

Biotech Daily

Tuesday August 1, 2023

Daily news on ASX-listed biotechnology companies

- * JULY BDI-40 UP 3.5%, ASX200 UP 3%, BIG CAPS DOWN 1.45%, NBI UP 1%, CC UP 1%
- * TODAY: ASX UP, BIOTECH FLAT: KAZIA UP 19%; STARPHARMA DOWN 11%
- * CURVEBEAM AI \$25m IPO
- * HYDRIX RECEIPTS UP 44% TO \$14m
- * CARDIEX RECEIPTS UP 29% TO \$5.5m
- * CONTROL BIONICS RIGHTS RAISE \$1.1m OF HOPED-FOR \$2.9m
- * IMRICOR WINS NETHERLANDS VISION-MR TRIAL APPROVAL
- * FIVEPHUSION, ALLARITY DEFLEXIFOL COLON CANCER TRIAL
- * IMMUTEP: EMA RULES EFTI TOXICOLOGY STUDIES 'NOT NEEDED'
- * NEUROTECH ENROLS 1st MARIJUANA NTI164 RETT PATIENT
- * ARGENICA ARG-007 'REDUCES ALPHA-SYNUCLEIN UPTAKE, AGGREGATION'
- * PHARMAUST EPICHEM LIQUIDATION
- * MONASH UNI IMMUNE RESPONSE FOR INTESTINAL WORM INFECTIONS
- * IDT EGM 30% OPPOSE PLACEMENT SHARES, 17% DIRECTOR OPTIONS
- * OSTEOPORE LATE NOTICE FOR 'ROBODEBT' DIRECTOR MICHAEL KEENAN
- * AUSCANN EXPANDS EU CANNABIS CORP MARIJUANA COLLABORATION
- * MICROEQUITIES TAKES 7% OF MACH7
- * KAZIA CEO DR JOHN FRIEND APPOINTED MANAGING DIRECTOR
- * BIO-MELBOURNE 'PROTOTYPES FOR MANUFACTURING' SEMINAR

MARKET REPORT

The Australian stock market was up 0.54 percent on Tuesday August 1, 2023, with the ASX200 up 40.3 points to 7,450.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and two were untraded.

Kazia was the best, up 2.5 cents or 19.2 percent to 15.5 cents, with 41,186 shares traded. Next Science climbed 9.5 percent; Nova Eye, Opthea and Universal Biosensors improved more than four percent; Resonance rose 3.9 percent; Antisense and Emvision were up more than two percent; Cyclopharm, Immutep, Nanosonics, Paradigm, Pharmaxis and Telix were up more than one percent; with CSL, Neuren, Pro Medicus and Resmed up by less than one percent.

Starpharma led the falls for the second day in a row, down 2.5 cents or 11.4 percent to 19.5 cents, with 6.2 million shares traded. Atomo and Cynata lost more than six percent; Medical Developments and SDI were down five percent or more; Avita, Mesoblast and Micro-X fell more than four percent; Volpara was down 3.4 percent; Compumedics, Polynovo and Prescient shed more than two percent; 4D Medical lost 1.45 percent; with Clinuvel, Cochlear and Genetic Signatures down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Twenty-six of the Biotech Daily Top 40 Index (BDI-40) climbed in July, with 16 up by more than 10 percent; while 12 fell, with just four down by more than 10 percent.

The BDI-40 was the best of the indices, up 3.5 percent in July and up 25.1 percent for the 12 months to July 31, to a cumulative market capitalization of \$21,691 million, compared to the benchmark ASX 200 up 6.7 percent to 7,410 for the year and 2.9 percent for the month (see charts below).

The collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell again in July, down 1.45 percent to \$194,704 million – and down 4.85 percent for the year to July 31, 2023 - with the Magic Pudding of CSL distinctly off-the-boil.

CSL fell 3.5 percent in July to \$129,526 million, while Cochlear improved 4.1 percent to \$15,704 million and Resmed was up 2.5 percent to \$49,474 million.

The Nasdaq Biotechnology Index (NBI) was up 1.3 percent to 4,130 points for the month and up 5.8 percent for the year.

Medical Developments was the July BDI-40 best - having lost more than 50 percent of its value in the past 12 months - up 41.8 percent to \$95 million

Atomo improved by \$5 million or 38.5 percent to \$18 million, followed by Alcidion (32.5%), Cynata (31.8%), Resonance (26.3%), Avita (18.5%), Emvision (17.6%), Volpara (17.3%), Dimerix (16.7%), Genetic Signatures (16.0%), Cyclopharm (14.9%), Amplia (13.3%), Antisense (12.8%), Imugene (12.2%), Orthocell (11.6%) and Pharmaxis (11.4%).

Starpharma led the July falls, down \$37 million or 29.1 percent to \$90 million, followed by Kazia (13.9%), Universal Biosensors (10.9%) and Prescient (10.8%).

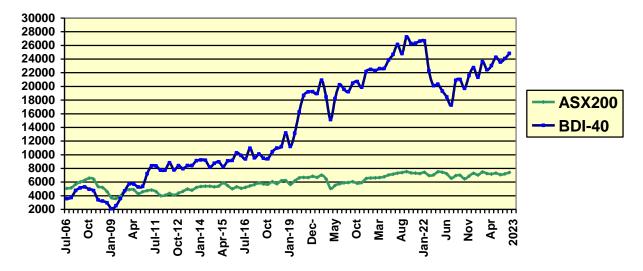
Actinogen Compumedics, Immutep, Next Science, Nova Eye, Paradigm, Proteomics and Telix slipped by less than 10 percent.

Outside the BDI-40 Botanix and Mach7 Technologies continued their consistent improvements.

On the Nasdaq, Eyepoint (formerly Psivida) was up 42.4 percent to \$638 million, while the Brisbane-based Protagonist fell 30.3 percent to \$1,654 million.

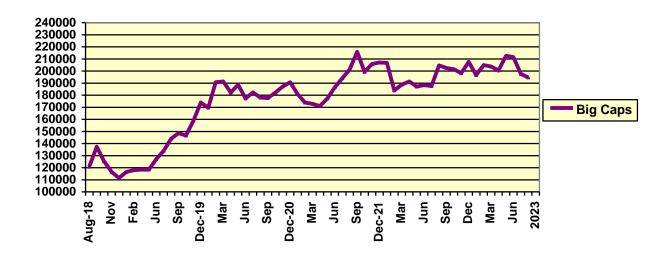
The 11 companies that comprise Cannabis Corner were up a collective 1.3 percent in July to \$805 million, but down 3.1 percent for the year to July 31. Five companies improved, two fell and four were unchanged.

From low bases, Avecho was up 66.7 percent to \$15 million and Melodiol (Creso Pharma) recovered 57.9 percent to \$30 million, followed by Botanix up 12.3 percent to \$192 million. Emyria lost 17.9 percent to \$32 million.

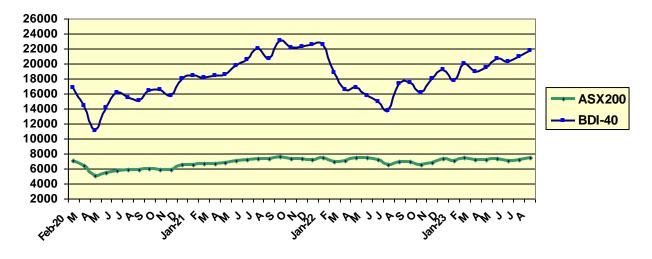


BDI-40 v ASX200 Jun 30, 2006 to Jul 31, 2023- Adjusted

Big Caps \$m (Cochlear, CSL, Resmed) Jun 30, 2018 – Jul 31, 2023



BDI-40 (\$m) v S&P ASX 200 - Jan 31, 2020 - Jul 31, 2023 (pre-Covid to date)



CURVEBEAM AI (ARTIFICIAL INTELLIGENCE)

Curvebeam AI expects to raise \$25 million at 48 cents a share in an initial public offer to list on the ASX under the code CVB and commercialize its imaging systems.

The Melbourne-based Curvebeam AI (artificial intelligence) said that the offer was fully underwritten by Bell Potter Securities, it hoped to list on August 23, 2023, and when completed it would have an indicative market capitalization of \$153.7 million.

The company said that it "develops and manufactures natural bilateral weight bearing [computed tomography] devices, providing point of care medical imaging" intended to develop software as a service.

Curvebeam said it had a co-marketing and distribution partnership with Stryker Corp and its Hirise computed tomography (CT) imaging equipment was US Food and Drug Administration cleared, Australian Therapeutic Goods Administration approved and had Conformité Européenne (CE) mark.

The company said its bone density module for was targeted for submission by July 2024. Curvebeam said that it had 37 granted patents and 27 patents pending.

The company said its forecast revenue for the year to June 30, 2023 was \$11 million, primarily from the Hirise device.

Curvebeam managing-director Greg Brown told Biotech Daily that manufacturing was based in Hatfield Pennsylvania, with the corporate office in Melbourne.

Mr Brown said that most of the artificial intelligence for the imaging systems had been developed at the University of Melbourne.

The company said its scanners would "support medical practitioners in the clinical assessment and management of musculo-skeletal health conditions" and combined with artificial intelligence would automate the analysis of images "assessing, for example, a patient's bone mineral density to assist in the clinical assessment of fracture risk". Curvebeam said the flagship product was the Hirise CT scanner, which has the ability to perform weight bearing CT scans, with the patient standing in a normal, weight bearing pose, as well as more traditional non-weight bearing CT scans.

The company said that the weight bearing CT scans had advantages "including being quicker and easier" than traditional computed tomography or magnetic resonance imaging (MRI) devices, lower dose radiation than traditional CT, and a more accurate doctor diagnosis due to the unique alignment data that can be derived from the scan being performed under a standing load.

Curvebeam said it was developing the Inreach device for high resolution wrist scanning for bone micro-structural assessment, targeted for commercialization by July 2026.

The company said that 170 devices had been placed worldwide to date, including at US medical institutions such as Mayo Clinic and at the University of Califonia Los Angeles. Curvebeam said the funds raised in the initial public offer would be used to invest in expanded sales and marketing, continued research and development, new product development and further clinical trials.

The company said it had more than 70 employees at its corporate headquarters in Melbourne and operational headquarters in Hatfield, Pennsylvania.

"We believe this company holds the potential of advancing care in orthopaedics and bone health around the world, and as we reach this critical juncture of an [initial public offer], the vision is shared by a range of institutional investors who continue to back the business," Mr Brown said.

The company said that Bell Potter Securities and Lodge Corporate were the joint lead managers to the offer and its institutional investor base included Karst Peak, Tenmile, Firetrail, Acorn Capital, SG Hiscock, Ilwella and Frazis Capital.

The prospectus is at: https://cvboffer.computersharecas.com.au/offer/home/.

<u>HYDRIX</u>

Hydrix says receipts from customers for the year to June 30, 2023 were up 44.2 percent to \$14,090,000 compared to the previous corresponding period.

Hydrix said that receipts from customers for its product development services and heart monitoring devices for the three months to June 30, 2023 rose 4.0 percent to \$3,248,000. The company said it had a cash burn of \$1,222,000 for the year to June 30, 2023, with cash and cash equivalents of \$1,153,000 at June 30, 2023, compared to \$1,940,000 at June 30, 2022 and had 1.17 quarters of funding available.

Hydrix said it expected a "positive trend in improved business performance of Hydrix Services" and the "commencement of revenues from Hydrix Medical product sales" would lower cash used in operations.

The company said it had raised \$3.1 million through a recent capital raising and had \$3.034 million "pro forma cash available".

Hydrix was up 0.2 cents or 7.1 percent to three cents.

CARDIEX

Cardiex says receipts from customers for the year to June 30, 2023 were up 28.9 percent to \$5,534,000 compared to the previous corresponding period.

Cardiex said that receipts from customers for its Sphygmocor, Xcel, GTH Pro and Oscar 2 central blood pressure devices for the three months to June 30, 2023 were up 6.8 percent to \$1,625,000.

The company said it had a cash burn of \$2,004,000 for the three months to June 30, with cash and cash equivalents of \$716,000 compared to \$1,456,000 the previous year, and had 0.42 quarters of funding available.

Cardiex said it had a convertible note facility and had received subscriptions of \$2.3 million, of which \$2.175 million was received in cash, with a further \$750,000 received to date, and was in the process of filing for a US dual listing.

The directors of the company said that they believed, if required, they had the ability to raise additional capital on a timely basis.

Cardiex fell one cent or 5.6 percent to 17 cents.

CONTROL BIONICS

Control Bionics says its non-renounceable rights issue has raised a total of \$1,133,341 of a hoped-for \$2,865,000.

In May, Control Bionics said it hoped to raise \$2,865,000 in a one-for-three, nonrenounceable rights offer at 9.5 cents a share, a 9.5 percent discount to the last closing price, with funds going towards commercializing its products, regulatory approval and acquisition of distributors (BD: May 17, 2023).

Today, Control Bionomics chief executive officer Jeremy Steele said that "the addition of this capital provides us with headroom as we expand our existing operations in the US, Australia and Japan".

"Whilst the amount raised is lower than we initially sought, this capital will support the business into 2024 and we will assess the need for additional capital at a later time," Mr Steele said.

Control Bionics did not mention the shortfall.

Control Bionics was unchanged at 7.9 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says it has Netherlands ethics approval for a 64-patient, safety and efficacy trial of its Vision-magnetic resonance imaging ablation catheter for ventricular tachycardia. Imricor said the Netherlands' Medical Ethics Review Committee, Leiden The Hague Delft had approved its prospective, single-arm, multi-centre trial, which was intended to support Conformité Européenne (CE) mark certification for the heart scan.

The company said the first patient had been "identified" and the first procedure was expected to take place in mid-August.

Imricor chief executive officer Steve Wedan said that "since founding the company 17 years ago, the goal has always been to develop technology that enables complex cardiac arrhythmias like ventricular tachycardia, or VT, to be treated utilizing real-time [three-dimension magnetic resonance imaging] which we call interventional cardiac magnetic resonance for guidance."

"We believe real-time [three-dimension magnetic resonance imaging] imaging can add tremendous value to [ventricular tachycardia] ablations in terms of effectiveness, time savings, and cost... all in an environment that is free of ionizing radiation," Mr Wedan said. Imricor was up 10 cents or 20.8 percent to 58 cents.

FIVEPHUSION PTY LTD

Fivephusion says it would trial Allarity Therapeutics's drug response predictor diagnostic in a 50-patient, phase lb/lla trial of Deflexifol for colon cancer.

In June, Fivephusion executive director Dr Bill Ketelbey told Biotech Daily that Deflexifol was a combination of the chemotherapy drugs 5- fluorouracil and its bi-modulator leucovorin, a drug that potentiates 5-fluorouracil antitumor activity, for the treatment of solid tumors (BD: Jun 14, 2023).

Fivephusion said that Boston's Allarity would support the planned phase lb/lla trial of Deflexifol in combination with oxaliplatin and bevacizumab in first-line treatment of unresectable metastatic colorectal cancer, at trial sites in Australia.

The company said Allarity would receive biopsies from the trial and analyze them usings its diagnostic to identify a patient's response to treatment.

The company said that following the conclusion of the trial, it would determine whether to use Allarity's diagnostic in an international, phase III trial.

Fivephusion is a private company.

IMMUTEP

Immutep says the European Medicines Agency advises further toxicology studies for eftilagimod alpha (efti) are not necessary for a marketing authorization application. Immutep said that in May it had requested scientific advice from the European Medicines Agency, in particular whether further toxicity studies would be required before seeking marketing authorization for efti in Europe.

The company said the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) had come to the conclusion based on available clinical data and an acknowledgment that additional studies in animal models were "unlikely to provide relevant information".

Immutep was up half a cent or 1.6 percent to 31 cents with 1.1 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it has enrolled the first of 14 patients in its phase I/II trial of its marijuanabased NTI164 for Rett syndrome patients.

In July, Neurotech said it had ethics approval for the trial of its NTI164 marijuana treatment for Rett syndrome in females (BD: Jul 10, 2023).

Neurotech was unchanged at 5.6 cents.

ARGENICA THERAPEUTICS

Argenica says ARG-007 reduces the uptake of the alpha-synuclein protein, a Parkinson's indicator, by 84 percent and aggregation by 90 percent, in-vitro.

Argenica said intracellular uptake and accumulation of insoluble protein deposits, like alpha-synuclein, was a "common element of major age-related neurodegenerative disorders" including Parkinson's disease and Alzheimer's disease.

The company said data published in the journal Biomedicines showed ARG-007 to "significantly" reduced the uptake of alpha-synuclein protein aggregates in enteroendocrine cells, the main site of alpha-synuclein misfolding and aggregation.

Argenica said it had also shown ARG-007 to inhibit alpha-synuclein in a cell free assay, at doses of five, 10 and 20 micrograms.

The company said it would begin pre-clinical studies of the efficacy of ARG-007 for Alzheimer's disease in mice, with data expected "early" in 2024.

Argenica chief executive officer Dr Liz Dallimore said "the scientific community now understands that neurodegenerative diseases are extremely complex, however the aggregation and accumulation of several proteins in the brain appear to be an important contributor."

"The ability of a therapy such as ARG-007 to work on a number of these protein aggregates is very important from a scientific perspective, and we look forward to progressing preclinical studies in this area further," Dr Dallimore said. Argenica was up 3.5 cents or 9.6 percent to 40 cents.

PHARMAUST

Pharmaust says Grant Thornton has been appointed as the liquidator for the voluntary winding-up of its wholly owned subsidiary Epichem.

Last year, Pharmaust said Epichem would receive up to \$32,000 for medicinal chemistry services to Geneva's Drugs for Neglected Diseases Initiative (DNDI), but the partnership would cease in March 2023 due to the development of monepantel "reaching a new phase and changes in the DNDI program funding" (BD: Nov 3, 2022).

Last year, the company said its \$3.4 million for the year to June 30, 2022 was primarily from Epichem's synthetic and medicinal chemistry contracts (BD: Aug 26, 2022).

Today, Pharmaust said that following the end of its contract with DNDI, Epichem had been operating at a loss, with its shortfall funded by Pharmaust.

The company said that despite Epichem's best endeavors, contracts to replace the DNDI contract could not be secured, and it engaged external advisors to conduct a review of Epichem and following the report it determined it would not provide further funding.

Pharmaust said the voluntary liquidation of Epichem was not expected to impact the rest of its operations and it would enable the company to focus all its resources on the clinical development of monepantel in human diseases and the canine anti-cancer and licencing activities.

Pharmaust fell half a cent or 6.2 percent to 7.6 cents.

MONASH UNIVERSITY

Monash University says its research could lead to vaccines and improved treatments for intestinal worm infections.

Monash University said that about 25 percent of the world's population were infected with helminths, or parasitic worms, which usually lived in the gut.

The University said some people could fight the parasites with immune responses and some who failed to develop effective immune responses had chronic infection.

The Monash Biomedicine Discovery Institute study used animal models to discover a protective immune feature that might be lacking in people who were chronically infected, namely a group of immune cells called T-follicular helper (TFH) cells which behaved differently at cellular and molecular levels during acute, resolving and chronic infection. Monash University said that in some models the cells protected against chronic illness but in others they didn't.

The research article, titled 'Heterogeneous Tfh cell populations that develop during enteric helminth infection predict the quality of type 2 protective response' was published in Mucosal Immunology with an abstract at: <u>https://pubmed.ncbi.nlm.nih.gov/37392971/</u>. First author Dr Aidil Zaini said that blocking the TFH response impaired worm clearance and promoted chronic infection, so the key was to develop ways to facilitate the protective mechanism.

IDT AUSTRALIA

IDT says its extraordinary general meeting passed all resolutions but with 30.06 percent opposition to its placement and about 17 percent opposition to the issue of options. IDT said 35,501,328 votes (69.94%) supported the issue of the tranche two placement shares, with 15,256,498 votes (30.06%) opposed, but the largest number of opposition votes were against the issue of 3,000,000 options to director Geoffrey Sam, with 89,341,645 votes (83.48%) in favor and 17,678,353 votes (16.52%) against. The company said the issue of 6,000,000 options to director Mark Simari and 3,000,000 options to director Jane Ryan, and 20,000,000 options for lead manager Taylor Collison faced similar opposition.

According to IDT's most recent filing, the company had 335,352,751 shares on issue, meaning the vote against Mr Sam's options amounted to 5.3 percent of the company, sufficient to requisition extraordinary general meetings.

IDT was unchanged at 6.8 cents.

OSTEOPORE

Osteopore has filed a late Appendix 3X 'Initial Director's Interest Notice' for director Michael Keenan who was appointed on July 18, 2023.

Osteopore said that the notice "was prepared at the time of Mr Keenan's appointment but was not lodged due to an administrative oversight".

According to ASX Guidance Note 22, the notice should have been filed within five business days.

The company said that having identified the administrative oversight the notice was "immediately lodged".

In July, Osteopore said it appointed the former Minister for Human Services, responsible for the illegal Robodebt program, Mr Keenan, as a director saying he had "experience and knowledge in public policy and corporate governance" (BD: Jul 18, 2023). Osteopore was unchanged at 7.7 cents.

AUSCANN GROUP HOLDINGS

Auscann says it has expanded its agreement with European Cannabis Corporation (ECC) to sell and distribute medical marijuana in Australia and New Zealand.

Auscann said ECC would provide a diverse cannabinoid product portfolio of raw flower and standardized full spectrum extracts, but the expansion had not resulted in any additional consideration.

The company said the ECC would also provide it with all necessary regulatory support for the products supplied, including documentation required to satisfy compliance with the Therapeutic Goods Administration's standard for medical cannabis.

Auscann non-executive director Robert Clifford said "having explored mutual opportunities with ECC since the binding term sheet announced in April 2022" the company was pleased to announce this agreement which expanded the relationship.

"We absolutely see this as a mutually beneficial move for each company, allowing opportunity for Auscann to market and sell ECC's ... products to patients and customers ... across Australia and New Zealand," Mr Clifford said.

Auscann was in a suspension at four cents.

MACH7 TECHNOLOGIES

Microequities Asset Management says it has increased its shareholding in Mach7 from 13,979,116 shares (5.83%) to 16,684,772 shares (6.95%).

The Sydney-based Microequities said that between April 14 and July 31, 2023 it bought 2,705,656 shares for \$2,160,176 or 79.8 cents a share.

Mach7 was up three cents or 3.6 percent to 85.5 cents.

KAZIA THERAPEUTICS

Kazia says it has appointed chief executive officer Dr John Friend as its managingdirector, effective immediately.

In May, Kazia said that its New Jersey-based chief medical officer Dr Friend has replaced chief executive officer Dr James Garner (BD: May 1, 2023).

Kazia was up 2.5 cents or 19.2 percent to 15.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will host the third seminar in its series, titled 'Scaling Medtech: Empowering Prototypes for Manufacturing Readiness'.

In March, the Bio-Melbourne Network said that it would host four seminars supporting the Victorian medical technology manufacturing sector, in collaboration with the Australian Medtech Manufacturing Centre (BD: Mar 14, 2023).

Today, the Network said the seminar would be "a primer on [medical technologies] prototyping and product development, from design to working models and large-scale manufacturing".

The Bio-Melbourne Network said the seminar would include speakers from Nutromics, Outerspace Design, Integra Systems and Jumar Bioincubator, who would discuss options for prototyping, local business models and how new infrastructure and services could help organizations achieve manufacturing readiness.

The Network said the event would be at the Jumar Bioincubator in Elizabeth Street, Melbourne, and online, on August 24, 2023 from 4pm to 6:45pm (AEST). For registration, go to: www.bit.ly/3qgQlew.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JULY 31, 2023

Company \$Am	Aug-22	Jul-23	Aug-23
Cochlear	14,177	15,084	15,704
CSL	140,369	134,243	129,526
Resmed	50,072	48,251	49,474
BDI-20			
Avita	210	660	782
Clinuvel	874	888	907
Compumedics	34	32	30
Cyclopharm	132	188	216
Cynata	57	22	29
Genetic Signatures	155	75	87
Immutep	295	374	362
Kazia	71	36	31
Medical Developments	180	67	95
Mesoblast	624	928	932
Nanosonics	1,404	1,430	1,430
Neuren	710	1,580	1,649
Nova Eye	29	50	46
Opthea	453	257	266
Pharmaxis	40	35	39
Polynovo	999	1,070	1,118
Pro Medicus	5,141	6,943	7,184
Starpharma	265	127	90
Telix	2,281	3,644	3,599
Volpara	173	191	224
Second 20			
4D Medical	209	231	238
Actinogen	108	73	67
Alcidion	197	120	159
Amplia	18	15	17
Antisense	54	39	44
Atomo	44	13	18
Dimerix	50	24	28
Emvision	125	91	107
Impedimed	132	363	394
Imugene	1,408	572	642
Micro-X	62	62	62
Next Science	232	125	113
Orthocell	92	69	77
Paradigm	258	277	252
Patrys	49	21	22
Prescient	121	65	58
Proteomics	93	104	99
Resonance	32	19	24
SDI	101	98	105
Universal Biosensors	67	55	49
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* Biotech Daily editor, David Langsam, owns shares in 4D Medical, Acrux, Actinogen, Alcidion, Alterity, Amplia, BTC Health, Clarity, Cochlear, Control Bionics, Cynata, Nanosonics, Neuren, Patrys, Pharmaxis, Polynovo, Telix, Volpara and non-biotech stocks. Through Australian Ethical Superannuation he has an indirect interest in other companies: https://www.australianethical.com.au/personal/ethical-investing/companies-we-invest-in/. These holdings are liable to change.

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