



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Nanosonics

**By TIM BOREHAM**

**ASX Code:** NAN

**Share price:** \$4.15

**Shares on issue:** 302,607,616

**Market cap:** \$1.255 billion

**CEO:** Michael Kavanagh

**Board:** Steve Sargent (chairman), Mr Kavanagh, Dr David Fisher, Marie McDonald, Geoff Wilson, Dr Lisa McIntyre, Dr Larry Marshall, Dr Tracey Batten

**Financials (year to June 30, 2023):** revenue \$166 million (up 38%), net profit \$19.9 million (up 431%), earnings before interest, tax depreciation and amortisation \$26.7 (up 270%), cash of \$112.2 million (up 19%)

**Major identifiable shareholders:** Maurie Stang 6.3%, Selector Funds Management 6.2%, Yarra Capital Management 5.6%, Bernard Stang 5.4%.

Reflecting on his 10 years as CEO of the medical device play - a milestone achieved last month - Michael Kavanagh says the numbers tell the story.

A decade ago, Nanosonics turned over \$14.8 million, two years after its Trophon probe sterilization device was approved in the US. The company also lost \$5.8 million.

Fast forward to 2022-'23 and the company posted \$166 million of revenue and made a net profit of just under \$20 million.

Mr Kavanagh adds the numbers tell only part of the story.

“The part I’m most proud of is the amazing capabilities we have built into the business,” he says.

“We are one of a handful of labs in the world today expert in biofilm on medical devices, especially in very small lumens of less than one millimetre in diameter.

“We have had to build capabilities in biosciences, microbiology and chemistry.”

Having Trophon-ized hospitals around the world - especially in the US - Nanosonics is poised to commercialise its second instrument, called Coris (see below).

## **Tackling hospital infections**

Based in Sydney, Nanosonics was founded in 2001 by microbiologist Dr Ron Weinberger and engineer Stuart Hodgetts, who were inspired by the need for hospitals to reduce infections caused by poorly-cleaned medical devices.

The first device iteration was the Trophon EPR - as in Enhanced Protection and Reprocessing - which uses hydrogen peroxide vapor to disinfect ultrasound probes much more thoroughly than the old manual methods.

Nanosonics claims the Trophons protect 98,000 patients daily from ultrasound probe cross contamination - or 25 million a year.

Hey! That’s almost the size of Australia’s population.

Nanosonics listed in May 2007, raising \$27 million at 50 cents apiece.

The company launched the Trophon EPRs in 2009, which the US Food and Drug Administration approved in 2011, and launched the pimped-up Trophon 2s in 2018.

Previous to his decade-long Nanosonics gig, Mr Kavanagh was marketing head honcho at Cochlear.

Another key contributor is Maurie Stang, who chaired the company from 2007 until July last year.

On October 3 this year, long-time chief financial officer McGregor Grant stepped down, in favor of former local GE Healthcare CEO Jason Burriss. Mr Grant has since won a board seat on, and is chair of, device play Impedimed.

A notable recent Nanosonics board addition is Dr Larry Marshall, the sometimes-controversial scientist and entrepreneur who headed CSIRO for more than eight years.

## **Germes gone with Trophon**

About the size of a microwave, Trophons sanitise probes to certified high level disinfectant (HLD) standards.

The units protect against nasty bugs including drug-resistant bacteria, fungi, blood-borne viruses, venereal diseases and - if anyone still cares - Sars-Cov-2.

The Trophon process takes seven minutes and produces harmless water and oxygen as a byproduct of the disinfectant hydrogen peroxide.

Pre-Trophon, sterilization standards have ranged from a quick 'once-over' with a cloth to a procedure involving an isolating room with dangerous chemicals.

As well as selling (or leasing) the units, Nanosonics also makes money from servicing and consumables. The latter consists mainly of the hydrogen peroxide canisters that are used in the procedure (rather like a dishwasher powder tablet).

In the US, the Trophons were distributed exclusively by GE Healthcare. But this arrangement was revised and the company now mainly sells directly.

## **Hospitals are doing it hard**

Nanosonics continues to grow its base of Trophons - albeit at a slower run rate than pre-pandemic.

"Our customers [hospitals] are experiencing one of the most difficult operating environments for a very long time," Mr Sargent told last week's AGM.

"Costs are rising at a faster rate than revenue and governments have increasing budgetary pressures."

As of June 2023, Nanosonics had an installed base of 32,450 Trophons, up nine percent for the year and 55 percent higher than five years ago.

Of these, 28,390 are in the US (up nine percent). Europe and the Middle East account for a further 2,100 (up 10 percent) and Asia Pacific (mainly Australia) another 2,050 (up eight percent).

The full-year accounts show 2,600 newly installed Trophons, down 16 percent year-on-year.

But there were 1,800 upgrades from Trophon to the bells-and-whistles Trophon 2.

These units include enhanced audit features to enable hospitals to keep up with ever-stricter compliance requirements.

## **Coris takes a flexible approach**

A new product, Coris, is intended for flexible probes commonly used in procedures such as colonoscopies, gastroscopies, enteroscopies, endoscopic ultrasounds and bronchoscopies.

They have more fiddly bits than rigid endoscopes and are harder to clean, a process requiring scrubbing and long hours of standing.

As a guide, up to 200 manual actions are required (such as brushing and flushing) to clean the instruments. Because the channels can be one millimetre in diameter, “extensive biofilms” - that is, gunk - remain after cleaning. Cleaning the probes costs \$US11 to \$US37 each - more than mere lunch money.

Coris delivers a “novel sonicated mist” that penetrates probe surfaces including the body handle and all crevices, thus reducing the risk of pathogens. As with the Trophons, the Corises emit harmless oxygen and water.

The company says 60 million endoscopies are done each year in the US, Europe, and Australia, with gastroscopies (especially colonoscopies) accounting for 45 million.

Mr Kavanagh expects Coris to have “at least the same” financial impact as Trophon, although the revenue from equipment sales are likely to be lower, because the Corises are placed centrally, rather than at the point of care (as with the Trophons). But the units are likely to be used more, resulting in higher consumables income.

“With Coris we clearly understand the problem and have been able to innovate in a very complex area,” Mr Kavanagh says.

## **Star spangled spanner in the works**

Not for the first time, the FDA recently showed “it’s my way or the highway” by demanding that testing of Nanosonics’ key new product, Coris, be carried out on its shores and not here. An FDA submission under the agency’s de novo (novel device) route is now expected in the March quarter of 2024.

Mr Kavanagh says the FDA wanted to see more work in relation to “human factors” - that is, ensuring the instrument can be easily used and not misused.

He says the FDA’s demands were a blessing in disguise: “It’s lot better to know [the requirements] before you submit for approval, rather than to have to go back and re-do them.”

Nanosonics is part of the FDA’s Safer Technologies Program (Step), a ‘concierge’ style process to improve communication with the agency and streamline the route to approval.

“The review does not bypass statutory requirements or make it faster, but it certainly helps the cause,” Mr Kavanagh says.

## **Finances and performance**

Consolidating its post-pandemic recovery, Nanosonics reported revenue of \$166 million, 38 percent higher, in the year to June 2023.

Net profit surged 431 percent to \$19.9 million. Adjusted to exclude expenditure on growth initiatives, earnings from the existing sales grew 175 percent to \$32.5 million.

At August's full-year profit, management guided to 15 to 20 percent revenue growth in 2023-'24. At last week's AGM, management declined to update the current-year outlook, given only four months of it had elapsed.

The 2022-'23 research and development bill amounted to \$29.5 million, up 32 percent and attributable mainly to the Coris program.

The R&D spend accounted for 18 percent of revenue, compared with the industry standard of 12 percent. But Mr Kavanagh says this proportion will decline as the company matures and grows its revenue.

Capital sales (that is, Trophon units) accounted for 67 percent of total revenue (\$54.2 million, up 44 percent), with consumables (the cartridges) and service income accounting for the rest (112 million, up 35 percent).

Over the last 12 months, Nanosonics shares have traded between \$3.28 (mid-October 2022) and \$5.80 (late April this year). They peaked at a record \$8 in December 2020 and have traded as low as 18 cents (November 2018).

## **What the brokers say**

Broker Wilsons' Nano-watcher Dr Shane Storey says the company's full-year earnings beat expectations, but the Coris delay announcement was "clearly the biggest disappointment".

He notes the "ongoing dismay of investors who have long awaited Nanosonics' second product" and the firm chalks in a modest \$12.8 million of inaugural Coris revenue in the 2025-'26 year.

Dr Storey still rates Nanosonics as "overweight" – which is current stockbroker-marketing-speak for "a buy" - but has downgraded his valuation from \$6 to \$5.46.

RBC Capital Markets concurs the profit was okay, but lower-than-expected new Trophon sales, the Coris delay and weak guidance were all negatives.

For its two bobs' worth, Citi rates the stock a sell, with a revised valuation from \$4.20 a share to \$3.90.

"It remains unclear when markets outside the US will become material," the firm harrumphs.

## **Dr Boreham's diagnosis:**

Is Nanosonics undervalued?

Mr Kavanagh notes the Trophon business generated a pre-tax profit of \$44 million, which means the company would be wildly profitable if it simply stopped investing in new products.

The installed Trophon base is still ticking up and with the average unit now seven years old, more users will be angling for an upgrade.

Management cites an "installed base opportunity" of 140,000 units: 60,000 in the US, 40,000 in Europe/Middle East and 40,000 in Asia Pacific.

If Crucible's slide rule is correct, Nanosonics has a 23 percent overall market penetration. But this is skewed by a market share approaching 50 percent in the US and only five percent in Europe and the Asia Pacific (albeit with 85 percent saturation of the Australian market).

Not surpassing, the company is ramping up its sales efforts in the UK, Ireland, and Germany, while it's got more than a weather eye on the germ-obsessed Japanese market.

One broker opines the company is "catalyst-less" until Coris gets to market - a claim with which Mr Kavanagh can't agree.

"The growth prospects for the business for Trophon alone are still quite robust and the business continues to evolve," he says.

As one market luminary - possibly Warren Buffett - once said: the share market is the transfer of wealth from the impatient to the patient.

On that note, Nanosonics' 15 percent share slide since its financial results might present an opportunity for the true believers.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he likes to think he posits probing questions while keeping clean at the same time.***