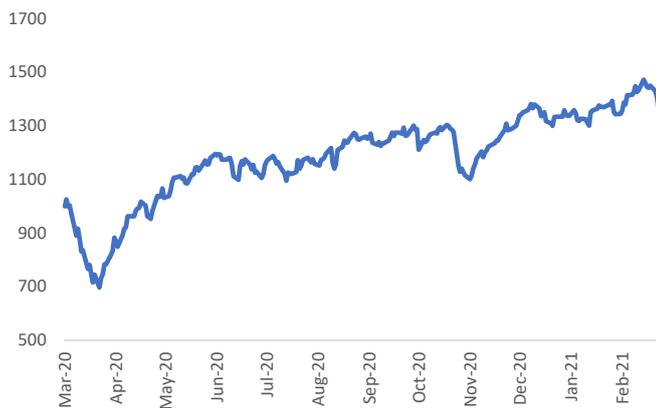




SECTOR OVERVIEW

The IIR Pharma & Biotech Index increased 2.5% over the month of February. Since the start of March 2020, the index is up 37.7%. This compares to the ASX All Ordinaries Accumulation Index which is up 9.6% for the 11 month period. Seven companies in the index experienced share price rises of in excess of 100% in February, with Bard1 Life Sciences Limited (ASX: BD1) leading the pack, up 380% after receiving positive results from its cancer diagnostic technology.

IIR Pharma & Biotech Index¹



SPL was the strongest performer in the top 10, with the share price increasing 38.7%. SPL's share price was buoyed by announcements regarding the expansion of the AND0466 clinical program to include a global trial and a research agreement signed with MSD to conduct a pre-clinical evaluation of dendrimer Antibody Drug Conjugates utilising SPL's DEP technology. The company also announced VIRALEZE antiviral spray has successfully registered in Europe, allowing for sales to commence.

OPT's downward share price trend continued in February with the share price declining 16.9%. The announcement that the company had finalised Phase III study designs failed to generate any enthusiasm in the market.

Top 10 Constituents of IIR Pharma & Biotech Index at 28 February 2021

Company	ASX Code
Pro Medicus Limited	PME
Nanosonics Limited	NAN
Polynovo Limited	PNV
Mesoblast Limited	MSB
Clinuvel Pharmaceuticals Limited	CUV
Telix Pharmaceuticals Limited	TLX
Starpharma Holdings Limited	SPL
Paradigm Biopharmaceuticals Limited	PAR
Opthea Limited	OPT
Imugene Limited	IMU

DIAGNOSTIC STOCKS MAKING A CHARGE

Three of the top ten performers in the IIR Pharma & Biotech Index were companies that have developed or are developing *In Vitro* Diagnostic (IVD) devices/tests. As such, we thought this was a good time to take a look at the IVD market and ASX-listed companies that provide exposure to this market.

IVDs are tests performed on samples taken from the body, such as swabs or blood, to detect diseases and other conditions. IVDs can also be used to monitor a persons health to help cure, treat or prevent disease. IVDs have been brought into the spotlight during the COVID-19 pandemic with IVDs being a key tool used to determine the prevalence of the virus in the community.

IVDs are used to test for antigens, antibodies or genetic markers. IVDs are either designed for use at Point of Care (POC) or in the laboratory. IVD tests performed in the laboratory are the most prevalent, however, advancements in technology are seeing growth in the POC segment.

According to MarketsandMarkets, the global IVD market is forecast to reach US\$118.5 billion by 2027. With respect to IVD technology, the market can be segmented into immunoassay/ immunochemistry, molecular diagnostics, biochemistry/clinical chemistry, microbiology, haematology, coagulation/haemostasis, urinalysis, and other technologies. Currently, the immunoassay/ immunochemistry segment is the largest for the IVD market, however, the molecular diagnostics segment is expected to be one of the fastest growing segments due to the rise of personalised medicine and technological advancements.

The success of personalised medicine depends on the development of accurate and reliable diagnostics and the identification of predictive biomarkers. In the FDA's report "Paving the Way for Personalised Medicine" published back in 2013, the FDA commented that "the sheer pace of the development of IVDs over the past decade has been staggering. Volumes of information arising out of the human genome project combined with a dramatic decrease in costs of DNA sequencing, for example, are giving way to an explosion of publications linking particular genetic markers to diseases or conditions and a rapid application of this information in the development of new molecular diagnostic tests".

Diagnostics are becoming increasingly important for the detection and monitoring of a range of diseases. The benefits of early detection for diseases is also becoming a greater focus due to the improved outcomes associated with early detection. Improvements in technology are allowing for more accurate and improved diagnostic testing. There are a number of companies listed on the ASX that have commercialised or are developing diagnostic technology/devices that can provide exposure to the market (see below table).

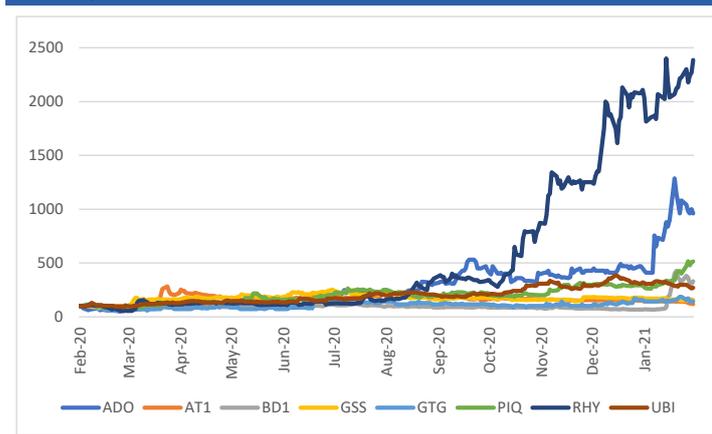
1. The IIR Pharma & Biotech Index is a market capitalisation weighted index and currently includes 143 stocks across the Pharmaceutical, Biotech, Health Care Suppliers, Health Care and Equipment, Health Care Technology and Life Sciences GICs sectors. The index excludes the five largest companies in these sectors being ANN, COH, CSL, FPH and RMD.

ASX-listed IVD Companies

Company	ASX Code	IVD Segment
Anteotech Ltd	ADO	Immunoassay/Immunochemistry
Atomo Diagnostics Limited	AT1	Immunoassay/Immunochemistry
Bard1 Life Sciences Limited	BD1	Immunoassay/Immunochemistry
Genetic Signatures Limited	GSS	Molecular Diagnostics
Genetic Technologies Limited	GTG	Molecular Diagnostics
Proteomics International Laboratories Limited	PIQ	Immunoassay/Immunochemistry
Rhythm Biosciences Limited	RHY	Immunoassay/Immunochemistry
Universal Biosensors, Inc	UBI	Coagulation/Haemostasis

Companies operating in the IVD market have performed well over the 12-months to 28 February 2021. All but one of the companies (AT1) has outperformed the IIR Pharma & Biotech Index. The below chart shows the indexed share price performance of the above listed companies over the 12-month period. RHY has been the best performer on the back of the continued development of its ColoSTAT diagnostic test for colorectal cancer. This has seen the share price increase more than 2,200%. ADO has been the second best performer with the company progressing towards commercialisation of its COVID-19 rapid antigen test.

IVD Companies Share Price Performance



In the below table, we have provided the 1H'FY'21 sales and earnings that were announced in February. The products for a number of the companies are still in development. GSS is currently the only company in the group that is generating positive earnings from its diagnostic test sales. GSS's sales revenue grew significantly in 1H'FY21, primarily on the back of demand for its COVID-19 diagnostic test.

1H'FY21 Sales Revenue

Company	1H'FY21 Sales (\$m)	Change on pcp (1H'FY20)	1H'FY21 NPAT (\$m)
Anteotech Ltd	0.55	503.5%	-1.47
Atomo Diagnostics Limited	4.58	388.5%	-2.55
Bard1 Life Sciences Limited	0.15	na	-3.25
Genetic Signatures Limited	18.84	625.3%	4.40
Genetic Technologies Limited	0.02	2704.8%	-3.48
Proteomics International Laboratories Limited	0.58	-37.6%	-1.87
Rhythm Biosciences Limited	0.00	na	-2.01
Universal Biosensors, Inc	3.20*	-53.6%*	-7.64*

*Represents FY'20 sales and NPAT as company has CY reporting.

Given the majority of companies are still in the development phase we take a look at the cash position of the companies and the cash runway based on the operating cashflow position in 1H'FY21. The cash runway suggests the number of years the company can continue operating without having to raise additional capital based on the cash outflows in 1H'FY21. Note we have removed government grants and rebates and ATO cashflow boosts from the operating cashflow as these are one-off cash injections. Therefore, the following provides the cash runway without the companies receiving any rebates for R&D. GSS is currently the only cashflow positive company and therefore the cash runway is not applicable for this analysis.

AT1 had the greatest cash runway based on 1H'FY21 with 8.9 years of coverage. For companies in the development phase, investors should take into consideration the ease with which companies can raise capital if the cash runway is limited. BD1 and RHY have relatively low cash coverage compared to the other companies, however, recent positive announcements is expected to support any capital raising requirements for these companies to advance their products to commercialisation.

Cash Runway

Company	Cash Position (\$m)	Cash Runway (years)
Anteotech Ltd	6.4	2.0
Atomo Diagnostics Limited	24.7	8.9
Bard1 Life Sciences Limited	7.3	1.0
Genetic Signatures Limited	36.3	na
Genetic Technologies Limited	16.4*	2.0*
Proteomics International Laboratories Limited	7.5	2.5
Rhythm Biosciences Limited	6.0	1.1
Universal Biosensors, Inc	23.6	2.8

*Does not include US\$6.56m capital raised in January.

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: Bard1 Life Sciences Limited (ASX: BD1); MGC Pharmaceuticals Ltd (ASX: MXC); Bionomics Limited (ASX: BNO); Anteotech Ltd (ASX: ADO); and Optiscan Imaging Limited (ASX: OIL).

Bard1 Life Sciences Limited (ASX: BD1)

BD1's share price skyrocketed in February after the announcement of the positive test data for the company's cancer diagnostic tests for both Ovarian and Breast cancer.

BD1 aims to develop best-in-class diagnostic tests using its platform technologies for the screening, diagnosis, treatment selection and/or monitoring cancers. Post the merger with Sienna Diagnostics in 2020, the company's cancer diagnostic portfolio includes the hTERT test to be used as an adjunct to urine cytology testing and diagnostic tests using the SubB2M technology. The hTERT test is currently revenue generating while the SubB2M tests are in development.

On February 11, the company announced that data released by Griffiths University regarding use of the SubB2M technology showed 100% specificity and 100% sensitivity for the detection of all stages of ovarian cancer. This was followed by an announcement on 15 February with data from the SubB2M technology showing 100% specificity and over 95% sensitivity for the detection of all stages of breast cancer. While data released is

preliminary, the results are significant and support the commercial potential for the SubB2M diagnostic tests.

The company's share price was up 638.2% at one point on the back of the announcements before tapering off to finish the month up 380%.

MGC Pharmaceuticals Ltd (ASX: MXC)

MXC's share price was up 238% in February. The share price was driven by the announcement that the company was going to list on the London Stock Exchange and was going to raise GBP\$6.5m as part of the IPO.

MXC is currently undertaking a pre-clinical research program into the use of cannabinoids into the treatment of Glioblastoma Multiforme (brain cancer). In vitro results have shown that the formulated cannabigerol (CBG) can eliminate therapy-resistant glioblastoma stem cells. During the month, the company announced that the study has been expanded to explore the use of the nano technology in relation to the most effective treatment delivery systems.

The program is being conducted in collaboration with the National Institute of Biology ('NIB') and the Neurosurgery Department at the University Medical Centre in Ljubljana, Slovenia. It is focused on testing cannabinoid formulations on fresh glioblastoma tumour tissues, obtained from patients after surgical removal of the tumour, to determine the optimal cannabinoid preparation for the effective treatment of the remaining cancer. The program will test cannabinoid alone and in combination with chemotherapeutic temozolomide.

During the month, the company also announced that it had signed a supply and distribution agreement with biopharmaceutical group, Swiss PharmaCan AG, for its ArtemiC Rescue food supplement. The agreement has a minimum of three years of global exclusivity and includes a minimum wholesale order of 40,000 units. The company said that it has received an initial wholesale order of 10,000 units which has a retail value of \$850,000.

Bionomics Limited (ASX: BNO)

During the month, BNO raised \$16m to progress the Phase IIb clinical trial of the use BNC210 in Post Traumatic Stress Disorder (PTSD). The placement was made to institutional and sophisticated investors with the new shares issued at \$0.145 per share, a 20% discount to the 30-day VWAP as at 5 February 2021 but represented a 263% premium to the capital raise completed in September 2020. Subsequent to the placement, the company announced an Entitlement Offer, providing shareholders the opportunity to acquire shares in the company at the same price as the placement offer to institutional and sophisticated investors. The company will seek to raise up to \$20m through the offer. As part of the capital raising activities approved by shareholders at the General Meeting on 26 August 2020, Apeiron agreed to underwrite the further raising to the amount of A\$15,000,000 at a minimum price of A\$0.06 per share. This underwriting obligation has been fully fulfilled by this capital increase.

During February, the company also announced results from the BNC1210 7-day dosing pharmacokinetic study exceeded blood exposure expectations. BNC210 is a novel oral tablet formulation that will be progressing to a Phase IIb trial in 2021. The study involved ten healthy volunteers that received 900mg twice a day for the 7-day period. The tablet has steady-state 12-hourly exposure levels ranging from 33-57 mg.h/L which exceeded the predicted blood exposure of ~25mg.h/L which was necessary to meet the primary endpoints for the PTSD study. The tablet formulation

replaces the liquid suspension formulation which did not provide sufficient blood exposure to exhibit efficacy.

In January, the company completed the treatment of patients in its Phase II clinical trial for the use of BNC105 in combination of Nivolumab for the treatment of colorectal. The results from the trial are expected to be received in 2Q'CY21.

BNO's share price was up 160% in February and the stock is up 231% over the 12-months to February-end.

Anteotech Ltd (ASX: ADO)

ADO continued its positive momentum in February. As mentioned in the previous edition of our newsletter, ADO was one of the best performers in the IIR Pharma & Biotech Index in 2020.

During the month, the share price reacted positively to the news that one of its customers, Ellume, had secured an agreement with the US Department of Defence for its COVID-19 at home test. Ellume's home test is the first non-prescription over-the-counter self-test authorised by the FDA for emergency use. Ellume integrates AnteoBind technology in their proprietary quantum dot diagnostics platform.

Increased promotional activity of AnteoBind and AnteoBind kits saw ADO record sales of \$545,583 in 1H'FY21, up from \$90,410 in the pcp. As Ellume commences large scale production of their home test, the company anticipates that sales will increase modestly.

With respect to the COVID-19 rapid antigen test, plans to accelerate the prospective clinical trial by six months have been completed. AnteoTech and contract research organisation, Novotech, have finalised arrangements to conduct a Prospective Clinical Trial through Novotech's Indian laboratories. A 'Prospective Clinical Trial' is one where patients are selected based on their symptoms. The trial will include a full evaluation of the COVID-19 rapid test using nasal samples as well as saliva samples direct from patients. The trial will be performed in Q2'CY21.

The share price was volatile over the month of February, with the share price up 235% throughout the month, hitting highs of \$0.335 per share before finishing the month up 135% with the price closing at \$0.235 per share.

Optiscan Imaging Limited (ASX: OIL)

OIL's share price lifted on the back of the announcement that the Breast cancer study was progressing to the next stage. The study will involve 20 breast cancer patients at three Melbourne hospitals using OIL's FIVE2/Viewn vivo endomicroscope. The endomicroscope enables real-time 3D *in-vivo* imaging of human tissue at the cellular level. It provides instant virtual biopsies for cancer screening enabling faster diagnosis and treatment. The instrument is hand-held and allows surgeons and pathologists to instantly view tissue at 1,000 times magnification enabling clinicians, surgeons and pathologists to identify cancerous tissue on the surface of a specimen in real-time, reducing the need to have specimens sent to a laboratory for processing.

OIL's share price finished the month up 131.8%. The share price is up 844% over the 12-months to February-end.

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