



Biotech Daily

Thursday September 1, 2022

Daily news on ASX-listed biotechnology companies

- * AUGUST BDI-40 UP 0.6%, ASX200 UP 0.6%, BIG CAPS DOWN 1%, NBI DOWN 1%
- * TODAY: ASX, BIOTECH DOWN: MICRO-X UP 17%; ACTINOGEN DOWN 9%
- * ELLUME IN VOLUNTARY ADMINISTRATION; ANTEO \$123k CLAIM
- * GENETIC SIGNATURES REVENUE UP 25% TO \$35m; PROFIT UP 74% TO \$3m
- * CARDIEX REVENUE DOWN 14% TO \$4.5m; LOSS UP 105% TO \$11.4m
- * CRESO REVENUE UP 43% TO \$4.3m; LOSS DOWN 63% TO \$6m
- * NUHEARA REVENUE DOWN 64% TO \$3.9m; LOSS UP 96% TO \$14.1m
- * NUHEARA REQUESTS 'CAPITAL RAISING' TRADING HALT
- * IMEX RIGHTS RAISE \$2m; TOTAL \$4m
- * FRANCE, ISRAEL ORDER MICRO-X 'NEXT GENERATION' MOBILE X-RAY
- * PHARMAXIS WINS PARKINSON'S UK \$4.9m GRANT FOR PXS-4728 TRIAL
- * IMUGENE OPENS 2nd VAXINIA TRIAL COHORT; RELEASES ESCROW SHARES
- * SDI PAYS \$18m FOR 2.4ha SITE FOR WAREHOUSING, FUTURE HQ
- * TRUSCREEN 5-YEAR DEAL WITH ZAPCO FOR SINGLE USE SENSORS
- * FMR (FIDELITY) REDUCES TO 8.3% OF NANOSONICS
- * IMEX M-D GERMAN ARANGO, JORGE MARIN INCREASE, DILUTED TO 14%
- * MILLA PALACIO INCREASES, DILUTED TO 6%
- * ASX SUSPENDS AUSCANN FOR TRANSACTION, RECOMPLIANCE
- * CYCLOPHARM APPOINTS KEVIN BARROW DIRECTOR
- * POLYNOVO: PROF DAVID MCQUILLAN OFF BOARD TO CTO, CSO
- * RECCE: ALISTAIR MCKEOUGH DIRECTOR, MAGGIE NIEWIDOK CO SEC
- * CANN LOSES DIRECTOR JOHN SHARMAN

MARKET REPORT

The Australian stock market fell 2.02 percent on Thursday September 1, with the ASX200 down 141.2 points to 6,845.6 points. Twelve of the Biotech Daily Top 40 stocks were up, 22 fell, five traded unchanged and one was untraded.

Micro-X was the best, up two cents or 16.7 percent to 14 cents, with 819,981 shares traded. Antisense climbed 15.4 percent; Amplia was up 10 percent; Cyclopharm rose 7.75 percent; Compumedics improved 3.85 percent; Cynata, Neuren, Paradigm, Pharmaxis, Polynovo and Volpara were up more than one percent; with CSL and Mesoblast up by less than one percent.

Actinogen led the falls, down 0.7 cents or 9.0 percent to 7.1 cents, with 1.7 million shares traded. Impedimed lost 8.6 percent; Clinuvel shed 6.7 percent; Genetic Signatures was down 5.15 percent; Atomo, Kazia, Starpharma and Telix fell four percent or more; Alcidion, Dimerix, Immutep, Imugene and Next Science were down more than three percent; Resonance shed 2.9 percent; Avita, Emvision, Nova Eye, Oncosil, Opthea, Pro Medicus and Universal Biosensors were down more than one percent; with Cochlear, Proteomics and Resmed down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Spring has sort of sprung in Australian biotechnology, but Melbourne still feels like Winter.

The Biotech Daily Top 40 Index (BDI-40) continued its recovery, following last month's 26.4 percent surge, managing to edge up just 0.6 percent to a collective market capitalization of \$17,444 million. But as sports tragics say: "A win is a win."

The ASX200 was also up 0.6 percent to 6987 points, while the Nasdaq Biotechnology Index (NBI) fell 1.05 percent and the collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell 1.0 percent. CSL's 0.7 percent increase to \$141,400 million almost balanced Resmed's fall of 6.0 percent to \$47,046 million and Cochlear easing 0.5 percent to \$14,097 million.

For the year to August 31, 2022, all indices fell, with the Big Caps down 6.2 percent, the ASX200 down 7.3 percent, the BDI-40 down 24.5 percent and the NBI down 27.8 percent.

In August, 19 of the BDI-40 companies were up, with 11 up more than 10 percent; while 20 companies fell, with 12 down by more than 10 percent.

In most cases, the largest movement was from the lowest base, with the biggest, Pro Medicus, up \$548 million but just 10.7 percent and Imugene up \$117 million or 8.3 percent.

Compumedics was the best by percentage, up \$12 million or 35.3 percent to \$46 million, followed by: Nova Eye and Paradigm (31.0%), Actinogen (29.6%), Proteomics (18.3%), Universal Biosensors (14.9%), Patrys (14.3%), Clinuvel (14.1%), Antisense (13.0%), Pro Medicus (10.7%) and Avita (10.0%).

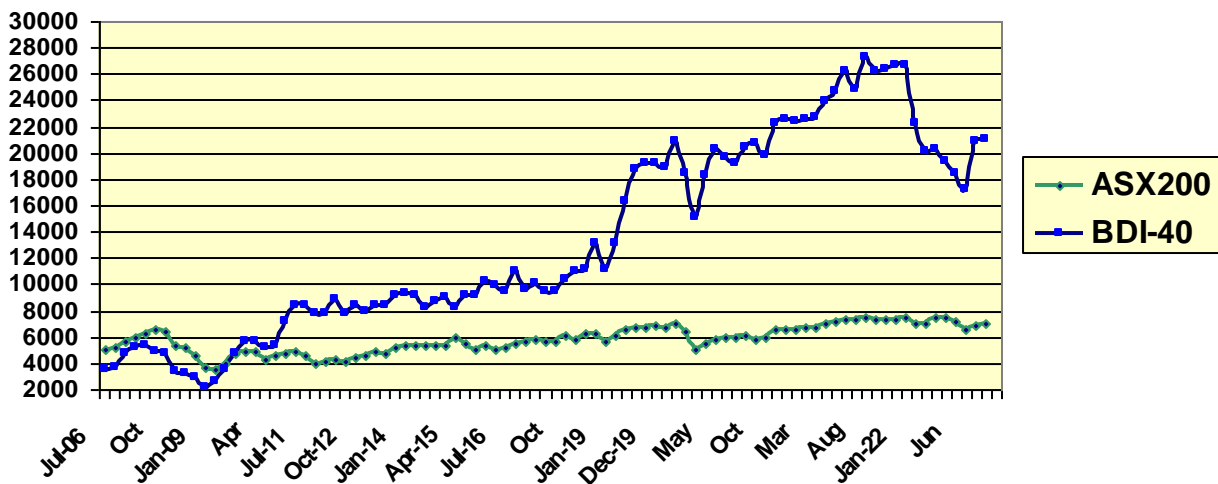
Kazia led the falls for the second month in a row, but the reason became apparent on August 1, when it said the paxalisib arm of the GBM Agile trial did not meet the criteria for continuing. Kazia lost \$37 million or 52.1 percent to \$34 million, followed by: Medical Developments (22.3%), Immutep and Orthocell (16.3%), Atomo (15.9%), Cynata (15.8%), Telix (14.9%), Next Science (14.7%), Polynovo (13.2%) and Nanosonics (11.4%).

There was little excitement outside the BDI-40, with the exception of Pacific Edge falling a further 39.4 percent in August to \$324 million – a long way from \$1,038 million a year ago. Resapp was up 69.7 percent to \$168 million, on a better offer from Pfizer.

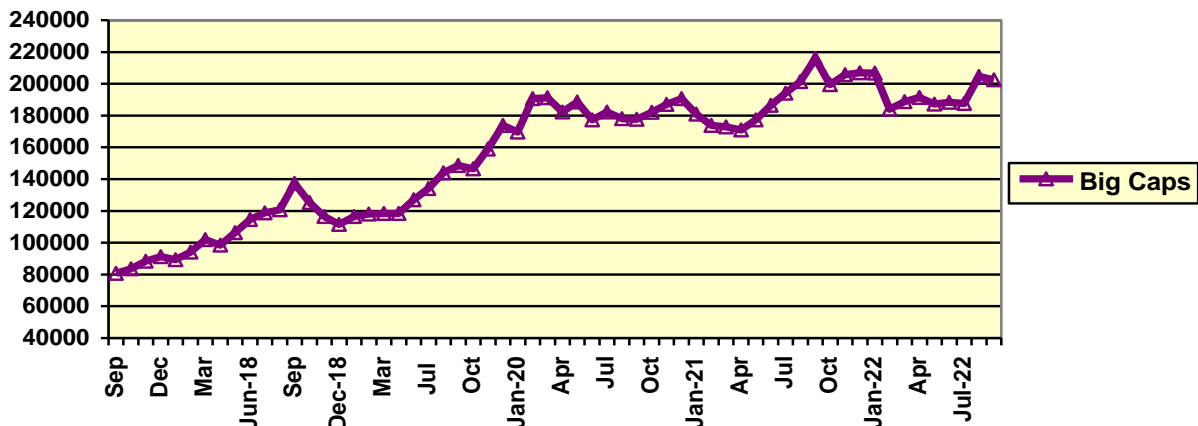
Cannabis Corner improved 19.0 percent in August, but 3.3 percent below August 31, 2021. Five climbed, five fell and one was unchanged with the heavy lifting undertaken by Cronos up \$85 million or 54.8 percent to a record \$240 million, Incannex recovering 36.1 percent to \$358 million and Emyria up 21.3 percent to \$74 million. Althea fell 38 percent to \$31 million and Zelda lost \$28.6 percent to \$15 million.

On the Nasdaq, Eyepoint (formerly Psivida) was up 11.9 percent to \$498 million, Redhill with Australian assets was up 6.3 percent to \$84 million and Queensland's Protagonist retreated 9.7 percent to \$626 million.

BDI-40 v ASX200 Jun 30, 2006 to Aug 31, 2022- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Aug 31, 2017 – Aug 31, 2022



ELLUME

Ellume says its directors have appointed John Park and Joanne Dunn of FTI Consulting as voluntary administrators, effective immediately.

Last year, Ellume recalled “specific product lots of [severe acute respiratory syndrome coronavirus-2] tests” after they reported false positive test result rates higher than was observed in clinical testing (BD: Oct 7, 2021).

In February, 2021 Ellume said the US Government would provide \$US231.8 million (\$A302.8 million) to produce its Sars-Cov-2 home tests (BD: Feb 2, 2021).

Today, Ellume said its US business was not subject to the voluntary administration and would continue to trade its business as usual until further notice.

Biotech Daily asked Ellume chief executive officer Dr Sean Parsons whether the administration related to the company’s Sars-Cov-2 tests or the general business.

“It relates to the whole Australian business including all products,” Dr Parsons told Biotech Daily. “The US business and US facility is ongoing,” Dr Parsons said.

In its media release, Ellume said the administrators would “identify the best path to secure the viability of the business” and “control of Ellume USA remains with its directors”.

FTI’s John Park said the administrators would “seek to maximize the chances of Ellume exiting Administration process in an orderly fashion”.

“The administrators intend to trade the company on a business-as-usual basis, while we conduct an independent assessment of the financial position and ongoing viability of the business,” Mr Park said.

Dr Parsons said the company “set out to spark a revolution in the way infectious diseases are diagnosed”.

“I am incredibly proud of Ellume’s achievements in what has been an unprecedented, challenging and dynamic time,” Dr Parsons said.

“We are entering into a voluntary administration process for the Australian business to help determine the best course of action to secure and strengthen a future for Ellume,” Dr Parsons said.

The media release said that a meeting of creditors would be held in mid-September.

Separately, Anteo said it supplied Ellume with Anteobind, had \$123,000 owing and would work with Ellume and the administrators on supply for US test manufacturing.

Ellume is a public unlisted company.

GENETIC SIGNATURES

Genetic Signatures says record revenue for the year to June 30, 2022 was up 25.2 percent to \$35,421,000 with net profit after tax up 74.4 percent to \$3,063,000.

Genetic Signatures said the revenue growth was “driven by demand for Easyscreen Sars-Cov-2 detection kit, though sales of other Easyscreen kits have increased proportionally”.

Genetic Signatures chief executive officer John Melki told Biotech Daily that revenue came from the company’s gastro-enteric tests as well as the tests for sexually transmitted disease and respiratory tests.

The company said the freight and warehousing costs continues “as a significant cost due to increased volumes and general global logistics”.

Genetic Signatures said that \$31.6 million of its revenue was derived from the Asia Pacific region with the rest of the world adding a further \$3.8 million.

The company said diluted earnings per share rose 74.4 percent to 2.11 cents, with net tangible asset backing per share up 7.9 percent to 37.0 cents, and it had cash and cash equivalents of \$36,897,000 at June 30, 2022, compared to \$30,121,000 at June 30, 2021.

Genetic Signatures fell five cents or 5.15 percent to 92 cents.

CARDIEX

Cardiex says revenue for the year to June 30, 2022, was down 14.4 percent to \$4,499,562 with net loss after tax up 105.3 percent to \$11,383,382.

Cardiex said revenue was from sales of its central blood pressure and cardiovascular devices and services to hospitals, clinics, research institutions and pharmaceutical companies.

The company said that the loss was driven by increased staff costs in the US and Australia, product development expenditure and marketing costs.

The company said diluted loss was up 73.43 percent at 11.1 cents a share, net tangible asset backing per share was down by 34.1 percent to 5.4 cents, and it had cash and cash equivalents of \$1,455,590 at June 30, 2022, compared to \$3,665,259 at June 30, 2021.

Cardiex fell one cent or 3.2 percent to 30 cents.

CRESO PHARMA

Creso says revenue for the six months to June 30, 2022, was up 42.4 percent to \$4,317,041, with net loss after tax down 62.6 percent to \$6,017,618.

Creso said its revenue came from sales of marijuana products, with sales of \$2.6 million from North America, \$1.7 million from sales in Europe and the Middle East, with \$35,030 in sales from the Asia Pacific.

The company said diluted loss per share fell 69.7 percent to 0.56 cents, net tangible asset backing per share was down 50 percent to 1.2 cents, with cash and cash equivalents of \$3,140,635, at June 30, 2022, compared to \$13,654,203 June 30, 2021.

Creso fell 0.1 cents or 2.6 percent to 3.8 cents with 1.45 million shares traded.

NUHEARA

Nuheara says revenue for the year to June 30, 2022 was down 64.0 percent to \$3,865,582, with net loss after tax up 95.7 percent to \$14,094,436.

Nuheara said the revenue was primarily from the direct-to-consumer sales of its sound filtering Iq buds Max as well as original equipment manufacturer sales and service.

Nuheara said diluted loss per share fell 64.8 percent to 15.31 cents, with last year's net tangible asset backing per share of 0.4 cents turned to negative 2.5 cents, and cash and cash equivalents of \$410,153 at June 30, 2022, compared to \$7,276,355 at June 30, 2021.

Nuheara last traded at 24 cents (see below).

NUHEARA

Nuheara has requested a trading halt pending "release of an announcement regarding a potential capital raising".

Trading will resume on September 5, 2022.

IMEX HEALTH SERVICES

Imex says that its one-for-eight under-written rights offer at 48 cents a share has raised \$1,975,112 taking the total raised with its placement to about \$4 million.

Last month, Imex said it had raised \$2 m in a placement and hoped to raise the same amount in the rights offer (BD: Aug 3, 2022).

Imex fell four cents or 7.4 percent to 50 cents.

MICRO-X

Micro-X says that French distributor DMS and Israeli distributor Inframed have placed the first orders for its next generation Rover Plus mobile x-ray unit.

Micro-X said the next generation unit included its in-house designed and manufactured generator and an extended capability x-ray tube, "greatly increasing the overall imaging capability of the mobile x-ray unit".

The company said the increased imaging capability made the Rover Plus suitable for specialized imaging needs in emergency departments, operating theatres, and military deployed hospitals.

Micro-X said the specialized x-ray tube was previously manufactured by a third-party and would be manufactured in-house, contributing to cost savings and margin improvement.

The company said it had 510(k) clearance from the US Food and Drug Administration under a Note to File for the Rover Plus, because the technical file remained largely unchanged from the previous generation Rover.

Micro-X said it was still pursuing its Conformité Européene mark certification for the first-generation Rover, and once granted, an extension for the Rover Plus would be sought.

Micro-X managing-director Peter Rowland said the launch was "the culmination of many months of amazing innovation and hard work from our technical and regulatory teams, who have combined to make this next generation Rover a reality".

"We are excited to ramp up our marketing and outreach activities to our customers and believe that our Mobile DR range offers compelling product features at competitive pricing," Mr Rowland said.

Micro-X was up two cents or 16.7 percent to 14 cents.

PHARMAXIS

Pharmaxis says the British charity Parkinson's UK has granted it GBP2.9 million (\$A4.9 million) to fund a 40-patient phase II study of PXS-4728.

Pharmaxis said that the development of isolated rapid eye movement sleep behavior disorder was "the strongest predictor" for Parkinson's disease and dementia.

The company said that the trial at the University of Sydney and the University of Oxford, would recruit patients with the disorder for the placebo-controlled, phase II trial to evaluate whether PXS-4728 could reduce neuro-inflammation, measured by nuclear scanning techniques.

Pharmaxis said the trial would begin recruiting patients in early 2023.

Pharmaxis was up 0.1 cents or 1.3 percent to 7.7 cents.

IMUGENE

Imugene says it will begin a second cohort in its up to-100-patient, phase I trial of CF33-hNIS Vaxinia virotherapy and pembrolizumab for advanced solid tumors.

In May, Imugene said it had dosed the first patient in the trial with a low dose of Vaxinia at the Duarte, California-based City of Hope (BD: May 18, 2022).

Today, the company said the trial at multiple US sites, would begin a cohort which would see patients does with both Vaxinia and pembrolizumab.

Imugene said the trial was expected to run for about 24 months.

Separately, Imugene said it would release 94,170,967 shares from voluntary escrow on September 9, 2022.

According to its most recent filing, Imugene had 5,866,594,610 shares on issue.

Imugene fell one cent or 3.85 percent to 25 cents with 25.7 million shares traded.

[SDI \(FORMERLY SOUTHERN DENTAL INDUSTRIES\)](#)

SDI says it will pay \$17.8 million for a six-acre (2.4 hectare) site, seven kilometres from its current Bayswater headquarters, initially as a warehouse and to be its main office.

SDI said that following renovation work, it would relocate its warehouse to the location in January 2023 and over the next six to 10 years would redevelop the remaining area to relocate the existing manufacturing and office facilities and then sell the current site.

SDI said that acquisition would be funded through a secured bank loan.

SDI was up 2.5 cents or 2.9 percent to 89.5 cents.

[TRUSCREEN](#)

Truscreen says that Hong Kong's Zapco International will produce single-use sensors for its cervical cancer screening device.

Truscreen said the five-year agreement included Zapco implementing cost improvement initiatives.

Truscreen chief executive officer Juliet Hull said the single use sensor usage was "a key consumable component impacting on the financial performance of Truscreen".

"With [single use sensor] demand growing, year on year from greater placement of our screening devices in the market and expected to be well over 200,000 units this year, any improvements in manufacturing yield and process can make a material contribution to our bottom line," Ms Hull said.

Truscreen was up 0.3 cents or 7.1 percent to 4.5 cents.

[NANOSONICS](#)

Fidelity Management and Research (FMR) says it has reduced its shareholding in Nanosonics from 27,940,361 shares (9.33%) to 24,976,093 shares (8.27%).

The Delaware-based FMR said it bought and sold shares between April 30, 2018, and August 30, 2022 at prices ranging from \$2.4502 to \$8.1606.

Nanosonics was unchanged at \$4.12 with 899,389 shares traded.

[IMEX HEALTH SERVICES](#)

Imex managing-director German Arango says he has increased and been diluted from 5.089 shares (15.48%) to 5,506,372 shares (14.13%)

Mr Arango said that with Jorge Marin and Digital Imaging Solutions, he bought shares in and was diluted in the recent entitlement offer (see above).

[IMEX HEALTH SERVICES](#)

Milla Paula Inari Palacio says she has increased and been diluted in Imex from 52,076,672 shares (6.99%) to 2,336,257 shares (5.99%)

The Sydney-based Ms Palacio said that with Irukandji Investments Pty Ltd for the Londgreach Family Trust and Rio Negro Pty Ltd for the Medallo Trust she bought shares in the entitlement offer and was diluted in the recent placement (see above).

Carlos Jaime Palacio is a non-executive director of Imex.

AUSCANN

The ASX says that Auscann has been suspended pending an announcement of a proposed transaction and recompliance with the chapters 1 and 2 of the Listing Rules. The ASX said it acted under Listing Rule 11.1.2 to require the proposed acquisition to be conditional on approval by Auscann shareholders and under Listing Rule 11.1.3 to require the company to recompile with chapters 1 and 2 of the Listing Rules; and expected Auscann to remain suspended until it had recompiled. Auscann last traded at four cents.

CYCLOPHARM

Cyclopharm says it has appointed Kevin Barrow as a non-executive director, effective from today.

Cyclopharm said Mr Barrow was currently the chief executive officer of the Butterfly Foundation and previously worked for Philips Australia, Becton Dickinson and Eli Lilly. Cyclopharm was up 11 cents or 7.75 percent to \$1.53.

POLYNOVO (FORMERLY CALZADA)

Polynovo says Prof David McQuillan has resigned as a non-executive director and has been appointed chief technical and scientific officer.

In 2012, Calzada appointed Prof David McQuillan as a director (BD: Aug 8, 2012).

Today, Polynovo said Prof McQuillan had spent 15 years in academic research focused on tissue engineering and regenerative medicine, including at the US National Institute of Health, as well as 20 years managing research and development for regenerative medicine and wound healing companies, including Lifecell, Kinetic Concepts and Tela Bio. The company said Prof McQuillan held a Bachelor of Science and Doctor of Philosophy from Monash University.

Polynovo was up 2.5 cents or 1.9 percent to \$1.335 with 2.8 million shares traded.

RECCE PHARMACEUTICALS

Recce says it has appointed company secretary Alistair McKeough a director and replaced him as company secretary with Maggie Niewidok, effective from today.

Recce said Mr McKeough was appointed company secretary in 2017 and was formerly head of professional services at Automic Group, which acquired his legal, company secretarial and corporate governance business, Whittens & McKeough, in 2018.

The company said Ms Niewidok was a solicitor and company secretary and had worked "across a broad industry base of ASX listed companies".

Recce was up three cents or 3.8 percent to 82 cents.

CANN GROUP

Cann Group says John Sharman has resigned as a director "due to his other business commitments", effective today.

Mr Sharman was appointed the chief executive officer of Universal Biosensors in 2020.

Cann chair Allan McCallum said that Mr Sharman had been "a valuable member of the board and we want to thank him sincerely for his contributions to the company".

The company said the search for a replacement was underway.

Cann fell one cent or 3.5 percent to 27.5 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT AUGUST 31, 2022

Company \$Am	Sep-21	Aug-22	Sep-22
Cochlear	15,339	14,177	14,097
CSL	141,973	140,369	141,400
Resmed	58,540	50,072	47,046
BDI-20			
Avita	672	210	231
Clinuvel	1,867	874	997
Compumedics	73	34	46
Cyclopharm	155	132	133
Cynata	75	57	48
Genetic Signatures	212	155	139
Immutep	451	295	247
Kazia	183	71	34
Medical Developments	259	180	140
Mesoblast	1,080	624	630
Nanosonics	1,996	1,404	1,244
Neuren	250	710	727
Nova Eye	61	29	38
Opthea	460	453	462
Pharmaxis	57	40	42
Polynovo	1,475	999	867
Pro Medicus	6,584	5,141	5,689
Starpharma	489	265	255
Telix	1,912	2,281	1,941
Volpara	294	173	161
Second 20			
Actinogen	183	108	140
Alcidion	383	197	184
Amplia	24	18	19
Antisense	109	54	61
Atomo	130	44	37
Dimerix	87	50	47
Emvision	219	125	123
Impedimed	187	132	125
Imugene	2,212	1,408	1,525
Micro-X	126	62	55
Next Science	291	232	198
Oncosil	38	60	57
Orthocell	88	92	77
Paradigm	450	258	338
Patrys	73	49	56
Prescient	125	121	118
Proteomics	116	93	110
Resonance	53	32	32
Universal Biosensors	155	67	57
Uscom	23	13	14

* Biotech Daily editor, David Langsam, owns shares in Acrux, Actinogen, Alcidion, Alterity, Amplia, BTC Health, Clarity, 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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