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Bioshares

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Edition 908

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

Companies covered: Top 6 Stock Picks (AVR, DXB, MX1, NEU, RNO, 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 - Current)	9.5%
Cumulative Gain	2128%
Av. Annual gain (20 yrs)	20.7%

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Bioshares Top 6 Picks

Each year Bioshares picks its top six stocks for the year ahead, as well as reviewing the picks made at the same time last year. Over 2021, our Top Six Picks gained only 10%, with two standout performers, Cogstate and Patrys. Both stocks exactly doubled in price.

For Cogstate, the approval of the world's first disease modifying drug, Aduhelm, was going to be a key event for the company. The approval increases the need for an accessible and validated cognitive test in the community as well as increasing the level of clinical trial activity with the next Alzheimer's disease drugs in development. The company secured a record US$41 million of clinical trial work in the September quarter alone.

Bioshares 2021 Stock Pick Performance

Company	Code	Price 18-Dec-20	Price 22-Dec-21	Change
Cogstate	CGS	$ 1.15	$ 2.30	100%
Cyclopharm	CYC	$ 2.50	$ 1.59	-36%
Adalta	1AD	$ 0.125	$ 0.082	-34%
Micro-X	MX1	$ 0.39	$ 0.26	-34%
Patrys	PAB	$ 0.018	$ 0.036	100%
Cynata	CYP	$ 0.70	$ 0.47	-33%
			Av.	**10%**

Patrys is an oncology company with a unique approach to treating tumours using its cell penetrating antibodies. Awareness of this company's technology and preclinical progress were key drivers of performance, with the stock reaching a high of $0.063 when a six month delay in its program caused a sharp retraction in its share price. The stock should continue to perform well with clinical studies due to start towards the end of next year.

Cyclopharm's stock price fell during the year with a delay in gaining FDA approval. It should be a better year for the company in 2022 if US regulatory approval can be secured. Adalta's price was also down for the year with the company announcing that its lead drug candidate would be reformulated as an inhaled product following preclinical data showing rapid distribution of the injected drug to the liver.

Cynata's share price fell by a third over the year with slower than expected clinical progress and a restructured deal with Fujifilm which will see Cynata take control of the clinical GvHD program and Fujifilm likely to manufacture the stem cell products.

The fall in the share price of Micro-X was surprising given the strong progress the company continues to make with the world's first cold cathode x-ray instruments. Whilst sales were down 11%, 2022 could be a breakout year for the company with the stock included in the Top Six Picks for 2022.

Top 6 Stock Picks - Track Record

2021	10%
2020	57%
2019	103%
2018	-73%
2017	-35%
2016	84%
2015	53%
2014	41%
2013	62%
2012	36%
	33.8%

Top 6 Stock Picks for 2022

Anteris Technologies - Heart Valve for US$10 Billion Market

Anteris Technologies (AVR: $10.60) is commercialising an aortic heart valve that is delivered in place by a catheter. Last month the company announced that the first five patients had been implanted with the DurAVR heart valve. After seven days, all patients continued to progress well, with a 30 day follow-up being the next clinical milestone.

The Anteris device is the only single piece 3D aortic heart valve that is delivered by catheter (transaortic valve replacement or TAVR). TAVR procedures are generally used for older patients who are ineligible for open heart surgery (SAVR). However with TAVR procedures becoming more common in younger patients, there is a need for a more durable device with a longer life span.

The Anteris product uses tissue derived from bovine pericardium that is treated using the company's proprietary ADAPT process. This process has been used in the company's CardioCel and VascuCel products that have shown little or no calcification of the implanted tissue after 10 years.

Other advantages of the DurAVR valve is that it's manufactured using 90% less sutures than the incumbent products from Medtronic and Edwards Lifesciences. The DurAVR valve has also shown to deliver increased orifice area for blood flow and a lower pressure gradient (less restriction) than the CoreValve and Sapien 3 TAVR devices from its respective competitors.

Anteris recently entered into an underwriting agreement for options that will raise $14.6 million.

Anteris is capitalised at $175 million.

Bioshares recommendation: **Speculative Buy Class B**

Dimerix - An Overlooked Biotech with Value

Dimerix (DXB: $0.23) is an overlooked biotech that is about to embark on a global Phase III study at 75 sites. It's a stock that should start to garner more attention in 2022.

Dimerix is capitalised at just $74 million. It will shortly start a study treating a form of kidney disease, called FSGS, in 250 patients across 167 sites in 18 countries.

Whilst interim results are not expected until Q1 2023, progress with enrolment and expectation of a positive trial result in early 2023 may see the stock price rise. The addressable market for FSGS is estimated by the company at over US$1 billion a year with no current approved therapies. There are an estimated 210,000 patients living with FSGS. Of those, 80,000 are in the US with one quarter at end stage renal disease.

In a small Phase IIa study in seven patients with FSGS, an average 29% reduction in proteinuria levels was achieved with 86% of patients showing an improvement. It was a crossover study so each patient received placebo or DMX200 with a washout period in between treatments.

The company's therapy is also being assessed in two Phase III COVID-19 studies with top line results expected next year. One of those studies is seeking to recruit 622 patients with 485 patients recruited to date in the UK.

Bioshares recommendation: **Speculative Buy Class A**

Micro-X - Ready for Breakout

It should be a breakout year for Micro-X (MX1: $0.255). Micro-X has developed the world's first cold cathode x-ray tube allowing it to substantially reduce the size, weight and cost of building x-ray machines. To date over 250 are in use in 30 countries, with adoption aided by the need for more instruments to diagnose COVID-19.

There will be two main drivers for this company next year. The first, which will come from a series of announcements, will be the appointment of multiple regional distribution deals for the Mobile DR x-ray units. Last year the company moved its distribution arrangement with Carestream from exclusive to non-exclusive. It took the company around six months to gain FDA approval and complete development of the instrument under its own brand, including sourcing the detector.

Last month, the company presented all of its wares at the RSNA event in Chicago, which was the first time the company had attended a conference since the start of the pandemic. The company expects to sign on about 20 regional distributors in the US and around 10 in Europe.

The second major driver will be the release of the Argus instrument around mid next year for sale to bomb disposal units. The backscatter instrument will be used to detect IEDs. Demonstration units are expected to be ready in Q1 next year. No regulatory approvals will be required and we expect some rapid, early sales next year. Gross margins for the product should be around 70%.

In the last month, the company presented its products at three events. These were the RSNA meeting, at the US Bomb Technicians Association tradeshow in Florida, and the technology was presented by the TSA at the Future Travel Experience conference in Las Vegas. Micro-X has a contract with the TSA to design the next generation of baggage handling systems, including automated self-service booths that will use the Micro-X CT baggage scanner. If Micro-X wins the contract to supply its instruments for automated CT scanning, it represents a potential market of 11,000 instruments for the US alone.

Comments from bomb disposal technicians were highly favourable according to Micro-X. "This product is what we have been looking for and waiting for, for years." The company has already received seven requests for product demonstrations early next year.

Continued over

At the RSNA event, there was 'considerable attention' for the brain CT scanner which is in development for use in ambulances to diagnose stroke. Strong interest has also been received from multiple product distributors for the lightweight mobile x-ray instrument.

Bioshares recommendation: **Speculative Buy Class A**

Neuren Pharmaceuticals - NDA Submission in 2022

Following positive Phase III trial results in Rett syndrome by its partner (Acadia Pharmaceuticals) with trofinetide, Neuren Pharmaceuticals (NEU: $3.61) was recently added to the Bioshares Model Portfolio.

Both Phase III primary endpoints were reached with statistical significance, with diarrhea and vomiting being side effects at times, although these are manageable with other medications. Around 95% of participants in the 187-patient study elected to continue with treatment in the open label phase.

Acadia expects to file the drug candidate for approval with the FDA mid next year with a decision likely in 1H 2023.

Other drivers for Neuren will be the commencement of three Phase II studies with the company's second drug candidate, NNZ-2591. Results from these studies are expected in the second half of next year. A fourth Phase II study, in Prader Willi syndrome, is expected to start in mid 2022.

Neuren's approach of tackling genetic disorders by gauging preclinical efficacy in knockout mice (altered to mimic the target disorder) has worked well with trofinetide. The same approach taken with NNZ-2591 has achieved consistently good preclinical results with NNZ-2591 having improved bioavailability to trofinetide. This means less drug is required with likely less side effects.

Neuren expects to receive around $111 million over the next two years should trofinetide gain US approval. The company stands to receive a royalty (estimated between 10%-15%) from product sales, with higher royalties as sales increase.

Another major forthcoming milestone for the company is out-licensing the rest-of-world rights to trofinetide with Acadia having North American marketing rights only.

With a market capitalisation of $455 million, Neuren is a potential takeover target in 2022.

Bioshares recommendation: **Speculative Buy Class A**

Rhinomed - Nasal Swab Demand Key Driver in 2022

Rhinomed (RNO: $0.27) manufactures and sells nasal stents to improve breathing, through pharmacies in the US, Australia and the UK, as well as online. The products include Mute (for sleeping), the Turbine (for use in sport), and the rechargeable Pronto range which deliver essential oils.

Mute generates the majority of the revenue of these products. Sales growth was interrupted due to reduced shopping in pharmacies during the pandemic in the US. Whilst foot traffic into pharmacies in the US remains significantly lower, sales through online channels are increasing. The company shipped just under 75,000 units in the September quarter. Sales are expected to grow both through pharmacies but also now through Amazon into Europe.

However the short-medium term driver for this stock will be large contracts to supply its nasal swab, called the Rhinoswab. The product was launched this year with orders received last quarter totalling $3.0 million. Revenue from the Mute and other nasal stent products last year was $3.9 million (up just 9% of the PCP).

This week the company announced results from a trial conducted at the Royal Children's Hospital in Melbourne with its pediatric nasal swab. The results showed equivalence to the combined nasal and throat swab with a sensitivity of 96.2%. The trial involved 254 children with indications of a respiratory infection. This is an improvement on other nasal (only) swabs which have a sensitivity of 88%.

The trial also showed that 82% of children preferred the Rhinoswab to the combined nasal-throat swab. Rhinomed CEO Michael Johnson said that the test hit the endpoint of laboratory equivalence to the nasal-throat swab and that the swab is clearly preferred.

Other advantages of the swab include a more objective approach to sampling, no requirement for healthcare workers to administer the test, and a faster throughput through self-administration of the test. Johnson said there is no real variance with the way the test is used, with the sampling procedure being the most random aspect to standard respiratory infection testing.

In a mass surveillance trial conducted in NSW schools for SAR-CoV-2 in 15,000 students with the Rhinoswab device, the investigators found that self collection, which could be completed in less than five minutes, was preferred by students, protected healthcare workers and improved turnaround times (to 3 hours and 25 minutes). The Rhinoswab delivered adequate sampling material in 99.9% of cases.

The more immediate market for the company's nasal swabs is for use with self-administered rapid antigen tests, and for use in children. The less obtrusive approach to patient sampling also favours use of this test for repeat testing in schools or in the workplace. Johnson said that the company is in dialogue with a number of rapid antigen test product companies with its swab able to be used with any test.

With the emergence of a more contagious strain of SAR-CoV-2, living with the coronavirus and regular testing is likely going to be required for many years to come.

Bioshares recommendation: **Speculative Buy Class A**
(Rhinomed has been added to the Bioshares Model Portfolio)

Continued over

Bioshares Model Portfolio (22 December 2021)

Company	Code	Price (current)	Price added to portfolio	Recommend-ation	Cap'n ($M)	Date added
Telix Pharmaceticals	TLX	$7.85	$7.85	Spec Buy A	$2,238	December 2021
Clinuvel Pharmaceuticals	CUV	$29.00	$20.31	Buy	$1,433	November 2020
Neuren Pharmaceuticals	NEU	$3.61	$3.25	Spec Buy A	$455	December 2021
Opthea	OPT	$1.28	$0.16	Spec Buy A	$445	November 2014
Immutep	IMM	$0.49	$0.32	Spec Buy A	$417	March 2019
Cogstate	CGS	$2.30	$0.24	Accumulate	$393	April 2019
Aroa Biosurgery	ARX	$1.02	$1.11	Spec Buy A	$349	November 2021
Anteris Technologies	AVR	$10.60	$8.70	Spec Buy B	$175	December 2021
Antisense Therapeutics	ANP	$0.20	$0.22	Spec Buy A	$142	November 2021
Micro-X	MX1	$0.255	$0.38	Spec Buy A	$117	May 2017
Chimeric Therapeutics	CHM	$0.27	$0.27	Spec Buy A	$88	December 2021
Patrys	PAB	$0.036	$0.013	Spec Buy B	$74	July 2020
Dimerix	DXB	$0.23	$0.09	Spec Buy A	$74	December 2018
Rhinomed	RNO	$0.27	$0.27	Spec Buy A	$70	December 2021
Pharmaxis	PXS	$0.11	$0.26	Spec Buy A	$50	December 2016
Acrux	ACR	$0.10	$0.31	Spec Buy A	$28	July 2017

Portfolio Changes

IN:
Rhinomed has been added at $0.27. Telix Pharmaceuticals has been added at $7.85.

OUT:
CYP has been removed.

Telix Pharmaceuticals - Ready for Illuccix Launch in US and Australia

Telix Pharmaceuticals (TLX: $7.85) has become one of the top five global radiopharmaceuticals that uses molecularly targeted radiation. This week the company gained FDA approval for its Illuccix product which is used to image prostate cancer cells.

The label is for patients with prostate cancer with suspected metastases and suspected recurrence of disease when PSA levels are elevated. Wilson HTM is forecasting sales of $74 million for the product next year and sales of $146 million in 2023. The product is due to be launched in the first quarter of next year in the US and Australia. Telix estimates the total addressable market in the US at US$725 million.

The test is currently sold for use in trials and under compassionate use, with 3200 patients imaged in the September quarter. However with approval the price of the test will increase considerably. Sales in the September quarter were $1.16 million.

The company has had a frenetic deal making period since listing in 2017 at $0.65 per share, setting up its global distribution network of its radioisotope-linked diagnostics and therapies. It now employs 170 staff which has been largely due to organic growth since the company was formed in 2015.

Other stock drivers in 2022 will be the completion of the Phase III kidney cancer imaging study in 252 patients, with regulatory submissions to follow. Recruitment into the study is 75% complete.

The company will also be filing Illuccix for approval in Hong Kong and Taiwan in the first quarter of next year and is in discussion with the Chinese regulator (NMPA) through its licensor for those regions and equity investor, China Grand Pharmaceutical and Healthcare Holdings (China Grand Pharma).

China Grand Pharma is a logical future acquiror of Telix, with the company having previously acquired another Australian radiopharmaceutical company, Sirtex Medical.

Telix is capitalised at $2.2 billion. Clinical progress in multiple programs and early growth in Illuccix product sales should see the stock continue to appreciate in 2022.

Bioshares recommendation: **Speculative Buy Class A**
(Telix has been added to the Bioshares Model Portfolio.)

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, LBT Innovations, Opthea, ResApp Health, Pharmaxis, Dimerix, Adalta, Actinogen Medical, Patrys, Antisense Therapeutics, Imugene, Exopharm, Immutep, Invex Therapeutics, Anteris Technologies, Chimeric Therapeutics, Neuren Pharmaceuticals, Neurotech International, Aroa Biosurgery

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