ISSN 1443-850X

Subscribe to Bioshares
$550/
24 issues

More details can be found on the back page

Bioshares

3 June 2022
Edition 918

Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies

Companies covered: **DXB, EX1, NTI, PAB, RAD, TLX**

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-35.8%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 - May '15)	23.0%
Year 15 (May '15 - May '16)	33.0%
Year 16 (May '16 - May '17)	16.8%
Year 17 (May '17 - May '18)	-7.1%
Year 18 (May '18 - May '19)	-2.3%
Year 19 (May '19 - May '20)	39.5%
Year 20 (May '20 - May '21)	86.8%
Year 21 (May '21 - May '22)	-15.6%
Year 22 (May '22 - Current)	-2.1%
Cumulative Gain	1580%
Av. Annual gain (21 yrs)	19.0%

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.
ACN 085 334 292
PO Box 447
Flinders Lane Vic 8009
AFS Licence No. 258032

Mark Pachacz - Editor/Analyst
Email: mark{at}bioshares.com.au
Ph: 0403 850 425

Edition Number 918 (3 June 2022)

Copyright 2021 Blake Industry and Market Analysis Pty Ltd. ALL RIGHTS RESERVED. Secondary electronic transmission, photocopying, reproduction or quotation is strictly prohibited without written consent of the publisher.

Telix Gains CMS Approval for Illuccix

Telix Pharmaceuticals (TLX: $4.09) has received 'Transitional Pass-Through (TPT) Payment Status' for its prostate cancer diagnostic, Illuccix, from the US federal agency Centers for Medicare and Medicaid Services (CMS). Illuccix was launched earlier this year in the US market.

The TPT program is designed to "foster innovation and increase access to cutting-edge treatments that benefit patients." The program allows early reimbursement whilst Medicare in the US collects data to establish permanent reimbursement rates.

CMS and private health insurers will also recognise the HCPCS Level II code for reimbursement. Both reimbursement payments will start from July this year.

The Illuccix test will be used for patients with suspected prostate cancer metastases undergoing initial therapy, as well as patients who have been treated and it is believed the cancer is progressing (elevated PSA levels).

To the end of last year Telix had administered over 13,000 doses of Illuccix, with that number expected to have increased substantially since the US commercial launch. (Previously the product was sold under compassionate and other early use programs.)

This will now provide full reimbursement for the radiopharmaceutical tracer and the PET-CT scan in the hospital outpatient setting. The wholesale price for Illuccix is US$4700 and is expected to include an additional 3% with the TPT status. Currently Illuccix is being reimbursed through a Not Otherwise Classified code. The HCPCS Level II code (A9596) will make the reimbursement significantly more streamlined and accessible.

Continued over

Exopharm Introduces Significant Cost Cuts

Exopharm (EX1: $0.16) has announced a significant cost cutting decision. Director and CEO pay will be reduced by 20% and the COO and the Senior VP of Finance have left the company. A new international travel cost program has also been implemented. The company held cash reserves of $5.6 million at the end of March.

The company has cited the deteriorating financial markets, particularly around the biotech sector as a driver of its cost reduction program. This move may be replicated by other biotechs with low cash reserves and a weak share register with insufficient institutional investors.

At this point access to sufficient funding for biotech companies is likely to be an increasing risk and investors may consider increasing their portfolio weighting to companies in stronger financial positions.

Bioshares Recommendation: Speculative Hold Class C

PSMA-PET imaging is included in the National Comprehensive Cancer Network (NCCN) guidelines in the US for prostate cancer imaging with those guidelines recently changed for use as an alternative (no longer adjunct) imaging technique. Danielle Meyrick, Chief Medical Officer for Telix, said this is very much seen 'unequivocally' as the gold standard for prostate cancer imaging.

As a result, Illuccix sales can be expected to accelerate in the September quarter. Illuccix was launched in the US in mid-April with sales to be reported in the June quarter cashflow statement.

The approval of Pluvicto from Novartis in March this year is expected to increase demand for the Illuccix test, with Pluvicto being a radiopharmaceutical therapy targeting PSMA. Meyrick said the approval of Pluvicto was a landmark event for the nuclear pharmaceutical sector.

It requires gallium-68 PET imaging, such as Illuccix , to select patients for therapy. (We note that Novartis also received approval for its own PSMA nuclear imaging agent at the same time, called Locametz.) In the US and Europe, the prostate cancer imaging market is estimated by Telix at US$1 billion a year.

Illuccix binds to PSMA which is expressed around 100 times more on prostate cancer cells than other healthy cells in the body and is even more highly expressed in metastatic disease.

Illuccix is also approved and reimbursed (under the Medicare Benefits Schedule (MBS)) for use in Australia. It was launched this month.

Prostate Cancer Imaging Modalities

Prostate cancer has historically been imaged using CT scans however this relies on changes in the tissue and needs to be a particular size before they can be defined as malignant according to Meyrick. MRI is a powerful tool for imaging cancers, however also relies on structural/morphological changes in the tissue. Nuclear medicine bone scans have been used for over 70 years, however focuses on picking up high bone turnover and is particularly problematic in people with arthritis.

PET scans (18F-FDG) rely on the increased metabolic demand of cancerous tissues compared to healthy tissue, according to Meyrick. But in prostate cancer it is poor in detecting early-stage disease and does not detect all lesions.

In a 32-patient study comparing Illucix with bone scans, Illuccix achieved a sensitivity of 83% (compared to 50% for bone scans) and a specificity of 92% (84% for bone scans). The accuracy in those same patients when using MRI was 72% compared to an overall accuracy of 91% for Illuccix. According to Meyrick, the importance of this product is that with its superior detection or rejection of imaging spots, a more appropriate therapy can be prescribed. In one patient imaged with a bone scan, a metastatic lesion in the ribs was missed with bone scanning but picked up with Illuccix.

In a lesion picked up with both MRI and Illuccix, whilst the tumour was confirmed with Illuccix, with MRI the lesion would have needed to be monitored for growth to confirm malignancy.

Advantages of Illuccix

Meyrick said that there has been very strong demand for Illuccix since launch in April with most of the 128 sites in the US now routinely dispensing Illuccix. She said that clinicians have been desperately waiting for this test. Lantheus Holdings launched its F18 labelled PSMA imaging test, Pylarify, in December last year. In the first quarter Pylarify generated sales of US$7 million (without reimbursement), US$32 million in the next quarter (with some reimbursement), and now has full reimbursement. Sales in 2022 of Pylarify are forecast by Lantheus to be between US$385 - US$420 million.

The F18 tracer from Lantheus is produced in a cyclotron with the treatment needing to be three hours from manufacture. The gallium-68 diagnostic isotope from Telix can be prepared in a nuclear pharmacy on the benchtop in a generator, or in a central facility using a cyclotron. It can be accessed from 128 nuclear medicine pharmacies in the US which covers 85% of the US PET imaging market compared to 23 sites for Pylarify (as of 17 May this year).

(Gallium-68 has a half-life of 68 minutes where F18 has a half-life of 110 minutes. However, the significant advantage of using Gallium-68 is that it can be produced in a nuclear pharmacy, from Germanium-68 which has a half-life of 271 days, where F18 needs to be produced in a central cyclotron facility.)

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

2022 Blake Award for Excellence Winner

Congratulations to Telix Pharmaceuticals which received the inaugural 'Blake Award for Excellence' at the 16th Bioshares Biotech Summit, held in Albury recently.

Bioshares Biotech Summit Coverage

Radiopharm Theranostics - Six Therapeutic Studies to Commence in 2023

CEO of Radiopharm Theranostics (RAD: $0.185), Riccardo Canevari, believes that the next big platform in oncology, following immunotherapy and cell therapies, will be radiopharmaceuticals.

Canevari highlighted the said the approval of Lutathera (in 2018) from Novartis (where Canevari was working at the time), for the treatment of neuroendocrine tumours and the more recent approval this year of Pluvicto (also from Novartis) as key events for the sector. Lutathera achieved a stunning efficacy result in its pivotal trial achieving a hazard ratio of 0.21, meaning a 79% risk reductio of disease progression or death. For Pluvicto, reaching primary and secondary endpoints in prostate cancer was a game changer.

The interest is supported by the acquisitions of Advanced Accelerator Applications (AAA) in 2017 and Endocyte by Novartis in 2018 for US$3.9 billion and US$2.1 billion respectively. AstraZeneca also entered the space in 2020 in a collaboration with Fusion Pharmaceuticals in Canada and in 2021 Bayer acquired Noria Therapeutics and PSMA Therapeutics.

Whilst radiopharmaceuticals are only approved for the treatment of two solid tumour types, Canevari argued that there is no reason why the approach should not be successful against other solid tumours as well. He believes that it is only a matter of time when the other major pharmaceutical companies will enter the space.

Radiopharm is a new company in this field, having been formed in February last year, raising $20 million in a private raise in July, followed by an IPO on the ASX in November, raising $50 million (at $0.60 per share).

Canevari previously led the team at AAA when it was acquired by Novartis. He worked on both Lutathera and Pluvicto.

Radiopharm has five discrete assets it is commercialising, exploring monoclonal antibodies, a peptide, a single chain antibody and a small molecule as targeting agents using a range of commercially available imaging and therapeutic isotopes. The targeting agent is the most important asset Canevari argues in radiotheranostics. Radiopharm is seeking to hit several targets with its molecules. These include HER2, PDL1 and PSA.

The five Radiopharma programs are all in oncology with patients treated in three of those programs (167 patients so far). Of interest is that three of those programs are with alpha therapeutics (Ac225) although Canevari said the company is isotope agnostic using both alpha and beta emitters. He does not believe one is better than the other but depends on the type of disease (tissue) being treated.

The company will use the imaging products mainly for patient selection with the emphasis being on the therapies.

Radiopharm has four Phase IIa imaging trials underway with the lead asset, with one of those studies, imaging brain metastases, due to read out around mid year. Canevari believes this may show significant results over the standard-of-care.

In the second half of this year three Phase I therapeutic studies with two different assets are due to start – in breast cancer (targeting HER2), in NSCLC (targeting PDL1) and prostate cancer (targeting PSA with Ac225 as the isotope) – together with an imaging study with its fourth asset. Results from all four of those studies are expected next year. Two of the therapeutic studies will be conducted in Australia with the second two studies to be run in the US. The aim is to also commence an additional six therapeutic studies next year.

One of the challenges with using the alpha-emitter Ac225 is that it needs to be internalised into the cell very quickly as it releases daughter nuclides. This occurs with the recent targeting agent licensed, the humanised monoclonal antibody DUNP19, which binds to LRRC15. LRRC15 has very limited expression on healthy cells. Canevari believes this is an even better target than FAPi (fibroblast activation protein inhibitor), which has become a popular target in oncology. With radiopharmaceuticals safety is key, with the dose always being able to be increased to improve efficacy.

Radiopharmaceuticals this week appointed a COO, Vittorio Puppa, who will be based in New York City.

Bioshares recommendation**: Speculative Buy Class B**

Bioshares

Acuity Capital conducted a masterclass on at-the-market (ATM) financing at this year's Bioshares Biotech Summit, which is an alternative/additional financing option to listed companies. Below is a summary of the facility that Acuity provides. Acuity Capital was a sponsor of the event this year.

At-the-Markets and Life Sciences

Capital is the lifeblood of early-stage Australian life sciences and biotech companies. Adding an At-the-Market (ATM) solution to your capital management toolkit can help you raise capital at better prices with more flexibility.

The road to commercial success in the life sciences industry is typically long and challenging. As a result, raising capital at multiple points along the journey is as integral to the sector as PhDs or clinical trials.

The best way to meet the capital needs of a given company is not an exact science. However, a company that has the full suite of available capital management tools at its disposal is more likely to minimise capital costs, maximise flexibility and be in a stronger position to take advantage of market opportunities. This affords a company the longest runway possible to achieve commercial success.

An At-the-Market (ATM) solution allows a listed company to raise capital by issuing shares at or near the prevailing market price. Under an ATM, the company retains full control over the timing, minimum issue price and maximum number of shares to be issued. There is no requirement to use an ATM, though once established an ATM can be activated and put into 'capital raising mode' in as little as 30 minutes.

In this way, an ATM offers an alternative source of equity capital that is often more efficient and lower cost than traditional capital raising methods. ATMs have a fair, transparent pricing structure and can be a valuable source of additional capital. Importantly, ATMs place no restrictions on accessing other forms of capital and are therefore typically used as part of a diverse capital management toolkit to complement traditional capital raising methods. With an ATM in place, a company can:

– Reduce the cost of capital: ATMs broaden the capital raising options available to a company. They reduce reliance on any one source of capital and help to lower the cost of capital across all sources.
– Take advantage of market opportunities: the ability to quickly activate an ATM allows a company to take advantage of favourable short-term market conditions such as spikes in share price. This is often not possible using traditional capital raising methods.
– Maximise capital and reduce dilution: by giving companies control over the timing, minimum issue price and maximum number of shares to be issued, ATMs help maximise the capital raised while minimising dilution.

While ATMs are currently a relatively small part of the capital raising landscape for Australian listed life sciences companies, they are integral to the success of the sector in the United States. In 2021 alone, more than 700 ATMs were established by US companies with a total ATM facility size of more than US$140 billion; of these, nearly half were established by companies in the life sciences sector.

The popularity of ATMs across the US market reflects their efficiency and effectiveness in raising capital. In many scenarios, ATMs deliver better capital raising outcomes with comparatively low effort. This is true for companies both large and small, with household names such as Tesla, Bank of America and Blackrock choosing ATMs over a myriad of other debt and equity options available to them.

The outsized popularity of ATMs in life sciences can in large part be explained by the shared characteristics of many companies in the sector. Life sciences companies often have very long product development time horizons requiring multiple injections of capital to fund the next key development milestone. This often results in long periods of relative share price inactivity broken by short periods of high activity and large share price spikes, especially around milestone events. ATMs allow a company to benefit from these characteristics by acting quickly to raise larger amounts of capital at higher prices during the share price peaks.

Maximising capital while minimising dilution in this way lengthens the runway that companies have to achieve commercial success. This is particularly important for the life sciences sector given the complexity of the problems it seeks to solve and the incredible impact solutions can deliver.

For more information about ATM solutions for Australian-listed companies, contact Acuity Capital on 1300 180 979 or info@acuitycapital.com.au.

Bioshares Biotech Summit Coverage

Dimerix - Structural Regulatory Changes in Kidney Diseases Perfect Timing

During the pandemic, Dimerix (DXB: $0.17) was very pleased to have been able to complete two Phase II kidney disease studies. The company has now moved to a Phase III program in FSGS (kidney disease) involving 75 sites spread across 12 countries, including in the US where the company recently gained FDA approval (IND) to commence its study there as well. The first patient was treated in this study this week.

Dimerix CEO Nina Webster said that sclerotic kidney disease is a progressive three mechanism cycle that results in an acceleration of the disease as it progresses to end stage kidney failure. The drugs currently on the market all focus on the first mechanism of this disease by reducing hypertension across the bloodstream.

Dimerix's compound, DMX200, works on the second mechanism of disease, reducing inflammation in the kidneys. However only blocking one of these mechanisms allows upregulation via the other mechanism that is not blocked. In this way, blocking both pathways of disease provides more benefit than just the of sum of the parts according to Webster.

Webster said that the drugs that work on the first mechanism have been on the market since the early 1990s, which was the last real pharmaceutical innovation in this field, other than in the last two years.

Webster provided a summary of all the licensing delas completed during the pandemic in the kidney drug therapeutics field (see presentation on the Bioshares or ASX websites), highlighting that there is considerable commercial activity in this field now (10 major commercial deals since November 2020). One transaction of particular relevance was the deal between Travere Therapeutics and Vifor Pharma (being acquired by CSL) for US$845 million for European rights alone to its drug Sparsentan. This is of relevance because Sparsentan is also being developed for the treatment of FSGS and is at the Phase III stage of development.

There have also been six major M&A deals in the last two years in the kidney disease therapeutic space, the most significant being the bid by CSL for Vifor Pharma for US$11.2 billion.

So why is there suddenly so much activity in the kidney disease space now? Webster said that historically incentive programs in this field were lacking as well as a deficiency in public policy for this disease space. In 2018 the EMA and the FDA held workshops to determine how these barriers could be addressed.

In the US, the level of disease is remarkably high, with 40 million adults with kidney disease. "This is a huge number," said Webster. The annual cost to the US healthcare system is US$88 billion, of which US$55 billion is for assisting people with end stage renal failure. Webster said the dilemma then is how to prevent patients moving to end stage care (renal dialysis).

In 2019 a White House executive order was released to encourage more companies to develop therapies to prevent or slow the progression of this disease.

The 2018 regulatory workshops investigated the potential introduction of surrogate endpoints to accelerate drug development in the field. In 2019 the FDA published that it would accept surrogate endpoints, such as proteinurea and GFR (glomerular filtration rate) in clinical studies for certain conditions.

This was supported the following year by a number of publications that confirmed the direct link between proteinurea and kidney survival in FSGS (as the kidney fails an increasing amount of protein is leaked out through the kidney into the urine).

And in 2021 the FDA confirmed this change through the approval of the first kidney drug based on proteinurea levels in a rare kidney disease. If the endpoint is kidney failure then studies would have taken five to 10 years to complete according to Webster. But now these trials can be conducted in one to two years.

Webster said the timing was perfect for Dimerix which has moved into its Phase III program in FSGS this year.

FSGS is a severe condition that causes end stage kidney diseases on average five years after diagnosis. Even in patients who receive a transplant, FSGS reoccurs in around 40% of patients. There are currently no approved drugs for this disease said Webster.

The reason that Dimerix has moved into a major Phase III study is that in its Phase II study, 86% of patients experienced a benefit from DMX200 compared to placebo.

Novel Capital Raise Structure

To fund its Phase III program, Dimerix conduced a novel capital raise last year. The first step was a placement and SPP, which raised $24 million (at $0.20 per share). However, the structure included options (one for two) at a 100% share price premium to the raise ($0.40 per share). Those options will be activated by an accelerated trigger event. That trigger is the release of interim results, that if positive, will allow for funding of the second part of the study, de-risking the second half of the raise. Webster said that this 'accelerated trigger event (not date)' has never been seen before in biotech, with Webster having seen the concept previously in raises conducted by banks.

The Phase III design structure has three analysis endpoints, the first of which is the trigger event for activation of the options. This is an analysis of the first 72 patients treated (for 35 weeks) to confirm the same benefit seen in the Phase II study, which the company expects to see, measuring proteinurea.

Continued over

Part two recruits a further 72 patients treated also for 35 weeks. It will then use the results from those 144 patients and submit for accelerated approval with the FDA (with the surrogate marker of proteinurea) and bring the drug to market. Whilst on market, the study will continue until 286 patients are enrolled and all have been treated for a minimum 35 weeks. That is expected to take two years (104 weeks). The final analysis will use filtration rate through the kidneys (eGFR) as the final endpoint.

Path to Market

At this point Dimerix does not intend to bring DMX200 to market on its own but will seek a partner. However, it needs to be the right deal stressed Webster with the company currently funded to progress its Phase III FSGS program.

In response to questions, Webster said that one of the benefits at the moment is that Sparsentan has finished its Phase III FSGS trial with no other Phase III global programs underway in FSGS. Sparsentan is an angiotensin receptor blocker (ARB), similar to other drugs on the market. Given FSGS is a progressive disease, improved therapies are always needed with DMX200 delivering the same benefit with Sparsentan or any other ARB therapies. Current ARB drugs only slow down disease progression by around two years.

Bioshares recommendation: **Speculative Buy Class A**

Patrys - Can Its Antibodies Prevent Metastases?

By 2027 the sales of biologics are predicted to surpass the aggregate sales of small molecule drugs, with US$120 billion more sales and making up 55% of all drug sales. This is a positive aspect for Patrys (PAB: $0.022), an antibody therapeutics company, according to CEO James Campbell. However, small molecule drug sales are still expected to increase by around 50% over this period driven by CNS therapy product sales.

About 60% of biologic drug assets are transacted through a licensing/partnering deal at the preclinical stage, compared to 39% for small molecules. The average deal size for preclinical biologic deals is about twice that for small molecules.

Patrys has antibody assets that target cancer cells regardless of cell surface markers on the particular cancer type, as well as crossing the blood-brain-barrier. It inhibits the DNA repair processes in tumour cells. It does this by entering the cell nuclei, which is very rare.

Three of the poorly served cancers Patrys is looking at are glioblastoma, triple negative breast cancer and pancreatic cancer. The reason these are difficult to treat is because there are no cell surface markers to target. As mentioned, because the Patrys antibodies do not rely on cell surface markers, it has potential utility in these cancers as well.

In preclinical studies in these three indications, the Patrys antibody increases survival by between 41% - 47%. Studies have shown a 93% reduction in brain metastases. However, the interesting question for Campbell is whether the antibodies are killing the cancer cells or preventing metastases.

Patrys expects to be in Phase I studies around mid 2023 with is lead PAT-DX1 (a smaller version of its second drug candidate, PAT-DX3).

Looking back over the last two years, Patrys moved to two assets under development, raised around $20 million, with a market value that has increased from $15 million to $45 million. The funds raised have allowed the company to progress multiple applications of its technology, including the development of antibody drug candidates (where the Patrys antibodies can help deliver other therapeutics into cells or across the blood-brain-barrier). It has also significantly enriched its patent suite over this period to 12 patent families.

An area for Patrys to explore is the potential combination of its technology outside of the oncology space, to deliver other therapeutics, such as gene editing therapies and gene-modifying cell therapies, directly into the nucleus (using its surprisingly invasive technology). The aim for the next two years appears to be not just advancing its two leading programs which are funded into the clinic, but to expand the assets under development, including with partners bringing in non-dilutive funding.

Bioshares recommendation: **Speculative Buy Class B**

Neurotech International - Efficacy Results Pending

Neurotech International (NTI: $0.066) has worldwide rights to rare types of cannabinoids for the treatment of neurological conditions. The company's lead candidate is NTI164. CEO Alexandra Andrews said this compound is substantially different to other cannabinoid treatments. The NTI cannabinoid strains are high in CBDA, include a range of minor cannabinoids, and importantly has a very low level of THC (less than 0.3%), which is the part of cannabinoids that changes mental alertness.

In preclinical studies, NTI164 has shown to reduce brain cell inflammation by 60%, increase brain cell viability by up to 80%, and has reduced neuromarkers linked to multiple sclerosis.

Autism Spectrum Disorder (autism) affects one in 44 children. There is only one FDA approved drug for this disorder, Risperidone, which has considerable side effects. Ritalin is also used, off-label, but also comes with uncomfortable side effects.

In May 2021 Neurotech started a Phase I/II clinical study at Monash Children's Hospital in 20 children with autism. This trial uses a whole plant strain of its proprietary cannabinoid with the minor cannabinoids the key ingredient. The trial assessed four different doses of NTI164.

Continued over

Bioshares Model Portfolio (3 June 2022)

Company	Code	Price (current)	Price added to portfolio	Recommend-ation	Cap'n ($M)	Date added
Telix Pharmaceticals	TLX	$4.09	$7.85	Spec Buy A	$1,277	December 2021
Clinuvel Pharmaceuticals	CUV	$15.25	$20.31	Buy	$754	November 2020
Neuren Pharmaceuticals	NEU	$3.80	$3.25	Spec Buy A	$479	December 2021
Opthea	OPT	$1.35	$0.16	Spec Buy A	$469	November 2014
Cogstate	CGS	$1.68	$0.24	Buy	$286	April 2019
Aroa Biosurgery	ARX	$0.77	$1.11	Spec Buy A	$263	November 2021
Immutep	IMM	$0.43	$0.32	Spec Buy A	$366	March 2019
Genetic Signatures	GSS	$1.22	$1.24	Buy	$174	May 2022
Somnomed	SOM	$1.45	$2.05	Spec Buy A	$120	January 2022
Micro-X	MX1	$0.170	$0.38	Spec Buy A	$78	May 2017
Antisense Therapeutics	ANP	$0.098	$0.22	Spec Buy A	$71	November 2021
Rhinomed	RNO	$0.170	$0.27	Spec Buy B	$52	December 2021
Pharmaxis	PXS	$0.084	$0.26	Spec Buy A	$44	December 2016
Patrys	PAB	$0.022	$0.013	Spec Buy B	$45	July 2020
Chimeric Therapeutics	CHM	$0.11	$0.27	Spec Buy B	$44	December 2021
Dimerix	DXB	$0.170	$0.09	Spec Buy A	$55	December 2018
LBT Innovations	LBT	$0.093	$0.09	Spec Buy B	$30	April 2022
Acrux	ACR	$0.072	$0.31	Spec Buy B	$20	July 2017

Portfolio Changes

IN:
None

OUT:
None

In this study, it was planned to have a wash-out period whereby the children would be taken off therapy for four weeks and then enrolled in the Phase II/III study. However, Andrews said that very surprisingly the company was lobbied by parents in the study to continue children on treatment.

Neurotech is awaiting the efficacy results from the Phase II study in children with autism at Monash Children's Hospital. Pending positive results, chairman Brian Leedman expects the program to then move into a Phase III trial. Results are due this month.

Subsequent studies with NTI164 will look at the conditions of multiple sclerosis and cerebral palsy, which Andrews said are the two most advanced programs.

The key path to market for Neurotech is to develop NTI164 as a pharmaceutical. It will also be looking to develop the drug as a combination use, which Andrews believes is a faster path to market. The Phase II/III study in autism is expected to start in Q3 this year in Australia with the study expected to finish around mid 2023. An FDA approved study in the US is expected to start at the end of next year. Licensing discussions are due to begin towards the end of this year.

Neurotech filed two families of patents around the proprietary cannabinoid strains last year, which includes composition of product and combination use. At the end of March, the company had $2.3 million in cash.

The strains NTI is commercialising were originally grown in China in 1989. NTI has plant breeders' rights over these strains which are grown from protected clones and cannot be replicated from the seeds alone.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Immutep - Oral Presentation at ASCO

Immutep (IMM: $0.43) had two abstracts published at ASCO (American Society of Clinical Oncology) this week plus an oral presentation, being one of the 250 groups making oral presentations.

The oral presentation will be on the full data from 144 patients with NSCLC being treated with the company's lead drug candidate, IMP321. Recruitment was completed in November last year. Data from the oral presentation will be released by the company next week. The abstract on the first 75 patients treated with IMP321 with Keytruda showed an objective response rate (ORR) of 37% compared to around a historical 20% ORR with Keytruda alone. Data presented at ASCO last year showed an ORR of 36% on the first 36 patients.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

How Bioshares Rates Stocks

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "Take Some Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages of commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Cogstate, Opthea, ResApp Health, Pharmaxis, Dimerix, Adalta, Patrys, Antisense Therapeutics, Imugene, Anteris Technologies, Chimeric Therapeutics, Neuren Pharmaceuticals, Invex Therapeutics, Neurotech International, Aroa Biosurgery, Radiopharm Theranostics, Imricor

Disclaimer:
Information contained in this newsletter is not a complete analysis of every material fact respecting any company, industry or security. The opinions and estimates herein expressed represent the current judgement of the publisher and are subject to change. Blake Industry and Market Analysis Pty Ltd (BIMA) and any of their associates, officers or staff may have interests in securities referred to herein (Corporations Law s.849). Details contained herein have been prepared for general circulation and do not have regard to any person's or company's investment objectives, financial situation and particular needs. Accordingly, no recipients should rely on any recommendation (whether express or implied) contained in this document without consulting their investment adviser (Corporations Law s.851). The persons involved in or responsible for the preparation and publication of this report believe the information herein is accurate but no warranty of accuracy is given and persons seeking to rely on information provided herein should make their own independent enquiries. Details contained herein have been issued on the basis they are only for the particular person or company to whom they have been provided by Blake Industry and Market Analysis Pty Ltd. The Directors and/or associates declare interests in the following ASX Healthcare and Biotechnology sector securities: Analyst MP: ACR,CGS, CYC, DXB, IMM, OPT,CUV,MX1, NEU, PAB, PXS,RNO,SOM. These interests can change at any time and are not additional recommendations. Holdings in stocks valued at less than $100 are not disclosed.

Subscription Rates (inc. GST)

24 issues per year (electronic distribution): **$550**

For multiple email distributions within the same business cost centre, our pricing structure is as follows:	$900	2-3 email addresses
	$1200	4-5 email addresses
	$1500	6-10 email addresses

To subscribe, post/email this subscription form to:

Bioshares
PO Box 193 Richmond VIC 3121
info@bioshares.com.au

I enclose a cheque for **$** made payable to **Blake Industry & Market Analysis Pty Ltd**, or

Please charge my credit card **$** MasterCard ☐ Visa ☐

Card Number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Signature _____ Expiry date _____

Subscriber details

Name _____

Organisation _____

Ph ( ) _____

Emails _____

_____

The information provided in Bioshares, including general investment advice, is provided only for receipt and use in Australia and New Zealand, for subscribers to Bioshares, who are Australian or New Zealand citizens or commercial entities.