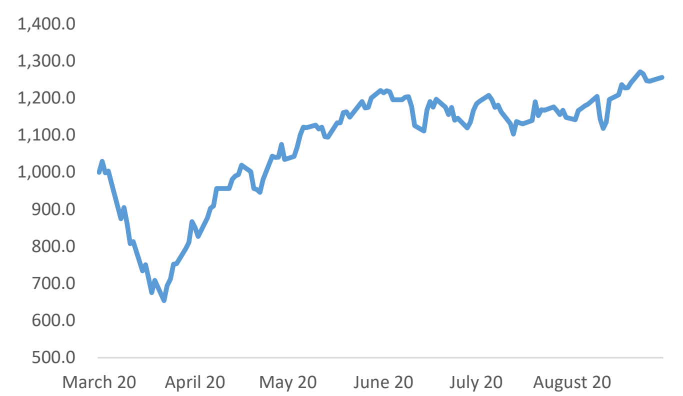
Big 5 Earnings Wrap Up

SECTOR OVERVIEW

The IIR Pharma & Biotech Index performed strongly in the month of August, increasing 9.4%. This compares to the broader market (ASX All Ordinaries Accumulation Index) which increased 3.7%. 24 stocks in the index increased by 30% or more with 53 stocks rising over 10% for the month.

The top 10 stocks increased 9.9%. A strong performance by Starpharma Limited (ASX: SPL) saw it move into the top 10. SPL and MSB were the best performers in the top 10, both increasing over 40% for the month on the back of promising developments for their respective products. The best performing stock in the index was Bionomics Limited (ASX: BNO), whose share price increased 100% over the month. At the AGM on 26 August 2020, BNO shareholders approved the subscription agreements with Apeiron Investment Group which will see Apeiron with an interest of 25% to 52%. The subscription agreements are expected to raise $20.4 million to $22.6 million. The capital raised will be used to fund the company's BNC210 Phase 2b clinical trial for the treatment of post-traumatic stress disorder (PTSD).

IIR Pharma & Biotech Index[1]



HOW THE BIG 5 FARED IN EARNINGS SEASON

With earnings season wrapping up at the end of August we thought we'd take a look at how the five largest companies in the sector fared. As you will see the Covid-19 pandemic provided opportunities for some companies but severely hampered others.

CSL Limited (ASX: CSL) - Market Cap $126.9 billion

CSL is the largest company in the biotech sector by market cap and is the largest company by market cap on the ASX.

CSL experienced another year of strong demand for its products with the company reporting revenue of US$8.8 billion for FY20, up 7.2% on the pcp with NPAT of US$2.1 billion, an increase of 9.6% on FY19. The company did not experience a material revenue impact from the Covid-19 pandemic in FY20. The biggest impact of Covid-19 on the business has been a reduction in plasma collection as a result of government imposed restrictions on movement. Plasma is an essential raw material in a number of the company's products and the inability to collect sufficient levels of plasma may result in shortages. The company opened 40 new plasma collection centres in the US in FY20 and will seek to open a further 20-30 collection centres in FY21.

One of the key developments for the company in FY21 will be the progress of the Covid-19 vaccine that the company is developing in partnership with the University of Queensland. The vaccine candidate has commenced clinical trials and if successful the company believes the vaccine will be available for use in 2021.

The company provided NPAT guidance for FY21 of US$2.1 billion to US$2.27 billion (constant currency), representing growth of over 8% on FY20. CSL's share price was up 18.7% over the 12 months to 31 August 2020.

Fisher & Paykel Healthcare Corp. Limited (ASX: FPH) - Market Cap $18.1 billion

FPH designs, manufactures and markets products and systems for use in respiratory care, acute care, surgery and the treatment of obstructive sleep apnea (OSA). FPH has been the best performer of the big five from a share price perspective over the 12 months to 31 August 2020 with the share price rising 115.4%.

The company has a March year-end and therefore the company's FY20 results do not include the June quarter. FPH announced a record result for its FY20 trading period, with revenue up 18% to NZ$1.26 billion and NPAT of NZ$287.3 million, an increase of 37% of FY19. The revenue increase was largely driven by growth in the use of the company's Optiflow nasal high flow therapy, demand for products to treat Covid-19 patient, and strong hardware sales. The company stated that the company was on track to deliver strong growth for FY20 before the coronavirus pandemic and in January, the demand for FPH's respiratory humidifiers accelerated in an unprecedented manner.

The company breaks its products down into two groups: (1) Hospital products; and (2) Homecare products. The hospital product group has experienced increased demand as a result of the Covid-19 pandemic, while the Homecare product group will likely be adversely impacted on the back of a lower OSA diagnosis rate and OSA mask resupply levels.

On 18 August, the company announced a trading update for FY21. For the first four months of FY21, the company has experienced strong demand for hospital respiratory care products, which continue to track the spread of Covid-19 around the world and reflects a changing trend in clinical practice to lead with nasal high flow therapy for the treatment of Covid-19 patients in hospital. Hospital hardware sales have increased over the first four months of FY21 with a revenue increase of 390% (constant currency) to July-end compared to the pcp. Overall hospital product group revenue has grown 91% in the first four months of trading on the pcp. The company continues to see lower diagnosis rates of OSA globally, coupled with mildly elevated rates of mask resupply. However, growth in home respiratory support is more than offsetting a decline in OSA flow generators, resulting in homecare revenue growth of 5% to July-end compared to the pcp.

1. The IIR Pharma & Biotech Index is a market capitalisation weighted index and currently includes 139 stocks across the Pharmaceutical, Biotech, Health Care Suppliers, Health Care and Equipment, Health Care Technology and Life Sciences GICs sectors. The index excludes the five largest companies in these sectors being ANN, COH, CSL, FPH and RMD.

Based on a number of assumptions the company has provided forecast FY21 revenue of ~NZ$1.61 billion (+27.8% on FY20) and a NPAT range of ~NZ$365 million to NZ$385 million (+27%-34% on FY20).

Cochlear Limited (ASX: COH) - Market Cap $12.5 billion

COH provides implantable hearing solutions globally and until the coronavrius pandemic had experienced year-on-year revenue and NPAT growth since FY2015 and a ROE of in excess of 40%. Covid-19 significantly impacted the company's sales with revenue falling by almost 60% in April. The impact was felt as elective surgery across the globe was halted and hospital resources reallocated for the treatment of Covid-19 patients. There has been some recovery in sales since April with a significant level of variability across countries, with developed markets recovering more quickly than emerging markets.

To shore up its balance sheet, the company raised $1.1 billion in March and extended its debt facilities. The company also suspended its dividend until trading conditions improved.

The company reported that cochlear implant units declined 7% in FY20. 1H'FY20 units were up 13% while 2H'FY20 units were down 26% with a large impact experienced in 4Q'FY20. The company reported FY20 revenue of $1.35 billion, down 6% in the pcp and a net loss of $238.3 million, compared to a $276.7 million net profit in FY19. The loss included a one-off $416.3 million patient litigation expense.

The company will provide a trading update at its AGM in October however has not provided FY21 forecasts at this stage due to the high level of uncertainty around the resumption of surgeries and the continued impact of Covid-19 in operating markets.

COH's share price has been the worst performer of the big five over the 12 months to 31 August 2020 with the company being the hardest hit by the Covid-19 pandemic. The share price declined 11.9% over the 12-month period. Although it has declined the share price has been surprisingly resilient given the environment.

Resmed Inc (ASX: RMD - Market Cap $8.5 billion

RMD develops, manufactures, distributes and markets medical devices and cloud based software applications that diagnose, treat, and manage respiratory disorders.

The company reported revenue of $2.96 billion in FY20, an increase of 13.4% on FY19, and NPAT of $621.7 million, a 53.7% increase on FY19.

Covid-19 has seen an increased demand for RMD's ventilator devices and masks, which can be used to treat Covid-19. Manufacturing capacity was restrained due to the varying government restrictions, restricting the company's ability to initially meet the demand for its products. The company believes the global demand for these devices has largely been met, however, this may change depending on the ability of regions to contain and control infection rates.

As was experienced by FPH, the company observed lower demand for sleep devices and masks during 4Q'FY20 and the company expects that Covid-19 will lead to a temporary decrease in demand from new patients for these products in FY21 with restrictions that have been placed on diagnostic pathways.

RMD's share price has increased 19.6% over the 12 months to 31 August 2020. Despite the strength of the results, the share price has experienced weakness since it released its results to the market which we attribute to the lower demand expected for sleep devices in FY21, slower growth in SaaS products and the expectation that ventilator sales will decline in FY21 with the company of the view global ventilator demand has been met.

Ansell Limited (ASX: ANN) - Market Cap $4.7 billion

ANN performed strongly in FY20 with the Covid-19 pandemic resulting in significant demand for the company's products in 2H'FY20 with ANN being a leader the global PPE sector. This demand is expected to continue in FY21.

The company reported revenue of $1.6 billion, up 9.3% on FY19. Revenue growth was largely a result a result of demand in 2H'FY20 with 1H'FY20 revenue up 2.4% and 2H'FY20 revenue up 12.7%. NPAT was up 19% on FY19 adjusted for the one-off costs of the Transformation Program.

ANN has two business units: (1) Healthcare Global Business Unit (HGBU) which manufactures and markets solutions for hospitals, surgical centres, dental surgeries, veterinary clinics, first responders, manufacturers, auto repair shops, chemical plants, laboratories and pharmaceutical companies.; and (2) Industrial Global Business Unit (IGBU) which manufactures and markets high-performance hand and chemical protective clothing solutions for a wide range of industrial applications including automotive, chemical, metal fabrication, machinery and equipment, food, construction, mining, oil and gas and first responders.

FY20 revenue growth was driven by the HGBU with sales up 12.5% with Exam and Single Use products driving growth in this business unit. Revenue in the IGBU was up 2.2% with chemical protection performing strongly, up almost 8%, while mechanical sales were down 2% on the pcp.

ANN shares were the second best performer of the five companies with the share price up 41.9% over the 12 months to 31 August 2020.

COMPANY NEWS

Below we look at stocks in the IIR Pharma & Biotech Index that made notable announcements during the month that were received well by the market. These include Kazia Therapeutics Limited (ASX: KZA), Starpharma Holdings Limited (ASX: SPL), Mesoblast Limited (ASX: MSB); Dimerix Limited (ASX:DXB); Regeneus Limited (ASX: RGS); Cynata Therapeutics Limited (ASX: CYP); and 4Dmedical Limited (ASX: 4DX).

Kaiza Therapeutics Limited (ASX: KZA)

KZA was the second best performing stock in the IIR Pharma & Biotech Index in August with the share price rising 95.5%. The share price rise was driven by the announcement that Paxalisib was granted Rare Pediatric Disease Designation from the FDA for the treatment of Diffused Intrinsic Pontine Glioma, a rare and highly-aggressive childhood brain cancer. The designation means the company may now be eligible to receive a Priority Review Voucher, which are valuable commodities in the biotech sector. The company subsequently announced that it had received Fast Track Designation for the treatment of glioblastoma and Orphan Drug Designation for Paxalisib for treatment in Malignant Glioma from the FDA.

These designations and approvals are significant milestones for the company in the development of Paxalisib. There is a significant need for development of treatment for brain cancer with low survival rates due to the challenging nature of brain cancer. Glioblastomas account for 60-70% of all gliomas and 88% of all glioblastoma patients succumb to the disease within three years.

Starpharma Holdings Limited (ASX: SPL)

SPL's share price performed strongly in the month of August, rising 44.3% and moving into the top 10 constituents of the IIR Pharma & Biotech Index. The share price rally was a result of the company announcing that development of SPL7013 as an antiviral nasal spray for protection against Covid-19 are well advanced with formulations developed, a manufacturer selected and a pilot manufacture completed.

SPL has undertaken extensive development activities for the SPL7013 nasal spray and based on discussions with regulators the company expects to be able to expedite approval of a SPL7013 nasal spray by leveraging existing non-clinical and clinical data of SPL's currently approved and marketed products.

SPL7013 was shown to inhibit infection of host cells of SARS-CoV-2 when applied to the cell either before or after exposure to the virus. Data showed that SPL7013 is highly selective, indicating potent antiviral efficacy compared with minimal cellular toxicity. The company stated that the selectivity of SPL7013 based on the selectivity index compared favourably to remdesivir and chloroquine.

The high potency and high selectivity of SPL7013 indicates that a final formulated product can have concentration that is several thousand-fold higher than the concentration shown to exert an antiviral effect on SARS-CoV-2.

SPL7013 has broad spectrum antiviral and virucidal effects, with activity demonstrated against a range of viruses including HIV, herpes simplex virus (HSV), human papillomavirus (HPV), adenovirus, H1N1 influenza virus, hepatitis B virus and Zika virus. Given the broad antiviral activity of SPL7013, a SPL7013 nasal spray has potential for application beyond SARS-CoV-2 for other common respiratory viruses and could be useful in pandemic preparedness in the future.

The company has subsequently reported that it has been awarded $1 million in funding by the Medical Research Future Fund (MRFF) to expedite development and commercialisation of its SPL7013 nasal spray for Covid-19.

The company has also announced that it has used its DEP drug delivery technology to create a long-acting, water soluble version of remdesivir, the antiviral drug currently being developed by Gilead and used to treat severe Covid-19 patients. The formulation could expand the potential application of remdesivir with the soluble formulation enabling subcutaneous injection rather than intravenous injection in hospital.

Mesoblast Limited (ASX: MSB)

MSB continued its strong performance with the share price up 40.5% over the month of August. The share price was highly volatile though with the share price falling steeply prior to the meeting with FDA committee regarding the review of its biologics licence application for Ryoncil for the treatment of steroid-refractory acute graft versus host disease in children.

The share price rebounded upon the announcement that the FDA Advisory Committee voted in favour of Ryoncil and that the available data supports the efficacy of Ryoncil in paediatric patients with steroid-refractory acute graft versus host disease. The Advisory Committee makes recommendations to the FDA regarding the safety and efficacy of drugs based on the available data. The FDA will consider the recommendation of the committee however the final decision regarding the approval of the product is made solely by the FDA. Ryoncil has been accepted for Priority Review by the FDA with an action date of 30 September 2020. If approved, MSB plans to launch Ryoncil in the US in 2020.

MSB's share price is up 270% for the 12 months to 31 August 2020.

Dimerix Limited (ASX: DXB)

DXB continued its strong share price performance in August, rising 66.3% over the month. The share price was up 647.5% over the 12 months to 31 August 2020.

The company's share price has been receiving support after the top line results were released from the phase 2a clinical study of DMX-200 in Focal Segmental Glomerulosclerosis (FSGS) on 27 July 2020. 10 patients were enrolled in the study, with 7 patients meeting all criteria for inclusion in the final analysis. The primary and secondary endpoints were met with the study. DMX-200 was found to be generally safe and well tolerated by FSGS patients. 86% (6 of 7) of patients demonstrated a reduction of proteinuria with DMX-200 versus placebo with an average 29% change from baseline in 24 hour proteinuria compared to placebo following treatment with DMX-200. Further to this, 29% of patients (2 of 7) achieved a greater than 40% reduction in prontenuria during treatment with DMX-200 compared to placebo.

A key differentiator of the study is that patients stayed on the standard treatment of care, irbesartan. As a result, the reduction in pronteinuria observed from DMX-200 is in addition to any reduction in proteinuria expected from the background therapy.

DMX-200 has Orphan Drug Designation in the US and Europe for the treatment of FSGS. The designation indicates that if approved, DMX-200 is likely to be of significant benefit to those affected by FSGS and that DMX-200 would provide a clinically relevant advantage as an alternative to any currently market products. Orphan Drug Designation provides regulatory and financial benefits to help bring DMX-200 to market in the US and Europe, including reduced fees during the product development phase, protocol assistance form the regulatory authorities and 7 year (US) and 10 year (Europe) market exclusivity following product approval.

DXB continues to undertake planning for its proposed global Phase III pivotal study of DMX-200 in FSGS and is expecting to release the results from the Phase 2 study of DMX-200 in diabetic kidney disease in September.

Regeneus Ltd (ASX: RGS)

During the month, RGS announced they had signed a licence and collaboration agreement with Kyocera, for Kyocera to exclusively develop and commercialise RGS's lead stem cell platform technology Progenza for the treatment of knee osteoarthritis in Japan. RGS will receive US$19 million in upfront, development and regulatory milestone payments as well as royalties on Progenza OA product sales in Japan.

Kyocera will fund manufacturing, development and commercialisation costs under the agreement. The market for osteoarthritis in Japan is estimated to be worth US$350 million.

RGS's share price was up 50% in August and is up 135.7% over the 12 months to 31 August 2020.

Cynata Therapeutics Limited (ASX: CYP)

CYP's share price increased 42.4% in the month of August. During the month the company announced that patient enrolment had opened for the MEND clinical trial. This follows ethics committee approval in May. The trial will investigate early efficacy of CYP's proprietary Cymerus mesenchymal stem cells (MSCs) in adults admitted to intensive care with Covid-19. The clinical trials will include 24 patients and will be based in NSW. 12 patients will receive Cymerus MSCs infusions and twelve patients will receive the current standard of care. The company is assessing opportunities to expand the program to other jurisdictions.

CYP is seeking to commence a Phase III clinical trial of the effect of Cymerus MSCs in patients with knee osteoarthritis in 2H'2020. Preclinical research showed MSCs can exert a number of important effects on knee osteoarthritis, including release of cytokines and growth factors that reduce inflammation and promote tissue repair, new blood vessel formation and regeneration of compromised cartilage which may result in improved outcomes for patients. The trial will involve 440 patients funded by a NHMRC project grant and in-kind contributions from participating institutions. CYP will supply Chymerus MSCs for use in the trial and will retain full commercial rights to the use of Cymerus MSCs in osteoarthritis. There are 30 million people in the US that are affected by osteoarthritis and according to Persistance Market Research the market will grow to US$11.6 billion by 2025.

CYP's share price has fallen 44.4% over the 12 months to 31 August 2020.

4Dmedical Limited (ASX: 4DX)

4DX commenced trading on the ASX on 7 August. 4DX raised $55.8 million through the issue of 76.4 million shares at $0.73 per share for the IPO. The company opened trading at $1.47 per share and finished the month of August trading at $1.485 per share, a 103.4% improvement on the IPO issue price.

4DX is an Australian-based medical technology company developing non-invasive respiratory imaging solutions that allow physicians to identify and treat patients with respiratory diseases more effectively by providing objective measurements of regional lung motion and air flow. 4DX's XV technology is the first and only FDA cleared respiratory imaging solution that utilises mathematical models and algorithms to convert sequences of X-ray images into four-dimensional quantitative data.

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