

Biotech Daily

Friday November 1, 2019

Daily news on ASX-listed biotechnology companies

- * 12-MONTH BDI-40 UP 104%, ASX200 14%, BIG CAPS 37%; CANNABIS CRASH
- * TODAY: ASX, BIOTECH FLAT: ONCOSIL UP 33%; PRESCIENT DOWN 16%
- * DR BOREHAM'S CRUCIBLE: PAINCHEK
- * CORRECTION: NEUREN PHARMACEUTICALS
- * 4DX: 'XV BEATS PFT, CT FOR LUNG HEALTH'
- * RAMACIOTTI \$2m GRANTS FOR BIOMEDICAL RESEARCH
- * AUSBIOTECH: ATMO WINS BIOCURATE \$7k FOR GAS-SENSING
- * NOVITA: 4 US CPT INSURANCE CODES FOR TALI TRAIN
- * MEDADVISOR: KINGS TRANSPORT TO DELIVER DRUGS
- * REGENEUS HAS TWO QUARTERS CASH
- * ESENSE: E-QUITS ORDERS 5L, \$18k MARIJUANA TERPENES
- * DISGRACED CHRIS COLLINS TRANSFERS 6% AMPLIA SHARES TO WIFE MARY
- * MERCHANT FUNDS TAKES 13% OF AUSCANN
- * ALCIDION CAPITAL RAISING TRADING HALT
- * EMVISON CAPITAL RAISING TRADING HALT
- * OBJ REQUESTS MATERIAL ACQUISITION TRADING HALT
- * CRESO REQUESTS PHARMACIELO ACQUISITION TRADING HALT

MARKET REPORT

The Australian stock market edged up 0.09 percent on Friday November 1, 2019, with the ASX200 up 5.7 points to 6,669.1 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and two were untraded. All three Big Caps were up.

Oncosil was the best, up 3.5 cents or 33.3 percent to 14 cents with 17.9 million shares traded. Osprey climbed 13.2 percent; LBT was up 9.8 percent; Avita rose 8.4 percent; Neuren improved 5.7 percent; Polynovo and Resonance were up four percent or more; Ellex, Genetic Signatures, Starpharma and Universal Biosensors rose more than two percent; Cochlear, CSL, Medical Developments and Resmed were up more than one percent; with Clinuvel, Cynata and Volpara up by less than one percent.

Prescient led the falls, down 0.9 cents or 15.8 percent to 4.8 cents, with eight million shares traded. Next Science lost 12.2 percent; Impedimed and Pro Medicus shed more than seven percent; Kazia, Opthea, Paradigm and Uscom fell four percent or more; Alterity, Proteomics and Telix were down more than three percent; Imugene shed 2.1 percent; Orthocell lost 1.55 percent; with Compumedics, Mesoblast and Nanosonics down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) has leapt 103.5 percent in the 12 months to October 31, 2019, the greatest leap forward in the 13 years of the index.

The benchmark ASX200 improved 14.3 percent for the 12-months, but the collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) rose a very significant 36.5 percent to \$159,000 million.

The Nasdaq Biotechnology Index (NBI) finally showed signs of recovery, up 7.7 percent for the month of October and 2.9 percent for the year to October 31.

For the month of October, the ASX200 fell 0.4 percent, the BDI-40 was up 3.4 percent; and the Big Caps rose 8.5 percent.

In October, the market cap of The Magic Pudding*, trading as CSL Limited, was up a further \$10.1 billion or 9.6 percent to a record \$116,204 million, followed by Resmed up 7.3 percent to a record \$30,565 million and Cochlear up 1.7 percent to a record \$12,231 million.

While Mesoblast has slipped from the BDI-40 Billion Dollar Club, Nanosonics has joined the Two Billion Dollar Club.

Twenty-four of the BDI-40 stocks were up, with 13 up by more than 10 percent, while 12 companies fell, with eight down by more than 10 percent. Four were unchanged.

From a low base, Actinogen recovered 270 percent to \$27 million on good trial data, LBT was up 92 percent to \$48 million on its first European sale, followed by Orthocell (61.3%), Oncosil (61.0%), Antisense (27.3%), Clinuvel (23.7%), Immutep (22.5%), Compumedics (16.5%), Medical Developments (16.0%) and Neuren (13.4%).

Kazia led the falls down 22.9 percent to \$27 million followed by Impedimed (22.0%), Osprey (20.0%), Cynata (18.8%), Next Science (17.4%), Patrys (13.0%), Universal Biosensors (11.4%) and Mesoblast (10.2%).

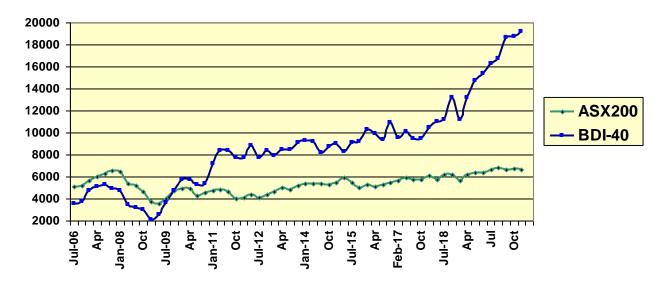
The 18 companies in Cannabis Corner tumbled 29.4 percent in October, down 42.3 percent from the July 31 high of \$1,913 million to \$1,103 million today. Thirteen companies fell, three were unchanged and just Palla Pharma (Tasmanian Poppy Industries) and the re-born Australian Primary Hemp (Alchemia) improved.

Botanix led the falls, down \$135 million or 56.0 percent on its failed acne trial, with investors working out that "inflammatory lesions" meant whitehead pimples, and the synthetic cannabinoid compound was no better than placebo. Althea lost 48.3 percent followed by Creso (46.6%), Cann Group (35.9%), Bod (32.5%), Cann Global (26.7%), Elixinol (25.7%), Zelda (21.9%) and Auscann (21.6%).

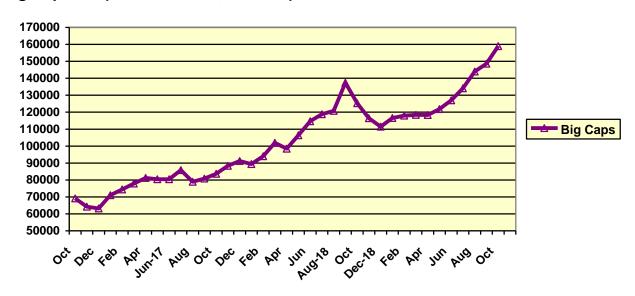
In the US, Eyepoint (Psivida) was up 22.5 percent to \$348 million, Israel's Redhill with Australian assets was up 15.9 percent to \$343 million and Queensland's Protagonist was up 9.6 percent to \$512 million.

* Norman Lindsay, 1918, Harper Collins

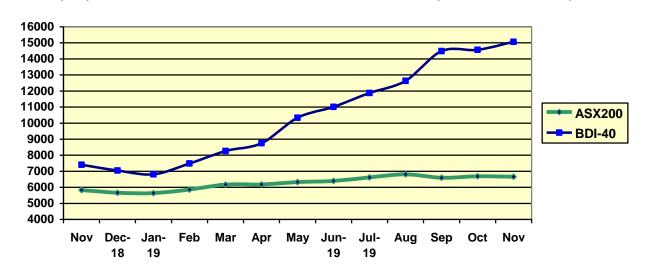
BDI-40 v ASX200 Jun 30, 2006 to Oct 31, 2019- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Oct 31, 2016 - Oct 31, 2019



BDI-40 (\$m) v S&P ASX 200 - Oct 31, 2018 - Oct 31, 2019 (current, raw data)



DR BOREHAM'S CRUCIBLE: PAINCHEK

By TIM BOREHAM

ASX code: PCK

Share price: 24 cents; Shares on issue: 945,324,245; Market cap: \$212.7 million

Chief executive officer: Philip Daffas

Board: John Murray (chairman), Philip Daffas, Adam Davey, Ross Harricks

Financials (year to June 30 2019): revenue \$215,464 (up 325%), loss of \$3.26 million (previous deficit of \$4.81 million), cash of \$4.56m (up 26%)

Also received a \$745,258 research and development tax rebate

Identifiable major holders: Peters Investments 10.4%, J&E Consulting 4%, Kreshnik Hoti 4%, Mustafa Abdul Wahed Atee 4%.

In a submission to the ongoing aged care royal commission, Queen of Pain Prof Jennifer Abbey presented a harrowing case study of a resident with a gangrenous-looking foot.

We'll spare you the pic that was provided.

The Adelaide professor of nursing and dementia specialist noted that while the resident spent most of her day screaming, visiting doctors believed her foot was 'dead' and could feel no pain.

Instead, they attributed the screaming to a loss of cognitive ability resulting from dementia and prescribed anti-psychotics.

"I recorded a 12-week battle between staff, doctor and family over whether she should instead receive pain relief such as morphine," she writes.

"That prompted me to devise a pain scale [the Abbey Pain Scale] now translated into about six other languages and thoroughly tested by the Australian Pain Society."

But the submission was far from an advert for her self-titled measuring stick, as she acknowledges pain scales have limited utility when the patient cannot verbalize their discomfort.

At the coal face of aged care, staff do not use the scale consistently - if at all - meaning there is no recording of patterns over time.

In this context, Painchek has been making huge and painless strides since rolling out its eponymous pain-measurement device in October 2017.

The smart-phone-based device assesses and scores pain levels in real time and then uploads the results to the internet 'cloud'.

The score is based on 42 checkpoints across six domains including facial expression, behavior, body movements and, when possible, vocalization.

Nine checks relate to the face, while the other 33 are assessed by way of a binary 'yes-no' checklist. The pain is assessed on a 42-point scale, zero to seven being little or no pain and anything over 16 being ... 'just shoot me'.

An adviser to Painchek, Dr Abbey says the ability to upload the results at the point-of-care directly to patient records is a "great advantage".

Painchek's purple patch

Painchek has been enjoying a pain-free purple patch since then Minister for Senior Australians and Aged Care Ken Wyatt announced a \$5 million trial of the device in April.

By that time the Coalition was in caretaker mode ahead of the May 18 election which, of course, it won, with Mr Wyatt replaced by Senator Richard Colbeck.

But the measure had a long gestation time and was executed at departmental level, so didn't fall into the arbitrary election promise category.

In any event, Painchek CEO Philip Daffas describes the program as a "big tick" for Painchek, given the Department did extensive due diligence.

The funding extends a Painchek licence to more than 1,000 residential facilities and 100,000 residents for one year.

In the June quarter, the company quadrupled its local penetration, increasing the number of contracted beds from 2,542 to 10,590 and the number of facilities from 34 to 142.

This growth excludes the government-funded trial, which is expected to start by the end of the year and is being delivered via a tie-up with aged-care service provider Ward Medication Management.

Client sign-ups include Churches of Christ in Queensland (28 facilities), the Baptist Union of Queensland - Carinity (11 facilities) and IRT Aged Care services (20 facilities).

An existing customer, Allity, agreed to increase the coverage of Painchek to 42 facilities, covering 3,620 beds.

Pain of course is a global phenomenon and the company is eyeing offshore markets.

In August, Singapore's Health Sciences Authority approved the use of the devices in the Lion City, with Painchek also signing a deal with premium nursing home provider Allium Healthcare.

In England, the company has struck a distribution agreement with Person Centred Software, which provides 'care management' systems to 1,200 providers covering 40,000 residents.

"I'm confident that UK sales will come on very, very quickly," Mr Daffas says.

Undeterred by the Brexit imbroglio, the company is setting up a London office as a base for pan-European expansion.

Painchek is approved by the local and European regulators, with US approval pending.

What about the kids?

At the other end of the chain of life, the infant market (kids three years and under) presents an even bigger opportunity because globally there are 400 million of them.

Under-threes might bawl like banshees, but it's hard to tell whether they're in pain or merely hungry or teething (or taking perverse delight in driving mummy and daddy around the bend).

In July, Painchek said it had partnered with Melbourne's Murdoch Children's Research Institute to assess the Painchek application for infants.

Called Painfaces, the study will compare Painchek-derived pain scores with those using observational pain assessment tools. Overseen by two independent assessors, the study will cover 100 children undergoing painful procedures at the Royal Children's Hospital emergency department.

The research will support Painchek applications for regulatory approval for child indications in the US, Europe and here.

Financials and performance

Painchek recorded a 325 percent revenue boost to \$215,464 in the year to June, with a loss of \$3.62 million (narrowed from \$4.81 million).

Painchek also recorded 'receipts' of \$35,000 in the June quarter, but with cloud-based subscription models the better measurement is annual recurring revenue, or ARR.

As of June 30, ARR stood at \$234,000 across 3,564 licenced beds. But with 7,000 beds signed up and due to be implemented this quarter, rolling ARR is now more like \$586,000.

"There has been zero churn of contracts over the last two years," Mr Daffas says.

Management is not silly enough to forecast profitability but says local take-up of 30,000-35,000 beds would be enough to get to breakeven. The government contract, if renewed, easily would blow the company over this threshold.

Painchek's cash has been bolstered by a two-tranche placement that raised \$4.15 million, at 14.5 cents apiece. Painchek shares have been an absolute howler, surging from 3.0 cents in late April to a high of 35.5 cents on September 19.

Painless evolution

For those who like a dollop of history, Painchek emerged from a research project at Curtin University, led by Prof Jeff Hughes and his PhD student Mustafa Atee.

The duo founded Epat Pty Ltd (as in Electronic Pain Assessment Technologies) as an inhouse venture, with Epat back-door listing in September 2016.

In early 2017, Painchek acquired the global pain assessment rights to the pertinent facial recognition from Swiss artificial intelligence leader Nviso. After a shareholder vote, Epat became Painchek on January 22 this year.

Prof Hughes remains as Painchek's chief scientific officer, while Atee is a senior clinical research officer.

Dr Boreham's diagnosis:

Mr Daffas has a simple vision for Painchek: "It will be like a thermometer, available everywhere and used as needed. Pain is almost like another vital sign."

A product called the Neurofen Fever Smart application monitors temperature via a patch, so you can see where the whole connected care game is heading. While Painchek has been focused on winning aged care facility contracts, the software is also relevant for home care.

"Aged care is not the care it used to be," Mr Daffas says. "People are being encouraged to stay home longer ... so you have to give careers the right tools to let them do their job."

Daffas says about 80 percent of 220,000 aged care residents in Australia are in some sort of pain but many can't communicate. Half of them suffer dementia, while 10 percent to 30 percent of hospital beds are taken up by patients living with dementia.

"But we will go global and keep expanding," Mr Daffas says. "It's what our shareholders expect."

Given we're living in a world of pain, Painchek is proving to be on a winner and so far, at least, it has avoided the setbacks of other ASX-listed application-based healthcare developers Respiri (asthma) and Resapp (respiratory disease).

Prof Abbey says it will still be imperative to educate staff about "differentiating pain from distress or the outpourings of unspeakable anguish that late-stage dementia appears to bring with it".

In your columnist's ever-humble view, Painchek is onto a winner but perhaps, just perhaps, a \$170 million market valuation takes care of the upside for now.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He often experiences a pain in the neck in his working day, but rest assured it's nothing physical.

CORRECTION: NEUREN PHARMACEUTICALS

Last night's edition reported that Neuren's North American licencee Acadia

Pharmaceuticals had begun its 180-patient, phase III trial of trofinetide for Rett syndrome.

The report incorrectly referred to a previous report in February saying the trial would begin by July 2019, when the company said it would begin "in the second half of 2019" meaning by the end of the year, and not by July.

Neuren and Acadia are ahead of schedule, not behind as implied by the incorrect report. Biotech Daily uses specific months to detail time lines, eschewing the vagaries of "quarters" and "halves", as they can be especially confusing when companies mix calendar and financial years.

In this case, the February sub-editor made a complete hash of it, has been retrospectively dismissed and will not be invited to the end-of-year Christmas Party.

We apologise unreservedly for the error.

Neuren was up 13 cents or 5.7 percent to \$2.42.

4DX LIMITED

4DX says a 32-patient, 13-month study shows that its XV technology is superior to "gold standard pulmonary diagnostics" to measure lung health.

4DX said the study, titled 'Novel x-ray velocimetry based quantitative regional lung function analysis to assess risk of radiation-induced pneumonitis and pulmonary fibrosis', was published in the journal Chest, with an abstract available at:

https://journal.chestnet.org/article/S0012-3692(19)31813-6/fulltext.

4DX said the results were presented by principal investigator Dr Stephen Shiao at the American College of Chest Physicians meeting in New Orleans on October 22, 2019. The company said the trial compared XV Technology to pulmonary function tests (PFT) at four time points and to computed tomography (CT) tests at one time point 4DX said it found that XV had "excellent" reliability and repeatability and correlated with PFT and CT tests.

The company said both ventilation heterogeneity and ventilation defect percent of XV were statistically significant when correlated with forced expiratory volume in one second (FEV1) and forced vital capacity.

4DX said XV was superior to PFT and CT tests in detecting and locating loss of lung function either as a result of disease or as part of off-target effects of treatment. The company said XV's increased sensitivity and richer data resulted in increased predictive power, greater certainty than PFT testing and the identification of subtle changes not reflected in PFT data.

4DX said clinicians "unanimously agreed" that XV report data was "clinically meaningful" over CT and PFT data following the results of the trial and an expert clinical panel, which reviewed XV.

4DX chief executive officer and co-author of the article Dr Andreas Fouras said that "exhaustive laboratory testing over the past 10 years has shown the capabilities of XV Technology, and it is extremely exciting to see the same capability borne out in a clinical trial".

4DX said the results would be incorporated into its 510(k) application to the US Food and Drug Administration for market clearance, which it expected to lodge by the end of 2019. The company said it submitted a pre-submission enquiry with the FDA for XV in 2018. 4DX is a public unlisted company.

RAMACIOTTI FOUNDATIONS

The Ramaciotti Foundations have provided more than \$2 million through its biennial Biomedical Research Award, Medal for Excellence and Health Investment Grants. A media release from Perpetual Trustees, which manages the Foundations, said the \$1 million Biomedical Research Award went to Darwin's Menzies School of Health Research's Prof Heidi Smith-Vaughn to help build the Ramaciotti Centre for regional and remote biomedical capabilities, which would "provide previously unimagined opportunities for regional and remote youth".

Perpetual said the South Australian Health and Medical Research Institute's Prof Tim Hughes won the \$50,000 Ramaciotti Medal for Excellence for his development and refinement of a kinase inhibitor therapy for chronic myeloid leukemia.

Perpetual said eight researchers received up to \$150,000 in grants.

AUSBIOTECH, BIOCURATE, ATMO BIOSCIENCES

Ausbiotech says Biocurate has awarded Atmo Biosciences with \$7,000 as recognition for the best presenting team at the Ausbiotech 2019 conference pitching event. Ausbiotech said Atmo's ingestible gas-sensing capsule technology, the Atmo Gas Capsule was developed at the Royal Melbourne Institute of Technology, Monash University and Alfred Health and detected gaseous biomarkers in the gut and transmitted the data wirelessly to deliver the right therapy to each patient.

Ausbiotech said Atmo was the best six-minute pitch at the Early Stage Investment Forum.

NOVITA HEALTHCARE

Novita says its Tali Train digital attention deficit learning and training program has further approvals for US reimbursement by the American Medical Association.

Novita said the current procedural terminology (CPT) codes would allow insurance reimbursements for Tali Train for up to \$US235.70 (\$A341.59).

Novita managing-director Glenn Smith said Tali Train was the "only approved early childhood digital cognitive assessment and training program ... with all development and compliance requirements achieved".

Novita was up 3.2 cents or 55.2 percent to nine cents with 682.7 million shares traded.

MEDADVISOR

Medadvisor says it has an agreement with Kings Transport to offer same-day delivery of medications to its network of 3,300 pharmacies' patients.

Medadvisor was unchanged at 4.8 cents with 1.2 million shares traded.

REGENEUS

Regeneus says it had cash at September 30 of \$1,012,000 and expected to spend \$730,000 for the three months to December 31, 2019.

Regeneus told an ASX query that costs were being reduced to about \$250 a month and it was hoping to place shortfall shares worth about \$755,000 and consider a further loan against an expected Federal Research and Development Tax Incentive.

The company said it was finalizing a commercial licensing deal for Progenza and completing a phase II trial for osteoarthritis.

Regeneus fell 0.3 cents or 3.85 percent to 7.5 cents.

ESENSE LAB

Esense says it has signed an additional order for five litres of marijuana terpenes, worth \$US12,500 (\$A18,095), under its UK E-Quits Group supply agreement. Esense was unchanged at 1.4 cents.

AMPLIA THERAPEUTICS (FORMERLY INNATE IMMUNOTHERAPEUTICS)

Former Innate director and US Republican congressman Christopher Collins says he has transferred his 3,329,570 shares (6.26%) to his wife.

Last month, Mr Collins pleaded guilty to insider trading charges and resigned from the US House of Representatives (BD: Oct 2, 2019).

Today, the New York-based Mr Collins said that on June 20, 2018 he sold 60,344 shares on market, on September 26, 2019 he sold 400,000 shares on market and on October 1, 2019 he transferred all 3,329,570 shares off-market to his wife Mary Collins. Amplia was unchanged at eight cents.

AUSCANN GROUP HOLDINGS

Merchant Funds Management says it has increased its substantial shareholding in Ausann from 39,400,000 shares (12.43%) to 42,570,578 shares (13.43%).

The Perth, Western Australia-based Merchant said that between October 18 and 31, 2019 it bought 3,170,578 shares for \$858,748 or an average of 27.1 cents a share.

Auscann fell half a cent or 1.8 percent to 27 cents.

ALCIDION GROUP

Alcidion has requested a trading halt "pending an announcement by the company to the market regarding a capital raising".

Trading will resume on November 5, 2019 or on an earlier announcement.

Alcidion last traded at 20.5 cents.

EMVISION MEDICAL DEVICES

Emvision has requested a trading halt "pending an announcement regarding a proposed capital raising".

Trading will resume on November 5, 2019 or on an earlier announcement.

Emvision last traded at 85 cents.

OBJ

OBJ has requested a trading halt pending a material acquisition announcement.

Trading will resume on November 5, 2019 or on an earlier announcement.

OBJ last traded at 1.5 cents.

CRESO PHARMA

Creso Pharma says it has requested a trading halt "pending an announcement regarding the proposed acquisition of the company by Pharmacielo" (BD: Jun 7, 2019).

Trading will resume on November 5, 2019 or on an earlier announcement.

Creso last traded at 20 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT OCTOBER 31, 2019

Company \$Am	Nov-18	Oct-19	Nov-19
Cochlear	10,249	12,032	12,231
CSL	85,156	106,061	116,204
Resmed	21,089	28,487	30,565
BDI-20			
Avita	125	1,105	1,114
Clinuvel	766	1,209	1,496
Compumedics	64	109	127
Cyclopharm	72	79	80
Cynata	107	165	134
Ellex	93	79	82
Genetic Signatures	59	108	102
Immutep	126	89	109
Medical Developments	316	331	384
Mesoblast	990	1,067	958
Nanosonics	899	1,895	2,042
Neuren	126	202	229
Opthea	134	838	876
Paradigm	107	555	572
Pharmaxis	108	75	79
Polynovo	388	1,415	1,494
Pro Medicus	945	2,893	2,772
Starpharma	542	427	432
Telix	178	398	415
Volpara	245	358	403
Second 20			
Actinogen	52	10	37
Alterity (Prana)	24	25	23
Amplia (Innate)	11	4	4
Antisense	15	33	42
Dimerix	17	15	17
Impedimed	152	91	71
Imugene	72	76	85
Kazia	21	35	27
LBT Innovations	20	25	48
Next Science	168	530	438
Oncosil	123	41	66
Optiscan	24	22	19
Orthocell	20	62	100
Osprey	54	20	16
Patrys	34	23	20
Prescient	19	21	22
Proteomics	19	26 52	26 53
Resonance	12	53 25	53 21
Universal Biosensors Uscom	42 19	35 17	31 17
OSCOTI	19	17	17

^{*} Biotech Daily editor, David Langsam, owns shares in Acrux, Amplia, Benitec, 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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