Biotech Daily

Friday March 7, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PERCHERON UP 9%; POLYNOVO DOWN 13%**

*** DR BOREHAM'S CRUCIBLE: POLYNOVO**

*** FEDERAL $143m FOR GENOMIC CANCER PROFILING PROGRAMS**

*** MCRI $10m WELLCOME GRANT FOR STREP-A VACCINE**

*** TELIX M-D CALLS FOR $500m NUCLEAR MEDICINE FUND**

*** DR ROBYN ELLIOTT MAY REPLACE POLYNOVO CEO SWAMI RAOTE**

*** RENERVE RECEIVES $140k FEDERAL R&D TAX INCENTIVE; TOTAL $517k**

*** ANTERIS APPOINTS COO DAVID ST DENIS DIRECTOR; $752k PA**

*** CAMBIUM APPOINTS 4% SHAREHOLDER LI-CHIEN CHIU DIRECTOR**

MARKET REPORT

The Australian stock market was down 1.8 percent on Friday March 7, 2025, with the ASX200 down 146.5 points to 7,948.2 points.

Eight of the Biotech Daily Top 40 companies were up, 26 fell, four traded unchanged and two were untraded.

Percheron was the best of the eight, up 0.1 cents or 9.1 percent to 1.2 cents, with 7.1 million shares traded. Emvision climbed five percent; Impedimed improved 4.8 percent; Aroa, Imugene and Paradigm rose two percent or more; 4D Medical and Syntara were both up 1.4 percent; with Resmed up by 0.65 percent.

Polynovo led the falls (see below), down 18 cents or 13.0 percent to $1.20, with 8.8 million shares traded. Medadvisor lost 11.1 percent; Medical Developments was down 6.1 percent; Atomo, Clarity, Immutep and Mesoblast were down five percent or more; Alcidion, Curvebeam, Cyclopharm, Nova Eye, Pro Medicus and Resonance fell more than four percent; Avita, Cochlear, Dimerix and Proteomics were down three percent or more; Nanosonics, Neuren, Opthea, Orthocell and Prescient shed more than two percent; Amplia, Clinuvel, EBR, Genetic Signatures, SDI and Telix were down one percent or more; with CSL down by 0.9 percent.

DR BOREHAM'S CRUCIBLE: POLYNOVO

By TIM BOREHAM

ASX code: PNV

Share price: $1.20; **Shares on issue:** 690,842,991; **Market cap:** $829.0 million

Chief executive officer: Swami Raote (potentially to be replaced by Dr Robyn Elliott as interim CEO)

Board: David Williams (chair), Dr Robyn Elliott, Christine Emmanuel-Donnelly, Leon Hoare, Andrew Lumsden

Financials (December half 2024): revenue $59.9 million (up 25%), earnings before interest, tax depreciation and amortization $7.25 million (up 276%), net profit $3.3 million (up 24%), cash of $30.4 million (down 33%).

Identifiable major holders: Fidelity Investments 6.5%, David Williams 3%

Corporate chieftains by nature are bemused by negative market reactions to seemingly robust financial results – and there were plenty of surprise movements in the healthcare sector during this year's profit reporting season.

But Polynovo chairman David Williams is simply "flabbergasted".

"I find myself in an extraordinary position to try to explain only a 28 percent growth rate, where in any other company or country you would be pretty happy with that."

He was speaking after the company's first (half) results last week, which resulted in the stock being birched by 8.5 percent on the day.

Driving home the point, he adds that sector titans Cochlear and CSL would be applauded for such growth.

The Polynovo evolution

Polynovo's commercialization has been on the back of Novosorb, its bio-resorbable lattice for complex wounds, burns and reconstructions.

As with so many biotechs, Polynovo evolved from interesting roots, having been known as Calzada and, earlier, Metabolic Pharmaceuticals. Metabolic owned AOD9604, a peptide that failed a large and very expensive obesity trial. The controversial molecule then became embroiled in a drug scandal at the Essendon Football Club.

AOD9604 is well-loved by bodybuilders and was sold to Lateral Innovations, a company associated with former Metabolic director Dr David Kenley, in April 2015 for $1.5 million.

The completely different Novosorb technology was developed by the Commonwealth Scientific and Industrial Research Organisation and spun-off in 2004 as Polynovo Materials, in a joint venture with Xceed Biotechnology. Metabolic bought 60 percent of this venture in 2008.

In 2009, Metabolic changed its name to Calzada and moved to full ownership of Polynovo in 2010 and in 2014, the company appointed David Williams as a director, then chairman and adopted the Polynovo moniker.

The current CEO, Swami Raote replaced Paul Brennan in 2022.

Mr Brennan built the company from minnow to hero but departed because of what Mr Williams dubbed as “increasing differences with the board in relation to Paul’s interaction with the company’s senior management team and his management style”.

The Florida-based Mr Swami had a 30-year career at Johnson & Johnson in roles including over-the-counter goods and pharmaceutical products and devices.

He then headed J&J Vision Care and was a senior advisor supporting the rollout of a digital health platform to Indian citizens.

Polynovo responded to this week’s media speculation regarding corporate governance issues, by announcing the proposed departure of Mr Raote. But we digress.

Burns are only the beginning

In a short commercial life of just over seven years, Polynovo sells Novosorb in 46 countries and has serviced 67,000 patients to date.

The company claims a leading position in difficult burns dressings in the US, the UK, Germany as well as here and in New Zealand.

In 2014, an initial product called Novopore - a dressing for pressure sores - was approved in the US and Europe.

In late 2015, the US Food and Drug Administration approved Novosorb BTM - as in biodegradable temporizing matrix - for reconstructive and surgical applications such as venous and diabetic ulcers and surgical and trauma uses.

A synthetic surgical product, Novosorb obviates the risks around rejection and bacteria - and religious and other objections towards biological products made from ovine or bovine collagen and porcine parts.

The foam itself looks like something you wrap a parcel in and then chuck away – but there’s a lot more to it than that.

In September 2022, the FDA approved the extension product for soft tissue regeneration, Novosorb MTX, which is BTM without the temporizing laminate.

All the way with MTX

MTX (matrix) has wide applications in trauma, plastic and reconstructive surgery - and is the key to the company's fortunes.

Polynovo launched MTX in the US in April 2024. The product generated $2.1 million in the December half and has racked up $3 million of sales since debut. The company expects MTX to replace BTM in the next three to five years, but with the addressable market greatly expanded as opposed to BTM sales being cannibalized.

The company has several entreaties before the FDA to expand the indications for MTX with different thicknesses and sizes. It plans to file for Syntrel, a hernia mesh, by March 2026, with a launch that year "if we get the right support from the FDA".

Syntrix (a plastic reconstructive mesh) is due for filing by June 2026.

Separately, other work is being undertaken for oncological applications, limb salvages and vascular wounds.

Not everything has gone Polynovo's way: last year the company abandoned a diabetic foot ulcer trial, on the back of what broker Bell Potter describes as "indifferent" results.

BARDA not be a disaster

In its munificence, BARDA is funding a paediatric trial for severe full-thickness burns at a cost of $35 million to $50 million.

BARDA is the US doomsday preparation authority, the Biomedical Advanced Research and Development Authority.

Dubbed CP-003, the trial has enrolled 120 patients, with an FDA pre-market approval application expected to be filed by July 2025.

Unless the FDA stops the approval clock for pesky questions, a decision is expected six months later.

"The BARDA trial is the most complex trial anyone could undertake," Mr Raote says. "It was a very hard trial to execute."

He says a successfully launched product "will give us enormous traction, not just with burns surgeons but plastic and reconstructive surgeons".

Finances and performance

Polynovo's group revenue increased 25 percent to $59.9 million.

The company reported a net profit of $3.3 million - 24 percent higher - having made a maiden profit of $5.2 million in the year to June 30, 2024.

The company treated 14,690 patients in the half year, compared to 22,205 in the full 2023-’24 year.

Novosorb sales accounted for $54.1 million of this turnover, with BARDA contributing the remaining $5.4 million (for product used in the trials).

Revenue from the US – the company’s maturest market – grew 28 percent to $41.2 million.

‘Rest of world’ revenue grew 28.6 percent to $12.9 million, albeit with a “bit of a tail-off” in the year to date.

In Europe, where the company leads the market in skin substitute procedures in Germany and the UK, revenue grew an “exceptional” 50 percent.

The region accounts for 14 percent of total sales. Europe now outpaces the US in terms of the number of units sold and the variety of procedures.

Asia Pacific revenue grew at a more sedate 10 percent, mainly because of fewer burns procedures in Australia.

Over the last 12 months, Polynovo shares have danced between $1.41 (on May 26 this year) and $2.72 (August 1 last year).

The shares peaked at $3.95 on Christmas Eve 2020 – but the Santa rally couldn’t be maintained.

Ten years ago, the stock was worth a mere eight cents and - yep - no-one rang the bell to buy by-the-wheelbarrow load.

Growth avenues

European revenues are inherently lumpy, given variable price mix, the incidence of public tendering and the company’s entry into new markets and geographies.

Speaking of which, Mr Raote is enthused about the company’s prospects in Turkey, despite reimbursement being lower.

The company recently signed up a distributor in Japan, “one of the best markets the company has ever laid its hands on”.

Polynovo also plans to enter the Middle Kingdom market and plans to launch a registration process “soon”.

To support all this growth, it has invested in a new manufacturing and research and development facility in Port Melbourne.

Operational by the end of the year, the plant will increase Polynovo’s capacity to $500 million of annual sales, well above the (underused) $180 million-a-year capacity.

Not losing sleep over Trump tariffs

Given the company makes its gear in Australia, the elephant is in the room is whether Trump's tariffs will stymie Polynovo's growth in its most important market.

The short answer is "no".

Mr Williams' intel is that Australia generally is not a Trumpian tariff priority, because we buy more stuff from the Yanks - including drugs and medical devices - than the few jars of Vegemite we send there.

The company also has considerable inventory already in the US.

"If the worst came to the worst … there's a fair bit of distance between us and some of our competitors in terms of pricing," Mr Williams says.

In other words, the company could absorb any tariff impact and remain competitive.

"I'm not losing any sleep over it."

A more pertinent question is whether the shake-out of the FDA will affect the approval process for the expanded indications for which the company has applied (or intends to apply).

"By anyone's standards, the new guy at the FDA (new commissioner Martin "Marty" Makary) is unpredictable and anything can happen."

An unpredictable Trump nominee? Who would have thought?

Mr Williams adds that - if anything - the FDA's bureaucracy-ladened process could be hastened.

Explaining the sell down - sorta

So why the harsh sell down?

The market's reaction is vexing given the company had pre-released its first-half revenue numbers in January.

Wilsons analyst Dr Shane Storey opines that the profit missed expectations, "but not materially".

The real 'culprit' was Polynovo's valuation in the first place.

Historically, the stock has traded at 12 times enterprise value (market capitalization less net cash on hand) to revenue.

This compares with a median 2.8 times for comparative wound care companies.

The firm values the stock at six times revenue, equating to a share price of $1.85.

Macquarie Equities says the company's underlying earnings fell 13 percent, accounting for foreign exchange tweaks and twerks.

The firm's values Polynovo at $2.80 per share, similar to broker Morgans' $2.85 a share appraisal.

Dr Boreham's diagnosis:

Mr Williams says Polynovo's revenue should be seen as only the beginning, as the wound care house expands its repertoire from burns to other procedures such as plastic and trauma reconstruction and hernias.

Polynovo doesn't exactly have the synthetic dressing market to itself, but the growth strategy is simple.

"We are going to continue to take market share," he says.

"In some markets we have gone from nothing a few years ago to number one in the market.

"In many markets where we are number two, number one is coming down the track very quickly."

However, Mr Raote adds Polynovo's strategy is to "grow slow to grow fast", which means winning the hearts and skilled hands of surgeons, incrementally.

Despite the emphasis on other new markets - including the aforementioned Turkey - Mr Raote stresses the US will continue to be the company's prime market.

He says the company's US market share remains a "slither" in the US$1 billion a year "complex care" wounds market.

"We have a big runway for growth and will get there in a structured fashion."

Currently, Polynovo is benefiting from the absence of a key rival, Integra Lifesciences. The FDA identified manufacturing problems in mid-2023 and Integra's dermal matrix Surgimed remains off market until next year.

But Mr Raote says competition is intense, with rivals lurking at every corner.

"Multiple players will come into this space and we just have to cope with that reality," he says. "We are not resting on our laurels."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is not resting on his laurels and prefers a comfy mattress to a comfy matrix.

FEDERAL GOVERNMENT

The Federal Government says it will give $143.4 million to two genomic profiling programs for identifying treatments for children and adults with cancer.

A media release from the Minister for Health and Aged Care Mark Butler said the Federal Government would grant $112.6 million to the Sydney-based Children's Cancer Institute for its Zero Childhood Cancer program.

The Government said that through the Zero program samples of a child's cancer and normal tissues were analyzed by the Children's Cancer Institute and partner organizations "at a molecular genomic level to identify treatments and which drugs were most likely to be effective".

The Federal Government said the program had supported more than 2,000 children, with $21 million of the funding to be used to extend the age range of patients to include 19-to-25-year-olds with paediatric-type cancers.

A separate media release from Sydney's Canteen Australia said the expanded program was "expected to support an additional 300 young Australians with cancer each year, totalling approximately 1,300 children and young people annually".

The Government said the Zero program sent patients' doctors a report highlighting critical genetic features of the tumor that could help diagnosis, prognosis and treatment strategies, and where possible, drugs were tested to see how they performed in laboratory models of the individual child's cancer.

The Federal Government media release said that the remaining $30.8 million would be awarded to the Sydney-based Omico's Precision Oncology Screening Platform Enabling Clinical Trials (Prospect) program, which provided "genomic profiling free of charge to patients with advanced, incurable or poor prognosis cancers, to identify potential treatments based on the genetic make-up of that particular tumor".

The Government said the Prospect program was led by Omico with "a range of national and international research and clinical partners" and had matched therapies for more than two-thirds of the 5,000 patients it had profiled.

The Federal Government said that "despite advances in oncology, cancer remains a leading cause of death in Australia for both children and adults, and improvements in survival rates have been uneven across cancer types".

The Government said that last year "more than 40,000 Australians were diagnosed with rare or less common cancers, which account for a quarter of all cancer diagnoses, and a third of all cancer deaths".

Mr Butler said the Government was "ensuring children and adults with rare cancers get the benefit of treatments and therapies that matches the exact genetic make-up of their specific tumor".

"The precision medicine that these world-leading programs make possible is a real game-changer in cancer care, particularly for children and adults with rare or otherwise incurable cancers," Mr Butler said.

"This funding will improve health outcomes for people with rare and less common cancers, by increasing access to treatment options, including to otherwise restricted clinical trials that may increase quality-of-life and extend life expectancy," Mr Butler said.

Children's Cancer Institute executive director Prof Michelle Haber said the children in the Zero program endured "gruelling treatment with life-long physical, emotional and psychological consequences".

"Nowhere else in the world do children with cancer have the opportunity of benefiting from a precision program of this depth and impact," Prof Haber said. "Zero is showing just what's possible when you combine cutting-edge research and technology with a multi-disciplinary team approach to drive clinical care."

MURDOCH CHILDREN'S RESEARCH INSTITUTE

The Murdoch Children's Institute says it has $10 million from London's Wellcome Trust to research streptococcus A human challenge models to develop a vaccine.

The Institute said research with Melbourne's Monash University and the University of Auckland had shown "how antibodies help to protect against contagious bacterial infections" caused by group A streptococcus, or strep A, including 'strep throat'.

The Institute, based at Melbourne's Royal Children's Hospital, said it studied blood and saliva samples from 25 healthy adults before and after being exposed to a low level of streptococcus A in a controlled environment.

The Institute said the study findings were "already contributing to efforts to accelerate the development of a strep A vaccine".

The MCRI said the funding from the London-based charitable foundation the Wellcome Trust, would open a project using its streptococcus A human challenge model in trial participants in Australia and the Gambia to test different ideas about which kinds of immune responses stop people acqquiring streptococcus A infections.

The Institute said "a vaccine that can product similar responses should prevent infections across the whole strep A disease spectrum".

The MCRI said the project would be conducted with Monash University, the Medical Research Council Unit The Gambia, London School of Hygiene and Tropical Medicine, University of New South Wales, the University of Auckland and the University of Sheffield.

The Institute said strep A infections affected about 750 million people and killed more than 500,000 a year, more than influenza, typhoid or whooping cough.

The MCRI said strep A could "also cause severe life-threatening infections like toxic shock syndrome, flesh eating disease and post-infectious illnesses such as acute rheumatic fever, rheumatic heart disease and kidney disease".

The Institute said the study, titled 'Streptococcus pyogenes pharyngitis elicits diverse antibody responses to key vaccine antigens influenced by the imprint of past infections', was published in Nature Communications, with the full article available at: https://www.nature.com/articles/s41467-024-54665-5.

MCRI research lead and grant recipient Dr Joshua Osowicki said "with Strep A being extremely common and every healthy adult having previously encountered it, all the participants had some antibodies against Strep A before the study".

"We found each person's pre-existing antibodies made a difference to what happened when they were exposed during the challenge," Dr Osowicki said.

"For some of the participants, the mixture of antibodies before the challenge helped to protect them from developing a strep throat infection," Dr Osowicki said.

"Even in those who did develop strep throat, with symptoms like a sore throat and fever, it was clear their pre-existing antibodies made a difference to clinical outcomes," Dr Osowicki said.

"The bulk of Strep A research has used animal models but only humans are naturally infected by Strep A," Dr Osowicki said.

MCRI researcher Dr Hannah Frost said by developing the world's only strep A human challenge model the research team had changed the vaccine development landscape.

"With this funding from Wellcome, we will answer some of the biggest and most stubborn questions that are standing in the way of developing, licencing and implementing a successful strep A vaccine," Dr Frost said.

"While this was traditionally a long and difficult process, bringing world experts and industry partners together would fast-track efforts to address the unmet global public health need for a safe and effective strep A vaccine," Dr Frost said.

TELIX PHARMACEUTICALS

Telix says its managing-director Dr Chris Behrenbruch has called for the Federal and State Governments to establish a $500 million nuclear medicines fund.

In an email not released to the ASX, Telix said Dr Behrenbruch believed the fund could be used to “accelerate the development and adoption of life-saving cancer treatments”.

The company said the fund would “facilitate manufacturing, supply, research, health infrastructure and workforce capabilities for this emerging field of medicine”.

Telix said it had issued a report that showed “several barriers hampering the adoption of therapeutic diagnostic treatments in Australia, including delayed regulatory approvals, fragmented public funding, and unregulated generic products”.

Telix said the report noted concerns with “the current practice allowing some hospitals to compound their own ‘home-brew’ radio-pharmaceuticals without Therapeutic Goods Administration oversight, potentially compromising patient safety, access and treatment consistency”.

The company said the report noted “Australia’s limited nuclear medicine manufacturing capacity” as another challenge and that the Australian Nuclear Science and Technology Organisation’s facility in Sydney was the only manufacturing plant for therapeutics in the country.

Telix said the report suggested that “based on current projections, the report warns that Australia will likely need additional manufacturing capacity to meet future demand”.

The company said the report recommended “enforcing TGA approvals to ensure product quality and patient safety, streamlining the reimbursement process, implementing an alternative separate payment funding model, and expanding sovereign manufacturing capabilities”.

Dr Behrenbruch said that despite its “reputation as a world leader in nuclear medicine” Australia’s healthcare system was failing to translate expertise into improved outcomes for Australian patients.

"Nuclear medicine in Australia is now at an inflection point where we need to move away from 'how it was always done', and towards a system that guarantees access to as many Australians as possible,” Dr Behrenbruch said. "We need a nationally coordinated effort between Federal and State Governments, scientists, clinicians and pharmaceutical companies, in order to meet demand.”

Last month, Telix said revenue for the year to December 31, 2024 was up 55.85 percent $783,207,000, with profit up 9.6-fold to $49,919,000 (BD: Feb 21, 2025).

The report, titled ‘Nuclear Medicines Report: Radiopharmaceuticals Empowering Australia’s Future’, is available at: https://bit.ly/41KsCTW

Telix fell 40 cents or 1.4 percent to $27.66 with 1.1 million shares traded.

POLYNOVO

Polynovo says that, following media speculation, it is proposed that chief executive officer Swami Raote will cease his employment with the company, effective from June 2025.

Polynovo said “last week there was a confidential discussion with the chief executive officer Mr Raote, requesting his agreement to cease his employment with Polynovo, effective [from] June 2025, at the end of his contractual notice period and to step down as chief executive officer effective from an earlier date”.

The company said non-executive director Dr Robyn Elliott would “be stepping into the role as acting chief executive officer pending the appointment of a permanent replacement”.

Polynovo said that no agreement had been reached.

Polynovo fell 18 cents or 13.0 percent to $1.20 with 8.8 million shares traded.

RENERVE

Renerve says it has received $139,537 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Renerve said the incentive was in addition to an initial $377,069 received in September 2024, resulting in a total $516,606, but did not disclose the period it undertook the research and development related to the incentive.
The company said it continued to develop its peripheral nerve repair products and expected to present results from a clinical study of its Nervalign nerve cuff in nerve repairs between March 27 to March 30, 2025.
Renerve fell half a cent or 3.85 percent to 12.5 cents.

ANTERIS TECHNOLOGIES GLOBAL

Anteris says it has appointed chief operating officer David St Denis as a non-independent director, effective from today, on $US475,000 ($A752,000) a year.
Anteris said Mr St Denis had been its chief operating officer since 2017 and V2V Medtech chief executive officer since April 2023, and previously had been Merck Inc head of commercial operations in Europe and Canada and worked for the then Millennium Pharmaceuticals (now Takeda Pharmaceutical).
The company said Mr St Denis held a Bachelor of Science from Mansfield's University of Connecticut, a Master of Arts from Boston University and a Master of Business Administration from Boston, Massachusetts' Babson College.
Last year, in its annual report for the 12 months to December 31, 2023, Anteris said Mr St Denis was paid an annual salary of $US415,800, not inclusive of superannuation or short-term and long-term incentives.
Today, the company said following his appointment as a director Mr St Denis would receive $US475,000 in total fixed remuneration, as well as short-term incentives equal to 80 percent of his salary and long-term incentives worth up-to a total $US2,000,000, pending performance milestones.
Anteris was unchanged at $12.00.

CAMBIUM BIO (FORMERLY REGENEUS)

Cambium says it has appointed Li-Chien Chiu as a director, effective from today.
Cambium said that following its recent capital raising, Mr Chiu held 800,357 shares, or 4.38 percent of the company.
Last year, the company said it had raised $3.0 million at a post-consolidation 46.37 cents a share in a placement, with $250,000 placed with major shareholder Taipei, Taiwan's Zheng Yang Biomedical Technology (BD: Dec 5, 2024).
Today, Cambium said Mr Chiu was chair of the Taipei, Taiwan-based Hocheng Corp, had more than 35 years of experience and had worked for Hostan Corp, Sanquan Construction and Hanyang Construction.
The company said Mr Chiu held a degree from California's University of San Francisco, but did not disclose the specific qualification.
Cambium was unchanged at 35 cents with 57 shares traded.