



# Biotech Daily

Thursday July 1, 2021

*Daily news on ASX-listed biotechnology companies*

- \* 15-YEAR BDI-40 UP 633% TO RECORD \$26b; BIG CAPS UP 1031%, ASX200 UP 44%
- \* TODAY: ASX DOWN, BIOTECH UP: ONCOSIL UP 19%; PRESCIENT DOWN 6%
- \* BTC PAYS \$2m TO DISTRIBUTE PHARMAXIS BRONCHITOL, ARIDOL; HALT
- \* MESOBLAST TO MEET FDA FOR REXLEMESTROCEL-L FOR BACK PAIN
- \* MICRO-X LAUNCHES VETERINARY ROVER MOBILE DR
- \* AUSCANN MARIJUANA FOR TASMANIA DEPARTMENT OF HEALTH
- \* ARGENICA 'ARG-007 SAFE, WELL TOLERATED, IN RATS'
- \* NEUROSCIENTIFIC: EMTINB SAFE IN MONKEYS
- \* FDA APPROVES NOXOPHARM DARRT-2 CANCER TRIAL IND
- \* TRUSCREEN: SERBIA ORDERS CERVICAL CANCER SCREENING DEVICE
- \* MEMPHASYS COMPLETES VERIFICATION, VALIDATION TO GO
- \* RESONANCE INCREASES ACUITY FACILITY TO \$7.75m
- \* BELLWETHER SUPER BELOW 5% OF BLUECHIIP
- \* REGAL FUNDS BELOW 5% OF HYDRIX
- \* JOANNE MOSS TO REPLACE LBT CHAIR KATE COSTELLO
- \* OSPREY APPOINTS STEVEN BRANDT DIRECTOR
- \* HANG LING LEUNG REPLACES REGENEUS CO SEC SANDRA MCINTOSH
- \* MILES DAVIS REPLACES BIONOMICS DR RAO; DR ERROL DE SOUZA ON \$702k

## MARKET REPORT

The Australian stock market fell 0.65 percent on Thursday July 1, 2021, with the ASX200 down 47.4 points to 7,265.6 points. Twenty-three of the Biotech Daily Top 40 stocks were up, 15 fell, one traded unchanged and one was untraded.

Oncosil was the best, up one cent or 18.9 percent to 6.3 cents, with 4.2 million shares traded. Resonance rose 16.1 percent; Alterity, Antisense, Osprey and Universal Biosensors climbed more than seven percent; Next Science and Uscom were up more than six percent; LBT was up 5.3 percent; Amplia, Impedimed and Orthocell improved more than four percent; Avita, Cynata, Dimerix, Medical Developments, Starpharma and Volpara rose more than two percent; Nova was up 1.6 percent; with Genetic Signatures, Kazia, Mesoblast, Neuren and Resmed up by less than one percent.

Prescient led the falls, down 1.5 cents or 6.1 percent to 23 cents, with 12.3 million shares traded. Optiscan fell 4.35 percent; Actinogen, Opthea, Pharmaxis, Pro Medicus and Telix lost three percent or more; Cochlear, Cyclopharm and Immutep shed more than two percent; Clinuvel, Imugene, Nanosonics, Patrys and Polynovo were down more than one percent; with CSL and Paradigm down by less than one percent.

## BIOTECH DAILY TOP 40 INDEX (BDI-40)

Both the Biotech Daily Top-40 Index (BDI-40) and the 'collective' Big Caps of Cochlear, CSL and Resmed closed the financial year at record highs.

We stress the 'collective' for the Big Caps (which are not included in the BDI-40) because it was the June 20.9 percent Resmed rise and Cochlear's 10.8 percent increase that compensated for CSL's 1.7 percent retreat.

For the year to June 30, 2021, the three Big Caps were up 6.4 percent, compared to the BDI-40 up 42.4 percent, the ASX200 up 24.0 percent and the Nasdaq Biotechnology Index up 19.8 percent.

Cannabis Corner looked good, climbing 55.8 percent for the year, but that was compared to June 30, 2020 when the sector was recovering from the realization that - despite the claims - marijuana wouldn't cure coronavirus. The 22 companies fell a collective 6.2 percent in June.

But for the 15 years since inception, the BDI-40 was up 517.5 percent, from a collective market capitalization of \$3,563 million to \$22,002 million. In adjusted terms it is up 633.3 percent to \$26,127 million, compared to the ASX up 44.1 percent for the 15 years.

The collective market capitalization for the three Big Caps on June 30, 2006 was \$17,156 million. They have climbed 1,030.98 percent in 15 years.

The year to June 30, 2021 saw huge gains and generally modest falls with 26 of the BDI-40 stocks up and 14 down. Five companies were up more than 500 percent.

Because we accept that "the market is never wrong" Biotech Daily is using the published market capitalization of the gravity-defying Imugene, but even discounting its doubling in May to near \$2 billion, the BDI-40 is still at a record level and through \$21 billion.

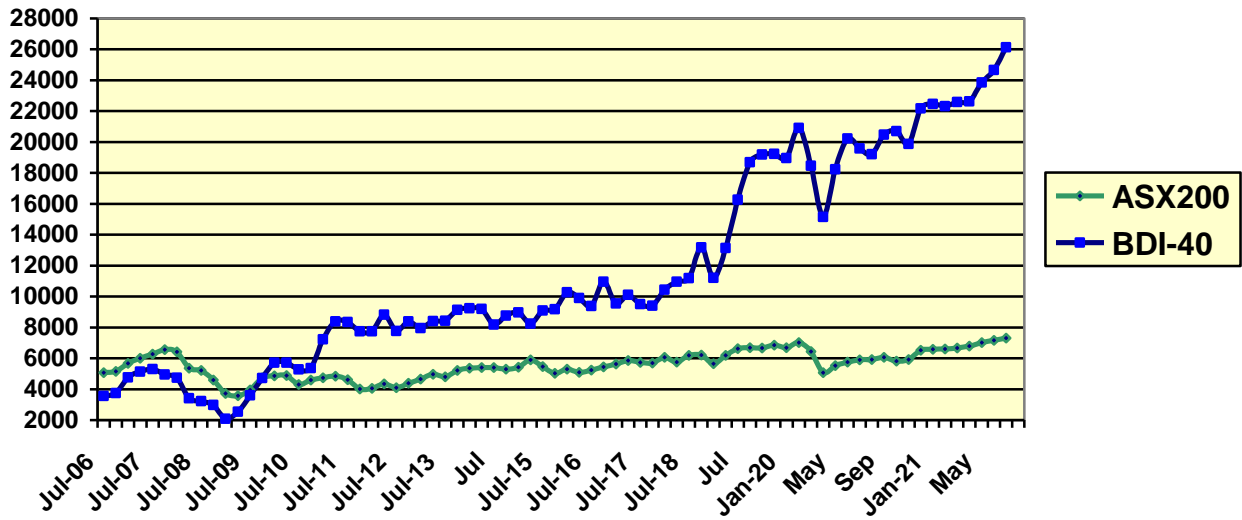
Imugene eased 10.5 percent in June to \$1,762 million, but was easily the best for the 12 months to June 30, up 1,214.9 percent, followed by Actinogen (764%), Optiscan (689%), Patrys (685%), Prescient (614%), Immutep (441%), Telix (427%), Universal Biosensors (326%), Kazia (287%), Amplia (263%), Alterity (222%), Antisense (211%), Impedimed (153%), Proteomics (149%) and despite adding \$3,369 million to the index, Pro Medicus was 15<sup>th</sup>, up 122.5 percent for the year.

LBT led the falls, down 59.3 percent to \$22 million, followed by Oncosil (55.2%), Nova Eye (53.1%), Genetic Signatures (48.9%), Dimerix (43.5%), Paradigm (32.8%), Avita (32.7%), Mesoblast (32.2%), Medical Developments (29.9%) and Opthea (26.1%).

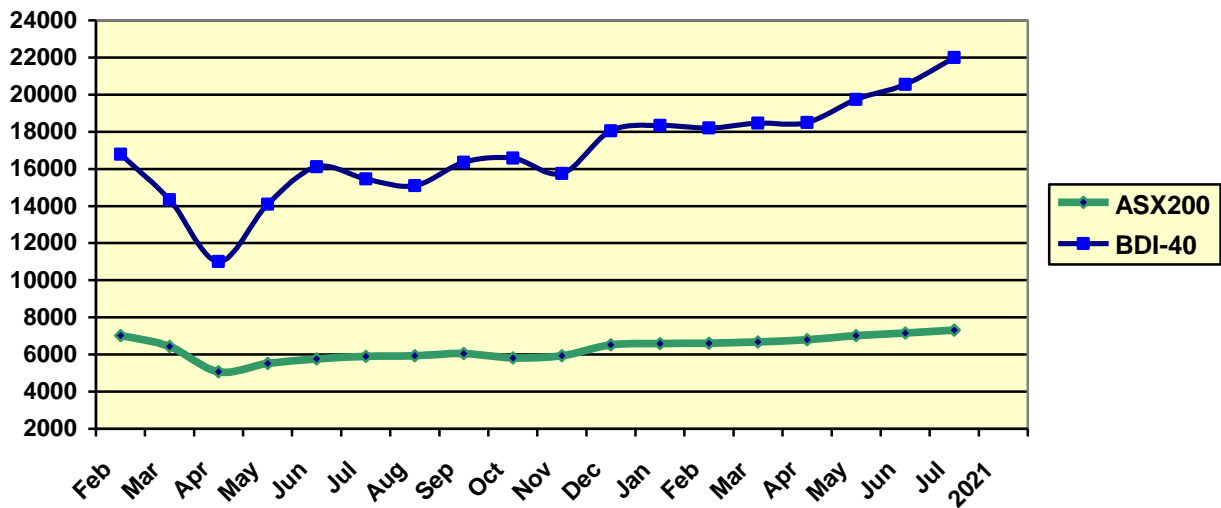
Outside the BDI-40, Alcidion, Anteo, Cogstate, Emvision, Imagion, Incannex, Micro-X, Noxopharm, Race and Rhythm all had a very strong 12 months.

On the Nasdaq, Queensland's Protagonist climbed 211.3 percent to \$2,839 million over the 12 months, while Eyepoint (Psivida) was up 151.8 percent to \$345 million, and Israel's Redhill with Australian assets was up 25.4 percent to \$429 million.

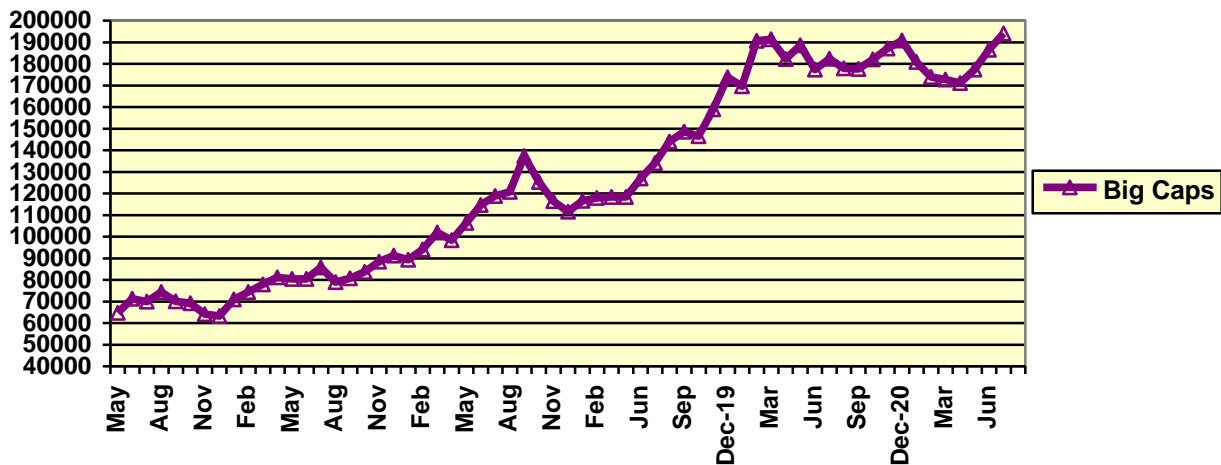
**BDI-40 v ASX200 Jun 30, 2006 to Jun 30, 2021- Adjusted**



**BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Jun 30, 2021 (current, raw data)**



**Big Caps \$m (Cochlear, CSL, Resmed) Jun 30, 2016 – Jun 30, 2021**



## BTC HEALTH, PHARMAXIS

BTC Health says it will pay Pharmaxis \$2 million for a 10-year exclusive distribution agreement for Bronchitol and Aridol and has requested a capital raising trading halt. BTC said its wholly-owned subsidiary Bioimpact would make a one-off payment of \$2 million to Pharmaxis within 10 business days for the agreement beginning from July 1, 2021 which had automatic renewals for subsequent three-year terms.

The company said it would be responsible for the promotion and sale of Bronchitol and Aridol to existing customers and respiratory clinics and responsible for approvals in Australia, New Zealand, Singapore, Malaysia, Hong Kong, and South Korea.

Last year, Pharmaxis said it received a \$US7 million (\$A9.2 million) milestone payment from the Parma, Italy-based Chiesi Farmaceutici SpA for the US approval of its Bronchitol for cystic fibrosis (BD: Jan 17, 2021).

In April, Pharmaxis said the Ankara, Turkey-based Gen Pharmaceuticals would pay EUR1.25 million (\$A2 million) to distribute Bronchitol in Russia (BD: Apr 14, 2021).

Today, Pharmaxis chief executive officer Gary Phillips said the BTC deal was part of a strategy to generate “non-dilutive cash and cost savings from the mannitol respiratory business late last year when Bronchitol was approved in the United States”.

BTC said Bronchitol was an inhaled dry powder form of mannitol, used to treat cystic fibrosis and enabled clearing lung mucus, while Aridol was a lung function test to diagnose asthma through measuring airway hyper-responsiveness.

BTC executive chair Dr Richard Treagus said the products were “an important move for the company into speciality pharmaceuticals, being a segment that fits strongly with our established capabilities and expertise”.

“Importantly for our shareholders this transaction will be profit accretive immediately,” Dr Treagus said.

BTC has requested a trading halt pending an announcement “in relation to a capital raise” and trading will resume on July 5, 2021 or on an earlier announcement.

BTC Health was untraded at 7.4 cents.

## MESOBLAST

Mesoblast says it has requested a type C meeting with the FDA to discuss its 404-patient phase III trial of rexlémestrocél-L for chronic inflammatory back pain.

In February, Mesoblast said that the randomized, controlled trial of rexlémestrocél-L (formerly MPC-06-ID) with and without hyaluronic acid compared to placebo “did not reach statistical significance across the entire study” (BD: Feb 11, 2021).

The company said at that time that the mesenchymal precursor cells were a “safe, durable, and effective opioid-sparing therapy for patients”.

Today, Mesoblast said it would discuss its pathway for approval in the US and a planned US trial would include 20 percent European Union patients “to provide regulatory harmonization, cost efficiencies and streamlined timelines, without initiating an EU trial”.

The company said that with its partner in Europe and Latin America, Grünenthal, the collaboration agreement had been amended, with Mesoblast eligible to receive payments up to \$US112.5 million prior to product launch in the EU, inclusive of \$US17.5 million already received, if certain clinical and regulatory milestones are satisfied and reimbursement targets are achieved.

Mesoblast said that cumulative milestone payments could reach \$US1 billion depending on the outcome of phase III studies and patient adoption, and it would receive tiered double-digit royalties on product sales as per the original agreement.

Mesoblast was up 1.5 cents or 0.8 percent to \$1.995 with 3.8 million shares traded.

## MICRO-X

Micro-X says it has launched a veterinary version of its Rover Mobile DR x-ray for use in small-animal hospitals and has appointed Melbourne's Medical Plus as its distributor.

Micro-X said its first sale was to Adelaide's Gawler Animal Hospital.

The company said the Rover x-ray cart had been modified with a new user interface and its imaging software was sourced from its partnership with Salt Lake City's Varex Imaging.

Micro-X said it had appointed Medical Plus as a non-exclusive distributor for three-years.

Micro-X was up 1.5 cents or 4.7 percent to 33.5 cents.

## AUSCANN GROUP HOLDINGS

Auscann says it will supply its 2.5mg and 10mg Neuvis equal tetrahydrocannabinol (THC) and cannabidiol (CBD) capsules to the Tasmanian Department of Health.

Auscann said that subject to official orders, the products could be supplied to hospitals, Ambulance Tasmania, and other health centres, hospitals or organizations.

Auscann was up 1.1 cents or 11.1 percent to 11 cents with 3.2 million shares traded.

## ARGENICA THERAPEUTICS

Argenica says its pharmaco-kinetic study of ARG-007 for stroke shows the drug is safe and well-tolerated in rats, with no adverse effects observed.

Argenica said the pharmaco-kinetic data showed "favorable" profiles in the dose range of 0.3mg/kg to 10mg/kg which included ARG-007's efficacious dose of about 1.0mg/kg, with a rapid time to reach maximum concentration in the blood, irrespective of sex or dose.

The company said no adverse effects were observed in the animals in each arm of the study, which showed that ARG-007 was "potentially safe and well-tolerated at the administered, pharmaco-dynamically relevant doses".

Argenica said it had begun the studies for a phase I trial which would include pharmaco-kinetics, genotoxicity, safety pharmacology and toxicokinetic studies.

Argenica chief executive officer Dr Liz Dallimore said the company was "very pleased to see the positive results of our pilot pharmaco-kinetics studies in confirming the feasibility of our study design and protocols ... [and] the company remains on track to initiate our phase I clinical trial [this year]".

Argenica was up half a cent or 2.5 percent to 20.5 cents.

## NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says its four-week pre-clinical Emtinb ocular safety and tolerance study in non-human primates has been completed "without any reported adverse outcomes".

In May, Neuroscientific said that a single dose of its Emtinb penetrates eye tissue for up-to six days and was active in rabbit ocular fluid for up-to 14 days (BD: May 5, 2021).

Today, the company said the study showed that Emtinb administered by intra-vitreous injection in non-human primates was "well tolerated" across all dose groups for 28 days and showed no signs of inflammation or reporting of abnormal findings.

Neuroscientific said the study investigated low, mid and high-dose Emtinb, with the high-dose group establishing a safety margin three times greater than the planned trial dose.

Neuroscientific chair Paul Rennie said the data was "very encouraging for the company as we move towards the first-in-man studies [by the end of the year]."

Neuroscientific fell one cent or three percent to 32.5 cents.

### [NOXOPHARM](#)

Noxopharm says the US Food and Drug Administration has granted investigational new drug approval for its about 100-patient, phase II, Darrrt-2 study.

Earlier this month, Noxopharm said the trial would treat patients with progressive, metastatic prostate, breast or lung cancers who had failed standard treatment and were eligible for low-dose, palliative radiotherapy to a single lesion (BD: Jun 10, 2021).

Today, the company said the study would combine Veyonda, or NOX66, with radiotherapy to an isolated tumor to trigger an abscopal, or whole-of-body, anti-cancer response.

Noxopharm said that the University of Texas MD Anderson Cancer Center and the Beverly Hills Cancer Center in Los Angeles had "sought to be involved in the study".

Noxopharm was up 1.5 cents or 2.3 percent to 66 cents with 1.3 million shares traded.

### [TRUSCREEN GROUP](#)

Truscreen says it has received its first order of six cervical cancer screening devices from its Serbian distributor MPG d.o.o Beograd, to be shipped this month.

Truscreen said its cervical cancer screening device has received product registrations in the Czech Republic, Slovakia and Poland and had pending registrations in Croatia, Slovenia, Macedonia and Bosnia Herzegovina.

Truscreen was up one cent or 16.95 percent to 6.9 cents.

### [MEMPHASYS](#)

Memphasys says its upgraded Felix sperm separation device has passed the verification process with several validation tasks expected to complete by September 30, 2021.

Memphasys was up 0.4 cents or 6.25 percent to 6.8 cents.

### [RESONANCE HEALTH](#)

Resonance says its controlled placement agreement limit with Acuity Capital has been increased from \$5 million to \$7.75 million and extended to July 31, 2023.

Resonance said following the increase it had \$5 million available but was not required to use it and there were no fees associated with the increase or with the extension.

Resonance was up 2.5 cents or 16.1 percent to 18 cents.

### [BLUECHIIP](#)

The Melbourne-based Bellwether Super says it has ceased its substantial shareholding in Bluechiip.

Bellwether said it sold shares between June 26, 2020 and June 30, 2021, with the single largest sale 2,500,000 shares for \$84,085 or 3.36 cents a share.

Bluechiip was up 0.7 cents or 17.1 percent to 4.8 cents with 4.6 million shares traded.

### [HYDRIX](#)

Regal Funds Management says it has ceased its substantial shareholding in Hydrix.

The Sydney-based Regal Funds said between November 26, 2020 and June 28, 2021 it bought and sold shares, with the single largest sale 2,452,468 shares for \$677,372 or 27.62 cents a share.

Hydrix fell half a cent or 2.7 percent to 18 cents with 3.2 million shares traded.



### LBT INNOVATIONS

LBT says it has appointed Joanne Moss as a non-executive director, effective immediately, and she will transition to chair in September 2021 replacing Kate Costello. LBT said Ms Moss had experience in the “the development, manufacture and commercialization of medical devices and digital diagnostics”.

The company said Ms Moss was currently a director of Ellume and previously worked for the Norton Rose Fulbright law firm, Pizza Hut Australia and Yum.

According to her LinkedIn page, Ms Moss holds a Bachelor of Laws from the University of Technology Sydney and a Master of Laws from the University of New South Wales.

The company said that subject to shareholder approval, Ms Moss would receive a grant of 1.25 million option exercisable at 8.1 cents and vesting over two years.

LBT was up 0.4 cents or 5.3 percent to eight cents.

### OSPREY MEDICAL

Osprey says it has appointed Steven Brandt as a director.

Osprey said Mr Brandt had more than 35 years of experience in the healthcare field and “extensive experience in new therapy adoption in the cardiovascular space”.

The company said Mr Brandt was currently a director of Nuwellis Inc and was previously the acting vice president at Thoratec Corp, a director of Vascular Solutions and worked for CHF Solutions, St Jude Medical and XRT Corporation.

Osprey was up 0.1 cents or 7.7 percent to 1.4 cents with 4.8 million shares traded.

### REGENEUS

Regeneus says it has appointed Hang Ling Leung as company secretary, effective from July 1, 2021, following Sandra McIntosh’s resignation on June 30, 2021.

Regeneus said Ms McIntosh had been with the company since 2009 and thanked her for the “tremendous contribution” she made to the company both as company secretary and head of corporate operations.

Regeneus was unchanged at 7.4 cents.

### BIONOMICS

Bionomics says it has appointed Miles Davies as a director replacing Dr Srinivas Rao, with chair Dr Errol De Souza to be paid a base \$US525,000 (\$A701,596) a year.

Bionomics said Mr Davies would replace Dr Rao as the second Apeiron Investment Group nominated director.

The company said Dr De Souza would continue as executive chair on a base salary of \$US43,750 a month, \$US22,000 a year for US health benefits, a short-term incentive of up-to 60 percent of base salary pending performance criteria and up-to 100 percent of salary for exceeding performance.

Bionomics said that as a long-term incentive and subject to shareholder approval, Dr De Souza would be granted 47,786,607 options exercisable at the 14-day volume weighted average price to the effective date, vesting quarterly over four years.

Bionomics was unchanged at 19 cents.

## BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JUNE 30, 2021

<b>Company \$Am</b>	<b>Jul-20</b>	<b>Jun-21</b>	<b>Jul-21</b>
Cochlear	12,410	14,927	16,546
CSL	130,312	132,081	129,797
Resmed	39,594	39,447	47,688
<b>BDI-20</b>			
Avita	966	564	650
Clinuvel	1,267	1,437	1,517
Compumedics	74	67	70
Cyclopharm	111	242	159
Cynata	71	80	72
Ellex	98	45	46
Genetic Signatures	307	162	157
Immutep	76	487	411
Medical Developments	458	338	321
Mesoblast	1,893	1,271	1,284
Nanosonics	2,050	1,673	1,770
Neuren	127	149	187
Opthea	635	525	469
Paradigm	708	501	476
Pharmaxis	26	37	40
Polynovo	1,679	1,792	1,865
Pro Medicus	2,750	4,805	6,119
Starpharma	419	721	607
Telix	325	1,266	1,714
Volpara	342	326	292
<b>Second 20</b>			
Actinogen	25	191	216
Alterity	18	60	58
Amplia	8	26	29
Antisense	36	118	112
Dimerix	69	48	39
Impedimed	62	194	157
Imugene	134	1,968	1,762
Kazia	45	164	174
LBT Innovations	54	26	22
Next Science	226	364	276
Oncosil	96	62	43
Optiscan	18	222	142
Orthocell	58	104	112
Osprey	16	41	33
Patrys	13	49	102
Prescient	22	64	157
Proteomics	39	125	97
Resonance	67	90	71
Universal Biosensors	35	115	149
Uscom	32	27	25

\* Biotech Daily editor, David Langsam, owns shares in Acrux, Actinogen, Alcidion, Alterity, Amplia, BTC Health, Cochlear, Control Bionics, Cynata, Nanosonics, Neuren, Patrys, 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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