Biotech Daily

Friday March 28, 2025

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.16 percent on Friday March 28, 2025, with the ASX200 up 13.0 points to 7,982.0 points. Sixteen of the Biotech Daily Top 40 companies were up, 16 fell, six traded unchanged and two were untraded.

Nova Eye was the best, up 1.1 cents or 11.7 percent to 10.5 cents, with 769,363 shares traded; followed by Prescient, up 0.5 cents or 11.6 percent to 4.8 cents, with 530,105 shares traded. Orthocell climbed 6.4 percent; Medadvisor and Proteomics were up more than four percent; SDI was up three percent; Avita and Neuren rose more than two percent; Alcidion, Cyclopharm, Immutep, Micro-X, Paradigm and Starpharma were up one percent or more; with CSL, Nanosonics and Telix up by less than one percent.

4D Medical led the falls, down 2.5 cents or 7.9 percent to 29 cents, with three million shares traded. Aroa and Mesoblast lost more than six percent; Actinogen and Atomo were down more than five percent; Compumedics and Medical Developments fell more than four percent; EBR, Polynovo and Pro Medicus were down more than three percent; Clarity, Dimerix, Impedimed and Syntara shed more than two percent; Cynata was down 1.3 percent; with Clinuvel, Cochlear, Emvision and Resmed down less than one percent.

DR BOREHAM'S CRUCIBLE: NANOSONICS

By TIM BOREHAM

ASX Code: NAN

Share price: $4.61

Shares on issue: 303,590,974

Market cap: $1.40 billion

CEO: Michael Kavanagh

Board: Steve Sargent (chair), Mr Kavanagh, Marie McDonald, Dr Lisa McIntyre, Dr Larry Marshall, Dr Tracey Batten, Gerard Dalbosco

Financials (half year to December 2024): revenue $93.6 million (up 18%), net profit $9.8 million (up 58%), earnings before interest and tax $8.7 million (up 187%), cash of $144.4 million (up 22.1%)

Major identifiable shareholders: Selector Funds Management 7.89%, ECP Asset Management 6.4%, Yarra Capital Management 6.3%, Maurie Stang 6.2%, Bernard Stang 5.4%

Nanosonics chief Michael Kavanagh says he's "very proud" of the device maker's ability to win US Food and Drug Administration (FDA) approval for its second medical probe sterilization device, Coris.

He's chuffed just not just by the assent, but because the device was approved under the more difficult de novo (new device) pathway.

Overwhelmingly, the FDA has approved devices under the 510(k) existing (predicate) device route.

"That's significant for an Australian company, it's not trivial," he says.

"[Coris] promises to be the benchmark against which all new devices will be measured and personally I'm very proud of it."

Initially, Coris is approved for cleaning colonoscopy probes, but the company plans further FDA submissions to expand these indications to cover all major categories of flexible endoscopes "over time."

The FDA assent isn't the first rodeo for Nanosonics, given its inaugural Trophon device (for ultra-sound probes) has been commercialized since 2009.

Nanosonics shares soared 15 percent on the day of the March 20 announcement.

From a nano-cap company to rather a big one

With a $1.4 billion market capitalization, Nanosonics is our third-biggest device company behind Cochlear and Resmed (and ahead of the $880 million market cap Polynovo and not including radiotherapy firm Telix).

The Sydney-based Nanosonics was founded in 2001 by Maurie Stang, who was 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.

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

The company launched the Trophon EPRs in 2009, which the FDA approved in 2011.

The company then launched the Trophon 2 – which incorporates a module to audit the procedures – in 2018.

In May 2011, the company struck an exclusive distribution with GE Healthcare for US and Canadian Trophon distribution (and non-exclusive rights elsewhere).

This compact was downgraded in early 2022 and the company has reverted mainly to direct sales, via a 130-strong US sales force.

A former Cochlear marketing executive, Mr Kavanagh joined the company in July 2012 before becoming CEO in October 2013, replacing long-time CEO Dr Ron Weinberger.

What's a Trophon?

About the size of a microwave, Trophons deliver a "sonicated mist" to sanitize probes to certified high level disinfectant (HLD) standards.

The units protect against nasty bugs including drug-resistant bacteria, fungi, blood-borne viruses and venereal diseases.

The Trophon process takes seven minutes and produces harmless water and oxygen, as a by-product of the disinfectant hydrogen peroxide.

To date, probe sterilizing has involved a time-consuming procedure in an isolating room with dangerous chemicals.

As well as selling (or leasing) the units, Nanosonics also makes money – more money, in fact - from servicing and consumables.

The latter consists mainly of the hydrogen peroxide canisters.

A better way? Of Coris, of Coris

Mr Kavanagh says the only common thread of Trophon and Coris is that they “are both owned by Nanosonics” (and they are both medical equipment cleaners.)

Coris is for cleaning flexible endoscopes, which have “complex channels” prone to biofilm build-up.

The key element is the interior lumens - channels - notably thin auxiliary air and water conduits to clean the endoscope’s camera and light source.

Some of these lumens are one millimetre in diameter and 3.5 metres in length, so we’re not talking about a quick spray with Handy Andy.

“When it comes to the mechanisms of action, the chemistry and the tech it is unique,” Mr Kavanagh says.

In short, Coris uses finely engineered frictional forces to debride the contamination from the walls of the endoscope lumens.

Mr Kavanagh dubs Coris as a “fantastic example of purpose meeting science which leads to innovation”.

The purpose of the device is clear.

In the US, around 35,000 adverse events with endoscopes occur annually and most are due to re-processing (re-cleaning) issues.

About 60 million endoscopies are undertaken globally annually, about one-third in the US.

The “science” refers to the need to understand the internal architecture of an endoscope.

Mr Kavanagh describes Coris as a “true marriage between physics, chemistry and biology”.

A key reason for the FDA approval was that Coris can be used intuitively by hospital staff.

“We call it advanced simplification,” Mr Kavanagh says. “Take the hood off and Coris is highly complex engineering. Put it back on and it is very simple to use.”

The size of the Coris prize

The company is coy on the likely price of the Corises, but because they are more sophisticated than Trophons they will be higher priced (see below).

The US addressable market of 15,000 units compares with 60,000 for Trophons, because the Corises will be more centrally located in endoscopy departments.

But they will be used more, which means greater consumables sales and - in total - more revenue over the life of the units.

Nanosonics' $145 million cash balance present the opportunity to fund or subsidize the initial Coris units - at least in some cases.

"Our cash balance gives us a large degree of optionality in respect of the business model and the rollout of the capital equipment," Mr Kavanagh says.

Broker Wilsons assumes a 30 percent market penetration, implying peak sales of $US250 million.

What now?

Nanosonics plans a staged launch Coris in the US in the December 2025 half, targeting selected hospitals to gain initial experience. A full rollout is planned by June 30, 2026.

Nanosonics will then apply for other applications that may include gastroscopies, enteroscopies, endoscopic ultrasounds and bronchoscopies.

The company is working on the requisite approvals in the UK, Europe and Australia, which are expected to be in place by the September quarter.

Finances and performance:

Nanosonics posted a December half year net profit of $9.8 million, 58.2 percent higher, with revenue gaining 17.5 percent to $93.6 million.

Capital equipment - sales of the units - chipped in $24.4 million, up 11 percent. Sales of consumables - the canisters and the like - contributed $69.2 million, up 20 percent.

North American revenue (mainly from the US) gained 17 percent to $84.7 million - 90 percent of total turnover.

Europe contributed $5.9 million, up three percent. Asia Pacific revenues - mainly from Australia - were flat at $3 million.

Australia's static result reflects the reality that the Trophons already have 70 percent market penetration in our wide brown land.

Research and development costs were $16.4 million, 24 percent of total expenses and 17 percent of revenue. Two-thirds of these costs pertained to Coris development.

Just to spice things up, the company cites a pre-tax 'Trophon-only' profit of $25.6 million, up 41 percent. This in effect is what Nanosonics would have made without other development costs, notably for Coris.

Confident management has upgraded full-year guidance to revenue growth of 11 to 14 percent, compared with the eight to 12 percent guided to earlier.

Nanosonics shares have risen steadily over the past year, from $2.64 in early April last year to the March 21 peak of $5.02.

The stock hit a pandemic-era record of $8 in December 2020.

Trophon numbers

Nanosonics reports that 1,730 Trophons were installed in the December half year. Allowing for a further 680 upgraded units, the installed base stood at 35,840.

Management notes a “significant upgrade opportunity” in North America (read: the US) with 940 new units installed.

A further 610 units were upgraded to Trophon 2s.

“In addition to continuing to grow the installed base, a core component of the North America growth strategy is to expand customer value for the existing 31,000 installed base,” the company says.

European installations grew more slowly than expected - 70 were added - but the company sees strong “adoption fundamentals” in the UK and Ireland.

Australian and New Zealand sales were lower, but that’s what happens when you account for 70 percent of the market already.

“Investment continues in Japan where the focus remains on market development to establish local [disinfection] guidelines,” the company says.

Trophon 2 units have a list price of $US7,950 ($A12,640) each, but ageing Trophon EPRs are advertised on-line for as little as $US200 (albeit with a hefty delivery fee).

Trumping Trump’s tariffs

Currently, Nanosonics makes the devices and at its Macquarie Park digs in Western Sydney.

In 2021, the company announced plans to more than double its manufacturing capacity.

But in the Trumpian made-in-America era, a US manufacturing presence is highly desirable.

In pre-Trumpian days, the company decided to expand its existing Indianapolis facility, to make Trophon and Coris consumables.

The facility has just been approved and is expected to be ready to go in the December half-year.

Mr Kavanagh says the company was motivated more by easier customer access and the environmental benefit of not shipping the material for long distances.

“It was serendipitous. It was part of our evolutionary strategy.”

He says the company remains committed to manufacturing in Australia and hopes the sector will remain tariff-free.

If not, the impact will be subdued because of the importance of consumables in the revenue mix.

“The world is a crazy place at the moment and you need to keep your options open,” Mr Kavanagh says. “Everyone is waiting to see what Trump does.”

Dr Boreham’s diagnosis:

The company first had the idea about flexible endoscope cleaning seven years ago.

“We had many failures but learned from them,” Mr Kavanagh says.

“There were many times we could have given up, but didn’t.”

Of course, gaining marketing approval is one thing and achieving sales is another.

Broker Morgans notes that “adoption rates typically are not linear, so further updates over the coming 12 months will aid the staging of market execution”.

Having done it all before with Trophon, the company has the benefit of experience.

“We have proven we can take a technology into North America and establish it as the standard of care,” Mr Kavanagh says.

Meanwhile the half-year results show the company is making a decent fist at maintaining Trophon growth, helped along by the fact that close to one-third of the machines are more than seven years old and need replacing.

“Nanosonics is now a two-product company,” Mr Kavanagh says.

“The Trophon show is definitely not over.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has done it all before but not always as successfully as Nanosonics.

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

The US Department of Health and Human Services (HHS) says it will cut “about 10,000 full-time employees” from all agencies, including the Food and Drug Administration.
A media release from the Department said the restructuring would save $US1.8 billion ($A2.9 billion) a year and “serve multiple goals without impacting critical services”.
The HHS said that, with other efforts including early retirement, its workforce would be reduced from 82,000 full-time employees to 62,000 full-time employees.
The Department said it currently had “many redundant units” and would consolidate its 28 divisions into 15 divisions, including a “new Administration for a Healthy America, or AHA, and will centralize core functions such as human resources, information technology, procurement, external affairs and policy”.
The HSS said its regional offices would be reduced from 10 to five.
The Department said it would prioritize “ending America’s epidemic of chronic illness by focusing on safe, wholesome food, clean water, and the elimination of environmental toxins”.
HHS secretary Robert F Kennedy Junior said the Department wasn’t “just reducing bureaucratic sprawl”.
“We are realigning the organization with its core mission and our new priorities in reversing the chronic disease epidemic,” Mr Kennedy said.
“Over time, bureaucracies like HHS become wasteful and inefficient even when most of their staff are dedicated and competent civil servants,” Mr Kennedy said.
“This overhaul will be a win-win for taxpayers and for those that HHS serves,” he said.
“That’s the entire American public, because our goal is to Make America Healthy Again (sic),” Mr Kennedy said.

ARTRYA

Artrya says it has US Food and Drug Administration 510(k) clearance to commercialize and sell its Salix coronary anatomy platform for coronary plaque identification.
Last year, Artrya said it filed a 510(k) application to the FDA for approval of its Salix coronary anatomy product; and last month, the company said it responded to unspecified FDA queries about its Salix application as part of the “review process to clarify technical details, request further data, or seek additional evidence to support claims made in the application” (BD: Sep 30, 2024; Feb 28, 2025).
Today, Artrya said the artificial intelligence (A.I.)-based Salix for detecting coronary artery disease imaging markers gave a “non-invasive, point-of-care assessment within 10 minutes of a coronary computed tomography angiogram (CCTA) scan being taken”.
The company said the system allowed physicians “to quickly identify, analyze and edit the extent and type of arterial plaque, the main cause of heart disease, along with stenosis and calcification, which provide a holistic view of patient risk”.
Artrya said it would work with its US partners to expand access to Salix in 15 hospitals, and clinical centres in the southeast US (BD: Jun 11, 2024).
Artrya chief executive officer Mathew Regan said that for decades, heart disease had “been treated reactively, waiting for symptoms to appear before taking action”.
“Salix is the first major advancement in 50 years that delivers a comprehensive point-of-care assessment within just 10 minutes,” Mr Regan said.
Mr Regan said FDA clearance for Salix coronary anatomy provided “valuable insights into the FDA process” which we will use to expedite the clearance of submissions, starting with Salix coronary plaque and then Salix coronary flow expected this year.
Artrya was up seven cents or 8.75 percent to 87 cents with 3.1 million shares traded.

AVECHO BIOTECHNOLOGY

Avecho says it has received $US3 million ($A4.8 million) from Sandoz Group AG for the commercial rights to its marijuana capsule for insomnia in Australia for 10 years.

Earlier this month, Avecho said the Basel, Switzerland-based Sandoz would pay $US3 million up-front for the exclusive right to develop and sell its tocopheryl phosphate mixture (TPM) cannabidiol (CBD) capsule for insomnia in Australia (BD: Mar 3, 2025).

At that time, the company said the deal included $US16 million in potential milestone payments as well as tiered royalties ranging from 14 percent to 19 percent on sales; and it would retain the right to commercialize the product in all other jurisdictions, with Sandoz granted a first right of refusal.

Today, Avecho said it aimed for its capsule to be the first pharmaceutical cannabidiol product registered with the Australian Therapeutics Goods Administration as an over-the-counter medicine.

The company said would continue to fund and oversee its ongoing phase III trial, which, if successful, would lead to it working with Sandoz to secure TGA approval.

Avecho chief executive officer Dr Paul Gavin said the up-front licencing fee from Sandoz strengthened the company's "financial position, providing the necessary support to accelerate ongoing research and commercial activities,".

"With ample capital to complete our pivotal phase III trial through to the interim analysis, our primary focus is to advance the study to this key inflection point as swiftly as possible," Dr Gavin said.

Avecho was unchanged at 0.5 cents with 83.6 million shares traded.

RENERVE

Renerve says its 23-patient study shows its Nervaign Nerve cuff led to "significantly lower post-surgery measures of pain" in the foot or ankle pain ($p = 0.021$).

Renerve said the study compared 13 patients treated with Nervalign to 10 patients treated with standard-of-care following peripheral nerve repair surgery, with endpoints being an improvement in pain score and whether the patient "would elect to have the procedure again following the surgery and their recovery period".

The company said the Nervalign group reported an average reduction in Kaiser Permanente pain score from 7.1 to 0.4, a 94.4 percent improvement, compared to the standard-of-care average reduction from 7.1 to 3.3, a 53.5 percent improvement.

Renerve said 12 patients treated with Nervalign, or 92.3 percent "would elect to have their surgery again", compared to seven patients, or 70 percent, treated with standard-of-care.

The company said the study results showed "the benefits to patient outcomes from the use of the Nervalign nerve cuff as a protection for a recently repaired nerve after surgery".

Renerve managing-director Dr Julian Chick said the data were "very significant results for the development of Renerve's products, as they highlight the utility of the Nervalign nerve cuff in reducing patients' pain following peripheral nerve surgery".

"The results clearly demonstrate the patient benefits that follow from the proper repair and regeneration of a nerve that is returned to normal function post-surgery," Dr Chick said.

"The Nervalign nerve cuff facilitates the patient's repair process is protected during the initial post-operative recovery and regeneration period," Dr Chick said.

"Thereafter, because the nerve cuff is absorbed naturally after six months, there is no longer a lasting 'foreign body' at the site of repair to create potential complications for the patient," Dr Chick said.

Renerve was up three cents or 26.1 percent to 14.5 cents with 7.85 million shares traded.

COMPUMEDICS

Compumedics says it has been the victim of a cyber security incident caused by a ransomware attack, impacting data on “some” of its systems in Australia and the US.
Compumedics said all servers were taken offline as a precaution, with its Australian servers being restored as they were checked.
The company said some of its Nexus 360 web-based patient data and laboratory management system customers were still offline.
Compumedics said it was taking steps to contain and remediate the incident and secure its network, with the impacted data backed-up daily and an independent investigation underway to “understand what happened, its impact on customers’ data including their patient reports and to ensure its systems are secure”.
The company said it had made a report to the Australian Cyber Security Centre and would determine what further notifications were required as the investigation continued.
Compumedics fell 1.5 cents or 4.3 percent to 33.5 cents.

RACE ONCOLOGY

Race says it has initiated the first Australian site for its up-to 53-patient, phase I trial of RC220 bisantrene in solid tumors at Sydney’s Southside Cancer Centre.
Earlier this month, the company said it had ethics approval from Adelaide’s Bellberry for an open-label, phase I, safety, tolerability and pharmaco-kinetics trial of RC220 bisantrene alone and with doxorubicin for advanced solid tumors (BD: Mar 14, 2025).
At that time, Race said the study included a dose escalation stage one, dosing up-to 33 patients with an intra-venous infusion of RC2230 bisantrene alone on day-1, followed by a combination of RC220 and doxorubicin on a 21-day cycle.
The company said the final number of stage one patients was expected to most likely be in the range of 12 to 18 patients.
Today, Race said it was waiting for governance approval to activate the site for patient recruitment, with the trial to be conducted in Australia, Hong Kong and South Korea.
Race managing-director Dr Daniel Tillett said the company was “pleased to have reached the milestone of our first clinical site initiation in preparation for patient enrolment as soon as we receive governance approval”.
Race was up two cents or 1.8 percent to $1.15.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says the Australian Patent Office has granted it a “second generation patent” for its Oxidx finger-prick blood test for measuring oxidative stress levels.
Proteomics said that the patent, titled ‘Methods for measuring relative oxidation levels of a protein’, would protect its intellectual property until March 2039.
The company said it had second generation patent approval in Europe and Japan, with the patent pending in the US, Singapore, India and China.
Proteomics said its original patent protection in Australia and the US patents were valid until 2026 and 2028, respectively.
Proteomics managing-director Dr Richard Lipscombe said the second-generation patent was an extension to the life span for intellectual property protection of Oxidx in Australia.
“The Oxidx test is attracting wide-ranging interest, from sports shoe companies to horse trainers, and we are looking forward to bringing it to market in the coming months,” Dr Lipscombe said.
Proteomics was up two cents or 4.1 percent to 50.5 cents.

AUSBIOTECH

Ausbiotech says it has launched its Industry Growth Program for commercializing and supporting small-to-medium life sciences businesses and start-ups.

Last year, Ausbiotech said it was appointed an industry partner for the Federal Government's Industry Growth Program (BD: Aug 14, 2024).

Today, the industry organization said the program was created by the Federal Government to support small and medium-sized enterprises and start-ups that build "Australian capabilities in priority areas" including life sciences, as defined by the Government's $15 billion National Reconstruction Fund.

Ausbiotech said 28 Australian biotechnology and medical technology companies were admitted to the first cohort of the program at an event held at Brisbane's Translational Research Institute.

The organization said the program would help businesses to "learn and grow along their company's innovation and commercialization journey".

Ausbiotech said as part of the program it would develop a commercialization advisory support service using its "3,000-strong industry network and almost 40 years of expertise to help translate and advance breakthrough research into globally competitive companies".

Ausbiotech chief executive officer Rebekah Cassidy said the program was "focused on developing capabilities across the commercial pipeline, growing international partnerships and enabling opportunities for access to capital to these start-ups".

"It's one of the many ways we're supporting the growth of home-grown health innovation to support the long-term health of Australians and the wealth of our nation," Ms Cassidy said.

BIO NEW SOUTH WALES

Bio NSW says it began its inaugural 'Bioinvest Catalyst' event at a dinner last night, to be followed by a mid-year follow-up event and formal investor pitch in November.

In 2023, the Sydney-based Bio NSW said it would formally launch in Sydney, modelled on similar organizations, such as the Bio-Melbourne Network and Life Sciences Queensland (BD: Aug 22, 2023).

Today, the industry organization said the three-part event would "foster meaningful connections, ultimately translating into investment deals, capital deployment, and an accelerated expansion of the life sciences ecosystem in NSW".

Bio NSW said the state was "home to 40 percent of Australia's life sciences companies, totaling 2,905 nationwide, supporting over 32,000 direct, high-value jobs and more than 100,000 indirect roles".

The organization said the "'Bioinvest Catalyst' series aligns with national strategies to position Australia as a leader in the global life sciences industry".

Bio NSW founding chair Dr Brad Walsh said the organization was "established to champion and accelerate the life sciences sector in NSW, and I am pleased to see the investment committee delivering on this commitment to our members".

"The sector is thriving in NSW, providing important, lifesaving medicines, medical devices and diagnostics for patients around the globe," Dr Walsh said.

"The 'Bioinvest Catalyst' events encompass the first step in a broader strategy to increase sector-specific funding and drive long-term growth," Dr Walsh said.

IMRICOR MEDICAL SYSTEMS

One Funds Management Ltd says its Imricor holding was diluted below the five percent substantial threshold due to the issue of shares on March 28, 2025.

Last week, Imricor said it raised $70.0 million at $1.41 per Chess depository interest (CDI), at no discount to its last traded price, in a placement to institutional and sophisticated investors (BD: Mar 20, 2025).

In 2022, the Sydney-based One Funds said it increased its substantial shareholding from 7,180,000 shares (5.05%) to 9,500,000 shares (6.63%) (BD: Jun 28, 2022).

According to its most recent filing, Imricor had 319,985,092 Chess depository interests on issue, meaning that One Funds' 9,500,000 share-holding amounted to about 2.97 percent of the company following the capital raising.

Imricor fell six cents or 3.9 percent to $1.475.