17%
Research and development	(29.5)	(22.3)	▲ 32%
Other income	1.3	0.5	▲ 160%
Other gains/(losses) - net	1.8	(0.1)	
Earnings before interest and tax	**19.6**	**1.8**	▲ 989%
Finance income/(expense) - net	2.0	(0.2)	
Profit before income tax	**21.6**	**1.6**	▲ 1,250%
Income tax (expense)/benefit	(1.7)	2.1	
Profit after income tax	**19.9**	**3.7**	▲ 438%

Total revenue

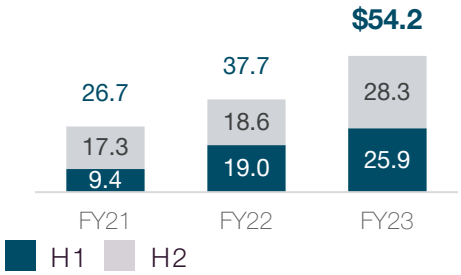
Total revenue for the year was $166.0 million, up 38% (30% in constant currency) on prior corresponding period. The growth in revenue was attributable to:

- growth in total units;
- increased consumables volumes associated with growth in new installed base and improved ultrasound procedure volumes;
- favourable pricing associated with the transition to the largely direct North American sales model;
- increased service revenue; and
- favourable foreign exchange associated primarily with a relatively stronger USD.



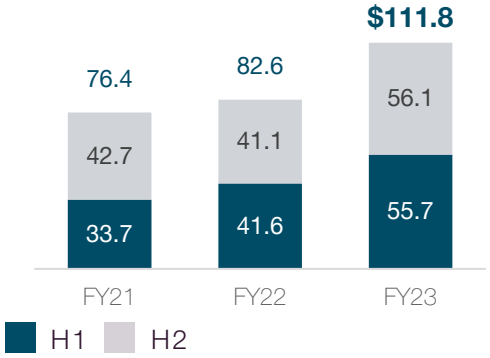
Capital revenue

Capital revenue for the year was $54.2 million, up 44% (35% in constant currency) on prior corresponding period. This increase is a result of 4,410 units being sold during the year together with improved pricing under the new North American sales model and favourable foreign exchange.



Consumables and service revenue

Consumables and service revenue for the year was $111.8 million up 35% (28% in constant currency) on prior corresponding period. This growth was driven by new installed base consumables usage, growth in service revenue with favourable pricing and foreign exchange.



Regional financial performance

North America

Total revenue for the year in North America was $150.4 million, up 41% (32% in constant currency) on prior corresponding period.

Capital revenue for the year was $48.9 million, up 46% on prior corresponding period.

Consumables and service revenue was $101.4 million, up 38% on prior corresponding period.

These increases were attributable to growth in total units installed, increased consumables associated with new installed base, increase in service revenue and favourable pricing and foreign exchange.

Europe and Middle East

The market challenges experienced in the first half of the year, relating to ongoing impacts of COVID-19 and budgetary pressures experienced by the hospital systems, continued into the second half.

Total revenue for the year in the Europe and Middle East region was $8.1 million, up 8% on prior corresponding period with revenue in the second half up 25% versus the first half.

While total trophon units installed grew 18% on prior corresponding period, this growth was largely driven by upgrades installed under the Managed Equipment Services (MES) sales model where no capital revenue is recognised. As a result, capital revenue for the year was $1.9m, down 10% on prior corresponding period.

Revenue associated with consumables and service was $6.2 million, up 15% on prior corresponding period with consumables and service revenue growing 30% between the first and second halves.

Asia Pacific

Total revenue for the year in Asia Pacific was $7.5 million, up 27% on prior corresponding period. Capital revenue for the year was $3.3 million, up 74% on prior corresponding period reflecting the strong growth in upgrades as well as ongoing growth in new installed base.

Revenue associated with consumables and service for the year was $4.2 million, up 5% on prior corresponding period.

Other financial results

Gross profit

Gross profit margin for the year was 78.7% compared with 76.4% in prior corresponding period primarily driven by favourable capital and consumables pricing in North America together with favourable foreign exchange. These benefits were partially offset by higher freight costs associated with increased shipping volumes under the new largely direct sales model in North America.

Investing for growth – Operating expenses

Global operating expenses were $114.2 million up 26% versus prior corresponding period. These expenses can be broadly broken down into investments in the following categories:

- **Market development** comprising approximately 46% of our total operating expenses. These investments are associated with continuing to drive ongoing growth in mature markets such as the USA, ANZ and UK, where the majority of our current revenue is derived, as well as investing in expanding our geographical presence in emerging trophon markets such as Japan, China and a number of European markets.
- **Research and development** representing approximately 26% of operating expenses. These expenses support ongoing R&D in the trophon franchise as well as new product categories like CORIS in endoscopy reprocessing, as well as research activities in broader infection prevention areas.
- **Operations, HQ and support** representing approximately 28% of operating expenses and is associated with development of scalable manufacturing capacity to support ongoing growth in global demand as well as setting up manufacturing operations for new product introductions. These expenses also include our first full year in the new global headquarters which provides capacity to support the ongoing growth.

Profit before tax

Other income for the year was $1.3 million, up $0.8 million compared with FY22. The increase in other income was mainly attributable to NSW State Government funding associated with the Jobs Plus Program.

Profit before tax for the year was $21.6 million compared with $1.6 million in FY22, resulting from strong growth in total revenue, higher gross profit margin and improved operating leverage with total operating expenses reducing as a percentage of total revenue to 68.8% compared with 75.2% in FY22.

Working capital

Free cash flow for the year was $19.8 million compared with a net outflow of $0.2 million in FY22.

Cash and cash equivalents were $112.2 million at 30 June 2023, providing a strong foundation for continued investment for growth, as well as potential M&A opportunities to expand the Company's product portfolio. The Company has no debt and continues to regularly review its capital management strategy.

During the year, the Company's inventory increased $2.9 million to $25.5 million. The increase was driven by the need to carry more 'safety' inventory as a result of the transition to a largely direct selling model in North America and the primary use of sea freight to manage freight cost. The Company continues to monitor freight and logistics challenges and plans to reduce inventory during FY24 as the broader supply chain complexities ease.

Total trade and other receivables increased 39% or $10.9 million to $38.8 million with the increase in receivables associated with higher sales attributed to the more direct business model in North America.

CORE TROPHON BUSINESS PROFITABILITY (EXCLUDING NEW PRODUCT DEVELOPMENT AND COMMERCIALISATION)

A significant proportion of the Company's operating expenses are associated with future earnings opportunities from new product development and expansion. Presented below is the profitability profile of the current core trophon business without those product expansion investments.

Excluding operating expenses of approximately $22.4 million associated with the development and commercialisation preparation of the CORIS technology, the pro forma profit before tax of the current trophon business in FY23 was approximately $44.0 million.[7] This includes all operating and investment costs associated with developing emerging trophon markets that do not currently contribute significantly to revenue as well as R&D associated with the trophon technology roadmap.

The unaudited pro forma profit and loss statement[7] of the trophon business alone excluding new product expansion investments is:

$ millions	FY23	FY22	Change %
Total revenue	**166.0**	**120.3**	▲ 38%
Gross profit	**130.6**	**91.9**	▲ 42%
%	78.7%	76.4%	
Operating expenses	**(91.7)**	**(76.1)**	▲ **20%**
Operating expenses as a % of sales	55.2%	63.3%	
Other income	1.3	0.5	▲ 160%
Other gains/(losses) - net	1.8	(0.1)	
Earnings before interest and tax	**42.0**	**16.2**	▲ 160%
Finance income/(expense) - net	2.0	(0.2)	
Profit before income tax	**44.0**	**16.0**	▲ 175%
Income tax expense[8]	(11.5)	(4.1)	▲ 180%
Profit after income tax	**32.5**	**11.8**	▲ 175%

As the trophon business continues to grow, improvements in operating leverage are being achieved with operating expenses as a percentage of sales reducing to 55.2% in FY23 from 63.3% in FY22.

The pro forma profit before tax of $44.0 million in FY23 represents 26.5% of revenue demonstrating the strong underlying profitability of the stand-alone trophon business.

After adjusting for the after-tax impact of the CORIS investments, the return on equity of the trophon business is approximately 22%.[9]

[7] Pro forma profit and loss statement is unaudited and reflects total Company results less operating costs associated with new product development and commercialisation. Operating costs reflect unaudited management allocation estimates where resources are shared between trophon and new products development and commercialisation. The pro forma profit and loss statement also includes income received from the Jobs Plus Program.

[8] Effective income tax expense for the trophon business is the difference between the total Company income tax less tax benefit attributable to CORIS investments which was calculated by applying Australian corporate tax rate and the maximum R&D tax offset rate.

[9] Return on equity is calculated based on the pro forma profit after income tax of the trophon business divided by the average equity for FY23.

R&D / NEW PRODUCTS

Research and development continues to be a cornerstone of the future growth of the Company. During the year the Company invested $29.5 million in R&D, up 32% compared with the prior corresponding period.

Through our R&D investments, the Company has built depth in its capacity and capabilities with programs across chemistry, microbiology, biochemistry, physics, and core engineering disciplines as well as medical and regulatory affairs. Indeed, the Company has built several unique capabilities which provide strategic advantage in areas such as biofilm production and testing in very small diameter lumens. These important investments position the Company well to expand its activities as a leading infection prevention company.

Our next transformational product, CORIS, progressed against key milestones during the year and was recently presented at the Association for Professionals in Infection Control and Epidemiology (APIC) in the USA, with further scientific presentation and publications planned during the remainder of calendar 2023.

A key benefit of CORIS being accepted into the FDA Safer Technologies Program (STeP), is the opportunity for more interactive and timely communication with the FDA about key aspects of their requirements for a de novo submission since CORIS is considered a new class of product with no predicate. This should lead to a smoother and more timely review process once the de novo submission is made.

Recent consultation with the FDA through the STeP program, gave us early notice that certain testing originally scheduled to be conducted in Australia is now required to be completed in the USA. The Company is taking the necessary preparatory steps to conduct this testing which necessitates the set-up of a clinical simulation laboratory in the USA, similar to the one established at Nanosonics HQ in Sydney. In parallel, the in-use clinical trial plans will go ahead in Australia as previously planned.

The required testing in the USA will impact the FDA de novo submission date which will likely move into Q3 FY24. Given that the FDA submission is the key priority, there will also be an impact on the timing for commercialisation plans for other markets including Australia and Europe, which will be clearer once the FDA de novo submission is made.[10]

The new CORIS platform aims to deliver a solution to one of the biggest unmet needs in instrument reprocessing – the reprocessing failures of flexible endoscopes. This represents a significant opportunity for Nanosonics in a growing market with over 60 million[11] 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, the CORIS business model will include capital equipment together with an annuity revenue opportunity 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.[12] CORIS aims to automate a significant proportion of the current manual cleaning, including complex channel cleaning and deliver significantly superior cleaning outcomes compared to those achievable today.

CORIS is being designed as a global solution, ultimately to be used across all channeled flexible endoscope types.

[10] All research and new product development programs involve inherent risks and uncertainties which can impact commercialisation timelines.

[11] References on file; available upon request.

[12] 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.

BUSINESS OUTLOOK – FY24

Nanosonics is well positioned to continue to grow the trophon business, introduce the CORIS technology as well as invest in its longer-term strategic growth agenda.

With a growing opportunity pipeline, it remains to be seen whether hospital budgetary pressures will impact the timing of trophon purchases.

Recognising the uncertainties, the Company targets for FY24 include:[13]

Total revenue growth of 15-20%.

- Growing capital revenue with increased growth in both installed base and upgrade volumes over FY23;
- Increasing consumables revenue aligned with growth in new installed base;
- Maintaining current pricing levels; and
- Increased service revenue.

Gross margin of between 75-77%.

- A change in sales mix compared with FY23, with an increase in the proportion of capital revenue resulting from growth in the sales of both new installed base and upgrade units, and an increase in service revenue; and
- Increased trophon product COGS, as the Company sells off higher cost inventory due to a temporary increase in component costs associated with units manufactured during FY23.

Operating expenses to grow between 17-22% including investments in CORIS commercialisation. Operating expenses include:

- Increases in investment to prepare for the commercialisation of CORIS;
- Ongoing investment in R&D with overall R&D expenditure reducing as a percentage of revenue in FY24;
- Ongoing investment in emerging markets for trophon including Japan and China; and
- Costs associated with implementation of a new ERP system with the majority of the associated expenses incurred in FY24.

All guidance is subject to ongoing uncertainty in relation to hospital budgetary pressures as well as broader economic and geopolitical conditions.

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 further expand its product portfolio.

[13] The FY24 outlook assumes an AUD/USD rate of 0.70.

BEYOND FY24

In addition to the targeted growth in FY24, beyond FY24 Nanosonics is targeting:

- Continued expansion of the trophon franchise across all regions including growth in installed base, upgrades, and consumables/service;
- Europe and the Middle East and Asia Pacific to become material contributors to the global trophon business;
- Ongoing expansion of the product portfolio with the global introduction of 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; and
- 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.

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 22 August 2023 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/10031297-qw12rt.html.

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