

SECTOR OVERVIEW

The IIR Pharma & Biotech Index performed strongly over the month of November, rising 16.6%. Market sentiment was up across the board with the ASX All Ordinaries Accumulation Index up 10.2% for the month. Since we commenced the Index in March 2020, the Index has increased 30.1% to 30 November 2020.

IIR Pharma & Biotech Index¹



Strong performances from Telix Pharmaceuticals (ASX: TLX) and Imugene Limited (ASX: IMU) saw these two companies enter the top 10 constituents of the Index with Starpharma Holdings Limited (ASX: SPL) and PYC Therapeutics Limited (ASX: PYC) falling out of the top 10.

IMU was the best performing stock in the top 10 in November rising 114.3%. This was closely followed by TLX which increased 113.7%. PME was the biggest decliner of the top 10 in November, with the share price falling 8.8%. This was after a 19.7% increase in October. MSB recovered the large portion of its October loss in November with the share price up 36%.

Top 10 Constituents of IIR Pharma & Biotech Index at 30 November 2020

Company	ASX Code	% Weighting
Pro Medicus Limited	PME	11.6%
Mesoblast Limited	MSB	9.2%
Polynovo Limited	PNV	8.0%
Nanosonics Limited	NAN	7.5%
Clinuvel Pharmaceuticals Limited	CUV	3.8%
Telix Pharmaceuticals Limited	TLX	3.7%
Opthea Limited	OPT	2.9%
Paradigm Biopharmaceuticals Limited	PAR	2.5%
Mayne Pharma Group Limited	MYX	2.2%
Imugene Limited	IMU	2.1%

COVID-19 VACCINE RESULTS ARE IN FOR FRONT RUNNERS

It's hard to believe the year that has been. Who would've thought we'd be dealing with a pandemic when the year commenced and then we would have an effective vaccine for the pandemic before the year came to a close. It is an incredible feat for the world and the biotech sector. When the best minds are combined with adequate funding and support it would appear there is little that can't be achieved.

1. The IIR Pharma & Biotech Index is a market capitalisation weighted index and currently includes 143 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.

According to the World Health Organisation (WHO) Covid-19 Draft Landscape at 10 December, there are 13 vaccine candidates in Phase III trials and as it currently stands we have the efficacy results from 5 of the late stage trials and vaccinations have commenced for those candidates that have received approval. The status of the late stage candidates and the results are tabled below.

While the results from some late stage trials have been released there remains a number of unknowns with respect to the vaccine candidates. The key unknown at this stage is the length of immunisation from Covid-19. Trial participants will continue to be monitored to gather this data over time which will be a key piece of information for the future.

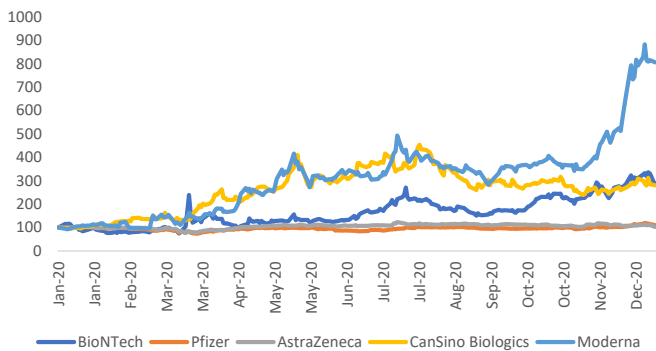
Late Stage Covid-19 Vaccine Candidates

Vaccine Developer/Manufacturer	Vaccine Candidate	Efficacy	Emergency Authorisation
University of Oxford/AstraZeneca	AZD1222	Efficacy of 90% when given as a half dose followed by a full dose at least one month apart. Efficacy of 62% when given as two full doses at least one month apart. Combined efficacy of 70%.	No
Pfizer/BioNTech	BNT162b2	Efficacy of 95% consistent across age, gender, race and ethnicity.	Approved in UK, US, Canada, Kuwait, Bahrain, UAE & Saudi Arabia.
Moderna/NIAID	mRNA-1273	Efficacy of 94.5%	No
Novavax	NVX CoV2373	Unknown	No
Janssen Pharmaceutical Companies	JNJ-78436735	Unknown	No
Gamaleya Research Institute	Sputnik V	Efficacy of 92%.	Approved in Russia
Medicago Inc	CoVLP	Unknown	No
Sinovac	CoronaVac	Unknown	Limited use in China
Sinopharm/Wuhan Institute of Biological Products	Vero Cell	Unknown	Limited use in China & UAE
Sinopharm/Beijing Institute of Biological Products	BBIBP-CorV	Efficacy of 86%.	Approved in UAE & Bahrain with Limited use in China.
Baharat Biotech	Covaxin	Unknown	No
Cansino Biological Inc/Beijing Institute of Technology	Ad5-nCoV	Unknown	Limited use in China
Anhui Zhifei Longcom Biopharmaceutical/Chinese Academy of Sciences	ZF2001	Unknown	No

Source: World Health Organisation, Company websites.

The share price performance of companies associated with the lead vaccine candidates has varied over 2020. Despite having first mover advantage in the Western world, Pfizer's share price has not been the best performer. Moderna has been the best performer YTD by some margin. The share price accelerated in November with the stock up 126.4% for the month with the market anticipating the company receiving emergency use authorisation by the FDA before the end of the year.

Indexed Share Price Performance of Companies Associated with Lead Vaccine Candidates



Source: Yahoo Finance, IIR

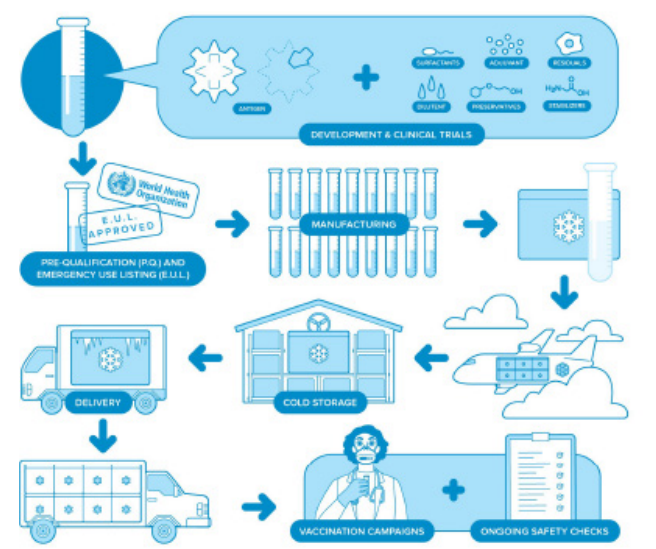
Distribution of Vaccines

This will be the largest global vaccination program in history and with that comes significant challenges with respect to scaling up manufacturing and distribution. With government support companies were able to commence scaling up manufacturing capabilities in anticipation of approval so manufacturers have had a head start to some degree. Limited amounts of the vaccine will be available this year with manufacturing to be ramped up significantly in 2021. However, the manufacture of the vaccine is only one piece of the puzzle.

Once the vaccine has been made in bulk quantities it is bottled in glass vials and packaged for cold storage and transport. Glass vials are commonly used given it is durable and able to maintain its integrity in extreme temperatures.

Vaccines require refrigerated storage with some vaccines requiring greater degrees of cooling than others. For example, the Pfizer/BioNTech vaccine needs to be stored at around -70 degrees celsius. This compares to the University of Oxford/AstraZeneca vaccine that can be stored at 2-8 degrees celsius. When a vaccine is too hot or too cold it becomes less effective or inactive. As such the cold chain for distribution is of great importance and requires specialised equipment for transport.

Journey of a Vaccine



Source: World Health Organisation

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: Rhythm Biosciences (ASX: RHY); Telix Pharmaceuticals (ASX: TLX); Imugene Limited (ASX: IMU); Race Oncology Limited (ASX: RAC); and ImpediMed Limited (ASX: IPD).

Rhythm Biosciences Limited (ASX: RHY)

RHY soared on the news that the preliminary results from the ColoSTAT prototype test-kit outperformed the current market standard. The test-kit demonstrated superior performance to both the market standard faecal immunochemical test and commercially sourced biomarker test kits based on previous testing undertaken by the CSIRO. ColoSTAT had a Sensitivity of 77% and Specificity of 95%. This compared to the market standard test which has a Sensitivity of 63% and Specificity of 95%.

The ColoSTAT prototype test-kit encompasses five individual biomarker tests that have been technically validated. Results for each of the biomarkers are fed into RHY's proprietary algorithm which are then combined and processed with all the relevant data to deliver a final result. ColoSTAT has shown to accurately distinguish between cancerous and healthy blood samples.

The company is seeking to increase the compliance rate of tests with the current standard test experiencing sub-optimal compliance at a global level. The company believes that ColoSTAT has the potential to widen the patient pool outside the standard 50-74 year old bracket which is important as colorectal cancer is not an "old persons" disease, it is the most common cause of cancer deaths for those aged 25-29 in Australia.

RHY's share price climbed 180% in November and the positive momentum has continued into December as the company appoints a global manufacturer for ColoSTAT.

Imugene Limited (ASX: IMU)

IMU was the second best performing stock in the index in November, with the share price increasing 114.3%.

During the month the company announced it had received IND approval from the FDA to initiate a Phase I clinical trial of its checkpoint immunotherapy candidate, PD1-Vaxx, in the US. The clinical trial will seek to determine the safety and optimal dose of PD1-Vaxx as a monotherapy in non-small cell lung cancer patients.

During the month, the company also announced the interim results from the Phase II trial of HER-Vaxx in advanced gastric cancer. The interim analysis showed a statistically significant hazard ratio of 0.418 and a reduced risk of death of 58.2% for those patients treated with HER-Vaxx plus chemotherapy as compared to chemotherapy alone. The median overall survival for patients receiving HER-Vaxx plus chemotherapy was 14.2 months, compared to 8.8 months in patients treated solely with chemotherapy. The trial indicates that B-cell activating immunotherapy vaccines can induce active antibody responses. There was no added toxicity when HER-Vaxx was combined with the chemotherapy treatment. The study was designed to measure the efficacy, safety and immune response in 68 patients with metastatic gastric cancer over expressing the HER-2 protein. Given the significance of the results, the IDMC provided guidance that it is appropriate to reduce the overall number of patients required to complete the study.

The company has a healthy cash balance with \$26.6m in cash at 30 September 2020. The company had 38.045 million options at \$0.026 expiring on 30 November. The company secured an agreement with an existing institutional shareholder to underwrite the balance of the options not exercised by the expiry date.

Telix Pharmaceuticals Limited (ASX:TLX)

TLX's share price was up 113.7% in November on the back of a number of announcements. On 2 November, the company announced it had entered into a strategic commercial partnership with China Grand Pharmaceutical and Healthcare Holdings Limited (CGP) for TLX's portfolio of Molecularly-Targeted Radiation (MTR) products. TLX has appointed CGP as its exclusive partner for the Greater China market and has granted CGP exclusive development and commercialisation rights to TLX's MTR portfolio. The partnership is for an initial 10 years and the material terms of the partnership include:

1) Therapeutic Products:

- ◆ US\$25m up-front, non-refundable payment by CGP to TLX to be credited against future regulatory and commercial milestone payments.
- ◆ Up to US\$69m in regulatory milestone payments.
- ◆ Up to US\$156m in commercial milestone payments, primarily relating to net sales performance.
- ◆ Program related investment of up to US\$65m for clinical costs associated with the development of TLX591 (prostate cancer) and TLX250 (renal cancer).
- ◆ Royalties on product sales.

2) Imaging Products:

- ◆ Exclusive commercial partnership for TLX's core imaging portfolio including TLX250, TLX591 and TLX599.
- ◆ Minimum annual purchase obligations to maintain exclusivity for the Greater China market.

In addition to the above, CGP will make a one-time strategic equity investment of US\$25m in TLX in the form of a private placement of 20.95m TLX fully paid ordinary shares at a price of \$1.69. These shares will be escrowed for 12-months from the date of issue. Additionally, CGP is unable to trade in TLX shares for a period of 12-months.

In late November, the company announced that its NDA for TLX591-CDx, a radiopharmaceutical targeting Prostate-Specific Membrane Antigen (PSMA) for the imaging of prostate cancer has been accepted for filing by the FDA. The company will be seeking to commence a Phase III clinical trial in 2021.

TLX also acquired TheraPharm GmbH during the month. TheraPharm are a Swiss-German company developing diagnostic and therapeutic solutions in haematology. The acquisition will provide TLX access to a portfolio of patents, technologies, production systems, clinical data and know-how in relation to the use of MTR in haematology and immunology. The terms of the acquisition include: (i) an upfront payment of EUR€10.2m comprising EUR€10m in TLX ordinary shares and a EUR€0.2m completion payment; (ii) a EUR€5.0m cash payment upon successful completion of a Phase III pivotal registration trial with Y-anti-CD66-MTR that meets the primary endpoint; (iii) EUR€5.0m cash payment upon approval of Y-anti-CD66-MTR in either US or Europe; and (iv) 5% royalty on net sales for the first three years of sales of Y-anti-CD66-MTR from the date of approval.

Race Oncology Limited (ASX: RAC)

RAC's positive momentum continued in November with the share price up 111.2% for the month. During the month, the Bisantrene data was published in the European Journal of Haematology.

The company also initiated a breast cancer clinical trial program after positive preclinical results. The company appointed George Clinical as the CRO to scope and cost a proof-of-concept clinical trial for the use of Bisantrene in combination with cyclophosphamide in breast cancer patients. Bisantrene was the subject of a series of Phase II and Phase III clinical trials in advance breast cancer patients in the 1980's & 1990's. The Phase III trial showed that Bisantrene had the same efficacy as the standard of care treatment, Doxorubicin, but caused significantly less damage to a patients heart. The company will be seeking to release further details about the trial once the scope and cost has been determined.

The company has had a big year with Bisantrene shown to be a potent inhibitor of Fat Mass and obesity associated protein, which has recently been shown to play a central role in a wide range of cancers. This research has transformed the potential of Bisantrene from a chemotherapeutic to a targeted therapeutic agent with a broad application across oncology. The company's share price is up 852.6% YTD, reflecting the new found potential of Bisantrene.

ImpediMed Limited (ASX: IPD)

IPD is a medical technology company that uses bioimpedance spectroscopy (BIS) technology to generate data to maximise patient health. During the month, IPD announced AstraZeneca had entered into a second contract for its SOZO Digital Health Platform to be used in a Phase II clinical trial to measure fluid volume in patients with chronic kidney disease. The clinical trial is scheduled to commence in January 2021 and run for approximately 18 months. An additional 200 SOZO devices will be leased across 24 countries for the trial. This takes the total number of devices to be leased across the two contracts to 375 across 31 countries. The second contract is valued at over \$2m, with the two contracts combined expected to generate revenues of \$4.5m.

The company also announced the first commercial sales of the SOZO heart failure application. Phoenix Healthcare network has initially purchased five SOZO units with implementation to begin in 2021. The SOZO fluid analysis for heart failure is a novel tool for assessing fluid overload in heart failure patients. It utilises IPD's HF-Dex heart failure index which is a measure of extracellular fluid as a percentage of total body water.

The Phoenix Healthcare network includes over 80 independent companies that provide products and consultation services to skilled nursing facilities in the US and Canada. The products and services are provided with a focus on cardio pulmonary rehabilitation, remote monitoring, pharmacy and training. Approximately 25% of first-time US Medicare heart failure hospital patients are discharged to skilled nursing facilities. This is up from just 5% thirty years ago.

IPD's share price increased 96.4% in November. In addition to the announcements the share price was buoyed by an upgrade to the target price by two brokers covering the stock.

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