



Biotech Daily

Wednesday December 1, 2021

Daily news on ASX-listed biotechnology companies

- * NOVEMBER BDI-40 UP 1%; ASX200 DOWN 1%; BIG CAPS UP 1%
- * TODAY: ASX, BIOTECH DOWN: STARPHARMA UP 11.5%
- IMUGENE DOWN 8%
- * CHIMERIC, CASE WESTERN UNI CORE-NK LICENCE OPTION
- * TELIX: 'EXCEPTIONAL AUTHORIZATION' FOR ILLUCIX IN BRAZIL
- * CLARITY HALF-WAY IN 'PROPELLER' PROSTATE CANCER IMAGING TRIAL
- * ANTERIS: DURAVR 7-DAY FOLLOW UP IN 5 PATIENTS
- * MGC RAISES \$10m
- * AUDEARA: RCM, US FCC CERTIFICATION FOR A-02 TV BUNDLE
- * BIONOMICS WINS BNC210 US FDA FAST TRACK STATUS FOR ANXIETY
- * NEUROTECH: 'MARIJUANA BOOSTS PREDNISONE, IN-VITRO'
- * NUHEARA RECEIVES \$1.7m FEDERAL R&D TAX INCENTIVE
- * STARPHARMA TO LAUNCH VIRALEZE IN VIETNAM
- * PHARMAUST MANUFACTURES SMALL MONEPANTEL TABLETS
- * RESAPP AGM 20% OPPOSE 6m EVOLUTION CAPITAL OPTIONS
- * EPSILON, VALENS DEAL EXTENDED 2 MONTHS
- * VIBURNUM REDUCES TO 9.9% IN ADHERIUM
- * M-D WESLEY STRINGER TAKES 7.6% OF PROBIOTEC
- * RHYTHM: OTTO BUTTULA EXEC CHAIR, CEO GLENN GILBERT M-D
- * CYCLOPHARM LOSES DIRECTOR TOM MCDONALD

MARKET REPORT

The Australian stock market fell 0.28 percent on Wednesday December 1, 2021, with the ASX200 down 20.1 points to 7,235.9 points. Seven of the Biotech Daily Top 40 stocks were up, 25 fell, five traded unchanged and three were untraded.

Starpharma was the best, up 12.5 cents or 11.5 percent to \$1.21, with 1.1 million shares traded. Optiscan and Universal Biosensors climbed more than two percent; Medical Developments and Orthocell were up one percent or more; with CSL, Genetic Signatures and Next Science up by less than one percent.

Imugene led the falls, down 4.5 cents or 8.2 percent to 50.5 cents with 37.2 million shares traded. Pro Medicus lost 7.4 percent; Oncosil was down 6.7 percent; Cynata, Prescient and Resonance fell more than four percent; Actinogen, LBT, Nova Eye, Opthea and Telix were down more than three percent; Antisense, Avita, Clinuvel, Dimerix, Kazia, Mesoblast, Nanosonics, Neuren, Paradigm, Patrys and Polynovo shed more than two percent; Cochlear and Resmed were down more than one percent; with Osprey, Proteomics and Volpara down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Despite the roller coaster ride at the end of November, both the Biotech Daily Top-40 Index (BDI-40) and the three Big Caps closed the month just below their record highs.

The benchmark ASX200 fell 0.9 percent and the Nasdaq Biotechnology Index (NBI) fell 4.0 percent.

The collective market capitalization of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed 0.6 percent in November to \$206,981 million, propped-up by CSL climbing 2.3 percent to \$139,795 million, while Cochlear fell 4.4 percent to \$14,326 million and Resmed was down 2.4 percent to \$52,860 million.

For the year to November 30, the BDI-40 climbed 24.6 percent, the ASX200 was up 11.3 percent, the Big Caps rose 17.5 percent and the NBI was up 5.2 percent. The 22 companies in Cannabis Corner were up 33.9 percent for the year (see below).

November showed the value of a diverse portfolio. While Cochlear and Resmed fell, CSL held up the Three Big Caps.

Just 10 of the BDI-40 companies were up, with five up by more than 10 percent, while 29 fell, five by more than 20 percent and 13 by more than 10 percent.

But a 14.3 percent increase by Pro Medicus to \$6,522 million and Imugene up 14.9 percent to \$3,139 million counter-balanced all the large, modest and small falls.

Universal Biosensors was November's best, up 18.9 percent to \$157 million, followed by Imugene and Proteomics, both up 14.9 percent, followed by Pro Medicus (14.3%), Telix (11.1%), Impedimed (9.0%), Amplia (8.0%), Paradigm (7.7%), Mesoblast (7.0%) and Starpharma (1.4%).

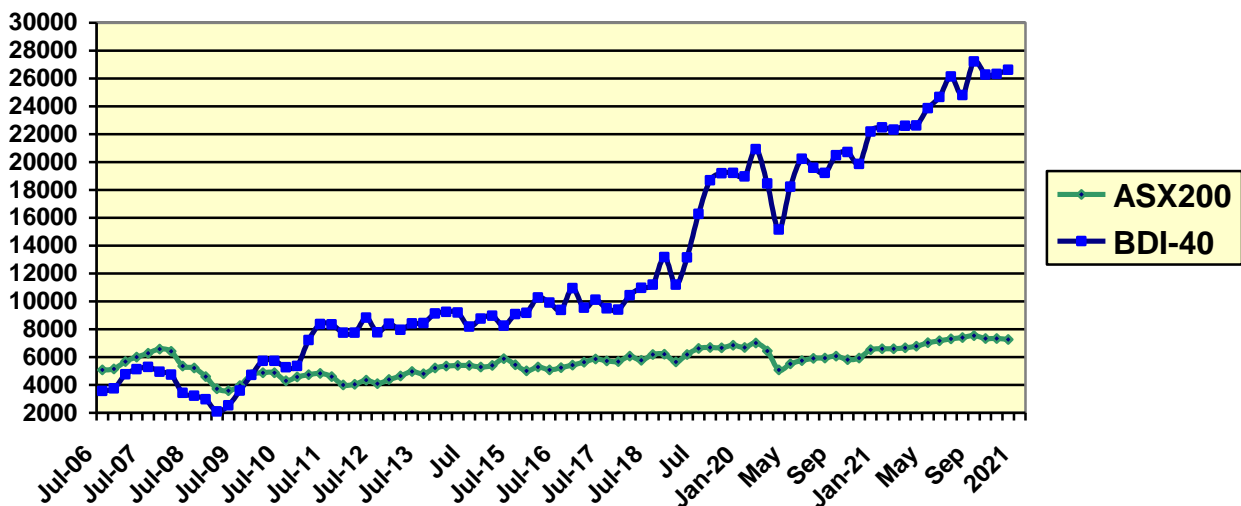
Clinuvel led the falls from a near record high, down \$483 million or 25.4 percent to \$1,422 million, followed by Osprey (24.0%), Polynovo (22.5%), Ellex (21.7%), Antisense (20.1%), LBT (18.1%), Immutep (16.6%), Cynata (14.8%), Alterity (14.3%), Prescient (13.3%), Optiscan (12.3%), Compumedics (11.6%) and Avita (11.5%).

Outside the BDI-40, Aroa Biosurgery and Rhythm Biosciences were at 12-month highs, with IDT, Micro-X, Race Oncology and Trajan holding steady.

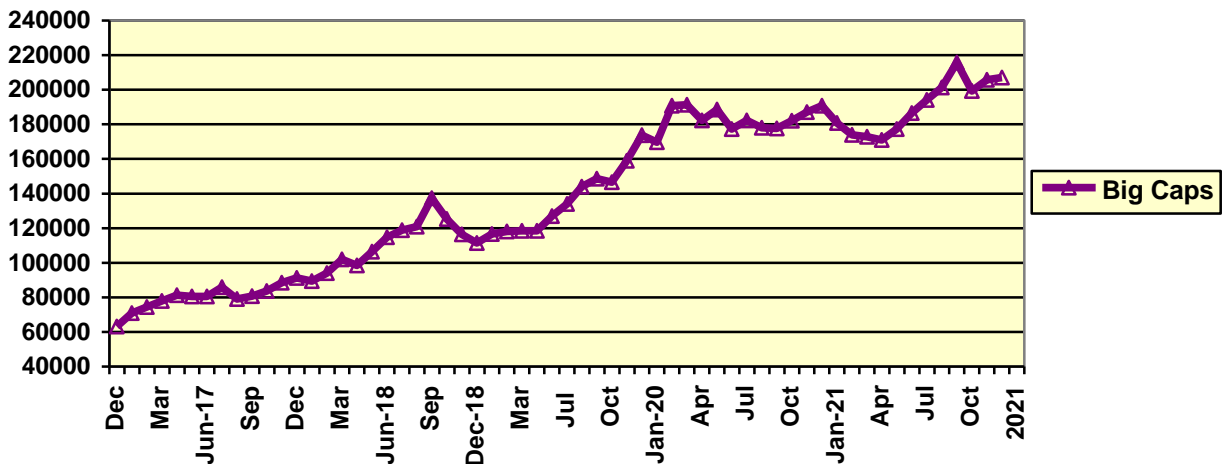
The collective market capitalization of the 22 companies in Cannabis Corner was up 7.5 percent in November to \$1,941 million, with just five up, 14 down and three unchanged; but Incannex added \$200 million or 40.9 percent to \$689 million, with Cronos jumping \$19 million or 237.5 percent and Emyria up \$42 million or 110.5 percent - countering all the falls.

On the Nasdaq, Eyepoint (formerly Psivida) climbed 71.3 percent to \$752 million, Queensland's Protagonist was up 14.3 percent to \$2,252 million, but Redhill, with Australian assets, lost 37.6 percent to \$211 million.

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



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



CHIMERIC THERAPEUTICS

Chimeric says it has an option to licence the Core-NK anti-cancer platform from the Cleveland, Ohio-based Case Western Reserve University.

Chimeric said the “clinically-validated, off-the-shelf, robust, enhanced natural killer (Core-NK) platform developed by the University’s Dr David Wald enabled “the accelerated development of multiple next generation off-the-shelf [natural killer] cells and [chimeric antigen receptors natural killer cell] products”.

The company said that Core-NK was “a transformative platform technology” which completed a phase I trial in June 2021 in both solid tumors and blood cancer.

Chimeric said that it intended to “rapidly move to complete full licencing of the platform and expects to pay [the University] development milestones and industry standard royalty payments based on commercial net sales”, with upfront fees associated with the agreement to be funded from existing cash reserves.

The company said that the Core-NK platform would be developed “with enhanced activation and expansion features with plans to study it as a combination therapy in blood cancers”

Chimeric said that three initial chimeric antigen receptors natural killer cell (Car-NK) products would be developed using the platform with its existing chimeric antigen receptors.

The company said it would “explore additional opportunities to further leverage the Core-NK platform to develop additional NK and Car NK products through internal development and/or partnerships with other biotech and pharmaceutical companies”.

Chimeric chief executive officer Jennifer Chow said the platform was “truly transformative for Chimeric”.

“It provides us with a platform technology that triples our current portfolio by enabling us to accelerate the development of multiple new, off the shelf, NK cell assets that work in perfect synergy with our existing pipeline,” Ms Chow said.

Chimeric was unchanged at 27 cents with 1.6 million shares traded.

TELIX PHARMACEUTICALS

Telix says Brazil has granted an “exceptional authorization” for its Illucix prostate cancer imaging product, allowing unrestricted sales ahead of full regulatory approval.

Telix said the Brazil Health Regulatory Agency authorisation for Illucix, the kit for the preparation of 68-gallium, prostate-specific membrane antigen injection (68 Ga-PSMA-11), would allow manufacturing and distribution partner, the Porto Alegre, Rio Grande do Sul-based MJM Produtos Farmacêuticos e de Radioproteção Ltda to manufacture and distribute Illucix in Brazil ahead of a full regulatory approval expected next year.

Telix said the approval would allow “wide-spread clinical access” to prostate cancer imaging for men in Brazil.

The company said Illucix had approval from the Australian Therapeutic Goods and Administration and had applied for US Food and Drug Administration approval and was progressing market authorization applications in the European Union and Canada.

Telix managing director Dr Christian Behrenbruch said that “prostate cancer is the most commonly diagnosed male cancer in Brazil, with approximately 65,840 new cases each year.”

“[Prostate-specific membrane antigen-positron emission tomography] imaging has the potential to have a profound impact on the management of prostate cancer, enabling clinicians to detect prostate cancer right throughout the body,” Dr Behrenbruch said.

Telix fell 25 cents or 3.8 percent to \$6.35 with 338,537 shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has recruited 15 of 30 patients for its 'Propeller' 64-copper-SARbis-PSMA imaging trial in patients with confirmed prostate cancer.

In August, Clarity said that the 30-patient, phase I, positron emission tomography (PET) imaging trial of participants with confirmed prostate cancer using 64-Cu-SAR-bis-PSMA was a blinded, dose-ranging, non-randomized study prior to radical prostatectomy, with primary endpoints of safety, tolerability and efficacy in the detection of primary prostate cancer compared to histopathology (BD: Aug 10, 2021).

Today, the company said the main goals of the trial were to determine the safety and tolerability of 64Cu SAR-bisPSMA in patients with untreated, confirmed prostate cancer and planned for radical prostatectomy, examine 64Cu SAR-bisPSMA at different dose levels, determine the ability of 64Cu SAR-bisPSMA to detect primary prostate cancer and compare diagnostic properties of 64Cu SAR-bisPSMA against 68Ga PSMA-11, the standard of care for prostate cancer imaging in Australia.

Clarity executive chair Dr Alan Taylor said the company was "well on-track to explore and validate the benefits of the ... platform, including the logistical, manufacturing and treatment benefits associated with the perfect pairing of copper-64 and copper-67".

"These benefits hold promise of providing a large patient population with early, accurate and precise detection of prostate cancer," Dr Taylor said.

Clarity was up half a cent or 0.6 percent to 90 cents.

ANTERIS TECHNOLOGIES

Anteris says that all five patients in the first-in-human Duravr heart valve study have passed the seven-day follow up.

Last week, Anteris said it implanted five of 10 patients with its Duravr transcatheter heart valve for severe aortic stenosis in Tbilisi, Georgia (BD: Nov 22, 2021).

Today, Anteris chief executive officer Wayne Patterson said the company was "excited to see all patients are benefiting from the Duravr valve".

"The 30-day follow up will be an important marker and give us clear insights as to how beneficial Duravr has been in these patients from a clinical perspective," Mr Patterson said.

Anteris fell five cents or 0.6 percent to \$8.70.

MGC PHARMA

MGC says it has raised GBP5.5 million (\$A10.2 million) in a share placement at 2.0 pence (3.8 Australian cents) a share.

MGC said the share price was a 13 percent discount to the London Stock Exchange closing price on November 29, 2021.

The company said the funds would be used for Cimetra applications and trials, the Malta production facility, costs of Cimetra dosing trials and Cannepil trials and general working capital.

MGC said Turner Pope Investments was the lead manager and bookrunner for the placement and it would pay Turner Pope a fee of GBP15,000, six percent of the funds received in cash and the equivalent of four percent of the funds in options, exercisable at 2.0 pence each.

MGC was unchanged at 4.1 cents with 2.6 million shares traded.

AUDEARA

Audeara says it has Australia's Regulatory Compliance Mark and US Federal Communications Commission certification for its A-02 TV headphone bundle.

Audeara said the A-02 TV bundle was a combination of its A-02 Personalised Headphone and BT-02 television transmitter and would "incorporate the next generation of Audeara personalization technology as well as Bluetooth 5.0, which improves the range and connection strength to audio devices".

The company said the A-02 TV bundle was due to complete mass production in January 2022 and would be launched in Australia by April 30, 2021.

Audeara was up one cent or 8.7 percent to 12.5 cents.

BIONOMICS

Bionomics says the US Food and Drug Administration has granted BNC210 fast track designation for social anxiety disorder and other anxiety-related disorders.

Bionomics said the fast-track designation facilitated and expedited development and the review of new drugs that showed "the potential to address unmet medical need in the treatment of a serious or life-threatening disease or condition".

Last month, the company said it had US FDA approval for a 150-patient, phase II trial of BNC210 for acute social anxiety disorder (BD: Nov 1, 2021).

Today, Bionomics said the 'Prevail' study was expected to begin "by the end of 2021".

Bionomics fell half a cent or 3.85 percent to 12.5 cents.

NEUROTECH INTERNATIONAL

Neurotech says its marijuana-derived NTI164 in combination with prednisone can reduce inflammatory biomarkers, in-vitro.

Last month, Neurotech said it had lodged two Australian provisional patent applications relating to its marijuana for "neuro-inflammatory disorders" to (BD: Oct 14, 2021).

Today, the company said that pre-clinical studies conducted in human neuronal cells demonstrated that NTI164, when combined with prednisone "significantly reduce and normalize the levels of key inflammatory markers" including tumor necrosis factor (TNF)-alpha, cyclo-oxygenase-2 (COX-2) expression, interleukin-6 (IL-6), interleukin-1a (IL-1a) and granulocyte-macrophage colony-stimulating factor (GM-CSF) levels.

Neurotech said when combined with NTI164, prednisone showed a 33 percent reduction of TNF-alpha, an 87 percent reduction in the suppression of IL-6, a 34 percent reduction in COX-2 protein, a 53 percent reduction in IL-1a and a 54 percent reduction in GM-CSF.

Neurotech chair Brian Leedman said that "from a company development perspective, we can't understate the clinical significance of these results".

"We have prednisone, one of the world's most commonly used off-patent pharmaceutical drugs for neuro-inflammatory disorders, including rheumatoid arthritis, Alzheimer's and multiple sclerosis, demonstrating significant improvement in efficacy using anywhere from 70 percent to 90 percent less active dosage when used in combination with NTI164," Mr Leedman said.

"Given the very well documented adverse side effects of prednisone usage, the potential to create a combination treatment with NTI164 and prednisone which increases efficacy and significantly reduces side effects is now a major driver for the company," Mr Leedman said.

Neurotech was unchanged at 6.1 cents with 2.75 million shares traded.

[NUHEARA](#)

Nuheara says it has received \$1,743,030 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Nuheara said the rebate related to research and development expenditure for the year to June 30, 2021.

Nuheara fell 0.1 cents or five percent to 1.9 cents with 1.3 million shares traded.

[STARPHARMA](#)

Starpharma says its Viraleze antiviral nasal spray has been registered for sale in Vietnam and would be launched this week with an initial contract for 100,000 units.

In August, Starpharma said that its Viraleze anti-viral nasal spray reduced viral load by more than 99.9 percent in mice with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (BD: Aug 23, 2021).

In October, Starpharma says Perth's Healthco Australia and Ho Chi Minh's Truong Bao Land International Investment Co would distribute its Viraleze anti-viral spray in Vietnam, with a first order for 100,000 units (BD: Oct 26, 2021).

The company said the 100,000 units was part of the three-month agreement, with further orders expected on signing an ongoing distribution agreement currently being finalized.

Today, Starpharma said a portion of Viraleze from the initial supply orders would be donated to hospitals and other healthcare organizations in Vietnam and a further ongoing distribution agreement for additional orders of Viraleze was being finalized.

Starpharma said Viraleze was registered in Europe, Vietnam, India and New Zealand and partnered with London's Lloyds Pharmacy and Bologna's Admenta Italia Group.

Starpharma was up 12.5 cents or 11.5 percent to \$1.21 with 1.1 million shares traded.

[PHARMAUST](#)

Pharmaust says it has completed manufacturing 2,000 smaller sized non-good manufacturing practice monepantel tablets.

Pharmaust said the tablets were for planned motor neuron disease and Covid-19 clinical trials and had been shaped to make them easier to swallow.

Pharmaust fell 0.3 cents or 3.1 percent to 9.5 cents.

[RESAPP HEALTH](#)

Resapp said its annual general meeting voted more than 20 percent opposition to issue 6,000,000 options to its placement lead manager Evolution Capital Advisors Pty Ltd.

Resapp said the resolution to issue 5,000,000 options to Evolution nominee LTL Capital Pty Ltd and 1,000,000 options to nominee Mishtalem Pty Ltd was opposed by 56,902,532 votes (20.33%) with 223,013,642 votes (79.67%) in favor.

The company said it faced 18.23 percent opposition to the remuneration report, with 16.06 percent against the ratification of the issue of 94,827,588 shares in the April placement and 14.18 percent against the issue of 6,250,000 shares to Avanti Med Ltd under a device development agreement, with the election of director Brian Leedman and the 10 percent placement capacity passed easily.

According to its most recent filing, Resapp had 859,197,077 shares on issue meaning that the opposition to the Evolution options amounted to 6.6 percent, sufficient to requisition extraordinary general meetings.

Resapp fell 0.4 cents or 6.15 percent to 6.1 cents.

[EPSILON HEALTHCARE \(FORMERLY THE HYDROPONICS CO\)](#)

Epsilon says the Kelowna, British Columbia-based Valens Canada has agreed to extend their binding heads of agreement to January 31, 2022.

In September, Epsilon said it had a partnership with Valens Canada and received its first order worth \$540,000 for the use of its Southport Queensland marijuana manufacturing facility (BD: Sep 9, 20, 2021).

Today, the company said it extended the deadline for the definitive agreement from November 30, 2021 to January 31, 2022.

Epsilon fell one cent or 8.7 percent to 10.5 cents with 2.3 million shares traded.

[ADHERIUM](#)

Viburnum Funds Pty Ltd says it has reduced its shareholding and has been diluted from 238,989,991 shares (11.24%) to 219,057,245 shares (9.94%).

The Nedlands, Western Australia-based Viburnum said between September 24 and 27, 2021, it sold 19,932,746 shares for \$326,775 or 1.64 cents a share.

The company said it was diluted on November 26, 2021, due to share issuances.

In an application for quotation of securities on November 26, 2021, Adherium said it issued 4,679,359 fully paid shares to be issued to directors in lieu of cash director fees.

Adherium was up 0.1 cents or 9.1 percent to 1.2 cents with 1.2 million shares traded.

[PROBIOTEC](#)

Probiotec managing-director Wesley Stringer says he has increased his shareholding in the company from 4,927,873 shares (6.59%) to 6,207,777 shares (7.63%).

Mr Stringer said he exercised 1,260,000 options at \$2.1176 each and corrected a past notice with the addition of 8,000 shares.

Last week, Probiotec said its annual general meeting approve a loan of up to \$2,668,176 to Mr Stringer to exercise the 1,260,000 options (BD: Nov 24, 2021).

Probiotec was up three cents or 1.4 percent to \$2.17.

[RHYTHM BIOSCIENCES](#)

Rhythm says non-executive chair Otto Buttula has been promoted to executive chair with chief executive officer Glenn Gilbert appointed managing-director.

Rhythm said the changes were effective from today.

The company said Mr Buttula's remuneration would change from \$84,000 to \$150,000 a year, excluding superannuation, while Mr Gilbert's remuneration would remain unchanged.

Rhythm fell 9.5 cents or 5.2 percent to \$1.74.

[CYCLOPHARM](#)

Cyclopharm says that director Tom McDonald has retired "for personal health reasons", effective from today.

Cyclopharm said it acknowledged and thanked Mr McDonald "for his significant and valuable contribution as a director of the company since joining the board in 2017".

The company said it would start a search process for a replacement.

Cyclopharm was untraded at \$1.81.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT NOV 30, 2021

Company \$Am	Dec-20	Nov-21	Dec-21
Cochlear	14,491	14,987	14,326
CSL	135,300	136,629	139,795
Resmed	40,953	54,157	52,860
BDI-20			
Avita	624	548	485
Clinuvel	1,000	1,905	1,422
Compumedics	92	67	60
Cyclopharm	193	186	169
Cynata	93	88	75
Ellex	51	60	47
Genetic Signatures	255	199	188
Immutep	166	487	406
Medical Developments	431	351	343
Mesoblast	2,440	1,031	1,103
Nanosonics	2,005	1,792	1,647
Neuren	139	238	227
Opthea	777	448	420
Paradigm	668	444	478
Pharmaxis	36	57	52
Polynovo	2,122	1,247	966
Pro Medicus	3,078	5,705	6,522
Starpharma	518	435	441
Telix	988	1,693	1,881
Volpara	347	300	287
Second 20			
Actinogen	32	243	229
Alterity	65	70	60
Amplia	25	25	27
Antisense	59	169	135
Dimerix	50	82	79
Impedimed	178	277	302
Imugene	539	2,733	3,139
Kazia	174	192	187
LBT Innovations	36	33	27
Next Science	240	247	245
Oncosil	143	38	36
Optiscan	63	130	114
Orthocell	78	103	100
Osprey	36	25	19
Patrys	31	77	74
Prescient	43	180	156
Proteomics	55	101	126
Resonance	71	48	48
Universal Biosensors	82	132	157
Uscom	26	21	16

* 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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