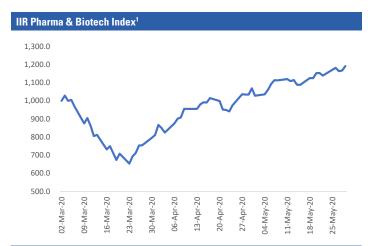


# Pharma and Biotech Stocks on the Move

### **Sector Overview**

The Pharmaceutical and Biotech sector was on the move in May with the IIR Pharma & Biotech Index up 11.4% for the month. This follows the 31.7% increase in April after rebounding from the 18.5% decline in March, when the brunt of the coronavirus sell-off was felt. The 46.8% rise across April and May has been well above the broader market with the ASX All Ordinaries Index increasing 15.1% over the last two months and slightly above the S&P/ASX Emerging Companies Index rise of 42.9% from 31 March to 31 May. Of the 139 stocks currently in the IIR Pharma & Biotech Index, 58% (80) of stocks increased over the month of May.



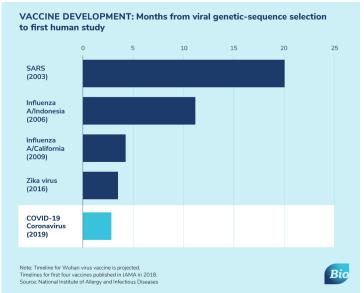
The top ten constituents of the IIR Pharma & Biotech Index account for 64.3% of the index as at 31 May 2020. As such movements in these stocks will have a significant impact on the index. The top 10 constituents were significant contributors to the rise in the index over May with the top 10 rising 13.4%. Over the two months from 31 March 2020 to 31 May 2020, of the top 10 constituents MSB has been the best performer from a share price perspective, up 188.8%, followed by PAR (+81.8%) and PNV (+71.3%). Whilst it has recovered from its March lows, AVH was the only company in the top 10 that saw the share price fall over the two month period, declining 6.9%.

Top 10 Constituents of IIR Pharma & Biotech Index at 31 May 2020		
Company	ASX Code	% Weighting
Pro Medicus Limited	PME	13.7%
Nanosonics Limited	NAN	10.0%
Mesoblast Limited	MSB	9.9%
Polynovo Limited	PNV	8.3%
Clinuvel Pharmaceuticals Limited	CUV	5.5%
Avita Medical Ltd	AVH	4.6%
Opthea Limited	OPT	3.7%
Mayne Pharma Group Limited	MYX	3.3%
Paradigm Biopharmaceuticals Limited	PAR	3.0%
Medical Developments International Limited	MVP	2.4%

## **Impact of Coronavirus**

The coronavirus pandemic has seen unprecedented measures put in place, the ramifications of which has stretched far and wide. Pharma and biotech has been not been immune to the impacts of coronavirus. One of the key disruptions has been delays to clinical trials with access to participants restricted and hospital resources prioritised for coronavirus patients. Some trials have been temporarily suspended while others have continued but the rate of enrolment has slowed significantly, with the exception of Covid-19 vaccine and therapeutic trials which have been prioritised and fast-tracked. Lock down measures have also resulted in a reduction of staff at research laboratories and pathology labs have experienced a significant decline in routine testing as people steer clear of medical centres.

While the sector has experienced disruption we have seen biotech companies step up to the challenge with a rapid response to Covid-19. Biotech companies globally are responding to coronavirus faster than they ever have, as highlighted in the below chart. And it's not only vaccines, there's also been a swift response in the development of diagnostics and potential therapeutics. According to the World Heath Organisation (WHO), at 30 May there were 10 vaccines in clinical trials and 121 candidate vaccines in preclinical evaluation.



Source: BIO

Capital reserves have been a key concern on the back of the coronavirus. We have seen a number of companies tap the market in recent months for capital to boost their balance sheets. MSB recently completed a US\$90m capital raising, COH completed an \$800m raising and PAR raised \$35m just to name a few. A large number of the companies in the sector are in the research and development phase and therefore are generating little-to-no revenue. As such they are heavily reliant on capital raisings to continue development of their products. While some companies have significant cash reserves to weather the coronavirus storm, there are a number of companies that have low levels of cash and will need to successfully raise capital to continue operations.

<sup>1.</sup> 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.

Below we look at stocks that have recently made notable announcements resulting in positive share price movements. These include Mesoblast Limited (ASX: MSB), Prescient Therapeutics Limited (ASX: PTX), THC Global Group Limited (ASX: THC) and Emvision Medical Devices Ltd (ASX: EMV).

## Mesoblast Limited (ASX: MSB)

MSB's share price continued to rise in May, up a further 19% after increasing 142.6% in April. The share price increase comes after the FDA accepted remestemcel-L for priority review with an action date of 30 September 2020 and the company received clearance for an IND from the FDA for remestemcel-L to treat patients with acute respiratory distress syndrome (ARDS) caused by Covid-19. Remestemcel-L is being developed for various inflammatory conditions and is believed to counteract the inflammatory process implicated in these diseases by down regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

Remestemcel-L was made available for compassionate use and in a planned randomised controlled trial. An initial trial of remestemcel-L on Covid-19 patients on a ventilator showed an 83% survival rate with 75% of the patients successfully coming off ventilator support within a median of 10 days. This compared to only 9% of ventilator dependent Covid-19 patients coming off ventilators with standard care treatment and a 12% survival rate. The company has commenced a Phase II/III trial in up to 300 ventilator dependent Covid-19 patients evaluating whether remestemcel-L can reduce the mortality rate of patients with moderate/severe ARDS. The company is enrolling patients in up to 30 sites throughout the US. Enrolments for the trial are expected to be complete in three to four months with interim analysis planned that may see the trials finish early due to either success or failure. During May, the company secured US\$90 million in funding via a placement of 43 million shares to existing and new institutional shareholders at a price of \$3.20 per share (a 7% discount to the share price at close of trading on 8 May, last trading day before company went into a trading halt for the capital raising announcement. The proceeds will be used to scale-up manufacturing of MSB's remestemcel-L product as well as working capital and general corporate expenses.

According to worldometers.info at 2 June, 53,402 (2%) of active cases) are classified as serious or critical.16,949 of these cases being in the US. The US has double the rate of severe or critical cases than Brazil, the country with the second most severe or critical cases at 8,318. There is an immediate need for improved outcomes for ventilator dependent Covid-19 patients with the extent of the longer-term need to be determined by the success or failure of the quest for a vaccine.

#### Prescient Therapeutics Limited (ASX: PTX)

PTX opened 31.1% higher when it came out of its trading halt on 26 May announcing it had entered into an exclusive global licensing agreement with the University of Pennsylvania (UPenn) for a universal immune receptor (UIR) platform and a non exclusive licence with Oxford University to use the Spy Tag/SpyCatcher molecular binding system employed by the UPenn platform. The company intends to build a universal cell therapy platform called "OmniCAR" for next generation cell therapy, with a focus on CAR-T.

The OmniCAR platform could be a game changer for the company with UIR's considered to be the next generation of CAR-T cell therapy with the potential to alleviate a number of the limitations with the current CAR-T treatments. The platform is currently in pre-clinical trials and PTX intends to undertake both internal and external development of the platform. While UIRs have the potential to alleviate some of the issues currently being experienced with the use of CAR-Ts we note that UIRs will encounter their own set of unique challenges through the development phase.

Compensation for the licence agreements was not disclosed by PTX, however, the CEO stated on the investor call that the deal was largely back-ended with a minimal up-front payment negotiated. As such, the company will be able to fund the upfront payment and initial development through existing cash reserves.

### Sienna Diagnostics Limited (ASX: SDX)

During April, SDX announced a merger agreement with BARD1 Life Sciences Ltd (ASX: BD1), a cancer diagnostics business. Under the terms of the agreement, BD1 will acquire 100% of the issued shares in SDX. SDX shareholders will receive 13 BD1 shares for every 5 ordinary fully paid shares held in SDX. The offer valued SDX shares at \$0.06 per share based on BD1's share price of \$0.023 at 6 April 2020. The offer of \$0.06 per share represented a 172.7% increase on the trading price of \$0.022 prior to the announcement. The share price jumped after the announcement to reflect the merger valuation. Shareholders will vote on the merger at the SDX shareholder meeting to be held in June 2020. The Board has unanimously recommended to shareholders to accept the offer in the absence of a more attractive offer and subject to the Independent Expert report.

Subsequent to the merger announcement, SDX announced that it obtained an exclusive worldwide licence to develop and commercialise SubB2M, a unique cancer probe, from the University of Adelaide. SubB2M binds to a unique sugar molecule only present in cancer cells. In pilot clinical studies, SubB2M detected cancers with 100% sensitivity and specificity for mid-to-late stage cancers and >95% specificity and 100% sensitivity for early stage cancers. There is the potential to combine SubB2M with BD1's cancer tissue specific technology to provide the basis for a new highly sensitive and specific assay for the screening of serum and other bodily fluids from individuals at high risk of certain cancers, including breast and ovarian.

The company also announced that it has signed exclusive distributor agreements in New Zealand and Israel for the sale of SDX's hTERT IVD to pathology labs to assist with the diagnosis of bladder cancer. At the end of May, SDX was trading at 7.4 cents per share, a 236.4% increase from 31 March 2020.

## THC Global Group Limited (ASX:THC)

THC experienced a 20% share price rise over May. During the month, the company announced the acquisition of Tetra Health, a clinic network in Australia that facilitates access to medicinal cannabis. Tetra Health has a network of over 600 referring physicians, 30 prescribing physicians and a national network of dispensing pharmacies and has over 1,100 active patients in Australia with prospective patients in excess of 10,000. Tetra Health will continue to be a product agnostic solution for patients and medical professionals post acquisition. Total consideration for the Tetra Health is \$2.5m in THC shares and \$500,000 in cash to be paid to the vendors over 6 months plus 5m unlisted options

exercisable at \$0.40 with an expiry date two years after issue. The acquisition has been completed. The acquisition of Tetra Health advances THC's footprint in the medicinal cannabis industry across the supply chain.

During May, the company also announced that its medicinal cannabis product is now available via prescription in Australia. The full-spectrum cannabidiol (CBD) medicine to be distributed under the Canndeo brand was entirely produced in Australia using cannabis sourced from the company's Bundaberg cultivation facility and manufactured at the company's Southport Facility, a fully TGA GMP licenced facility. The company will continue to progressively roll-out its products over the coming months for both the Australian and international market.

### **Emvision Medical Devices Limited (ASX: EMV)**

EMV charged through its 52 week high during May to be trading at \$1.335 per share at 31 May, up 57% over the month. EMV commenced a clinical trial in January 2020 for EMV's portable brain scanner for stroke and traumatic brain injury diagnosis and monitoring. The primary objective of the clinical trial will be to collect imaging data from stroke patients that allows refinement and selection of the optimal imaging algorithms as well as early data on correlation with CT and/or MRI. The clinical trial will provide the company learnings and the ability to explore the potential of EMV's technology for diagnosing and monitoring time sensitive neurological disorders at the point of care, which is not possible at present. The company seeks to improve patient survival and other outcomes through the use of its technology. The company temporarily suspended its clinical trial in April as a result of the coronavirus, which was subsequently recommenced in May. The company is well capitalised with in excess of \$6m in cash after the company raised \$4.5m in a capital raising in November 2019.

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