



# BIOSHARES

Australia's Independent Biotech Investment Resource, est. 1999

21 July 2023  
Edition 941

	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)	-18.6%
Cumulative Gain	1267%
Av. Annual gain (22 yrs)	18.1%

Companies covered: **Half Year Review, LDX, NEU, Upcoming Biotech IPOs**

**2023 Top Six Picks: -12.6%**

## Capital Starts Return to Biotech Sector

Following a difficult period capital is beginning to return to the Australian biotech sector. With just \$77 million raised in the March quarter this year, the June quarter has seen \$383 in capital raised, highlighting a return of investor interest into the sector.

The interest is expected to continue, with three IPOs planned for August. These are CurveBean AI, Cleo Diagnostics, and Dragonfly Biosciences. (See page 7)

Overall the small-mid cap biotechs have yet to rebound from their slump in the first half of calendar year 2022. The Bioshares Index fell by 7% in the first half of this calendar year, however this excludes the large cap biotechs Telix Pharmaceuticals and Neuren Pharmaceuticals which continued their strong run, both up 54% this year.

There are positive signals that the year ahead should start to deliver broader positive gains for investors. The stellar gains in the first half of this calendar year have largely been with the leading companies in the sector that have shown strong sales growth or achieved regulatory approval (see page 2). US regulatory approval has also been well received at the smaller end of the market post June 30 with Lumos Diagnostics surging 1300% (see page 6).

Clinical trial progress has also been good following the impediments of the pandemic. A summary of developments is provided on pages 14-17.

The optimism emerging in the sector is also mirrored in the record attendance at next week's Bioshares Biotech Summit which has seen 200 people register for the event. Coverage of the Summit will be provided in subsequent editions of Bioshares.

Bioshares

### Index Performance

	1H 2022	2H 2022	1H 2023
Bioshares Index	-41.5%	8.1%	-7.0%
Bioshares Large Cap Index	-10.9%	5.8%	0.6%
Bioshares Botanicals Index	-53.3%	9.1%	-27.1%
Nasdaq Biotech Index	-20.7%	12.4%	-3.3%
ASX 300 Index	-12.2%	7.0%	2.2%

Bioshares is published by Blake Industry & Market Analysis Pty Ltd. ACN 085 334 292  
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AFS Licence No. 258032

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Edition Number 941 (21 July 2023)

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# FB RICE

The IP Navigators

AVATAR

**Top 10 Outperformers - 2H FY2023**

Company	Code	Change - Half
Avita Medical	AVH	165%
Botanix Pharmaceuticals	BOT	145%
Impedimed	IPD	128%
Arovella Therapeutics	ALA	117%
EBR Systems	EBR	96%
Kazia Therapeutics	KZA	74%
Cyclopharm	CYC	71%
4D Medical	4DX	60%
Telix Pharmaceuticals	TLX	54%
Neuren Pharmaceuticals	NEU	54%

**Outperformers****1. AVH +165%**

Back-to-back FDA approvals for Avita Medical (AVH) has seen the stock climb 165% in the last six months. AVH received FDA approval for the use of its Recell system in treating full-thickness skin defects (soft tissue injuries) and in treating vitiligo (skin discoloration). The new indications expand the potential market for the Recell system by more than five times. The newly PMA approved Recell system was launched July 1 for soft tissue injuries. The company is seeking to secure reimbursement in the doctor's setting for vitiligo with an anticipated launch in 2025.

**2. BOT +145%**

Botanix Pharmaceuticals (BOT) was the second-best performing biotech in the first half of 2023, with its share price up 145% over the six-month period. Following a very positive mid-cycle review meeting with the FDA, where no major clinical safety, management, or advisory board issues were raised, BOT has announced that its lead product, sofipironium bromide, is anticipated to be approved in September 2023. The drug, already on the market in Japan through distribution partner Kaken, is a treatment for primary axillary hyperhidrosis (excessive sweating).

**3. IPD +128%**

Impedimed (IPD) was up 128% for the period, with its next generation bioimpedance spectroscopy (BIS) system, the SOZO Pro, gaining FDA approval. IPD makes the only FDA approved BIS technology. In the wake of the National Comprehensive Cancer Network updating their guidelines to recommend regular screening for lymphoedema using BIS, it has also been a big six months for IPD in terms of achieving private payor reimbursement in lymphoedema.

**4. ALA +117%**

Arovella Therapeutics (ALA) enjoyed a surprising gain, with its share price more than doubling during the half. ALA generated positive pre-clinical data for its lead product, ALA-101, as well as advancing its collaboration with Imugene, working to treat solid tumours. The company has completed a capital raise of approximately \$6.3M to fund its imminent Phase 1 trial for ALA-101.

**5. EBR +96%**

EBR Systems (EBR) was up 96% for the half year, largely stemming from the success of its pivotal SOLVE-CRT trial. The trial met

all primary efficacy and safety endpoints. It intends to submit its final PMA submission to the FDA in early 2024. The company is well resourced to tackle regulatory approval, commercialisation, and eventually sales growth, with a cash balance of approximately \$128M following a \$35M capital raise.

**6. KZA +74%**

Kazia Therapeutics (KZA) saw its share price rise 74% following a very poor performance in 2H 2022 which saw the price down 85% following the discontinuation by study sponsors of the GBM AGILE pivotal trial. The trial results, assessing the drug candidate paxalisib in the treatment of glioblastoma, are expected later this year. Paxalisib is also the subject of nine other ongoing trials, including a new Phase II clinical collaboration to investigate the drug in children with advanced solid tumours. Paxalisib was recently awarded Fast Track Designation by the FDA for the treatment of solid tumour brain metastases.

**7. CYC +71%**

Cyclopharm (CYC) has reached its final major approval hurdle for its lung ventilation imaging agent, Technegas, in the United States, seeing its price increase 71% in anticipation of positive news. The review "goal date" for CYC's New Drug Application is September 29, with an FDA inspection of the company's New South Wales facility imminent. FDA approval would create an initial addressable market of US\$180M per annum. The company remains confident that the commencement of commercial sales of Technegas in the US will be shortly after the goal date in late 2023.

**8. 4DX +60%**

Signing its first software as a Service (SaaS) contract with the University of Miami and winning a commercial pilot with the US Department of Defense, it's been a big half for 4D Medical (4DX), prompting a 60% hike in its share price. The company has also shown growth in cash receipts, with six-month receipts as of March 30 reaching \$2M. The company capped off a successful half with a \$45M capital raise.

**9. TLX +54%**

Telix Pharmaceuticals' (TLX) Illuccix continues to be a success, notching \$98M in sales in the US and driving the company to its second consecutive quarter of positive operating cash flow. Alongside FDA approval of an expanded indication for Illuccix, TLX reported outstanding results from its Phase III Zircon study. In addition, the company has made a series of strategic acquisitions, including AI company Dedicaid and medical device developer Lightpoint Medical. After a strong half, TLX's share price was up 54%. (Post June 30, the company announced June quarter sales of Illuccix reaching \$121 million.)

**10. NEU +54%**

Neuren Pharmaceuticals (NEU) was up 54% over the period, after its drug DAYBUE (trofinetide) became the first FDA-approved treatment for Rett syndrome. NEU received an initial US\$40M milestone payment on the first commercial sale of the drug in the US by Acadia. The company stands to receive royalties quarterly, as well as further milestone payments of up to US\$350M. NEU has also been advancing its clinical pipeline, with active clinical trials in Phelan-McDermid syndrome, Pitt Hopkins syndrome, Angelman syndrome and Prader-Willi syndrome.

**Top 10 Underperformers - 2H FY2023**

Company	Code	Change - Half
Exopharm	EX1	-87%
Regeneus	RGS	-85%
Nutritional Growth Solutions	NGS	-83%
Pacific Edge	PEB	-83%
Nyrada	NYR	-81%
Lumos Diagnostics	LDX	-77%
Oncosil Medical	OSL	-73%
Noxopharm	NOX	-70%
Singular Health Group	SHG	-69%
Avecho Biotechnology	AVE	-67%

**Underperformers****1. EX1 -87%**

Exopharm (EX1) has been the worst performing biotech in the first half of 2023, with its share price falling by 87%. The company has found itself in trouble financially, with only one quarter of funding left as of March 30. EX1 has engaged in various cost cutting strategies, as well as completing various capital raises, raising around \$1.6M through a rights issue and a convertible note agreement.

**2. RGS -85%**

Regeneus (RGS) has likewise been in dire straits financially, reporting only half a quarter in funding remaining as of March 30. The company has recently agreed to merge with Cambium Medical Technologies, a clinical-stage regenerative medicine company based in the US. RGS has seen its share price fall by 85% during the half.

**3. NGS -83%**

After decreasing 45% in 2H 2022, Nutritional Growth Solutions' (NGS) share price has continued to plummet, dropping 83% over the last six months. This is despite NGS reporting a record period for the company in terms of US sales, an increase of 29% from the PCP. However, much like the other underperformers for the period, the company is simply running out of cash. In order to fund its expansion in North America, NGS is completing a strategic restructure to reduce costs and seeking to complete a capital raise.

**4. PEB -83%**

Pacific Edge's (PEB) share price decline of 83% was largely driven by the cessation of Medicare coverage for the company's Cxbladder test. The company claims that as a direct result revenue will be down substantially. The tests comprised 77% of PEB's operating revenue. The company is exploring available legal and other options to rectify the issue.

**5. NYR -81%**

Nyrada (NYR) has seen its share price fall 81% following the preclusion of its cholesterol drug from clinical evaluation. After an adverse signal was detected in its final toxicology study, the drug was ruled not suitable to be advanced into a first-in-human study. The Phase I/IIa study has been deferred indefinitely.

**6. LDX -77%**

Lumos Diagnostics (LDX) was one of the biggest underperformers in 2H 2022, losing 66% after its FebriDx test was not approved by the FDA. Although LDX has had a rough half to start 2023, the company has made significant gains since FebriDx was reconsidered and approved by the FDA just after the end of the financial year (see page 6).

**7. OSL -73%**

Also reporting a troubling financial position at the end of the March quarter was Oncosil Medical (OSL), which was down 73% over the half. Financial difficulties are the common theme amongst the underperformers for the half.

**8. NOX -70%**

Noxopharm (NOX) is down 70% for the half. NOX discontinued its DARRT-2 and CEP-2 Veyonda trials due to protracted timelines and predicted cost increases, as well as low patient acceptance of suppositories, Veyonda's route of administration. Beyond discontinuing the trials, the company has disbanded its clinical trials team to reduce headcount and expenses. Moving forward the company will be focusing on its Chroma and Sofra platforms.

**9. SHG -69%**

Singular Health Group (SHG) has decreased 69% over the period, showing financial instability in the first quarter of the year. The company has since completed a \$1.5M placement.

**10. AVE -67%**

Rounding out the top 10 biggest underperformers for 1H 2023 is Avecho Biotechnology (AVE), which is down 67%. The company, already in financial trouble with less than six months of funding available, is about to commence a Phase III trial for its CBD soft-gel capsule. Of the \$11M the company intended to raise in its entitlement offer, only \$2M was raised. In order to proceed through the clinical trial and into commercialisation of the product, it is likely the company will need to undergo another capital raise in the near future.

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## Biotech Sector Capital Raises 2H FY2023

(In order of completion)

### March Quarter Raises

Company	Code	Investment Manager or Investor	Type of Raising	Funds Raised (\$M)
Genetic Technologies	GTG	H. C. Wainwright & Co.	Placement	\$ 7.3
Anteris Technologies	AVR		Placement	\$ 35.0
CardieX	CDX	C2 Ventures, Mr Jarrod White	Placement	\$ 4.5
Respiri	RSH		SPP	\$ 1.9
Medibio	MEB	CPS Capital Group	Placement	\$ 1.2
Anatara Life Sciences	ANR	Taylor Collison and Candour Advisory	Rights Issue	\$ 0.3
Kazia Therapeutics	KZA		Placement and SPP	\$ 7.1
Nova Eye Medical	EYE	Taylor Collison, E&P Corporate Advisory and MST Financial Services	Placement	\$ 8.0
Anagenics	AN1	Hancock & Gore	Rights Issue	\$ 3.2
Zelira Therapeutics	ZLD		Placement	\$ 1.8
Dorsavi	DVL	Sixty Two Capital	Placement	\$ 0.8
Little Green Pharma	LGP		Placement and SPP	\$ 5.9
<b>Q3 TOTAL</b>				<b>\$ 77.0</b>

### June Quarter Raises

Company	Code	Investment Manager or Investor	Type of Raising	Funds Raised (\$M)
Botanix Pharmaceuticals	BOT	Jefferies and Euroz Hartleys	Placement	\$ 10.0
Elixinol Global	EXL	Canaccord Genuity	Placement and SPP	\$ 2.3
MGC Pharmaceuticals	MXC	Mercer Street Capital Partners	Placement and Convertible Note	\$ 5.4
Imagion Biosystems	IBX	Shaw & Partners and Mercer Street	Rights Issue and Convertible Note	\$ 2.9
Mesoblast	MSB		Placement	\$ 60.2
Living Cell Technologies	LCT	Alignment Capital	Placement and Rights Issues	\$ 2.0
Calmer Co International (Formerly Fiji Kava)	CCO		Placement	\$ 0.5
Avecho Biotechnology	AVE	Peak Asset Management and CPS Capital	Rights Issue	\$ 2.0
Oncosil Medical	OSL	Kidder Williams	Rights Issue	\$ 9.9
Cynata	CYP	Bell Potter Securities	Placement and SPP	\$ 7.0
PharmAust	PAA	Baker Young Limited	Placement	\$ 2.5
Nutritional Growth Solutions	NGS	Molo Capital	Placement	\$ 1.2
Exopharm	EX1	Alto Capital and Canary Capital	Rights Issue and Convertible Note	\$ 1.8
PYC Therapeutics	PYC	E&P Corporate Advisory	Placement	\$ 30.0
Melodiol Global (Formerly Creso Pharma)	ME1	EverBlu Capital and SBC Global Investment Fund	Placement and Convertible Note	\$ 7.5
Adalta	1AD	Peak Asset Management	Rights Issue	\$ 1.3
Bluechiip	BCT	MST Financial Services	Placement and SPP	\$ 2.9
4D Medical	4DX	Bell Potter Securities	Placement and SPP	\$ 45.0
LBT Innovations	LBT	Lind Global Fund II	Placement	\$ 1.5
Dimerix	DXB	Mercer Street Capital Partners	Rights Issue and Convertible Note	\$ 6.8
IDT Australia	IDT	Taylor Collison	Placement	\$ 5.0
Argenica	AGN	Euroz Hartleys	Placement	\$ 4.0
Arovella Therapeutics	ALA	Blue Ocean Equities and Baker Young	Placement	\$ 4.1

Continued over

## June Quarter Raises (cont'd)

Company	Code	Investment Manager or Investor	Type of Raising	Funds Raised (\$M)
Impedimed	IPD	Canaccord Genuity, Wilsons Corporate Finance and Jarden Australia	Placement and SPP	\$ 30.0
Optiscan Imaging	OIL	Peters Investments and Orchid Capital Investments (Underwriters)	Rights Issue	\$ 16.7
Firebrick Pharma	FRE		Placement	\$ 1.0
Medibio	MEB		SPP	\$ 0.6
Althea Group Holdings	AGH	Obsidian Global Partners	Convertible Note	\$ 2.2
Singular Health Group	SHG	180 Markets	Placement	\$ 1.5
Osteopore	OSX	Cadmon Advisory	Rights Issue	\$ 2.6
Immutep	IMM	Bell Potter Securities, Jefferies & Wilsons Corporate Finance	Placement and Rights Issues	\$ 80.0
EBR Systems	EBR	Bell Potter Securities, Morgans Corporate and Wilsons Corporate Finance	Placement and SPP	\$ 30.0
Chimeric Therapeutics	CHM	Bell Potter Securities, Lind Global Fund	Placement and SPP	\$ 2.3
Q4 Total				\$ 382.6
Q3 Total				\$ 77.0
<b>FY2023 2H Total</b>				<b>\$ 459.6</b>
FY2023 1H				\$ 902.0
FY2022 2H				\$ 552.0



# PiperAlderman

## Bioshares Model Portfolio (21 July 2023)

Company	Code	Price (current)	Price added to portfolio	Recommendation	Cap'n (\$M)	Date added
Telix Pharmaceuticals	TLX	\$10.36	\$7.85	Spec Hold A	\$3,260	December 2021
Neuren Pharmaceuticals	NEU	\$14.20	\$3.25	Spec Hold A	\$1,832	December 2021
Clinuvel Pharmaceuticals	CUV	\$18.06	\$20.31	Buy	\$892	November 2020
Anteris Technologies	AVR	\$21.90	\$21.50	Spec Buy A	\$336	September 2022
Aroa Biosurgery	ARX	\$0.92	\$1.11	Spec Buy A	\$315	November 2021
Immutep	IMM	\$0.33	\$0.32	Spec Buy A	\$286	March 2019
Opthea	OPT	\$0.57	\$0.16	Spec Buy A	\$264	November 2014
Cogstate	CGS	\$1.50	\$0.24	Buy	\$260	April 2019
Microba Life Sciences	MAP	\$0.32	\$0.30	Spec Buy A	\$108	June 2023
Somnomed	SOM	\$1.00	\$2.05	Spec Buy A	\$83	January 2022
Micro-X	MXI	\$0.105	\$0.38	Spec Buy A	\$48	May 2017
Antisense Therapeutics	ANP	\$0.055	\$0.22	Spec Buy B	\$40	November 2021
Pharmaxis	PXS	\$0.052	\$0.26	Spec Buy A	\$37	December 2016
Dimerix	DXB	\$0.072	\$0.09	Spec Buy B	\$23	December 2018
Patrys	PAB	\$0.010	\$0.013	Spec Buy B	\$21	July 2020
Rhinomed	RNO	\$0.061	\$0.27	Spec Buy B	\$17	December 2021
Immuron	IMC	\$0.076	\$0.08	Spec Buy A	\$17	May 2023
LBT Innovations	LBT	\$0.024	\$0.09	Spec Buy A	\$8	April 2022

**Portfolio Changes**

**IN:**  
None

**OUT:**  
None

## **Lumos Diagnostics Surges 1300% Following FDA Approval**

After a year preparing a resubmission for its rapid, point-of-care test, FebriDx, Lumos Diagnostics (LDX: \$0.069) has received clearance from the FDA to market its diagnostic in the US. The test, which has been approved as an aid in the diagnosis of bacterial acute respiratory infection and in the differentiation of bacterial infections from viral ones, has already been registered in 10 other regions, including the UK, Europe, Canada, and Australia.

The company's share price surged 1300% on the news and is currently trading 527% higher following the approval.

LDX's revenue remains consistent despite more than halving the number of staff and significantly reducing cash burn, reporting a revenue of US\$2M in Q3 FY2023. The company has been successful in consolidating its financial position, with CEO Doug Ward seeking to bring the company to cashflow positive as soon as possible.

The company's shift in focus has seen the service side of the business become the main source of revenue, with 95% of LDX's revenue coming from the provision of diagnostic test development services and contract manufacturing to clients. Lumos has also signed two new contracts worth up to US\$1.7M with Hologic, a global leader in women's health diagnostics.

Lumos had US\$4.3M in cash and cash equivalents as of March 30, with access to an additional US\$2.7M through a Convertible Notes facility. Striking while the iron is still hot from the FDA approval of FebriDx, the company has completed a \$4.75M placement and commenced a SPP to raise an additional \$4.75M, both at \$0.07 per share. Some of these funds will be used to buyback outstanding convertible notes which has placed considerable selling pressure on the stock this year.

Moving forward the company is looking to capitalise on the growing role of diagnostic tests in healthcare and provide clients with a unique, fully integrated diagnostic test development and manufacturing service. Strategic partnerships will continue to be a "key pillar" of the company's growth plan, hopefully providing long-term revenue growth.

Lumos is capitalised at \$28 million.

**Bioshares** recommendation: **Speculative Hold Class B**

*Executive chairman San Lanyon will be presenting at next week's Bioshares Biotech Summit in Hobart.*

**Bioshares**

## **Neuren Pharmaceuticals Moves to Worldwide License for Trofinetide and NNZ-2591 with Acadia**

Neuren Pharmaceuticals (NEU: \$14.20) announced this week a significant expansion of its partnership with US biopharmaceutical company Acadia Pharmaceuticals (NASDAQ: ACAD). The agreement not only sees Acadia's exclusive licence for trofinetide in North America expand to a worldwide licence, but also Acadia's acquisition of the exclusive worldwide licence for NNZ-2591 in Rett Syndrome and Fragile X Syndrome.

Importantly, it leaves Neuren with rights to commercialise NNZ-2591 for the four indications for which Phase II studies are currently underway by Neuren. Neuren is precluded from developing NNZ-2591 or any other compound in North America for an indication in which Acadia develops trofinetide, excluding Phelan-McDermid, Pitt Hopkins, Angelman, and Prader-Willi syndromes. This ensures that NEU's four Phase II clinical trials featuring NNZ-2591 will continue to advance as planned.

Neuren CEO John Pilcher said this deal removes the remote risk (of obstruction) to Neuren for its four prized indications with NNZ-2591 (with Neuren previously not able to develop NNZ-2591 in North America for indications that Acadia pursues with trofinetide).

The new deal between the two companies will see Neuren receive a US\$100M up-front payment, following the US\$40M up-front payment received for the North American licence. The milestone payments for the new deal include US\$35M for the first commercial sale of trofinetide for Rett syndrome in Europe, and US\$15M for the first commercial sale in Japan. In total the company stands to earn up to US\$427M in milestone payments.

Tiered royalties for trofinetide are higher for the rest of the world, ranging from the mid-teens to low twenties. The global payments related to NNZ-2591 are identical to the global payments for trofinetide. European trials with trofinetide to gain approval for Rett syndrome are not expected to be required according to Pilcher.

### **DAYBUE Launch Progress**

Acadia has reported that the launch of DAYBUE is going "according to plan". DAYBUE Q2 preliminary net sales were US\$23M following its launch in April, with Q3 net sales guidance set as high as \$55M. Acadia CEO, Steve Davis, has reported that the prevalent population is "adopting [DAYBUE] faster than expected" and that "demand has exceeded [their] plan".

Acadia's initial strategy was to focus on converting clinical trial patients to customers. To date more than 90% of clinical trial patients have been converted. The company then shifted its focus to high-volume treatment centres and community centres. The initial clinical trial patients now make up a minority of patients on commercial drug treatment.

Acadia COO Brendan Teehan reported that the company has established a "comprehensive support system for patients,

*Continued over*

caregivers, and providers" to "set the appropriate clinical benefit and treatment management expectations with physicians and families to ensure the optimal initiation and treatment journey for the patient". A large sales footprint is not required to sell DAYBUE said Pilcher, with the US market expected to function as a blueprint for commercialising the drug throughout the rest of the world.

Continued support for patients is particularly valuable as the drug may be one that patients will need to be on "for the long haul" according to Acadia.

Being a treatment for such a rare disease, DAYBUE's launch has not been completely seamless. Reimbursement has been somewhat of a barrier, with only 20% of covered lives having a formal written policy. Acadia has also acknowledged that certain payor plans may never have a formal written policy for Rett syndrome, relying exclusively on the medical exception rule. Most patients on the therapy today have been given access through a letter of medical necessity. Acadia is continuing to work alongside payors to rectify the issue.

Not only have most patients only had one or two scripts filled, but physicians are recommending that patients titrate up from the prescribed dose. This ultimately means that future compliance rates, prescription refill rates, dose per patient, and persistence are uncertain, making it difficult to predict future sales of DAYBUE at present.

Acadia intends to pursue regulatory approval of trofinetide in Europe while advancing its own clinical pipeline, which includes a

Phase III trial of ACP-101, a treatment for Prader-Willi syndrome and a potential competitor to Neuren's NNZ-2591 in the indication. CSO Dr. Kathie Bishop notes that while there is no current data, the two compounds might be "synergistic".

Acadia's other drug, Nuplazid, is expected to generate net sales of approximately US\$530M for the year. The company is well funded, with a cash position of US\$275M after payments to Neuren are accounted for.

### Summary

Whilst Neuren had multiple partnering options for rest-of-world rights for trofinetide, assigning global rights to Acadia provides a less complicated, cleaner structure removing any potential restrictions for Neuren around the NNZ-2591 commercialisation pathway for the US market. Acadia has also shown to be an excellent and reputable partner to date.

Following receipt of the US\$100 million payment from Acadia, Neuren will have \$226 million in cash, including payment of the US 5% withholding tax. Neuren is capitalised at \$1.8 billion.

**Bioshares** recommendation: **Accumulate**

*Neuren CEO John Pilcher will be presenting at next week's Bioshares Biotech Summit in Hobart.*

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## Forthcoming Biotech IPOs

Company: **CurveBeam AI**  
 Raise amount: \$25 million  
 Listing price: \$0.48 per share  
 Capitalisation on listing: \$154 million  
 Offer closes: 2 August  
 Expected listing date: 23 August  
 Lead Managers: Bell Potter Securities, Lodge Corporate

Company: **Cleo Diagnostics**  
 Raise amount: \$12 million  
 Listing price: \$0.20 per share  
 Capitalisation on listing: \$26 million  
 Offer closes: 28 July  
 Expected listing date: 11 August  
 Lead Managers: Taylor Collison

Company: **Dragonfly Biosciences**  
 Raise amount: \$3-5 million  
 Listing price: \$0.20 per share  
 Capitalisation on listing: \$35-38 million  
 Offer closes: Closed  
 Expected listing date: 1 August  
 Lead Managers: Finexia Securities, RM Corporate Finance



**BELL POTTER**



## The ASX-Listed Life Sciences Sector

### 30 June 2023: Capitalisation \$220 billion, 153 companies

#### Bioshares Large Cap. Index

Company	Code	Cap. \$m	Principal Activities	Change - Half	Change - Year	Price 30/6/23
CSL	CSL	133,753	Manufactures pharmaceutical products including vaccines and human plasma fractions	-3.6%	3.1%	\$277.38
Resmed Inc.	RMD	48,198	Manufactures diagnostic and treatment equipment for sleeping disordered breathing	6.0%	6.9%	\$32.81
Cochlear	COL	15,067	Manufactures cochlear hearing implants	12.2%	15.3%	\$229.07
Telix Pharmaceuticals	TLX	3,549	Development of molecularly-targeted radiation (MTR) therapies and diagnostics. Selles Illuccix for prostate cancer imaging.	54.3%	147.7%	\$11.22
Blackmores	BKL	1,838	Manufactures vitamin, mineral and herbal supplements and skin & hair products in Australia and N.Z.	30.5%	33.9%	\$94.24
Neuren Pharmaceuticals	NEU	1,580	Developing neuroprotective therapeutics. First product, DayBue, on market.	54.1%	222.4%	\$12.25
Nanosonics	NAN	1,431	Developing a novel disinfection technology. The first product, on the market, is a point of care ultrasound probe disinfection unit, branded Trophon EPR	10.5%	41.1%	\$4.74
Polynovo	PNV	1,063	Developing and selling novel polymer-based products for treating wounds and burns	-23.5%	14.0%	\$1.55
Clinuvel Pharmaceuticals	CUV	883	Markets an analogue of the alpha-MSH protein, named Scenesse, as a photo-protective agent	-17.5%	20.4%	\$17.88

**Capitalisation Total** 207,363

#### Bioshares Index

Company	Code	Cap. \$m	Principal Activities	Change - Half	Change - Year	Price 30/6/23
Mesoblast	MSB	924	Developing cellular medicines to treat advanced heart failure, chronic low back pain and acute graft versus host disease	30.5%	86.1%	\$1.14
Sigma Pharmaceuticals	SIG	890	Pharmaceutical manufacturing and wholesaling	37.7%	44.8%	\$0.84
Avita Medical	AVH	647	Markets ReCell, a skin repair product. Redomiciled to the US. Now Nasdaq listed and trades as CDIs. (20:1 share consolidation)	164.8%	273.4%	\$5.19
Imugene	IMU	584	Developing two B-Cell cancer vaccines, HER-Vaxx and PD1-Vaxx, and an oncolytic virus technology, CF33	-37.2%	-49%	\$0.09
Mayne Pharma Group	MYX	383	Manufactures, develops and markets generic drugs, with operations in Australia and the USA	10%	-12%	\$4.40
Immutep	IMM	374	Developing immuno-oncology drug candidates IMP761 and IMP321 (eftilagimod alpha)	14.5%	8.6%	\$0.32
Impedimed	IPD	363	Markets products that aid the diagnosis of secondary lymphoedema, muscle wasting and other disorders	127.8%	195.1%	\$0.18
AFT Pharmaceuticals	AFP	356	Development and sale of pharmaceuticals in Australasia and Rest-of-World	0.0%	1.5%	\$3.40
Anteris Technologies	AVR	332	Application of proprietary ADAPT technology to treat tissue used in the manufacture of cardiovascular prostheses	-3.7%	-25.8%	\$21.37
Aroa Biosurgery	ARX	317	Manufacture and sale of wound healing and soft tissue reconstruction products	-14.4%	40.2%	\$0.93
Cogstate	CGS	286	Markets cognitive performance diagnostic products	-15.8%	8.2%	\$1.65
Paradigm Biopharm.	PAR	278	Developing pentosan polysulphate sodium to treat bone marrow oedema, joint pain and mucopolysaccharidosis type I	-29.5%	2.6%	\$0.99
Trajan Group Holdings	TRJ	275	Develops and manufactures scientific instruments for life sciences sector (Listed Q2 2021)	3.4%	-9.5%	\$1.81



## Bioshares Index (cont'd)

Company	Code	Cap. \$m	Principal Activities	Change - Half	Change - Year	Price 30/6/23
EBR Systems	EBR	273	Developing wireless cardiac pacing system. (Listed Q4 2021)	95.7%	140.0%	\$0.90
Opthea	OPT	257	Developing OPT-302 to treat wet AMD (an eye disease)	-39.9%	-50.0%	\$0.55
Probiotec	PBP	228	Manufacturer, marketer and distributor of a range of over the counter (OTC) pharmaceuticals, complementary medicines and speciality ingredients	29.0%	24.4%	\$2.80
PYC Therapeutics	PYC	209	Developing VP-001 to treat retinitis pigmentosa	-18.8%	-13.8%	\$0.06
4D Medical	4DX	205	Commercialising a lung function imaging technology (XV) which uses existing x-ray imaging systems combined with image processing methods to image the lung in motion	59.5%	13.6%	\$0.67
Race Oncology	RAC	197	Completing the development of a chemotherapy drug, called Bisantrone, which was the subject of more than 40 phase II clinical studies during the 1980s and 1990s.	-39.1%	-37.2%	\$1.23
Volpara Health Technologies	VHT	189	Markets breast density assessment tools and analytics, for use with breast x-ray screening programs	42.9%	78.6%	\$0.75
Cyclopharm	CYC	186	A nuclear medicine company that markets the Technegas lung imaging system	70.9%	97.0%	\$2.00
Botanix Pharmaceuticals	BOT	171	Developing BTX1503 for the treatment of acne. BTX1503 combines synthetic cannabidiol with a transdermal drug delivery system, Permetrex.	145.3%	128.1%	\$0.13
Clovercorp	CLV	164	Development and production of omega-3 food additives from tuna oil	-3.2%	20.6%	\$1.20
Mach 7 Technologies	M7T	148	Development and sales of an enterprise imaging management platform	8.8%	26.5%	\$0.62
Medadvisor	MDR	136	Medication adherence software platform company	-3.8%	47.1%	\$0.25
Clarity Pharmaceuticals	CU6	127	A clinical stage radiopharmaceutical company focusing on the use of targeted copper theranostics. (Listed Q3 2021)	-29%	37%	\$0.70
Starpharma Holdings	SPL	127	Developer of pharmaceutical chemical scaffolds known as 'dendrimers'	-43.6%	-58.1%	\$0.31
Next Science	NXS	125	Commercialisation of anti-biofilm products	-15.3%	-19.4%	\$0.58
Alcidion	ALC	120	Specialist health IT solution provider	-34.5%	-13.6%	\$0.10
Recce	RCE	111	Development of broad spectrum antibiotics	-5.3%	-29.8%	\$0.63
INOVIQ	IIQ	110	Developing cancer diagnostics and therapies. (30 for 1 share consolidation conducted). Formerly Bard1. Acquired Sienna Cancer Diagnostics in 2020.	32.8%	117.9%	\$1.20
Microba LifeSciences	MAP	103	Developing therapeutics using microbiome derived drug candidates. Provides personalised microbiome testing and assessment. (Listed in 1H 2022)	-9.6%	50.0%	\$0.30
Proteomics International	PIQ	99	Provider of protein chemistry analytical services. Seeking to commercialise a diabetic kidney disease diagnostic.	-9.5%	-7.5%	\$0.86
SDI	SDI	98	Manufacture & distribution of amalgam (fillings) & other dental materials and product R&D	-8.3%	3.1%	\$0.83
Emvision Medical Devices	EMV	91	Exploiting low energy non-ionising microwave radiation to create 3D images, with the goal of developing a device to support the diagnosis of the two main types of stroke	-36.8%	-22.0%	\$1.17
Rhythm Biosciences	RHY	89	Developing Colostat, a blood test for the early detection of colorectal cancer	-58.6%	-64.3%	\$0.41
AnteoTech	ADO	80	Developer of a biological coatings technology that can be applied to immunoassays, bio-separations, drug delivery and other medical devices	-29.8%	-38.5%	\$0.04
Somnomed	SOM	79	Markets oral devices for the treatment of sleep apnea and snoring	-26.0%	-21.1%	\$0.96
Genetic Signatures	GSS	75	Development and sale of molecular diagnostics (MDx) kits and products.	-40.3%	-54.7%	\$0.53
Actinogen Medical	ACW	72	Developing Xanamem for the treatment of dementia in Alzheimer's disease patients	-60.0%	-20.0%	\$0.04
Immuron	IMC	72	Sales and development of hyper-immune bovine colostrum products for therapeutic use	14.5%	8.6%	\$0.32

## Bioshares Index (cont'd)

Company	Code	Cap. \$m	Principal Activities	Change - Half	Change - Year	Price 30/6/23
Orthocell	OCC	69	Developing and marketing regenerative medicine products	-14.6%	-13.6%	\$0.35
Medical Developments	MVP	67	Commercialising the Pentrox inhaler for temporary pain relief. Used widely in ambulances across Australia.	-47.6%	-46.9%	\$0.78
Pacific Edge	PEB	62	Commercialising a suite of bladder cancer test, to diagnose, triage and monitor patients. (Listed Q3 2021, primary listing in NZ)	-82.9%	-87.6%	\$0.08
Micro-X	MX1	62	Development of a mobile medical x-ray imager for hospitals, a version for deployed military use and a mobile security back-scatter imager	-7.7%	-14.3%	\$0.12
Optiscan Imaging	OIL	59	Manufactures confocal microscopes for clinical diagnosis	-20.0%	-27.3%	\$0.08
Prescient Therapeutics	PTX	58	Developing compounds to treat various cancers	-40.0%	-47.7%	\$0.08
Universal Biosensors	UBI	55	Development, manufacture and commercialisation of a range of in vitro diagnostic tests for point-of-care use	15.6%	-29.7%	\$0.26
Nova Eye Medical	EYE	50	Developing devices to treat glaucoma	-5.4%	43.2%	\$0.27
Imricor	IMR	50	Design, manufacture and sales of MRI-compatible products for cardiac ablation procedures to treat arrhythmias	-9.6%	34.7%	\$0.33
Arovella Therapeutics (Formerly Suda Pharm.)	ALA	42	Developing drugs for oro-mucosal administration. Recently acquired IP for anagrelide, with intent to develop it as an anti-cancer therapy	117.4%	117.4%	\$0.05
Antisense Therapeutics	ANP	41	Developing antisense compounds to treat multiple sclerosis and Duchenne Muscular Dystrophy	-39.2%	-21.3%	\$0.059
Vita Life Sciences	VLS	40	Development, manufacture and distribution of prescription and OTC medicines as well as complementary and alternative medicines, dietary supplements and health foods	15.1%	-13.3%	\$1.56
Argenica Therapeutics	AGN	37	Developing therapeutics to reduce brain damage following stroke (Listed Q2 2021)	-16.7%	-12.8%	\$0.38
Kazia Therapeutics	KZA	36	Developing GDC-084 for the treatment of glioblastoma multiform (a brain cancer)	73.9%	-74.0%	\$0.16
Pharmaxis	PXS	35	Developer of Bronchitol, which is approved in Europe and the USA for the management of cystic fibrosis. Developing a suite of compounds from amine oxidase platform.	-19.7%	-24.6%	\$0.049
Radiopharm Theranostics	RAD	34	Developing radiopharmaceutical products for diagnosis and treatment of disease. (Listed Q4 2021)	0.0%	-30.0%	\$0.11
Painchek	PCK	32	Commercialising a smartphone app which uses facial recognition technology to detect indications of pain. TGA cleared and CE Marked.	-26.5%	-10.7%	\$0.03
Respiri	RSH	32	Respiratory and pulmonary devices company. Markets Airsona, an ehealth product	-17.4%	-30.9%	\$0.04
Compumedics	CMP	32	Develops, manufactures and markets sleep diagnostic and monitoring equipment.	-10.0%	16.1%	\$0.18
Cryosite	CTE	31	Provides specialised storage services, especially for umbilical cord blood	-14.4%	-0.8%	\$0.63
Bionomics	BNO	26	Discovery and development of drugs to treat CNS diseases	-50.0%	-64.0%	\$0.02
Invion	IVX	26	Development of Photosoft, a photosensitiser derived from chlorophyll, which it is believed can accumulate selectively in tumours and be manipulated for therapeutic purposes.	-55.6%	-55.6%	\$0.00
IMEXHS	IME	25	Markets a radiology and imaging platform, in Latin and South America, and uses SaaS and PaaS revenue models. (Completed 50:1 consolidation)	30.4%	33.3%	\$0.60
Dimerix	DXB	24	Developing a combination therapy, DMX200, to treat chronic kidney disease.	-57.2%	-48.3%	\$0.062
PharmAust	PAA	24	Developing a veterinary anti-parasitic compound (PPL-1) as a human and animal cancer therapy	17.2%	7.1%	\$0.08
Oncosil Medical	OSL	24	Developing Oncosil, a brachytherapy for pancreatic cancer and liver cancer	-73.3%	-70.0%	\$0.01

## Bioshares Index (cont'd)

Company	Code	Cap. \$m	Principal Activities	Change - Half	Change - Year	Price 30/6/23
Living Cell Technologies	LCT	23	Development of NTCELL for the treatment of Parkinson's Disease, and potentially for eye and ear diseases	25.0%	87.5%	\$0.02
Genetic Technologies	GTG	23	Markets cancer risk tests	-33.3%	-33.3%	\$0.00
Vectus Biosystems	VBS	23	Developing an anti-fibrotic compound, VB0004, with applications in heart and kidney disease	-39.7%	-55.3%	\$0.44
Cynata Therapeutics	CYP	22	Stem cell technology company aiming to produce unlimited uniform, pharmaceutical grade MSCs from a single donor.	-58.3%	-65.3%	\$0.13
CardieX	CDX	22	Development of wearable blood pressure measurement devices	-56.9%	-50.0%	\$0.16
Biotron	BIT	22	Developing a drug to treat HIV. Testing drug library against SARS-CoV-2	-3.7%	-57.4%	\$0.03
EZZ Life Science Holdings	EZZ	21	Distributor of skin care products (EAORON brand) and develops consumer health products for Au, NZ and China. (Listed Q2 2021)	33%	61%	\$0.50
Patrys	PAB	21	Developing novel antibody therapies for a range of oncology indications. Focussed on 3E10, a cell penetrating antibody.	-63.0%	-50.0%	\$0.010
Rhinomed	RNO	20	Developing nasal stent technologies with applications for sport performance, sleep and drug delivery	-39.1%	-39.1%	\$0.070
IDT Australia	IDT	20	Manufacturer of pharmaceutical ingredients to international standards for major pharmaceutical groups.	-18.8%	-43.5%	\$0.07
Resonance Health	RHT	19	Markets FerriScan, a non-invasive tool for measuring liver iron levels	-30.0%	-25.0%	\$0.04
Chimeric Therapeutics	CHM	19	Developing CART T therapy for solid cancers licensed from the City of Hope Cancer Center (Listed Q1 2021)	-52.5%	-58.7%	\$0.038
Imagion Biosystems	IBX	19	Developing MagSense, a diagnostic technology which exploits the principles of superparamagnetic relaxometry	-33.3%	-40.7%	\$0.02
Firebrick Pharma	FRE	18	Developing nasal spray treatment for common cold.	-32.6%	-41.5%	\$0.16
Alterity Therapeutics	ATH	17	Developing PBT434 for synucleinopathies	-30.0%	-46.2%	\$0.01
Tissue Repair	TRP	16	Developing a biologically active pharmaceutical to stimulate wound repair pathways. Phase III trials to start in 2022. (Listed Q4 2021)	17.4%	8.0%	\$0.27
Heramed	HMD	15	Commercialising a home pregnancy monitoring technology	-48.0%	-33.0%	\$0.07
Invex Therapeutics	IXC	15	Developing a formulation of the diabetes drug exanatide to treat idiopathic intracranial pressure and other indications	-63.3%	-59.6%	\$0.20
Bluechiip	BCT	15	Development, manufacture and commercialisation of a tracking system for biological samples	-32.3%	-22.2%	\$0.02
Star Combo Pharma	S66	15	Develops, manufactures and markets nutritional and OTC products	-26.7%	-29.0%	\$0.11
BCAL Diagnostics	BDX	15	Developing an in vitro diagnostic for breast cancer using fingerprints of lipid biomarkers. (Listed Q3 2021)	17%	-13%	\$0.07
Amplia Therapeutics	ATX	15	Developing drug candidates to treat fibrotic cancers and fibrosis. Formerly Innate Immunotherapeutics.	-5.0%	-20.8%	\$0.08
Asian American Medical Group	AJJ	15	Manages liver treatment centres in Asia; expanding into radiation oncology	0.0%	0.0%	\$0.04
Biome Australia	BIO	14	Develops and sells evidence-based complementary	2.9%	-4.0%	\$0.07
Bio-Gene Technology	BGT	14	Commercialisation of the insecticides Flavocide (synthetic) and Qcide (plant-derived), in the fields of human health and crop protection.	-22.0%	-40.0%	\$0.08
Memphasys	MEM	13	Developing a sperm separation technology, SpermSep	0.0%	-65.0%	\$0.01
Bioxyne	BXN	13	Sale and distribution of probiotics	-16.7%	66.7%	\$0.02
Osteopore	OSX	13	Manufacture of 3D bioresorbable implants. Three products are FDA cleared and CE Marked for cranio-facial indications	-43.3%	-26.1%	\$0.09
Noxopharm	NOX	13	Developing a cancer treatment, NOX66, a formulation of idronoxil, which targets NADH oxidase 2.	-70.3%	-77.9%	\$0.04
Atomo Diagnostics	AT1	13	Manufactures rapid diagnostic test devices for OEM customers	-59.3%	-60.7%	\$0.02
Acrux	ACR	12	Developer of topical generic drugs	-40.0%	-19.2%	\$0.042
Neuroscientific Biopharm.	NSB	11	Developing EmtinB, an LRP-1 receptor agonist for the treatment of Alzheimer's disease	-36.0%	-55.6%	\$0.08

## Bioshares Index (cont'd)

Company	Code	Cap. \$m	Principal Activities	Change - Half	Change - Year	Price 30/6/23
Avecho Biotechnology	AVE	11	Commercialising a drug delivery system	-66.7%	-61.5%	\$0.01
LBT Innovations	LBT	10	Developer of innovative products which deliver productivity benefits across a range of life science settings	-48.3%	-61.5%	\$0.030
Adherium	ADR	10	Commercialising personal digital medication monitoring systems to improve patient compliance and medication efficacy	-50.0%	-71.4%	\$0.00
The Hydration Pharmaceutical Co.	HPC	9	Sells hydration liquids, powders and tablets in North America. Sold ANZ rights to Hydralyte in 2014 to Care Pharmaceuticals. (Listed Q4 2021)	-36.7%	-56.2%	\$0.06
USCOM	UCM	9	Markets Uscom, a non-invasive heart output function monitor, BP+ non-invasive central blood pressure product and digital ultrasonic spirometry products	2.2%	-29.2%	\$0.05
Adalta	1AD	9	Developing AD-214 for the treatment of idiopathic pulmonary fibrosis (IPF) and other human fibrotic diseases	-41.5%	-55.6%	\$0.02
Control Bionics	CBL	8	Design, manufacture and sale of wireless wearable electromyography (EMG) based augmentative and alternative	-47.3%	-61.3%	\$0.09
Visioneering Technologies	VTI	8	Markets a next-generation contact lens (100:1 share consolidation)	-37.5%	-5.7%	\$0.25
Island Pharmaceuticals	ILA	8	A drug repurposing company that focuses on the development of antivirals for infectious diseases (Listed Q2 2021)	-48.6%	-34.5%	\$0.10
Truscreen	TRU	8	Commercialising cervical cancer screening device for real time detection of cancerous and pre-cancerous tissue (Listed Q1 2021)	-47.5%	-50.0%	\$0.02
IhaleRx (formerly Lifespot Health)	IRX	7	Commercialising the Bodytel diagnostic software, which is deployed with its Medihale medical cannabis vaporiser system, as well as with patients with metabolic syndrome	-33.3%	-46.7%	\$0.04
Anagenics (formerly Cellmid)	AN1	6	Health and beauty business focusing on sale of anti-aging and wellness products.	-32.0%	-26.1%	\$0.02
Dorsavi	DVL	6	Commercialising a wireless sensor movement monitoring system and products for use in the Elite Sports, OL&S and medical/physiotherapy markets	-8.3%	-8.3%	\$0.01
Allegra Orthopedics	AMT	6	A developer and manufacturer of prosthetic implants and medical devices.	-47.6%	-69.4%	\$0.06
Singular Health Group	SHG	5	Developing medical imaging software (Listed Q1 2021)	-68.7%	-62.5%	\$0.04
Analytica	ALT	5	Markets the Pericoach product to aid in the management of female urinary incontinence.	0.0%	0.0%	\$0.001
Medibio	MEB	5	Commercialising a test for depression and anxiety	-50.0%	0.0%	\$0.001
Nyrada	NYR	4	Developing drugs to treat cardiovascular, neurological and chronic inflammatory diseases	-80.7%	-79.3%	\$0.03
HitIQ	HIQ	4	Develops and sells head impact mouthguards to assist in assessment of sport related concussion injuries (Listed Q2 2021)	-28.0%	-55.0%	\$0.02
Exopharm	EX1	4	Development of technology for improving the purification of exosomes, which are extra-cellular vesicles which transport bioactive molecules through out the body.	-86.7%	-93.8%	\$0.01
Hexima	HXL	4	Developing HXP124 to treat fungal infection of toenails (Re-listed Q4 2020). Program cancelled due to poor results (July 2022).	5.0%	-30.0%	\$0.02
Anatara Life Sciences	ANR	3	Developing a gastrointestinal dietary supplement	-17.6%	-49.1%	\$0.03
Holista Colltech	HCT	3	Markets dietary supplements and disinfectant products	-65.5%	-67.7%	\$0.01
Lumos Diagnostics	LDX	2	Develops and sells POC diagnostics for inflammatory diseases and infections. Lead product, FebriDx, is a finger prick test to differentiate between bacterial & viral infection.	-77%	-92%	\$0.01
Jayex Healthcare	JTL	2	Commercialisation of the Enlighten patient workflow platform	-18%	80%	\$0.01
Regeneus	RGS	2	Commercialisation of autologous adipose derived stem cells and factors. Markets HiQCell for human use and CryoShot for veterinary use.	-85.4%	-88.5%	\$0.01
Nutritional Growth Solutions	NGS	2	Development and sale of nutritional supplements for children. (Listed Q4 2020)	-83.3%	-90.9%	\$0.01

## Bioshares Index (cont'd)

Company	Code	Cap. \$m	Principal Activities	Change - Half	Change - Year	Price 30/6/23
TALI Digital	TD1	1	Software company developing tools for assessment and improvement of attention in children. Formerly Novita Healthcare.	-50.0%	-83.3%	\$0.00

Capitalisation Total 11,733

## Botanical Product Companies (Cultivated Production)

Company	Code	Cap. \$m	Principal Activities	Change - Half	Change - Year	Price 30/6/23
Vitura Health	VIT	287	Medicinal cannabis health and wellness business. (Formerly Cronos Australia)	-11.9%	106.2%	\$0.52
Incannnex	IHL	159	Developing medical cannabis products to treat OSA, TBI and ARDS and TMD	-42.9%	-52.4%	\$0.10
Elixinol Global	EXL	116	A supplier of hemp and medicinal cannabis products. To Acquire CansaCare Health GmbH	-5.4%	43.2%	\$0.27
Cann Group	CAN	46	Medicinal cannabis company focused on the breeding, cultivation and production stages. Holds Australian ODC cultivation (MC) and research license (CR). Acquired Satipharm in 2021.	-41.5%	-56.4%	\$0.12
Little Green Pharna	LGP	46	Sale and distribution of medicinal cannabis products	-13.9%	-31.1%	\$0.16
Neurotech International	NTI	33	Has acquired proprietary cannabis strains for treating autism, epilepsy and ADHD	-42.0%	-42.9%	\$0.04
Melodiol Global Health	ME1	18	Development of cannabis and hemp derived therapeutic, nutraceutical, and life style products with wide patient and consumer reach for human and animal health. (Formerly Creso Pharma)	-65.0%	-80.0%	\$0.01
Auscans Group Holdings	AC8	18	Developing medical cannabis products for the Australian market. (Acquired CansPal Animal Therapeutics in 2021)	0.0%	8.1%	\$0.04
Zelira Therapeutics	ZLD	17	Developer of medicinal cannabis therapeutic products (175 for 1 consolidation 1H 2022)	51.0%	55.7%	\$1.51
MGC Pharmaceuticals	MXC	17	A medical and cosmetic cannabis company with growing operations in Slovenia. Acquired Czech company Panax Pharma.	-54.5%	-68.8%	\$0.01
Althea Group	AGH	16	Supply of branded medicinal cannabis products in Australia. To cultivate, extract and manufacture medicinal cannabis. Holds ODC manufacturing license.	-29.5%	-27.1%	\$0.04
Medlab Clinical	MDC	15	Development, production and marketing of nutraceuticals cannabis product to treat cancer patients with intractable pain	-1.5%	-8.3%	\$6.60
Bod Australia	BOD	11	Developer and distributor of natural, evidence-based cosmetics and natural medicines. Holds medicinal cannabis import license. Overseas partner is Linsea SA.	-54.0%	-1.4%	\$0.07
Epsilon Healthcare (Formerly named THC Global Group)	EPN	6	A diversified global cannabis company with operations in Australia and Canada	-16.0%	-22.2%	\$0.02
Cann Global	CGB	5	Operates a hemp seeds business and conducts medical cannabis research (25 for 1 share consolidation 2022)	0.0%	5.0%	\$0.02
The Calmer Co Int	CCO	1	Cultivation and development of kava (piper methysticum) as an alternative treatment for anxiety, pain and insomnia. (Formerly Fiji Kava)	-80.0%	-91.2%	\$0.00

Capitalisation Total 812

## Listed Biotech Investment Funds or Companies

Company	Code	Cap. \$m	Principal Activities	Change - Half	Change - Year	Price 30/6/23
BTC Health	BTC	7	Provides capital and management expertise to high-growth Australian biotech, medtech and pharmaceutical companies	-30%	-35%	\$0.03

Capitalisation Total 7

Capitalisation Total - All Indices 219,915

## Selected Clinical Trial Developments &amp; Product Launches - 2H FY2023

Company	Code	Product/Application	Event
<b>Approval Stage</b>			
Telix Pharmaceuticals	TLX	Illucix ( <sup>68</sup> Ga-PSMA-11 injection)	Expanded indication for Telix's Illucix to include patient selection for PSMA-directed radioligand therapy
Aroa Biosurgery	ARX	Enivo pump and catheter	Key components of the company's new Enivo Tissue Apposition Platform received FDA clearance
AFT Pharmaceuticals	AFP	Maxigesic for management of mild to moderate acute pain	Maxigesic Rapid tablets gain FDA approval
Avita Medical	AVH	RECELL for treatment of full-thickness skin defects	RECELL system gains FDA approval for use in full-thickness skin defects. Previously used for treatment of severe burns
Starpharma	SPL	VIRALEZE nasal spray for respiratory viruses	Approved in Malaysia. Continuing discussion with potential commercial partners
Rhythm Biosciences	RHY	ColoSTAT blood test for early detection of colorectal cancer	UKCA mark granted
Cyclopharm	CYC	Lung ventilation imaging agent, Technegas	Accepted for review by FDA, with six-month review period ending 29 September 2023
CardieX	CDX	CONNQQT Pulse vascular biometric monitor	Approved by FDA
Compumedics	CMP	Okki - high-density ambulatory EEG amplifier	Approved by FDA
Nova Eye Medical	EYE	iTrack Advance - high precision hand-held delivery system of iTrack microcatheter for eye surgery	FDA clearance for US launch
Acruz Pharma	ACR	Aczone Gel for treatment of acne vulgaris	ANDA application for Aczone Gel approved by FDA
Adherium	ADR	Next generation Hailie sensors	Approved by Australian TGA
Adherium	ADR	Next generation Hailie sensors for use with Teva Pharmaceutical's HFA pressurised metered dose inhalers	Approved by FDA
Tali Digital	TD1	"ReadyAttentionGo!", a cognitive trainer for children aged 3 -10	Approved by Australian TGA
Althea Group Holdings	AGH	THC-dominant cannabis oil, Althea THC20: CBD1	Approved for sale in Ireland
Lumos Diagnostics	LDX	FebriDX rapid, point-of-care, diagnostic test	Approved by FDA
Allegra Orthopaedics	AMT	Sr-HT-Grahnite Spinal Cage Device	510(k) submitted to FDA.

<b>Approval Products - Additional Studies</b>			
Telix Pharmaceuticals	TLX	TLX250-CDx (89Zr-DFO-girentuximab) for imaging of clear cell renal cell carcinoma	New data demonstrated efficacy in imaging masses 2cm or smaller.
Micro-X	MX1	"Argus", an x-ray camera for IED detection	Micro-X has successfully conducted field testing with a pre-production version of the Argus X-ray Camera.
OncoSil Medical	OSL	OncoSil device for treatment of locally advanced pancreatic cancer in patients treated with FOLFIRINOX chemotherapy	Clinical study to expand approved use of OncoSil in the UK and the EU. First patient recruited and dosed (n=80).

Continued over

## Selected Clinical Trial Developments &amp; Product Launches - 2H FY2023

Company	Code	Product/Application	Event
<b>Phase III / Registration Studies</b>			
Telix Pharmaceuticals	TLX	TLX250-CDx ( <sup>89</sup> Zr-DFO-girentuximab) for imaging of clear cell renal cell carcinoma	Phase III Zircon study complete. Highly consistent results: 86% sensitivity, 87% specificity. All endpoints met.
EBR Systems	EBR	WiSE system (wireless cardiac pacing device for heart failure)	Positive results from pivotal SOLVE-CRT trial, with both efficacy and safety endpoints met. Final PMA submission to FDA imminent.
Mesoblast	MSB	Rexlemestrocel-L for treatment of chronic heart failure	Phase III Dream-HF trial results published. Treatment showed reduced cardiovascular death, myocardial infection, and stroke.
Universal Biosensors	UBI	Portable coagulation monitoring device, Xprecia Prime	Clinical study fully recruited (n=360) and completed. Submitted for FDA approval.
Dimerix	DXB	DMX-200 for treatment of FSGS (kidney disease)	FDA confirms inclusion of adolescent children in ACTION3 global Phase III trial is appropriate. Data Safety Monitoring Board review recommended no changes to study. Recruitment strong (n=116). Interim analysis anticipated in next six months. NMPA support for trials and potential registration in China.
Invex Therapeutics	IXC	Presendin (sustained release Exenatide) for treatment of idiopathic intracranial hypertension (IIH)	IIH EVOLVE Phase III clinical trial commenced in US, Germany, Israel, France. Lower than expected enrolment has led to IXC revising the clinical trial design to remedy current recruitment bottlenecks.
Firebrick Pharma	FRE	Nasodine Nasal Spray for the common cold	Recruitment going strong after the trial was paused over the summer period. Trial has now surpassed 80% recruitment.
Neurotech International	NTI	NTI164 for children with Autism Spectrum Disorder (ASD)	Significant, positive effects on severity of illness, with children re-classified from moderately ill at baseline to borderline/mildly ill after 52 weeks. Significant improvements also in social responsiveness and adaptive behaviour. Excellent safety results shown so far.
INOVIQ	IIQ	SubB2M/CA15-3 breast cancer test	Excellent accuracy (87%), sensitivity (81%), and specificity (93%). Outperformed a leading approved CA15-3 test. Successfully detected all-stages of breast cancer.

<b>Phase II</b>			
Clinuvel Pharmaceuticals	CUV	PRENUMBRA Instant (afemelanotide) for acute arterial ischaemic stroke treatment	First three patients of twelve in the Phase II CUV803 study have now received treatment. Drug well tolerated with preliminary reports of functional improvement in all patients
Neuren Pharmaceuticals	NEU	NNZ-2591 for treatment of Phelan-McDermid syndrome	Enrolment complete. Top-line results from the trial expected December 2023.
Neuren Pharmaceuticals	NEU	NNZ-2591 for treatment of Prader-Willi syndrome	Prader-Willi syndrome IND for NNZ-2591 approved by FDA. First site in US opened for Phase II trial. NNZ-2591 currently used in three other Phase II trials by Neuren for other neurological disorders
Paradigm Biopharma	PAR	Injectable pentosan polysulfate sodium (iPPS) for treatment of mucopolysaccharidosis type 1 (MPS I)	iPPS was well tolerated and safe. Meaningful improvements in pain, function, and an overall improvement in quality of life were observed in all patients.
Paradigm Biopharma	PAR	iPPS for knee osteoarthritis	Day 168 data shows a 21% improvement in mean cartilage loss score compared to 4% worsening in placebo group.
Anteris Technologies	AVR	DurAVR THV aortic valve replacement	12 patients have completed one-year follow up, showing sustained haemodynamic performance. All 20 study patients have reached 30-day follow up, with excellent results.
Immutep	IMM	Eftilagimod alpha (soluble LAG-3 protein) for the treatment of metastatic HER2-neg/low breast cancer and triple-negative breast cancer	First patient enrolled and dosed in integrated Phase II/III AIPAC-003 trial
Immutep	IMM	Eftilagimod alpha for treatment of non-small cell lung cancer (1L NSCLC)	Initial trial fully enrolled (n=21). Eftilagimod alpha is well tolerated and shows promising initial signals of efficacy: 67% overall response rate, 91% disease control rate. Results compare favourably to registration trials of other drugs. Study recently expanded to enrol 50 patients.

Continued over

## Selected Clinical Trial Developments &amp; Product Launches - 2H FY2023

Company	Code	Product/Application	Event
Immutep	IMM	Eftilagimod alpha for treatment of non-small cell lung cancer (1L NSCLC)	Initial trial fully enrolled (n=21). Eftilagimod alpha is well tolerated and shows promising initial signals of efficacy: 67% overall response rate, 91% disease control rate. Results compare favourably to registration trials of other drugs. Study recently expanded to enrol 50 patients.
Immutep	IMM	Eftilagimod alpha for treatment of non-small cell lung cancer (1L & 2L NSCLC) and second line head & neck squamous cell carcinoma (2L HNSCC)	Positive final data from TACTI-002 study. Median overall survival of 9.9 months and a 39% overall survival rate at 21 months, which compares favourably to 6.9 months and 10-15% respectively for standard of care.
Starpharma	SPL	DEP cabazitaxel for treatment of a variety of cancers	Enrollment and treatment of patients complete (n=76). Encouraging efficacy signals including tumour shrinkage and biomarker reduction observed. Final data pending.
Clarity Pharmaceuticals	CU6	<sup>64</sup> Cu-SAR-Bombesin for prostate cancer	Recruitment complete for BOP, investigator initiated Phase II trial
INOVIQ	IIQ	SubB2M-enhance CA15.3 breast cancer test	Positive results with 69% sensitivity and 78% specificity, which compares favourably to alternate tests.
Antisense Therapeutics	ANP	ATL1102 for treatment of Duchenne muscular dystrophy	Approval for ATL1102 Phase IIb trial awarded in Bulgaria and Turkey, with the first patient dosed. MHRA approval granted in UK, with approval still pending in Australia.
Immuron	IMC	Travelan for Travelers diarrhea	Initiated recruitment (n=60) for study determining safety and efficacy of the drug. Supplemented by two other Phase II studies with FDA IND approval and a clinical trial conducted by Uniformed Services University in the US.
Bionomics	BNO	BNC210 for PTSD	Enrollment complete for Phase IIb ATTUNE trial (n=200)
Firebrick Pharma	FRE	Nasodine Nasal Spray for COVID-19	Recruitment closed with release of results imminent. Due to low cases in South Africa, where all 5 sites are based, only 39 of the initial 210 subjects enrolled.
Alterity Therapeutics	ATH	ATH434 for treatment of Multiple System Atrophy	First patients enrolled in the US, Australia, Italy, and the UK. Trial approved granted in both France and Austria.
Biotron	BIT	BIT225 for improved immune function in HIV positive individuals	Completed clinical stage of two Phase II trials, in Thailand and Australia respectively. Detailed laboratory analysis underway with results anticipated mid-2023.
Amplia Therapeutics	ATX	AMP945 for treatment of pancreatic cancer	Completed enrolment of third cohort in first part of Phase 1b/2a ACCENT trial.
Incannex	IHL	Psilocybin-assisted psychotherapy for treatment of generalised Anxiety Disorder (GAD)	Interim review of Phase II PsiGAD clinical trial data indicates no safety concerns and projects a statistically significant benefit caused by treatment.
Neurotech International	NTI	NTI164 in children with PANDAS/PANS	Recruitment completed (n=15) with top-line results of the NTIPANS1 trial available next quarter.
Bod Australia	BOP	CBD formulation for insomnia	Recruitment completed (n=198). Trial results anticipated August 2023.

Phase I			
Telix Pharmaceuticals	TLX	131I-TLX-101 for Treatment of Newly Diagnosed Glioblastoma	IPAX-2 Study to confirm the safety profile of TLX101 is expected to imminently commence dosing patients at Australian sites (n=12)
Imugene	IMU	CF33-hNIS (VAXINIA), novel oncolytic virus for treatment of solid tumours	Phase 1 MAST trial commenced and treating final cohort for intravenous arm of study
Imugene	IMU	onCARlytics (on-CAR-19, CF33-CD19, HOV4) for treatment of solid tumours	IMU recently received FDA IND clearance to initiate a Phase 1 clinical study
Imugene	IMU	PD1-Vaxx for treatment of non-small cell lung cancer	First patient dosed in the combination cohort of the IMPRINTER study
Clarity Pharmaceuticals	CU6	<sup>64</sup> Cu-SAR-bisPSMA for use in prostate cancer imaging	Safe and well tolerated by all patients (n=30) in PROPELLER trial. Uptake of imaging agent higher compared to approved SOC.
Microba LifeSciences	MAP	MAP 315 for treatment of Ulcerative Colitis (Inflammatory Bowel Disease)	First patient dosed (n=32), marking Microba's maturation into a clinical-stage drug development company.
Prescient Therapeutics	PTX	PTX-100 for treatment of T cell lymphomas	Promising results, including an excellent safety profile and 7/10 patients showing favourable response compared to SOC. Progressing to Phase 1b cohort. Awarded orphan drug designation.

Continued over



## Selected Clinical Trial Developments &amp; Product Launches - 2H FY2023

Company	Code	Product/Application	Event
EMVision Medical Devices	EMV	Emvision Brain Scanner, which obtains images of the brain using microwaves for stroke detection	Successful completion of stage 1 (n=30). Stage 2 starting enrolment for up to 150 acute stroke and stroke mimic patients.
Pharmaxis	PXS	PXS-6302 for treatment of problematic scarring	Well tolerated with good safety profile, as well as a marked change in scar composition with 30% reduction in collagen content, but no overall improvement in scar appearance after 3 months.
Cynata Therapeutics	CYP	CYP-001 in steroid-resistant acute graft-versus-host-disease (SR-aGvHD)	Two-year patient follow up data from Phase I trial shows a two year survival rate of 60% (n=15), which is favourable to current approved drugs for SR-aGvHD
Chimeric Therapeutics	CHM	CORE-NK platform for treatment of both blood cancers and solid tumours	Dosing initiated in Phase 1b CHM0201 trial, building upon 24-month complete response seen in Phase 1a trial. Trial is intended to determine safety of CORE NK + Vactosertib.
Chimeric Therapeutics	CHM	CLTX CAR T cells for treatment of glioblastoma (brain cancer)	Third cohort in CHM1101 dose-escalation study showed no dose-limiting toxicities. Dosing of fourth cohort initiated.
PharmAust	PAA	MPL for treatment of Motor Neuron Disease	Interim analysis confirmed that the drug was well tolerated, with no SAEs. All patients elected to continue treatment with MPL. Good pharmacokinetic outcomes. Trial will proceed to next cohort in Phase I. Preliminary data suggests suppression of inflammation may be responsible for MND/ALS progression.
Argenica Therapeutics	AGN	Neuroprotective peptide ARG-007 to reduce brain damage in stroke patients	All doses of ARG-007 were safe and well tolerated. Drug showed rapid uptake, a critical requirement for neuroprotective drugs, and an extended half-life, suggesting prolonged efficacy.
Incannex	IHL	Anti-inflammatory drug IHL-675A	Well tolerated. Similar in tolerability to reference listed drug, Epidiolex, but with faster uptake and reaching higher maximum concentration.
PYC Therapeutics	PYC	VP-001 for treatment of Retinitis Pigmentosa Type 11	First patient dosed in "Platypus" Phase I Single Ascending Dose study
Zelira Therapeutics	ZLD	ZLT-L-007 for treatment of diabetic nerve pain	Safe and well tolerated. Topline results outperformed multi-billion-dollar annual revenue drug Lyrica. Company will move forward with formal FDA clinical trials.
InhaleRx	IRX	IRX211 for management of Complex Regional Pain Syndrome (CRPS)	First cohort in dose-escalation study completed.

Primary Endpoint Not Met or Study Halted			
Medical Developments	MVP	Penthrox inhaler for temporary pain relief	Clinical trials in China discontinued due to challenging regulatory environment and COVID restrictions
Bionomics	BNO	BNC210 for Social Anxiety Disorder	Updated analysis of PREVAIL Phase II study which did not initially meet primary endpoints shows BNC210 resulted in reductions in anxiety that were statistically significant. Meeting with FDA to discuss clinical path forward.
Cann Group	CAN	Satipharm CBD capsules for treating sleep disturbances	Preliminary view from Phase III clinical trial showed results were not statistically superior to a placebo. Haleon Australia terminated the Option and Evaluation Agreement covering the trial.
Starpharma	SPL	AZD0466 Monotherapy or in Combination in Patients with Advanced Haematological Malignancies	Study is sponsored by AstraZeneca. A voluntary partial clinical hold implemented on trial. Reasons for study halt allegedly not resulting from SPL's DEP Dendrimer.
Nyrada	NYR	PCSK9 Inhibitor for lowering high cholesterol	Adverse signal observed in final toxicology study, precluding Nyrada's drug candidate from clinical evaluation. Phase I/IIa Trial deferred.

**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**

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