



Biotech Daily

Friday March 5, 2021

Daily news on ASX-listed biotechnology companies

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- * **DR BOREHAM'S CRUCIBLE: COCHLEAR**
- * **NOVA EYE: 5-YEAR DATA BACKS 2RT FOR AMD**
- * **EURO PATENT FOR CARTHERICS T-CELL, NK-CELL CANCER PROGRAM**
- * **IMMUTEP EXPANDS PART B OF TACTI-002 TRIAL FOR NSCLC**
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- * **AZURE \$3m NSX IPO DATES CHANGE**
- * **LAZARD TAKES 6% IN MAYNE**
- * **MARK LAMPERT, BVF DILUTED TO 14% OF BIONOMICS**
- * **MEDICAL DEVELOPMENTS APPOINTS MARY SONTROP DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.74 percent on Friday March 5, 2021, with the ASX200 down 49.9 points to 6,710.8 points. Six of the Biotech Daily Top 40 stocks were up, 31 fell and three traded unchanged. All three Big Caps were down.

Dimerix was the best, up 1.5 cents or 6.4 percent to 25 cents, with 950,680 shares traded, followed by Osprey up 6.25 percent to 1.7 cents, with 7.9 million shares traded. Actinogen and Nova Eye climbed more than four percent; Universal Biosensors was up 3.5 percent; with Polynovo up 1.3 percent.

Alterity led the falls, down 0.3 cents or 9.1 percent to three cents, with 32.7 million shares traded. Impedimed lost 8.3 percent; Oncosil, Optiscan and Patrys fell seven percent or more; Uscom was down 6.25 percent; Clinuvel and Paradigm were down more than five percent; Cyclopharm, Prescient, Telix and Volpara fell more than four percent; Avita, Cochlear, Cynata, Medical Developments and Opthea were down more than three percent; Amplia, CSL, Genetic Signatures, Mesoblast, Neuren, Resonance and Starpharma shed two percent or more; Immutep, Imugene, Kazia, Nanosonics, Next Science, Orthocell, Pharmaxis, Pro Medicus and Resmed were down more than one percent; with Proteomics down by 0.9 percent.

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

By Tim BOREHAM

ASX code: COH

Share price: \$200.29; **Market cap:** \$13.2 billion; **Shares on issue:** 65,742,744

Chief executive officer: Diggory Howitt

Board: Rick Holliday-Smith (chair), Dig Howitt, Abbas Hussain, Yasmin Allen, Glen Boreham*, Alison Deans, Andrew Denver, Prof Bruce Robinson, Michael Daniell, Christine McLoughlin**

* No relation (although he does have the family's distinguished features)

** Ms McLoughlin joined the board on November 1 2020. Donal O'Dwyer resigned on October 20 2020

Financials (December half 2020): revenue \$743 million (down 4.5%), earnings before interest and tax \$175.6 million (down 4%), net profit after tax \$236.2 million (up 50%), underlying earnings per share \$1.91 (down 17%), dividend per share \$1.15 (down 28%)

Identifiable major shareholders: Blackrock Group 6.1%, Baillie Gifford & Co 6%, Veritas Asset management 5.6%, Vanguard Group 5.5%.

On a broader canvas of deferred surgeries for cochlear hearing implants, the coronavirus has highlighted some surprise silver linings amid the cloudy pockets for home-grown global champ Cochlear.

As Cochlear chief Dig Howitt explains, many hard-of-hearing folk recognized the extent of their impairment after they were forced to wear masks.

"People were subconsciously augmenting hearing with lip reading and were unable to do that and have realized their hearing loss is worse than it was," he says. "Anecdotally, people who have had hearing loss for some time are starting to take action."

Covid's surprise 'gift' has bolstered management's confidence that Cochlear can both increase its share of existing markets and create new ones.

In its 40th year, the home-grown leader in implanted hearing devices also received another unexpected present - from the normally miserly Australian Taxation Office (ATO).

The company had prudently assumed the legal costs incurred in (unsuccessfully) fighting a patent infringement case were not tax deductible, but sought the taxman's counsel.

The ATO said "we hear you". As a result, Cochlear's reported December half profit was boosted by \$59 million as a result of "patent litigation related tax and other benefits". Reciprocating the spirit of giving, the company pledged to return \$23.1 million of Jobkeeper payments to the public purse.

A quick recap ...

Cochlear is the pre-eminent supplier of not just the cochlear devices, but the associated equipment such as sound processors and other add-ons such as spare coils and cables, remote controls, repairs, shake-awake alarm clocks and travel insurance.

Cochlear was founded waaaay back in 1981, to commercialize Prof Graeme Clark's invention, when it was still part of the Nucleus Group. Prof Clark first implanted a device in 1978. The company listed on the ASX in 1995.

The Cochlear name is a reference to the cochlea spiral tunnel of the inner ear that receives vibrations and sends them to the brain for interpretation and the adjacent cochlear canal or duct and cochlear nerve. The Cochlear implant is implanted in the cochlea. Save that one for the next trivia quiz.

Apart from turning a dollar for shareholders, Cochlear's mission is to make cochlear implants the standard for people with severe or profound hearing loss, mixed hearing loss or single-sided deafness (a.k.a. deaf in one ear). Cochlear has a 60 percent market share overall, with an especially dominant position in the children's market in developed countries. As of June last year, the company had sold 550,000 implants.

Formerly the company's chief operating officer, Mr Howitt has run the show since July 2017.

December half hits and misses

Cochlear's half-year performance had a curate's egg quality, with a solid showing in key western markets including Japan, the US and the 'good' Korea (South Korea).

"There were ups and downs through the half and countries performed differently but the broad trend is fairly solid with building momentum." Mr Howitt says.

Mr Howitt attributes these gains to a mix of rescheduled surgeries, market share gains and "definitely some market growth". But sales in developing countries - notably India and Brazil - were some 30 percent off the pace.

One factor is that government subsidies largely disappeared in the virus crisis leaving insurers to fund procedures. Overall, implant sales fell three percent to \$454.7 million. Services (such as sound processors and upgrades) fell five percent to \$214.9 million.

Acoustics, which houses the bone conduction implant division, lost 11 percent to \$73.2 million. This is despite a strong uptake for Osia 2, the company's next generation bone conduction implant, when it was launched in the US.

Bone conduction implants are more suited to patients with mixed, or single sided, hearing loss. Typically, they have functioning cochleae, but a middle ear problem preventing sound transmission from the outer ear to the cochlea. There's been a degree of switching, with 70 percent of volumes pertaining to the older Baha product switching to Osia 2.

Meanwhile, Cochlear boasts 200,000 members for its Cochlear Family membership scheme - enough to fill the MCG twice (or the Covid capacity-constrained Gabba 10 times). The Cochlear Family is a loyalty-style club of users. While the membership uptick bodes well, there's usually a five-year lag between customers signing on and revenue flowing through.

Finances and performance

For the record, Cochlear's reported December half profit came in at \$236 million, 50 percent higher than a year previously when Covid-19 had not reared its ugly visage. Revenue declined four percent, to \$743 million.

The bottom line includes the \$59 million tax benefit. The operational measure - earnings before interest and tax, or Ebit - showed a less flattering four percent decline to \$175.6 million. While there were a lot of moving parts behind the numbers, the overall results were a tad better than expected, which is why the stock rose eight percent on the day.

A key pointer to management's confidence is the re-appearance of Mr Dividend, having been banished for the three months to June 30, 2020. Year-on-year, the pay-out was 28 percent lower and unfranked, as opposed to fully franked last time around. But income strapped self-retirees will take what they can. The dividend accounted for 60 percent of earnings, but management hopes to boost future payouts in line with its 70 percent target.

"We have always prided ourselves on being a strong cash-generating business and the first half was no exception to that," newly-installed chief numbers man Stu Sayers says.

In late March 2020, Cochlear became the life sciences trailblazer by announcing an \$880 million institutional raising, pitched at \$140 a share (a 17 percent discount). The accompanying share purchase plan was supersized from \$170 million to \$220 million.

In hindsight, the \$1.1 billion whip 'round was not justified, with broker JP Morgan now opining the company will return funds to shareholders (presumably by way of increased dividends or a share buyback). But let's face it, we were all petrified at the time and it seemed prudent of management to go to the well for funding.

Management has forecast underlying profit of \$225 million to \$245 million for the full year, which would be 46 percent to 59 percent above the surplus for the Covid-ravaged year to June 2020. Cochlear shares have remained comfortable above the \$200 a share, but shy of their record \$240 level attained in early February last year.

Spending and innovation

We've focused on revenue trends, but should mention that Cochlear's bottom line was helped by a \$33 million, 9.0 percent decline in operating expenses. Travel and conference expenses shrunk to virtually nothing. This, of course, is not unique to Cochlear and plenty of corporate bean counters will be Zooming in on making these savings permanent.

Capital expenditure fell to \$35.3 million compared with the normal \$100 million run rate, with this year's spending is expected to remain at similar levels.

On the innovation side, Cochlear released four products in the half-year and management pledges to maintain research and development spend within its targeted range of 10 percent to 12 percent of revenue. More broadly, management pledges not to crimp spending to meet profit guidance, in the event of the Covid impacts enduring for longer than expected. In other words, the company will take the opportunity to grow while its rivals are winded, as well.

Dr Boreham's diagnosis:

Mr Howitt says the guidance bakes in assumptions of a steady rather than radical improvement. In the first six weeks of 2021, sales actually were "a little slower" given renewed Western European and regional US lockdowns.

"We are confident that's a shorter-term issue rather than anything of concern," Mr Howitt says. "We can see more stability looking forward than over the last 12 months".

He adds that "there's still a level of uncertainty that influences our guidance" - which kind of means the guidance is educated guesswork.

In the meantime, brokers covering the stock fall fairly evenly into the buy, sell and neutral camps. On average, the analysts expect Cochlear to achieve earnings per share of \$3.87 in the year to June 30, 2021, compared with \$3.17 previously. Earnings are expected to recover sharply in the year to June 2022, to \$4.66 per share.

One wildcard is the degree to which existing patients return for equipment upgrades. If anything, the company expects growth to emanate from new customers. Despite the company's recent market gains, Mr Howitt does not expect this trend to continue - at least not in a linear manner.

"We have some very good competitors and they will launch good products," he says. "At some point that will moderate the share gains but we want to make it as hard as possible as we can."

Hear! Hear! That's the capitalist spirit.

Despite Cochlear's market-leading position, the untapped market remains capacious and there's no reason the company can't flourish after it shakes off its pandemic blues. Globally, 460 million people suffer hearing loss, with one in three over 65 having impaired hearing to a disabling degree.

Management believes 15 million people could benefit from a cochlear bone conduction implant, which implies it has penetrated only 3.6 percent of the market. Now there's a market opportunity worth shouting about ...

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort – or a direct number to Glen Boreham.

[NOVA EYE MEDICAL \(FORMERLY ELLEX MEDICAL LASERS\)](#)

Nova Eye says its retinal rejuvenation treatment (2RT) reduces age-related macular degeneration disease progression by up to 68 percent from baseline over five years. Nova said the five-year follow-up data analysis of 222 patients from its 292-patient laser intervention in early AMD (Lead) trial of 2RT for intermediate age-related macular degeneration (AMD) showed that the 2RT group patients, without coexistent reticular pseudodrusen (RPD), a fatty deposit associated with later stages of AMD, reported a significant treatment effect at five years.

The company said the 2RT patients without RPD showed a 68 percent reduction in the rate of progression when compared to the control group ($p = 0.002$).

Nova said that the 36-month, randomized, controlled multi-centre trial assessed whether 2RT could delay progression of intermediate AMD to late-stage disease.

In 2018, Ellex said the trial missed its primary endpoint, but showed a reduction in progression to late-stage AMD in 76 percent of 2RT patients, with 13.6 percent of the 2RT group and 17.2 percent of controls developing late AMD ($p = 0.122$) (BD: Sep 21, 2018).

In 2019, the company said that a four-year follow-up of 183 patients showed 2RT had a “rejuvenating” impact on the retina and potential for early intervention (BD: Jul 8, 2019).

Today, the company said the analysis, titled ‘Subthreshold Nanosecond Laser in Age-Related Macular Degeneration: Observational Extension Study to the Lead Clinical Trial’, was published in *Ophthalmology Retina* and an abstract of the article was available at <https://www.sciencedirect.com/science/article/abs/pii/S2468653021000695?via%3Dihub>.

Nova Eye director Tom Spurling said that “the improvement in the clinical response in patients without RPD at five years ... is very exciting, particularly given these patients did not receive further 2RT treatment during the last two-year observation period”.

Nova Eye

[CARTHERICS PTY LTD](#)

Cartherics says the European Patent Office has granted a patent relating to its chimeric antigen receptor (CAR) technology directed against the tumor-associated antigen, TAG-72. Cartherics said the patent, titled ‘Genetically modified cells and uses thereof’ would provide intellectual property coverage until November 2036.

The company said that the patent was part of a substantial patent family, with applications with a similar scope filed in relevant jurisdictions including the US, Japan, and Australia.

Cartherics said the patent protected its TAG-72 CAR construct, which it integrated into T-cell and natural killer (NK) cell product candidates, and demonstrated anti-tumor activity.

Cartherics is a private company.

[IMMUTEP](#)

Immutep says it has enrolled an additional 13 patients to its up-to 196 patient Tacti-002 trial of IMP321, or eftilagimod alpha, with Keytruda for cancers.

Immutep said the additional 13 patients had second-line non-small cell lung cancer (NSCLC) and would participate in the second stage of Part B of the trial.

The company said the further patient recruitment followed a preliminary safety and efficacy review by the data monitoring committee and its recommendation, which was based on the patients recruited in stage one of part B.

Immutep said the trial was a phase II, two-stage, non-comparative, open-label, single-arm, clinical study held at 12 study centres across Australia, Europe, the UK and US.

Immutep fell half a cent or 1.6 percent to 31 cents with 2.5 million shares traded.

BIO-MELBOURNE NETWORK

Bio-Melbourne says the National Modern Manufacturing Initiative has grants worth \$140 million for manufacturing priorities including medical technology products.

The Bio-Melbourne Network said the \$140 million would be granted between the 2020-'21 and 2023-'24, with up-to \$40 million available in each financial year, with applications opening on February 26 and closing on March 29, 2021.

Bio-Melbourne said that 2020-'21 funding would support projects in the medical products national manufacturing priority, specifically in the translation and integration streams.

For applications go to: <https://bit.ly/30eiv9v> and <https://bit.ly/3sPoPAz>.

AZURE HEALTH TECHNOLOGY (MERGED WITH INVICTUS BIOTECHNOLOGY)

Azure has amended the opening and closing dates for its \$3 million initial public offer at 20 cents a share to list on the National Stock Exchange (NSX).

Last month, Azure said it hoped to raise \$3 million to list on the NXS for its tocotrienol food additives and supplements (BD: Feb 22, 2021).

Today, the company said the offer opened on March 5 and would close on April 1, with trading expected to begin on April 16, 2021.

Azure is a public unlisted company.

MAYNE PHARMA GROUP

Sydney's Lazard Asset Management Pacific Co says it has increased its substantial holding in Mayne from 86,044,209 shares (5.13%) to 104,006,124 shares (6.19%).

Lazard said it bought shares between October 13, 2020 and March 3, 2021, with the single largest purchase 4,309,495 shares for \$1,222,950 or 28.4 cents a share.

Mayne was up half a cent or 1.8 percent to 28.5 cents with 1.6 million shares traded.

BIONOMICS

Mark Lampert and BVF Partners say their 119,401,557 shares in Bionomics have been diluted from 16.98 percent to 14.12 percent.

The San Francisco-based Mr Lampert said that the shares were diluted on March 2, 2021 following the issue of shares by the company.

Last month, Bionomics says it had raised \$15,991,634 at 14.5 cents a share for a phase IIb trial of BNC210 for post-traumatic stress disorder (BD: Feb 9, 2021).

Bionomics was up 2.5 cents or 9.6 percent to 28.5 cents with 1.1 million shares traded.

MEDICAL DEVELOPMENTS

Medical Developments says it has appointed Mary Sontrop as a non-executive director, effective immediately.

Medical Developments said Ms Sontrop was currently a director of IDT Australia and had previously worked with CSL for 28 years with responsibilities including plasma manufacturing and the turnaround of unprofitable manufacturing operations.

Medical Developments fell 17 cents or 3.3 percent to \$5.01.