



Biotech Daily

Friday July 9, 2021

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.93 percent on Friday July 9, 2021, with the ASX200 down 68.1 points to 7,273.3 points. Ten of the Biotech Daily Top 40 stocks were up, 21 fell and nine traded unchanged. All three Big Caps fell.

Alterity was the best, up 0.4 cents or 11.1 percent to four cents, with 61.3 million shares traded. LBT climbed 7.9 percent; Dimerix improved 6.7 percent; Next Science and Nova Eye were up more than three percent; Medical Developments and Resonance rose more than two percent; Neuren and Starpharma were up more than one percent; with Cyclopharm up 0.9 percent.

Optiscan led the falls, down two cents or 8.3 percent to 22 cents, with 897,538 shares traded. Actinogen lost eight percent, Genetic Signatures fell 4.3 percent; Amplia, Antisense, Clinuvel, Nanosonics, Orthocell, Polynovo, Prescient, Proteomics and Universal Biosensors shed two percent or more; Avita, Cochlear, CSL, Cynata, Mesoblast, Oncosil, Opthea, Pro Medicus and Telix were down one percent or more; with Kazia, Resmed and Volpara down by less than one percent.

[DR BOREHAM'S CRUCIBLE: POLYNOVO](#)

By TIM BOREHAM

ASX code: PNV

Share price: \$2.33; **Shares on issue:** 661,388,044; **Market cap:** \$1.54 billion

Chief executive officer: Paul Brennan

Board: David Williams (chair), Mr Brennan, Dr Robyn Elliott, Christine Emmanuel, Leon Hoare, Dr David McQuillan, Bruce Rathie, Andrew Lumsden

Financials: (December half 2020): revenue \$12.8 million (up 24%), net loss \$3.54 million (previous \$2.42 million deficit), operating loss \$200,000 (previously \$1 million loss) cash of \$7.66 million (down 5%)

Identifiable major holders: David Williams 2.9%, Vanguard Group 4.9%.

As many life science companies have discovered during the pandemic, every cloud has a silver lining.

For device-maker Polynovo, the silvery upside of the latter-day plague is discovering that business-building can still take place via webinars, video calls and other non-personal channels.

"I think business has permanently changed. It's a higher mix of digital and that's going to be beneficial in the long-term in relation to costs and our ability to reach [customers]," says chief executive Paul Brennan.

During the pandemic, the company signed up 22 new customers for its surgical reconstruction device in the US; and more than 30 in Germany, Australia and Switzerland. A further 30 evaluation programs are underway.

The core product is called Novosorb BTM (as in biodegradable temporizing matrix).

Not that Covid-19 has been an overall positive for the Melbourne-based Polynovo, given restricted access to hospitals and surgeons who won't change suppliers in a hurry.

While burns and other traumas were attended to, revenue was affected by postponed elective surgeries and there are "probably years of catch-up growth".

Mr Brennan says the US Covid experience has been "all over the shop, with 50 states acting like 50 individual countries".

Having said that, most of the US is open for trade - after all, the business of America is business - and physical access is about 60 percent of normal levels.

Don't mention the (drug) war

Polynovo has an interesting history - to put it mildly - having morphed from companies known as Calzada and Metabolic Pharmaceuticals.

The Novosorb technology itself 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. Metabolic owned AOD9604, a peptide that failed a large, randomized, controlled obesity trial and was then involved in the drug scandal engulfing the Essendon and Cronulla footy clubs.

In 2009, Metabolic changed its name to Calzada and moved to full ownership of Polynovo in 2010.

Calzada appointed David Williams, first as a director, and shortly afterwards as chair and changed its name to Polynovo in 2014.

Mr Williams is also the former chair and a current director of Medical Developments and runs advisory company Kidder Williams, among numerous other pursuits.

About Novosorb

Polynovo's core product, Novosorb BTM is a bioresorbable lattice for complex wounds and burns and reconstructions.

Only two millimetres thick, the foam looks like something you would wrap a parcel in but in reality it's a complex product. The material can be produced as a fibre, a cardiac stent or films and foams.

In essence, Novosorb provides a 'home' for cells to migrate and disrupts the ability of collagen protein fibres to form knots and bundles.

Eventually, the material biodegrades and is excreted via the usual channels (urine or respiration).

Apart from costing less, Novosorb is the only synthetic surgical matrix product on the market and thus obviates the risks around rejection and bacteria.

The other products are made from animal products such as ovine or bovine collagen, shark fin cartilage, pigs' bladders and bowels, fish skins or cadavers.

As Mr Brennan says: "Pick an animal".

The US Food and Drug Administration approved Novosorb BTM for burns in 2015, while European authorities followed suit in 2019.

That just about covers the world ...

Polynovo has been active on the distribution front, having recently inked deals this year covering Denmark, Iceland, Norway, Italy, Turkey and Poland.

The company already has arrangements in other countries including Sweden, Finland, Taiwan, Greece, Germany, Austria, South Africa, Saudi Arabia, Israel and India.

The company sells directly in Australia, New Zealand, Singapore, Malaysia, the UK, Ireland and the US.

In the US, the company has signed up its third group purchasing organization, or GPO. GPOs are not a venue for buying stamps but procure supplies on behalf of member hospitals.

The latest deal is with Premier Inc, which services around 4,100 facilities including 2,000 acute care hospitals.

Polynovo now has compacts with three of the top five GPOs that account for 90 percent of the market— and is keen to sign up the remaining two.

Currently, 60 percent of Novosorb's use is in burns and the remainder in wounds.

Mr Brennan says the longer-term aim is to get burns down to about 20 percent, with growth in other areas (such as scar revision, reconstructive surgery, traumas skin cancer excisions).

"The more non-burns you get the more predictable revenue stream it is, because you never know when a burn is going to happen or where," he says.

"We can respond to such happenstances but you can't bank them on a predictable monthly basis."

You BARDA be prepared

As with fellow ASX-listed US-focused burns house Avita Medical, Polynovo has the support of the US doomsday preparation house, the Biomedical Advanced Research and Development Authority (BARDA).

BARDA has extended \$US15.5 million to a fund pivotal full thickness burns trial, enrolling 100 patients over 25 sites including the US and Canada. Polynovo supplies material as an 'in kind' contribution.

The idea, of course, is that BARDA stockpiles Novosorb for a disaster. But as a US health agency it can't exactly order a product for an unregistered indication, so it needs Polynovo to win the label claim from the FDA.

Hence the trial...

Straining to help hernia sufferers

Polynovo is in the process of launching a hernia repair product and is expanding the capacity of its Port Melbourne facility (where it makes its material).

Described as an “ultrasonically welded film/foam construct” the device is dissolved by the body, unlike the permanent current standard-of-care meshes that are sutured on to the offending area where the bowel is trying to push through.

Meanwhile a chronic wounds trial is underway, with the first 10 patients recruited.

These patients are expected to be healed by July, after which the trial will be expanded to 40 patients. The idea of this phase is to collect health economic data to win reimbursement for US private insurers.

“It will give us a lot of good clinical evidence from a marketing point of view, as well,” Mr Brennan says.

Meanwhile, the company is eyeing studies into healing diabetic foot ulcers, venous leg ulcers and arterial ulcers - a collective \$400 million opportunity. Work at Adelaide’s Flinders University shows the device resulted in “remarkable” healing and saved limbs from being amputated.

“A lot of anecdotal studies are coming in,” Mr Brennan says. “We will be doing more formal trials in some of these indications as well.”

Polynovo’s other pursuits also include the US alternate care sector and the potentially lucrative plastics and reconstruction industry. The latter is an in-house project with a development timeline of three or more years.

Finances and performance

In the December 2020 (first) half, Polynovo increased sales by 24 percent to \$12.8 million, which is creditable under the Covid circumstances.

The net loss of \$3.54 million was higher than the previous \$1 million deficit, but the operating loss of \$200,000 signifies the company’s edging towards break-even status.

Belying their simplicity, the standard patches sell for around \$US950 (\$A1,270) and deliver a 90 percent margin, so the path to profit is clearly there if the company can achieve adequate volumes.

“We are not only half the price [of rival biologic products] but we have a better outcome,” company chair David Williams says.

“We are not worried about our competition at all, but some are reducing prices by 20 to 40 percent.”

Polynovo pocketed \$US1.35 million from BARDA during the half year and expects \$US5 million in the current year.

The importance of the US market cannot be underestimated, as it accounted for 80 percent of Polynovo's revenue during the half (the local market chipped in 14 percent).

But given the number of distribution agreements recently inked - especially in Europe - expect the 'rest of world' line item to become more substantive.

Polynovo shares fared well during Covid, peaking at \$4 on Christmas Eve last year. But Santa's munificence proved fleeting and the shares have lost 40 percent of their value since then.

Mr Brennan is baffled by the market's behavior.

"You grow your business by 40 percent during a pandemic with no travel and no elective surgery and that's very unimpressive," he says with just an inkling of sarcasm.

Dr Boreham's diagnosis:

Mr Brennan rues that Australian life science success is often judged by the price paid by an offshore acquirer.

But Polynovo is determined to continue to fly the Australian flag, in the same manner as Cochlear or CSL.

"Ultimately the best thing is not to focus on 'are you for sale' but 'how you are going to grow your business'," he says.

Besides, he says, with a substantive \$1.6 billion market capitalization, the company is "not exactly a plum acquisition target".

In revenue terms, Polynovo looks far from cheap, even after the recent valuation pull-back. But expect sales to grow exponentially, especially given the company's market share still barely registers in the US.

"We think long term we should be the market-dominant matrix and it's a matter of time and penetration to achieve that," Mr Brennan says.

Chairman Williams says no surgeon has ever failed to buy a Novosorb product after trialling it.

"It makes money and makes you look beautiful," he says. "It's like a gift from God."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He knows a few people who think they are a gift from God but are more like the work of the Devil.

LBT INNOVATIONS

LBT says it will present data from five clinical studies of its APAS Independence at the European Congress of Clinical Microbiology and Infectious Diseases.

LBT said the posters included “the first published data” showing the use of the automated plate assessment system (APAS) Independence for early reading of culture plates and improved screening of methicillin-resistant staphylococcus aureus (MRSA or “golden staph”) compared to total laboratory automation.

The company said the scientific data was “collectively the largest body of scientific data supporting key clinical benefits of the APAS Independence” with clinical studies conducted in Germany, the UK and South Australia.

LBT scientific director Dr Steven Giglio said that the “presentation of independent clinical data at the largest global conference in our industry is extremely important as it provides reference points for customers and clinicians when evaluating the APAS Independence”.

“Application of the APAS technology to early culture reads has the potential to further disrupt the current application of testing in clinical laboratories, with the potential to improve patient care through faster turnaround of results,” Dr Giglio said.

LBT said the on-line meeting would be held from July 9 to 12, 2021, with the posters available after the meeting at: <https://lbtinnovations.com/products/scientific-library/>.

LBT was up 0.7 cents or 7.9 percent to 9.6 cents with 1.3 million shares traded.

CANN GROUP

Cann Group says it has received \$1.2 million of about \$3.47 million the company alleged had been stolen “a cyber security incident, involving an unknown third party”.

In February. Cann Group said that the incident resulted in a missing payment to an overseas contractor and was being investigated (AVW: Feb 12, 2021).

In April, Cann Group said it has begun proceedings in Hong Kong’s High Court against Er Ya Trade Ltd to recover EUR2.25million (\$A3.47million) (AVW: Apr 1, 2021).

Today, the company said criminal investigations were continuing in various jurisdictions but there was no guarantee that “any formal prosecutions against any third parties involved in the cyber incident will either commence or result in any further funds being recovered”.

Cann Group was unchanged at 40 cents.

ALTHEA GROUP HOLDINGS

Althea says subsidiary Peak Processing Solutions will manufacture four of 48North Cannabis’ marijuana products with a minimum order of \$C1.25 million (\$A1.34 million).

Althea said that under the two-year, non-exclusive agreement, Peak would manufacture the Toronto-based 48North’s cannabidiol body lotion, a one-to-one ratio tetrahydrocannabinol/cannabidiol body lotion, cannabidiol bath salts and a one-to-one tetrahydrocannabinol/cannabidiol bath salts.

The company said the minimum order quantities were required to be purchased over 12 months from the first purchase order date for each product accepted by Peak.

Althea said the 48North Cannabis was a wholly-owned subsidiary of Toronto-based Delshen Therapeutics and produced cannabis products for “recreation, wellness and cannabis accessory sectors”.

Althea was up half a cent or 1.4 percent to 35.5 cents.

CRESO PHARMA

Creso says partners Adler Laboratories and Medara SA have completed Uruguay import procedures for its Anibidiol marijuana-based animal products.

Creso said the import protocol completion followed initial regulatory approval from Uruguay's Ministry of Agriculture and Animal Feed and marked the beginning of its "expansion through the Latin American region".

Creso was unchanged at 13.5 cents with 13.8 million shares traded.

MGC PHARMACEUTICALS

MGC says its extraordinary general meeting will vote to issue 64,200,000 performance rights to eight directors and ratify the Medicantl acquisition.

MGC said it proposed to issue 27,400,000 performance rights each to managing-director Roby Zomer and executive chair Brett Mitchell, 2,600,000 performance rights each to non-executive directors Dr Stephen Parker and Evan Hayes, and 2,100,000 performance rights each to non-executive directors Nativ Segev and Dr Ross Walker.

The company said the 64,200,000 performance rights were held in three classes.

A, B and C, class A with 17,100,000, class B with 39,900,000 and class C with 7,200,000 performance rights.

MGC said the hurdle for vesting the 17,100,000 class A rights was a 10-day volume-weighted average price (VWAP) of 8.75 cents, by April 1, 2022, or 125 percent of 10-day VWAP to April 1, 2021.

The company said the hurdle for the 39,900,000 class B rights would be a 10-day VWAP of 10.5 cents by April 1, 2023, or 150 percent of the 10-day VWAP to April 1, 2021.

MGC said the 7,200,000 class C rights would vest if the directors were with the company at June 30, 2021.

In April, the company said it would acquire the Zichron Yaakov, Israel-based clinical research company Medicantl for \$6 million in shares (BD: Apr 22, 2021).

In May, MGC says it had agreements with Health House International and Cannvalate to distribute its marijuana-derived medicines in Australia (BD: May 2, 2021).

Today, the company said the meeting would vote to ratify and approve the issue of shares for the acquisition of Medicantl and in relation to Cannvalate.

The meeting will be held at 1202 Hay Street, West Perth, Western Australia on August 12, 2021 at 4pm (AWST).

MGC was unchanged at 3.8 cents with 4.1 million shares traded.

IMUGENE

Imugene says it will issue 119,354,838 shares to the vendors of Vaxinia including executive chair Paul Hopper and the City of Hope's chair of surgery Prof Yuman Fong. Imugene said that US Food and Drug Administration approval of an investigational new drug application for a phase I trial of CF33 for breast cancer triggered the milestone share issue at 1.55 cents a share (BD: Jul 2, 2021).

The company said that Mr Hopper and related parties would receive 94,170,967 shares, with the other Vaxinia shareholders unrelated to Imugene receiving 25,183,871 shares.

Imugene was unchanged at 33 cents with 7.6 million shares traded.

ALTERITY THERAPEUTICS

Life Biosciences and its entities say their 269,905,533 share-holding in Alterity has been diluted from 13.3 percent to 11.2 percent.

In an application for quotation of securities on July 5, 2021 Alterity said it issued 322,857,900 shares to raise \$17,176,040 in a placement at 5.32 cents a share.

Alterity was up 0.4 cents or 11.1 percent to four cents with 61.3 million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

Ellerston Capital says it has become a substantial shareholder in Lumos with 8,155,980 shares or 5.43 percent of the company.

The Sydney-based Ellerston Capital said between June 29 and July 5, 2021, it bought 3,000,000 shares for \$3,840,890 or an average price of \$1.28 a share and converted convertible notes into 5,155,980 securities.

Earlier this week, Lumos opened on the ASX under the code of LDX following its \$63 million initial public offer at \$1.25 a share to develop and commercialize its point-of-care diagnostics (BD: Jul 5, 2021).

Lumos fell 2.57 cents or two percent to \$1.24.

INVION

Invion says executive chair Thian Chew will receive a chief executive officer base salary of \$309,000 a year and \$90,000 a year as the company's chair.

Invion said that Mr Chew would be entitled to a short-term incentive of a maximum of 50 percent of his chief executive officer salary based on set annual targets.

The company said that Mr Chew would be entitled to a long-term incentive equal to 2.5 percent equity in the form of premium priced options exercisable at 1.7 cents, vesting in four equal tranches on the grant date and on November 1, 2021, 2022 and 2023.

Invion was up 0.1 cents or 7.7 percent to 1.4 cents with 3.9 million shares traded.