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BIOSHARES

Australia's Independent Biotech Investment Resource, est.1999

25 March 2026
Edition 991

	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 - Dec '22)	-2.2%
Year 23 (CY2023)	-15.4%
Year 24 (CY2024)	40.8%
Year 25 (CY2025)	20.3%
Year 26 (CY2026 - current)	-17.1%

Companies covered: **ATX, BB1, CUV, CYC, IMM**

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Edition Number 991 (25 March 2026)

Immutep Halts Phase III Study in NSCLC; Stock Down 88%

An event which has surprised most people active in the Australian biotech sector, Immutep's (IMM: $0.047) Phase III study with its drug candidate eftilagimod alfa (efti), was stopped after a futility analysis indicated an unlikely positive outcome in patients with non-small cell lung cancer (NSCLC).

The study was seeking to recruit 756 patients, recruiting regardless of PD-L1 expression levels. The trial was seeking to show a benefit of adding efti to the checkpoint inhibitor Keytruda and chemotherapy, with Keytruda showing poor efficacy in patients with low levels of PD-L1 expression. The trial had enrolled more than half of the patients into the study.

Continued over

Amplia Therapeutics: Independent Review Reveals More Complete Responses in Patients with Advanced Pancreatic Cancer

An independent review of Amplia Therapeutics' (ATX: $0.26) Phase Ib/IIa pancreatic cancer study has pleasingly yielded better results than previous, which were assessed by the clinical investigators at each site.

In the highest dose of 400mg a day (oral delivery) of the company's drug candidate narmafotinib, an additional four complete responses (CR) were recorded, giving a CR rate of 7.8% (5/64). This is an impressive result, where to have even one complete response in advanced (metastatic) pancreatic cancer is unusual.

In a previous study by others with chemotherapy alone in 431 patients, just one person achieved a complete response in the primary tumour and metastases. In less advanced patients with non-metastatic disease, a complete response rate of around 5% has been achieved with current standard-of-care therapies.

Continued over

Blinklab Technology Selected by Moroccan Government for National Autism Screening Program

Blinklab (BB1: $0.785) has been requested by the Moroccan government to provide its smartphone-based autism test to form part of a national screening program in the country for all children above the age of 18 months.

At this point the deal will not be a revenue generator for Blinklab, other than having its costs covered by the government. The commercial terms may change upon regulatory approval. However the key benefit for Blinklab is real world experience in administering and managing distribution of the test.

Continued on page 3

– Immutep cont'd from page 1

In a Phase I single arm study in NSCLC with efti, Keytruda and chemotherapy in 51 patients, it showed an improvement in overall survival on 10.9 months compared to historical data.

Learnings from the study are that comparisons with historical data should be treated with some caution, and that a blinded Phase II study with a control arm may have been a better path forward than moving into a large Phase III study.

Immutep has achieved consistently good data with efti in a range of cancers which perhaps provided the company with the confidence to move directly into Phase III.

A breakdown of the study results is forthcoming, which will provide greater depth on the study's failure. Of interest will be comparisons of outcomes in patients with very low levels of PD-L1 expression. In the Phase I study, the Objective Response Rate (ORR) when adding efti was 54.5% in patients with less than 1% PD-L1 expression, compared to 32.3% from historical data without efti (22.2% difference).

In patients with PD-L1 levels greater than 50%, the ORR difference was just 12.9%, although there were just four patients in that group.

Immutep had a proforma cash balance of $129 million in cash at the end of last year, including an upfront fee of $30 million received from Dr. Reddy's Laboratories to commercialise efti outside of major markets including the US and Europe. The company's market capitalization is $69 million.

Immutep will incur costs to wind up the NSCLC study. Its cash runway is expected to last further than mid 2027 with the discontinuation of this study.

Bioshares recommendation: **Speculative Hold Class B**

IMM has been removed from the Bioshares Model Portfolio

– Amplia continued from previous page

The CR rate achieved by Amplia excludes the one pathological complete response, where the tumour was excised by surgery, but found to be necrotic with no live tumour tissue. Including that response would yield a CR of 9.4%.

CEO of Amplia, Chris Burns, said he had anticipated that there would be a difference is results when assessed by a centralized expert laboratory, which conducts this type of review daily.

The company also announced an additional partial response giving an Objective Response Rate (partial plus complete responses) of 35.9% (23/64). Four patients remain on therapy with one patient on therapy for almost two years.

The median overall survival in this Amplia study is 11.1 months, which is a 2.6 month improvement over the historical survival with chemotherapy alone (8.5 months). The five year survival rate in advanced pancreatic cancer is around 3%.

The safety profile was also good, particularly in anemia and peripheral neuropathy side effects compared to historical data from chemotherapy alone. Burns cited the excellent work that had been conducted in developing and optimizing narmafotinib at the former Cancer Therapeutics CRC.

Next Steps

A pivotal Phase II/III study will be next, which may involve between 400-600 patients. Amplia is seeking to transact a regional licensing deal first. That study may also explore a slightly higher dose (600mg a day), as well as patients taking narmafotinib each day, including when receiving chemotherapy. However Burns believes the current 400mg a day dose should also be effective.

Other trials by Amplia include a current pancreatic cancer therapy study in Australia and the US (up to 67 patients) with a different chemotherapy regime (FOLFIRINOX) and a possible study in ovarian cancer, also a stromal tumour like pancreatic cancer, where chemotherapy agents have difficulty penetrating the tumour. Narmafotinib acts by disrupting the fibrous tissue around such tumours, allowing chemotherapies to become more effective.

Amplia is capitalized at $133 million with $31.5 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class A**

Clinuvel CEO to Continue with Key Strategy Role

Clinuvel Pharmaceuticals (CUV: $9.85) has announced that its CEO, Philippe Wolgen will remain in the role following a search for his replacement. Wolgen was due to step down at the end of June this year.

The next two to three years will be a defining period for the next stage of the company's evolution. Having built a successful biotech business from the development of Scenesse for the treatment of EPP – company revenue of $105 million and net profit of $36 million in FY2025 – Clinuvel is in the midst of a major expansion with the investment in the development of new products and new product applications.

The first of these, Neuracthel, is expected to be filed for approval in Europe this year. It is a specialty generic of ACTH. There are two main ACTH products on the market – Cortropin Gel and Acthar Gel. Cortropin Gel generated net sales of US$347 million last year, up 75% on the PCP. And Acthar Gel sales are tracking at US$726 million, up 44% over the PCP. However most revenue is generated in the US (93% for Acthar Gel).

The next major milestone for Clinuvel is completion of the first Phase III vitiligo study, to be followed by a second Phase III study. This is also a major market opportunity for the company. The second Phase III study is expected to complete recruitment by the end of 2027. *Bioshares* expects an NDA filing in 2028, and product approval and launch in the first half of 2029 if all goes well. Clinuvel will use the same specialty treatment centres in the US (120 established) to deliver the vitiligo treatment with Scenesse.

Clinuvel is following a textbook path of forming a sustainable and profitable business from a niche market (in EPP), and then expanding the product opportunity with the same product (into vitiligo), or using its expertise in melanocortins to develop new products (Neuracthel) that will compete in substantially larger markets.

Maintaining the current CEO, who has driven the product development over the last two decades, will be highly beneficial to the company. The executive management team will be expanded, which will include a strengthening of the US base, allowing Wolgen to focus on global strategy and governance.

Clinuvel finished with $233 million in cash last year and is capitalized at $493 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

– Blinklab cont'd from previous page

Blinklab has had a long association with Morocco with some of its key staff being from the country. In January this year, a paper was published in the journal *Autism Research* detailing the results from a study involving 536 children aged between 8-12 years at eight different locations in Morocco.

That study showed that a smartphone based test can be used to generate an objective assessment of children with autism. "Our results serve as a starting point from which to investigate the diagnostic accuracy of accessible technology in future prospective clinical trials"

Since that study, the company has completed several trials, including a lead into its pivotal US study which delivered a sensitivity of 83.7% and a specificity of 84.7%, which is well in excess of the 65% performance hurdle required for a commercial test according to the company.

This week Blinklab commenced its pivotal validation study for FDA approval, which will seek to recruit 528 children across 10 sites. All 10 sites in the US have been onboarded with the first subject having now been assessed.

The trial is expected to take up to eight months to recruit. The company is aiming to file the product for approval before the end of the year with the FDA for use as an aid in the diagnosis of autism and to support decision making by medical practitioners.

The aim of early diagnosis and then early intervention of autism is to improve patient management and progression of the disorder. Chairman of Blinklab Brian Leedman believes that Morocco is leading the way in addressing the looming funding blowout required to support the growing burden of autism management on healthcare budgets. "In relation to Australia's own NDIS, an adult receives more than three times the level of funding support than a child. This represents a tsunami of funding to support the current wave of children being diagnosed with autism growing into adulthood."

Dr Kahlid Benhassan, Director of the Mohammed IV National Center for the Disabled in Morocco said: "Thanks to the simplicity and accessibility of smartphone technology, Blinklab makes early screening from as young as 18 months not only clinically reliable, but also practical and deployable across various healthcare and community settings".

In Morocco around 400,000 people are believed to have autism with 600,000 children born each year.

Blinklab is capitalized at $99 million with $5.5 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Cyclopharm: Technegas Adoption in US Building

Cyclopharm (CYC: $0.80) has announced agreements with two additional hospital networks for adoption of its Technegas instrument for the detection on blood lung clots (pulmonary emboli) in the US.

The University of Pennsylvania Health System has ordered two systems immediately with a further nine over time, and additional units beyond that in the states of Pennsylvania and New Jersey. It has also secured an agreement with North Western Memorial Hospital in Chicago to buy one system now and up to six additional units.

Cyclopharm's aim is to have between 250-300 units installed in the US by the end of this year. The company generates sales from the Technegas instrument, and also from the consumables used in the lung imaging process. CEO James McBrayer said that the Technegas instrument is a proven lung imaging technology which generates extremely low levels of radiation compared to CT scans.

The company's technology has also been selected (draft guidelines) as the preferred nuclear medicine imaging agent for ventilation-perfusion scans of the lungs by three nuclear medicine bodies – the US Society of Nuclear Medicine and Molecular Imaging, the American College of Nuclear Medicine, and the European Association of Nuclear Medicine.

The formal guidelines are due to be released in May, in which McBrayer said the company's technology is heavily featured. McBrayer does not believe the draft guidelines have yet to have had an impact on US sales.

Continued over

Cyclopharm Technegas Sales/Installations into USA and Other Milestones

Date	Region	Upfront units sold	Potential future units	Installed base announced (announced)
May '26	***To be incorporated into nuclear medicine guidelines***			
March '26	Northwestern Medicine, Chicago	1	6	
March '26	Uni of Pennsylvania, Pennsylvania & New Jersey	2	9+	
Feb '26	NIH, Maryland	1		46
Feb '26	St Charles Health SystemOregan	2		
Feb '26	UF Health Florida	2		
Feb '26	Texas Health presbyterian Hospital Dallas	1		
Jan '26	California (Stanford)	1		
Nov '25				40
Sept '25				35
July '25	***Appoints VP of Sales USA (Thomas Lukas)***			
May '25	Baylor Scott & White Health			33
May '25	University of Miami Health System			
May '25	UAB Medicine			
May '25	Montifiore			
April ' 25	Brooke Army Medical Center			
March '25	Dallas Medical Center			24
March '25	Mayo Clinic			
March '25	South Western Medical Center			
March '25	Morton Plant North Bay Hospital			
March '25	***5 year Federal Supply Schedule agreement***			
Jan '25	***Hospital Corporation of America Healthcare agreement***		169	
Oct '24	***Interim agreement with VA***			
2024	Barnes-Jewish Hospital / Washington University School of Medicine			17
2024	Emory University Hospitals			
2024	Boston Medical Centre			
2024	Indiana University			
2024	MGH - Harvard Medical			
2024	Long Island Jewish Medical Centre			
2024	New York Presbyterian Hospital			
2024	Stanford Uni Hospital			
2024	Uni Of Kansas Hospital			
2024	Yale Uni Research			
2024	VA - Martinez			
2024	VA - Sacramento			
2024	Tufts Medical Center			
Dec '23	Duke Hospital (NC) - First US sale			
Oct '23	***FDA approval for Technegas***			

Bioshares Model Portfolio (25 March 2026)

Company	Code	Price (current)	Price added to portfolio	Recommendation	Cap'n ($M)	Date added
Telix Pharmaceticals	TLX	$12.73	$7.85	Buy	$0	December 2021
Neuren Pharmaceuticals	NEU	$11.93	$3.25	Buy	$0	December 2021
PYC Therapeutics	PYC	$1.22	$1.03	Spec Hold A	$0	April 2025
Anteris Technologies	AVR	$8.05	$21.50	Spec Buy A	$0	September 2022
Clinuvel Pharmaceuticals	CUV	$9.85	$20.31	Buy	$0	November 2020
Cogstate	CGS	$2.17	$0.24	Buy	$0	April 2019
Dimerix#	DXB	$0.325	$0.09	Spec Buy A	$0	December 2018
Aroa Biosurgery	ARX	$0.57	$1.11	Buy	$0	November 2021
Botanix Pharmaceuticals	BOT	$0.041	$0.17	Spec Buy B	$0	July 2025
Actinogen Medical	ACW	$0.037	$0.04	Spec Buy B	$0	Feb 2026
Blinklab	BB1	$0.785	$0.855	Spec Buy A	$0	January 2026
Cyclopharm	CYC	$0.800	$2.87	Spec Buy A	$0	October 2023
Cynata Therapeutics	CYP	$0.300	$0.19	Spec Buy A	$0	March 2024
Amplia Therapeutics	ATX	$0.260	$0.061	Spec Buy A	$0	April 2024
Clever Culture Systems	CC5	$0.022	$0.09	Spec Hold B	$0	April 2022
Syntara	SNT	$0.031	$0.26	Spec Buy A	$0	December 2016
Immuron	IMC	$0.030	$0.092	Spec Hold B	$0	May 2024
Chimeric Therapeutics	CHM	$0.002	$0.004	Spec Buy B	$0	May 2025

IN:
None

OUT:
IMM (see page 1)

– *Cyclopharm cont'd from previous page*

The Technegas instrument can be installed in just one day, although requires a new electrical connection fitted at the hospital. As of February 19 this year, Cyclopharm had 46 revenue generating systems installed in the US. The company has a sales, marketing and support team of nine people in the US.

The company expects to release news about further sales once agreements are finalized.

Cyclopharm is capitalized at $97 million with a proforma cash balance of $20.8 million at the end of last year including a subsequent $14.2 million raise at $0.95 per share.

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

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