



# Biotech Daily

Monday October 1, 2018

*Daily news on ASX-listed biotechnology companies*

- \* **SEPTEMBER BDI-40 UP 11%, ASX200 DOWN 2%, BIG CAPS DOWN 9%,  
- BIONOMICS UP 106%, CLINUVEL 49%; PRESCIENT DOWN 15%**
- \* **TODAY: ASX DOWN, BIOTECH FLAT: IMMUTEP UP 19%; CYNATA DOWN 5%**
- \* **RHINOMED, COLUMBIA CARE SIGN 12-YEAR NASAL MARIJUANA DEAL**
- \* **MICRO-X NOTES RAISE \$3m**
- \* **LEO 'THE GUN' KHOURI TAKES MEDIBIO BACK TO BIOPROSPECT FUTURE**
- \* **CLINUVEL TO TRIAL SCENESSE FOR VARIEGATE PORPHYRIA**
- \* **PROBIOTEC COMPLETES \$24.5m FACILITY SALE, LEASEBACK**
- \* **AUSCANN, DAYACANN, KHIRON TO PROMOTE MEDICAL MARIJUANA**
- \* **IMUGENE: PRAVIN KAUMAYA ADVISOR, EX-CSO URUSLA WIEDERMANN**
- \* **RACE APPOINTS TOM LEE FOR PARTNERING, FUNDING**

## MARKET REPORT

The Australian stock market fell 0.57 percent on Monday October 1, 2018 with the ASX200 down 35.3 points to 6,172.3 points. Ten of the Biotech Daily Top 40 stocks were up, 10 fell, 11 traded unchanged and nine were untraded. All Big Caps were up.

Immutep was the best, up 0.9 cents or 19.15 percent to 5.6 cents with 16.8 million shares traded.

Avita climbed 14.3 percent; Mesoblast was up 8.8 percent; Medical Developments improved 5.25 percent; Ellex was up 4.3 percent; Paradigm, Prana and Starpharma rose more than two percent; CSL, Optiscan and Resmed were up more than one percent; with Cochlear and Nanosonics up by less than one percent.

Cynata led the falls, down 6.5 cents or five percent to \$1.235, with 112,592 shares traded.

Universal Biosensors fell 4.2 percent; Actinogen, Benitec, Impedimed and Neuren shed two percent or more; with Clinuvel, Polynovo, Pro Medicus and Telix down by less than one percent.

## [BIOTECH DAILY TOP 40 INDEX \(BDI-40\)](#)

Despite the loss of the \$1.87 billion Sirtex, the raw September Biotech Daily Top 40 Index (BDI-40) fell just 4.1 percent, with Clinuvel joining and Mesoblast rejoining the \$1 billion club. It is the first time the BDI-40 has had four companies worth more than \$1 billion.

Adjusting the BDI-40 for company departures, in the same way the S&P Indices calculate the ASX200, the adjusted September BDI-40 was up 10.9 percent compared to the ASX200 slipping 1.8 percent.

September was exceptional for biotechs, with Bionomics up \$249 million or 106.4 percent in the lead up to tomorrow's expected BNC210 results for post-traumatic stress disorder. That the company needed a weekend-plus trading halt is ... er ... interesting, but we'll know soon enough.

Unexpectedly, Clinuvel climbed \$348 million to \$1,054 million and Mesoblast returned to the Billion Dollar Club, up \$246 million to \$1,038 million.

The collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell for the first time in six months, down 8.8 percent for the month of September, but never-the-less up 49.8 percent on their value 12 months ago. CSL retreated 11.4 percent to \$91,094 million, Cochlear eased seven percent to \$11,574 million, but Resmed defied the trend, up 2.5 percent to \$22,643 million.

Twenty-one of the BDI-40 companies were up (nine by more than 20 percent and six by more than 30 percent), with 15 down (of which just three fell more than 10 percent) and four were unchanged.

Bionomics was September's best, up 106.4 percent to \$483 million. From a much higher base, Clinuvel had the second largest percentage rise, up 49.3 percent to \$1,054 million, followed by Genetic Signatures (46.2%), Factor Therapeutics (39.5%), Mesoblast (31.1%), Immuteq (30.3%), Admedus on a capital raising despite spending the month suspended (26.3%), Pro Medicus (22.6%), Starpharma (21.8%) and Cyclopharm (14.1%).

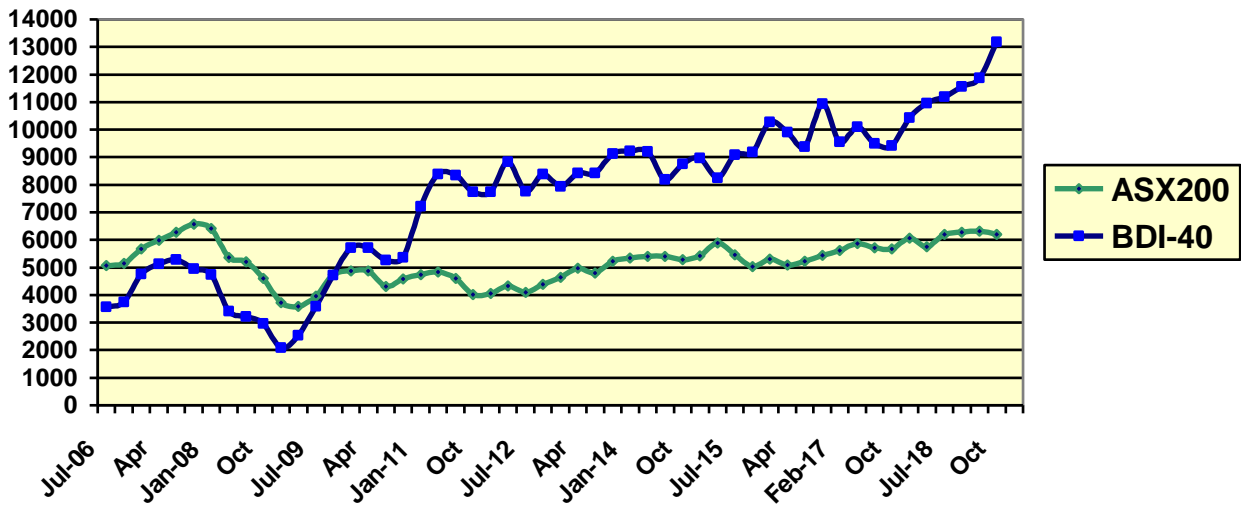
Prescient led the falls, down 15.0 percent to \$17 million, followed by sister cancer company Imugene (11.6%) and Compumedics (11.1%).

Outside the BDI-40, Rhinomed was at an all-time high, up 30.8 percent for the month and 126.7 percent for the year to \$34 million on marijuana-infused nasal dilators. Allegra was up 133.3 percent for the year to \$21 million, Biotron jumped 200 percent on Friday's understated trial results, IDT held firm at \$45 million, Resapp recovered to \$146 million and Medibio fell 60 percent to \$12 million on internal trouble.

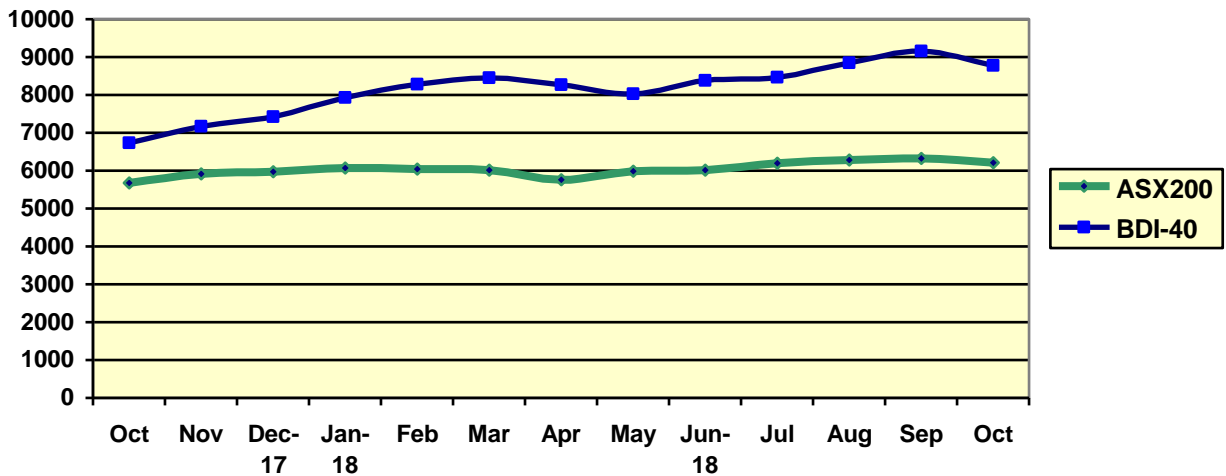
The collective 15 companies in Cannabis Corner were 4.25 percent higher, with five up seven down and three unchanged.

The September Nasdaq Biotechnology Index (NBI) slipped 0.2 percent, with Eyepoint (Psivida) up 143.7 percent to \$368 million, Israel's Redhill up 17.1 percent to \$260 million, Queensland's Protagonist up 6.3 percent to \$302 million and Vaxart (Biota) down 6.7 percent to \$28 million.

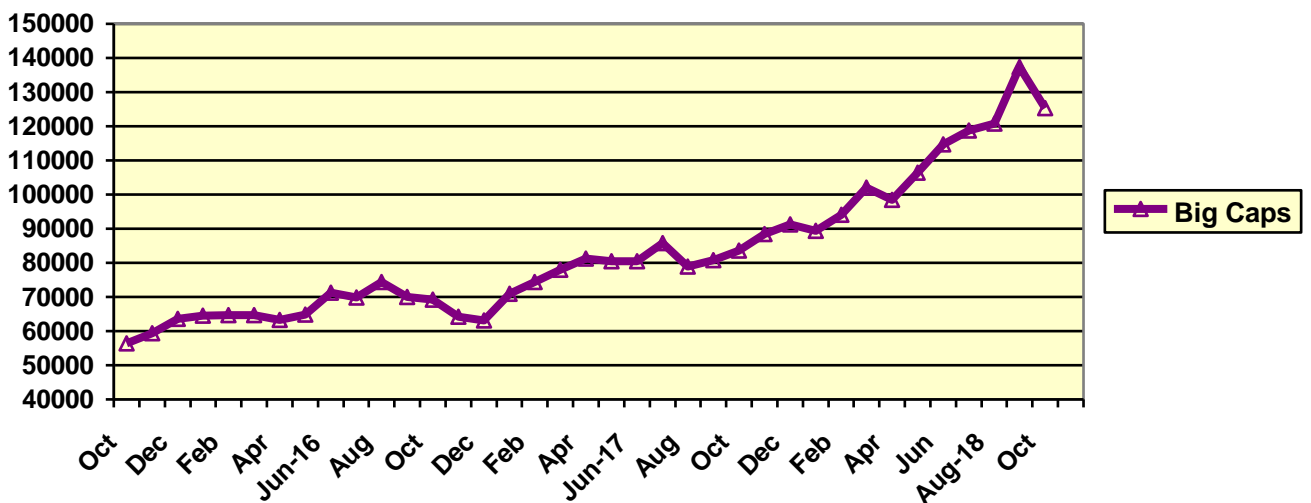
**BDI-40 v ASX200 Jun 30, 2006 to Sep 30, 2018- Adjusted**



**BDI-40 (\$m) v S&P ASX 200 – Sep 30, 2017 - Sep 30, 2018 (raw data)**



**Big Caps \$m (Cochlear, CSL, Resmed) Sep 30, 2015 – Sep 30, 2018**



## RHINOMED

Rhinomed says it has a 12-year licence to incorporate its nasal dilator technology into Columbia Care's medical marijuana products and services.

Rhinomed said the agreement with New York's Columbia Care LLC would "leverage Rhinomed's patented nasal technology platform and Columbia Care's extensive medical cannabis research and development, manufacturing and distribution capabilities".

The company said that it would receive revenues from products "on a cost plus double-digit return basis" and it would share net revenues on a double-digit percentage basis.

Rhinomed said that product development would begin "immediately on multiple products with potential for product launches in ... 2019".

The company said the agreement would produce reliable, dose-metered cannabis-based medicines administered nasally, including over-the-counter and clinical applications.

Rhinomed said that initial indications included obstructive sleep apnoea, post-traumatic stress disorder, pain relief, anti-nausea and other sleep-related conditions, to be distributed through Columbia Care's network of dispensaries, other US cannabis dispensaries with potential expansion, subject to separate agreements, through its more than 9,000 US pharmacy distribution network.

The company said the agreement covered the delivery of medical cannabis and cannabinoid compounds, analogues and derivatives in the US.

Rhinomed said it would optimize its nasal dilator platform for delivery of cannabinoid formulations and supply the customized product to Columbia Care, which would manufacture and place specific pharmaceutical formulations onto the platform, with Rhinomed retaining all intellectual property rights to its drug delivery platform.

The company said that any new intellectual property developed from the collaboration would be owned by the party responsible for the invention, with intellectual property invented jointly by Rhinomed and Columbia Care to be jointly owned.

Rhinomed said it was too early to assess whether the deal would affect its 2019 revenue.

The company said its platform was protected by a family of more than 60 patents, granted and pending, plus further design patents, brand and trademarks.

Rhinomed chief executive officer Michael Johnson said Columbia Care was "setting the standard of care for medical marijuana in the US".

"We believe that there is clear medical research support for, and a very real and significant commercial opportunity for nasal stents with medical cannabis formulations," Mr Johnson said.

Rhinomed climbed 9.5 cents or 33.3 percent to 38 cents with 2.4 million shares traded.

## MICRO-X

Micro-X says it has raised \$3,000,000 through the issue of 30,000 unsecured mandatorily convertible notes.

Micro-X said that pending potential capital raises and take-overs, the notes would convert to shares at the greater of 23 cents each and the lesser of 40 cents a share or a 20 percent discount to the potential capital raising.

The company said that if it failed to undertake a capital raising by April 30, 2019 it would convert the notes at the greater of 23 cents each and the lesser of 40 cents a share or a 20 percent discount to the 20-day volume-weighted price to the conversion notice.

Micro-X said that the funds would provide working capital to support production of the Carestream DRX Revolution Nano while it sought a partnership for strategic technology development and a material financial investment, expected by the end of 2018.

Micro-X fell 3.5 cents or nine percent to 35.5 cents.

## MEDIBIO (FORMERLY SOLAGRAN)

Medibio says it has received a Section 249D of the Corporations Act 2001 notice from Elias Leo 'The Gun' Khouri and associates requesting an extraordinary general meeting. Medibio said the notice came from Carakho Holdings Pty Ltd, SEK Investments Limited, Bejjol Pty Ltd, Mining Investments Limited, Gun Capital Management Pty Ltd, Joshua Khouri, Benjamin Khouri and Peta Slocombe who claimed to hold about 6.29 percent of the company.

The company said that the Section 249D notice sought the removal of chairman Chris Indermaur and director Andrew Maxwell and the appointment of Benjamin Richardson, Ms Slocombe and Elias Khouri as directors.

Medibio said it was "seeking legal advice as [to] the validity of the Section 249D notice". In August, chief executive officer Jack Cosentino resigned and last month resigned as a director, with Medibio saying a Ms Slocombe had also gone (BD: Aug 29, Sep 21, 2018). In 2014, the then Biopropect acquired a circadian rhythm heart-rate test for depression and other mental illnesses; major shareholder and former director Elias Khouri reduced his holding below substantial; the company dropped previous technologies including the Termilone anti-termite treatment, Solargran's pine needle extract for horses and the Frontier oil and gas development; and it changed directors, effectively becoming a new company (BD: Nov 19, 2012; Jan 22, Sep 16, Nov 5, 25, 2014).

In October 2014, Biopropect said that Baillieu Holst had re-initiated research coverage on the company and the Invatec test to diagnose mental health conditions through heart rate variability (BD: Oct 28, 2014).

On August 5, 2014, Baillieu Holst initiated coverage on Biopropect with analyst Stuart Roberts saying that the Invatec test was "based on measured differences in heart rate variability analyzed using proprietary algorithms".

On August 7, 2014 Mr Roberts emailed that Baillieu Holst was "Ceasing coverage" in Biopropect and withdrew the previous price target of 0.7 cents a share saying "After reviewing our portfolio of stock coverage, Baillieu Holst Research has decided that [Biopropect] no longer fits the industry segments which we target for coverage."

Subsequently, Mr Elias Khouri reduced his holding to below substantial and former Chemgenex executive, now Patrys chief executive officer and Invion director Dr James Campbell was appointed a director (BD: Sep 8, 10, 16, 2014).

Through Mining Investments Elias Khouri held as many as 700,000,000 shares (24.15%) in Biopropect (BD: Jun 11, 2014).

In 2011, the company appointed Mr Elias Khouri's son, Jacob Khouri, as a director, following Mr Khouri's resignation in 2010 (BD: Feb 16, 2011; Sep 17, 2010)

Also in 2011, Biopropect said that Senior Sergeant Anthony Langdon - then of Victoria's Water police - who was appointed to the board on September 1, 2008, would resign effective from August 15, 2011 (BD: Sep 22, 2008; Jun 22, 2011).

In 2010, Elias Khouri resigned as a Biopropect director citing the company's dispute with Solagran over its pine needle extract cure-all (BD: Sep 17, 2010).

In 2010, Biopropect and Solagran were involved in legal action and mediation over a joint development agreement (BD: Aug 23, 2007; Jun 28, Jul 8, Sep 7, Nov 2, 2010).

Biopropect alleged that during negotiations that culminated in the development agreement, Solagran "falsely represented to it that it held patents in Australia and the US (or would eventually hold such patents) that covered the manufacture of [conifer green needle complex]" sold by Solagran as Bioeffective A and it (Biopropect) had recently found a cheaper source of similar material (BD: Sep 17, 20, Oct 4, 2010).

Medibio fell half a cent or 8.2 percent to 5.6 cents.

## CLINUVEL PHARMACEUTICALS

Clinuvel says it is planning a six-patient, phase IIa proof-of-concept trial of Scenesse (afamelanotide 16mg) for variegate porphyria, expected to begin about April 2019.

Clinuvel said it had agreement with two European porphyria expert centres on a clinical trial protocol to evaluate the safety and efficacy of Scenesse for variegate porphyria with patients to receive six doses of Scenesse over six months of the during the Northern Hemisphere Spring and Summer, with a one-month follow-up.

The company said the CUV040 study would evaluate the impact of afamelanotide on the severity of skin disease in variegate porphyria patients, measured with physician assessment tools, with the extent of lesions assessed, along with patient reported outcomes, including impact on quality of life.

Clinuvel said that Scenesse was prescribed by porphyria experts centres in Europe for the treatment of erythropoietic protoporphyria, a genetic disorder which caused absolute light intolerance due to a deficiency of ferro-chelatase, an enzyme critical in the synthesis of haem, an iron containing compound part of haemoglobin.

The company said that the porphyrias were a group of nine genetic metabolic diseases, including variegate porphyria and erythropoietic protoporphyria, characterized by specific enzyme deficiencies along the biochemical pathway of haem synthesis.

Clinuvel said that variegate porphyria was “a rare autosomal dominant inherited disorder resulting from the deficiency of the mitochondrial enzyme protoporphyrinogen oxidase, the sixth enzyme of the haem biosynthesis pathway”.

The company said it was classified as a cutaneous and acute porphyria, with cutaneous symptoms characterized by adult-onset blistering lesions and chronic fragility of sun and light-exposed skin, especially the back of the hands and the face, restricting patients in their daily activities.

Clinuvel said that patients experienced phototoxicity and suffered episodes in Spring and Summer when the atmospheric intensity of light increases.

The company said that psychiatric disturbances, autonomic neuropathy and muscle weakness had been reported in some patients, with a prevalence ranging from 0.3 to two cases per 100,000 people, and patients forced to lead a life sheltered from light and avoid any mechanical contact with their skin surface or risk triggering wounds and long-lasting ulcerations.

Clinuvel clinical affairs director Dr Emilie Rodenburger said the family of disorders was “relatively unknown but cause a level of human suffering not recognized or discussed in public”.

“It is our hope that we can make a difference to these patients’ lives,” Dr Rodenburger said.

Clinuvel fell three cents or 0.1 percent to \$22.00 with 236,316 shares traded.

## PROBIOTEC

Probiotec says it has completed the \$24.5 million sale and leaseback of its manufacturing facility at 79-85 Cherry Lane, Laverton North (BD: Aug 27, 2018).

Probiotec said it received \$21.5 million in cash with \$3 million to be held in trust and released on completion of development works at 85 Cherry Lane, including a new warehouse and manufacturing facility, estimated to cost \$3 million and scheduled for completion within 12 months.

Probiotec was up one cent or 0.7 percent to \$1.47.

## AUSCANN

Auscann says its Chilean joint venture Dayacann company will collaborate with Canada's Khiron Life Sciences Corp to promote medical marijuana.

Auscann said Dayacann was a joint venture with Fundación Daya and had completed two harvests at its 30-hectare facility yielding more than one tonne of dried cannabis.

The company said that Khiron had medical marijuana cannabis operations in Colombia, where it was licenced for the cultivation, production, distribution and export of both tetrahydrocannabinol (THC) and cannabidiol (CBD).

Auscann said the two companies would "collaborate on the development of social, pedagogical, scientific, commercial and political activities to support cannabinoid medicines as a medical option".

The company said that through the collaboration Dayacann, Fundación Daya and Khiron could offer "new alternatives of medical cannabis to patients in Chile in addition to those currently provided by Dayacann and Fundación Daya", with Khiron providing funds to support the activities.

Auscann fell one cent or one percent to 98.5 cents.

## IMUGENE

Imugene says it has appointed the Ohio State University Comprehensive Cancer Centre's Prof Pravin Kaumaya to its scientific advisory board (SAB).

Imugene said that Prof Kaumaya was the lead inventor of its recently licenced peptide cancer vaccine programs (BD: Jun 7, 2018).

The company said that Prof Kaumaya had developed multiple cancer vaccines, was "a recognized world leader in cancer vaccine research and author of more than 130 peer-reviewed articles".

Imugene said that Prof Kaumaya was a professor of medicine at the Ohio State University's Department of Obstetrics and Gynecology.

The company said that Prof Kaumaya was an inventor on several issued and pending patents for peptide vaccines and therapeutic technologies.

Imugene said that Prof Ursula Wiedermann had retired as its chief scientific officer, but would continue on the scientific advisory board.

Imugene was unchanged at 2.1 cents with 5.7 million shares traded.

## RACE ONCOLOGY

Race says it has appointed Tom Lee to assist with partnering and funding opportunities in the US, with a focus on Houston, Texas.

Race said Mr Lee was "well-connected to the MD Anderson Cancer Centre and other institutions, opinion-leaders and investors in Texas" and would make introductions to opinion leaders and clinical trial groups at the MD Anderson Cancer Centre, including funding opportunities for Bisantrone for acute myeloid leukaemia clinical trials, as well as make introductions to potential investors, licencing and merger and acquisition partners, and investigate Texas grant and other non-dilutive funding opportunities.

Race said Mr Lee would receive 420,000 share options for the 12-month contract, vesting at 35,000 options per month, exercisable at 12 cents each by October 1, 2023.

The company said Mr Lee was the chief executive officer of the Houston-based Medical Innovators Co LLC and was formerly the MD Anderson Centre's director of active venture development "instrumental" in developing more than 45 companies from MD Anderson.

Race was untraded at 9.5 cents.

## BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT SEPTEMBER 30, 2018

<b>Company \$Am</b>	<b>Oct-17</b>	<b>Sep-18</b>	<b>Oct-18</b>
Cochlear	9,161	12,448	11,574
CSL	60,628	102,835	91,094
Resmed	13,848	22,087	22,643
<b>BDI-20</b>			
Bionomics	229	234	483
Clinuvel	321	706	1,054
Compumedics	65	90	80
Cyclopharm	51	64	73
Ellex	132	111	101
Impedimed	299	182	172
LBT Innovations	45	22	22
Medical Developments	305	256	274
Mesoblast	645	792	1,038
Nanosonics	781	1,054	1,076
Neuren	153	136	123
Opthea	144	126	121
Pharmaxis	85	115	122
Polynovo	166	372	395
Immutep	59	109	142
Pro Medicus	610	1,053	1,291
Reva	307	99	104
Starpharma	471	482	587
Telix	78	174	165
Volpara	60	153	161
<b>Second 20</b>			
Actinogen	35	62	56
Admedus	66	38	48
Airxpanders	223	57	61
Avita	42	130	141
Benitec	29	48	46
Cynata	59	129	131
Dimerix	15	16	17
Factor Therapeutics	41	43	60
Genetic Signatures	40	52	76
Imugene	36	86	76
ITL Health	38	15	15
Oncosil	56	137	125
Optiscan	38	26	27
Orthocell	23	24	24
Osprey	143	70	76
Paradigm	32	116	114
Prescient	12	20	17
Prana	30	25	23
Universal Biosensors	65	42	42
Uscom	19	22	21

\* Biotech Daily editor, David Langsam, owns shares in Acrux, Benitec, Innate, Mesoblast, Nanosonics, Neuren, Patrys, Polynovo, Prana, Telix, Volpara and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in a range of other biotechnology companies: <http://www.australianethical.com.au/who-we-invest-in>. These holdings are liable to change.

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