



Biotech Daily

Friday March 4, 2022

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.57 percent on Friday March 4, 2022, with the ASX200 down 40.6 points to 7,110.8 points. Seven of the Biotech Daily Top 40 stocks were up, 29 fell, three traded unchanged and one was untraded.

Nova Eye was the best, up 15 cents or 6.7 percent to 24 cents, with 23,867 shares traded. Emvision, Next Science and Patrys climbed more than three percent; Orthocell was up 1.25 percent; with Cochlear, CSL, Paradigm and Volpara up by less than one percent.

Avita led the falls, down 38 cents or 11.8 percent to \$2.83, with 696,060 shares traded, followed by Atomo down 11.5 percent to 11.5 cents, with 2.7 million shares traded.

Medical Developments and Polynovo lost more than eight percent; Actinogen and Antisense shed more than seven percent; Amplia and Opthea were down more than six percent; Mesoblast, Micro-X, Nanosonics and Prescient were down more than five percent; Cyclopharm, Immutep and Kazia fell four percent or more; Impedimed, Neuren, Pharmaxis, Resonance and Starpharma retreated three percent or more; Alcidion, Compumedics, Dimerix, Imugene and Proteomics shed two percent or more; Clinuvel, Genetic Signatures, Pro Medicus and Telix were down one percent or more; with Resmed down by 0.15 percent.

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

By TIM BOREHAM

ASX code: COH

Share price: \$222.50; **Shares on issue:** 65,775,238; **Market cap:** \$14.6 billion

Chief executive officer: Diggory Howitt

Board: Alison Deans (chair), Mr Howitt, Yasmin Allen, Glen Boreham, Andrew Denver, Prof Bruce Robinson, Michael Daniell, Christine McLoughlin and Michael del Prado

Financials (first half to December 2021): revenue \$821 million (up 10%), earnings before interest and tax \$217 million (up 24%), underlying net profit \$157.5m (up 26%), net profit \$169.3m (down 28%), dividend \$1.55 (up 35%), net cash \$505.6 million (down 10%)

Identifiable major shareholders: Blackrock Inc 7.13%, ABP (Algemeen Burgerlijk PSF) 5.5%, Baillie Gifford & Co 5.2%, State Street Corp 5.1%.

While biotech valuations have been smashed globally, Australia's home-grown 'three pillars' have delighted investors with their narrative of post-pandemic revenue recovery and resilience against the cost pressures we are seeing everywhere.

Firstly, sleep disorders house Resmed on January 28 reported a 12 percent surge in December quarter earnings and revenues. The stock bounced eight percent over the ensuing two trading days.

On February 16, CSL reported a five percent profit decline but better than expected numbers from its 'flu vaccine division, which was enough to add 14 percent to the value of the third-biggest ASX-listed company.

Completing the trifecta, Cochlear shares gained 16 percent after the hearing device half-year revenue numbers definitively beat market expectations on February 22 (the auspicious 22/2/22).

The lesson? When investors turn risk averse, they will always favor the stalwarts over the pre-revenue plays reliant on the next capital injection.

A year ago, the speculative minnows could pretty much rely on an equity raising with the flimsiest rationale. Those days are over.

But we digress. Cochlear's half-year numbers were a story of a stronger division - or geography - making up for a weaker one.

For example, subdued implant sales were offset by sales of other products and services - processor upgrades and the like - while revenue from emerging countries made up for sluggish sales in developed countries.

A word in your shell-like ...

Cochlear owes a debt of gratitude to a young fellow called Graeme Clark - later Prof Graeme Clark - who declared he wanted to “fix ears” after seeing his pharmacist dad struggle with hearing loss.

Inspired on a beach by the shape of a shell and a blade of grass, Prof Clark partnered with local entrepreneur Paul Trainor (Nucleus Group) and the University of Melbourne to develop the first implant, the Nucleus 22.

Cochlear was founded in 1981 while part of the Nucleus Group and listed in 1985. The 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.

So far 650,000 devices have been implanted.

Cochlear’s core business is not just the implants, but the sound processors and other add-ons, such as spare coils and cables, remote controls, repairs, shake-awake alarm clocks and travel insurance.

Long-running CEO Dr Chris Roberts stepped down in September 2015, to be replaced by the Denver-based Chris Smith. With a sales and marketing background, Mr Smith introduced a ‘direct to consumer’ focus. But he quit in July 2017 for family reasons and Mr Howitt - then chief operating officer - took over.

While not being overly acquisitive, in 2017, Cochlear paid \$US78 million (\$A115 million) for Sycle LLC, the world’s dominant supplier of audiology practice management software.

Hear about the results?

While Cochlear’s overall implant volumes rose seven percent from pandemic lows to 18,598 units, this was less than originally forecast because of staff shortages (mainly of nurses in operating surgeries). Implant sales crept up 0.7 per cent to \$458 million.

Volume declines were most evident in the US, where the Delta and Omicron Covid outbreaks resulted in operating theatres running below capacity. European implants have rebounded nicely, albeit with country-by-country variations.

The soft implant performance was more than offset by the ‘other stuff’. By that we’re talking about the services division (sound processor upgrades and the like) and acoustics (bone conduction implants).

Services revenue gained 19 percent to \$256 million (32 percent of total revenue).

Acoustics revenue surged 38 per cent to \$109 million and now accounts for 12 percent of total revenue.

The resounding fortunes of acoustics were driven by the western European rollout of the core Osia 2 device, following recent approval (Osia, by the way, stands for 'osseointegrated steady state implant').

The new Baha 6 Max Sound Processor is "driving strong demand for sound processor opportunities across all regions".

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 prevents sound transmission from the outer ear to the cochlea.

Geographically, revenue from developed economies fell two percent, while emerging ones picked up the slack with a 30 percent increase. Revenue from the Americas (mainly the US of course) rose 3.4 percent to \$388.4 million. Europe, the Middle East and Africa sales rose 21 percent to \$287 million, with Asia-Pacific sales up 8.2 percent to \$140.1 million.

To tackle the ongoing semiconductor shortage, the company spent an extra \$20 million to build its inventory as a buffer.

Finances and performance

Cochlear's statutory profit of \$169.3 million fell 28 percent, but the underlying result was 26 percent better at \$157.5 million.

The difference stems from the underlying number excluding an \$11.8 million gain from the company's innovation fund in the current half, a similar \$35 million gain in the previous half and \$59 million of patent dispute costs and a \$17.2 million Jobkeeper repayment in the previous half.

(The company chose to repay the proceeds from Jobkeeper - the government's pandemic wages support scheme - after it became evident the company really didn't need the handout. Plenty of other companies didn't need it either, but kept the dough anyway).

A key reason for investor jolliness was that the board maintained full-year earnings guidance at \$265 million to \$285 million, which at the midpoint would be 14 percent higher than last year's number. Given the number includes the \$18 million to \$20 million impost from a digital (cloud) program, the guidance in effect is five percent higher at the midpoint.

As a qualifier, the guidance does not factor in a "more material disruption from Covid that significantly impacts sales".

Encouragingly, management says the second (current) half-year is tracking in-line with the first half "with continuing intermittent Covid-related hospital or region-specific elective surgery restrictions".

Over the last 12 months, Cochlear shares have ranged in value between \$182 (late January 2021) and a record high of \$265 in mid-August of that year.

Two decades ago, the stock traded around \$40.

Keeping ahead of rivals

Cochlear earmarks 12 percent of its revenue to research and development and has expended \$2 billion since listing to stay ahead of its rivals.

When a provider slips up in the high-stakes medical devices world, rivals don't hang around to salve the bruises. In 2020, Cochlear's nearest competitor Advanced Bionics announced a "voluntary field corrective action" for some of its unused Hi-res Ultra and Hi-res Ultra 3D implants. Cochlear duly stole market share with its Nucleus Profile Plus, touted as the world's thinnest and most reliable implant.

"We think overall they have regained some of their [market] share, but we don't see them gaining the share from us," Mr Howitt says.

Still, there's no room for schadenfreude: in 2011, Cochlear was forced to recall its Nucleus CI500 implants because of a moisture related defect - at a cost of more than \$100 million. Cochlear last upgraded its processor in 2017. Given it normally does so every four years it's thought the company is overdue for another one.

Dr Boreham's diagnosis:

According to Mr Howitt, the wearing of masks during the pandemic has highlighted that "our hearing is worse than we thought it was". Indeed! Try being understood in a noisy shop or restaurant through the protective but sound muffling material.

For those still questioning Cochlear's growth credentials, the company has a 60 percent market share of implants, but has penetrated only five percent of the available market. About 1.5 billion of the world's people suffer some hearing loss - masks or no masks - with 60 million in the severe or higher category. Of these, only one in 20 have had an implant.

Cochlear accounts for 80 percent of the kids' market but only three percent of adults. This implies there's still a lot to be done in the six million-strong adult sector, with future annuity revenue coming from the children already implanted. The company has a more modest share of the services and acoustics markets: 29 percent and 10 percent respectively.

In the short term, the company risks further disruption from the pandemic as it continues to carve its path through humanity. In the longer term, we can't see - or hear - too many impediments to further growth.

With a healthy net cash balance, it will be intriguing to see what the company does with its war chest. "We are happy to have the cash," says chief finance officer Stuart Sayers. "We are thinking of the right things to do with it but we are in no rush."

Hear hear! It's better to have a lazy balance sheet than no balance sheet.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. We're hoping World leaders are hearing - and heeding - sage advice as no-one should be deaf to the repercussions of a wider conflict.

STARPHARMA

Starpharma says it disputes the Australian Therapeutic Goods Administration's classification of its Viraleze nasal spray as a medicine rather than a medical device. In an announcement titled 'response to Media Article' Starpharma said an article in the Nine Entertainments newspapers was titled 'Nasal spray not on Australian shelves'. The company said it had submitted an application to the TGA for its Viraleze anti-viral nasal spray as a medical device "in keeping with the approach taken in multiple other jurisdictions" and the regulatory process for the medical device application was ongoing. Starpharma said it did "not normally comment on ongoing regulatory processes and was not anticipating the TGA to make public comment, given we are currently awaiting a response from the TGA, having provided additional information as recently as last week, including information related to the nasal spray mechanism of action and the appropriateness of its classification as a medical device".

In a written response, the TGA told Biotech Daily what it had told Nine Entertainment: that "based on information provided by Starpharma to the TGA and information they have published in the public domain, Viraleze would be a medicine not a medical device".

The TGA said it discussed the differences between a medicine and medical device with Starpharma verbally and in writing on several occasions, as recently as mid-January.

"To date, Starpharma has not sought advice from the medicines authorization branch of the TGA nor have they submitted an application for this product to be included in the [Australian Register of Therapeutic Goods] as a medicine," the Federal authority said.

"The TGA continues to prioritize and expedite any applications related to Covid-19," the TGA said. "All applications require appropriate clinical and other evidence to demonstrate that the product meets the safety, quality, and efficacy requirements."

"The TGA would welcome a new submission for this product as a medicine with the appropriate clinical evidence," the Authority said.

Starpharma said that its submission for Viraleze as a medical device was "consistent with multiple other nasal sprays with anti-viral indications that are registered by the TGA as medical devices and have been marketed in Australia for several years, including by multinational companies".

"These products are all similar to Starpharma's nasal spray and share the same fundamental mechanism of action against viruses," the company said.

Starpharma said that Viraleze and the other anti-viral nasal sprays were "all registered as medical devices in Europe and multiple other regions".

The company previously said Viraleze contained the same anti-viral SPL7013 as its Vivagel BV for bacterial vaginosis and its condom coatings and in August, said that a 40 healthy volunteer study of Viraleze showed it was safe and well-tolerated, and SPL7013 was not absorbed into the bloodstream (BD: Aug 17, 2021).

The company has said on several occasions, as recently as Tuesday, that SPL7013 kills more than 95 percent of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) and its variants within one minute, in-vitro (BD: Mar 1, 2022).

Last July, the TGA said it had fined Starpharma \$93,240 for seven notices of "alleged illegal advertising" of Viraleze on two of the company's websites and its Youtube channel, which was not approved in Australia (BD: Jul 5, 2021).

The TGA said the Therapeutic Goods Act 1989 prohibited "advertising to the public for therapeutic goods that are not entered on the ARTG unless a specific exemption, approval or authority applies".

Today, Starpharma said Viraleze was registered in more than 30 countries, including Europe, Vietnam, India, New Zealand and Saudi Arabia.

Starpharma fell 3.5 cents or 3.9 percent to 85.5 cents with 1.8 million shares traded.

CSL

CSL says it has received applications for 74 percent of Vifor Pharma shares at the close of the main period for the public tender offer and says the offer was “successful”.

Last year, CSL said it would acquire the St Gallon, Switzerland-based Vifor Pharma for \$US11.7 billion (\$A16.4 billion) for its renal disease and iron deficiency expertise and raise \$7 billion in a placement and share plan (BD Dec 14, 2021).

Today, the company said it “welcomed the strong support it had received from Vifor shareholders for the acquisition and planned to waive the original 80 percent acceptance rate condition and to declare the offer successful”.

CSL said that a tender period for subsequent acceptance of the offer would begin on March 9 and run until March 22, 2022.

The company said that the regulatory approval process for the acquisition of Vifor was “on-track” and it was confident the transaction would be completed by mid-2022.

CSL was up 80 cents or 0.3 percent to \$258.30 with 835,361 shares traded.

CHIMERIC THERAPEUTICS

Chimeric says Be The Match Biotherapies will assist in the collection, transport and delivery of CHM1101 cellular starting material and drug product.

In November, Chimeric said that its scorpion venom-derived chlorotoxin chimeric antigen receptor T-cell (CLTX-Car-T) therapy CHM1101 was in trials for the treatment of cancer (BD: Nov 22, 2021).

Today, the company said that the Minneapolis, Minnesota-based Be The Match would increase its network of apheresis centres for the extraction of specific cells from blood and ensure the staff at the network of centres were qualified, trained and supervised to meet timelines for the trial.

Chimeric said that the cost of the agreement was not considered financially material but the agreement was considered market sensitive.

Chimeric was up half a cent or 3.2 percent to 16 cents with 1.3 million shares traded.

TISSUE REPAIR

Tissue Repair says the US Patent and Trademark Office has allowed a patent with claims to the method of manufacture of an isolated biological polysaccharide.

Tissue Repair said that the patent, titled ‘Method of making a beta glucan compound’ would provide intellectual property protection for its Glucoprime TR-987 for wound healing. The company was unable to disclose the duration of the patent at the time of publication.

Tissue Repair said that the patent allowance was a “significant achievement ... as no substantive examination report was issued during prosecution of the patent application”.

The company said that the composition and methods of use would be the subject of further related US patent applications and the potential for additional areas of protection around the technology.

Tissue Repair said that the allowed patent was a core component of its intellectual property and protected its process for the manufacture of its active pharmaceutical ingredient.

“There are no known alternative processes from which to produce the company’s proprietary polysaccharide molecule, the company said.

Tissue Repair fell one cent or 2.3 percent to 42.5 cents.

[CRYOSITE](#)

Cryosite director Andrew Kroger says he has increased his substantial holding from 20,983,203 shares (42.99%) to 22,543,702 shares (46.19%).

The London-based Mr Kroger said that on March 2 and 3, 2022, he acquired 1,560,499 shares for \$671,015, or 43 cents a share.

Cryosite was untraded at 44 cents.

[MICRO-X](#)

Micro-X says it has appointed Ilona Meyer as a non-executive director, effective from March 7, 2022.

Micro-X said Ms Meyer was currently the general counsel and head of legal and compliance of the Boehringer Ingelheim Group in Australia and New Zealand, and previously was Resmed's general counsel for the Asia-Pacific, as well as general counsel for Ruralco and Medtronic.

The company said Ms Meyer held a Bachelor of Laws and a Master of Laws from the Queensland University of Technology.

Micro-X fell one cent or 5.7 percent to 16.5 cents.