Biotech Daily

Monday July 3, 2017

Daily news on ASX-listed biotechnology companies

*** 10-YEAR BDI-40 UP 80%, ASX200 DOWN 9%, BIG CAPS UP 270%**

- Sirtex Up 336%; Mesoblast 311%, Starpharma 302%; Pharmaxis Down 87%, Acrux 86%

*** YTD: BDI-40 UP 3%, ASX200 9%, BIG CAPS 23%, NBI 21%**

*** JUNE BDI-40 UP 3%, ASX200 FLAT, BIG CAPS UP 7%, NBI 9%**

*** TODAY: ASX DOWN, BIOTECH UP: PRANA UP 16%, LIVING CELL DOWN 9%**

*** OSPREY LAUNCHES DYETECT FOR NON-KIDNEY-FAILURE PATIENTS**

*** INVITROCUE RAISES $685k FOR GARVAN CANCER DRUG TESTING**

*** PRANA PREPARES FOR PHASE I PBT434 FOR PARKINSON'S**

*** BOTANIX 'TOPICAL CANNABIDIOL BTX1503 SAFE FOR ACNE TRIAL'**

*** CELLMID: 'MIDKINE CRUCIAL FOR MELANOMA METASTASIS' IN MICE**

*** BARD1 REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** NOVITA READIES TALI TRAIN FOR ATTENTION DEFICIT TRIAL**

*** PENGANA (HUNTER HALL) REDUCES TO 12% IN AVITA**

*** THORNEY TAKES 15.5% OF OVENTUS**

*** PSIVIDA APPOINTS KRISTINE PETERSON DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.65 percent on Monday July 3, 2017 with the ASX200 down 37.0 points to 5,684.5 points. Eighteen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and three were untraded.

Prana was the best, up 0.8 cents or 15.7 percent to 5.9 cents with 1.0 million shares traded. Dimerix climbed 10 percent; Cellmid was up eight percent; Mesoblast improved 7.2 percent; Impedimed and Osprey rose five percent or more; Acrux, Factor Therapeutics and Pharmaxis were up four percent or more; Oncosil, Opthea and Polynovo rose two percent or more; Admedus, Medical Developments, Neuren and Universal Biosensors were up more than one percent; with Airxpanders, Nanosonics and Resmed up by less than one percent.

Living Cell led the falls, down one cent or 9.1 percent to 10 cents with 375,065 shares traded. Compumedics retreated 7.9 percent; Prima lost 3.6 percent; CSL shed two percent; Bionomics, Cochlear, ITL, Pro Medicus and Viralytics were down more than one percent; with Ellex, Clinuvel and Sirtex down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

For the 10 years to June 30, 2017, the Biotech Daily Top 40 Index (BDI-40) climbed 79.6 percent compared to the ASX200 down 8.8 percent, with the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) up 270.4 percent

The 11-year data shows the significance of specific time points, with the BDI-40 up 166.6 percent, the ASX200 up 12.8 percent and the three Big Caps up 400.1 percent,

The conclusion is inescapable: the benchmark index of the Top 200 ASX-listed companies is lacklustre, while the BDI-40 is up significantly and the Big Caps are little short of a Magic Pudding (see charts below).

The Big Caps were up 22.7 percent for the year to June 30 and 6.6 percent for the month.

Of the 40 companies composing the BDI-40 at June 30, 2007, 14 remain, with six successfully acquired, nine demoted and 11 departed, delisted or otherwise extinct.

For the 10 years to June 30, 2017, Sirtex was the best, up 336.3 percent from a market capitalization of $215 million to $938 million, followed by Mesoblast (311.0%), Starpharma (301.5%), Living Cell (215.0%), Opthea/Circadian (194.1%), Factor Therapeutics/Tissue Therapies (150.0%), Neuren (159.6%) and Bionomics (144.3%).

The few that have fallen over the 10 years but have remained in the BDI-40 were led by Pharmaxis tumbling 86.6 percent from $596 million 10 years ago to $80 million, followed by Acrux (85.7%), Prana (43.75%), Benitec (29.7%) and Psivida (6.1%).

Twenty of the BDI-40 companies were up for the year to June 30, with 19 down and one unchanged. Osprey was the most improved from a low base, recovering 202.9 percent from $34 million to $103 million, followed by Mesoblast also recovering 117.1 percent, LBT (111.7%), Opthea (102.7%) and Benitec (85.7%).

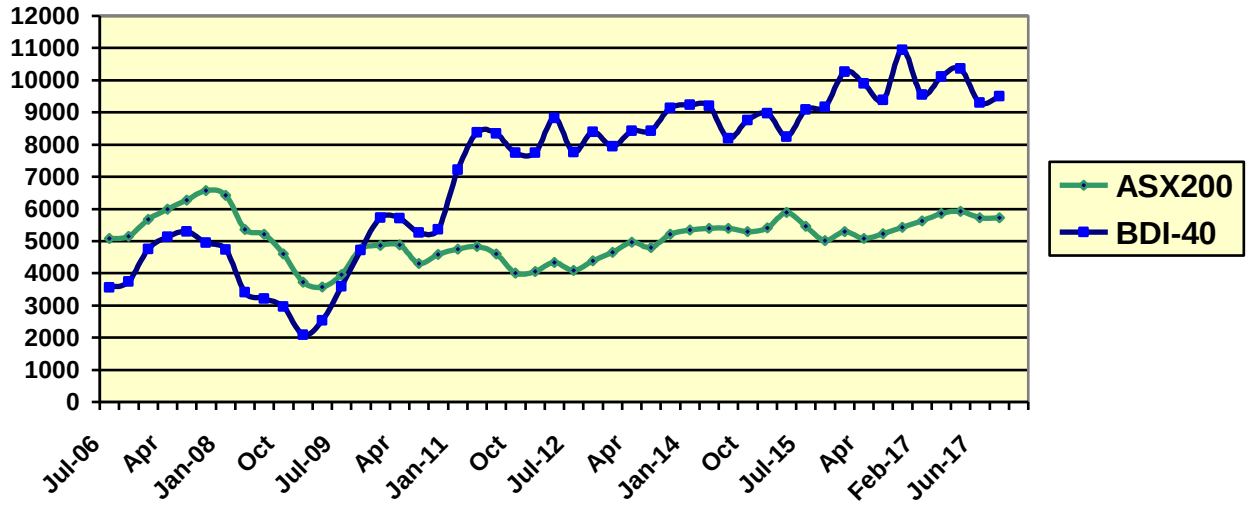
The 12-month falls were led by Acrux falling a further 70.0 percent from $120 million to $36 million, Atcor (68.0%), Prana (49.1%), Sirtex (35.9%) and Psivida (33.1%).
Outside the BDI-40, the most notable improvements for the year were Optiscan from a low base of $4 million, up 825 percent to $37 million, followed by Phylogica (250.0%), GI Dynamics (209.1%), Cynata (139.1%), Medlab Clinical (127.0%) and Imugene (121.4%).

The dual listed Unilife has all but disappeared, down 93.0 percent for the year to June 30, followed by Innate down 82.1 percent for the year and 91.6 percent for the month.
Adherium was down 69.0 percent for the year, followed by Biotron (57.9%), Anteo (57.1%), Genetic Technologies (48.5%), IDT (46.9%) and OBJ (44.4%).

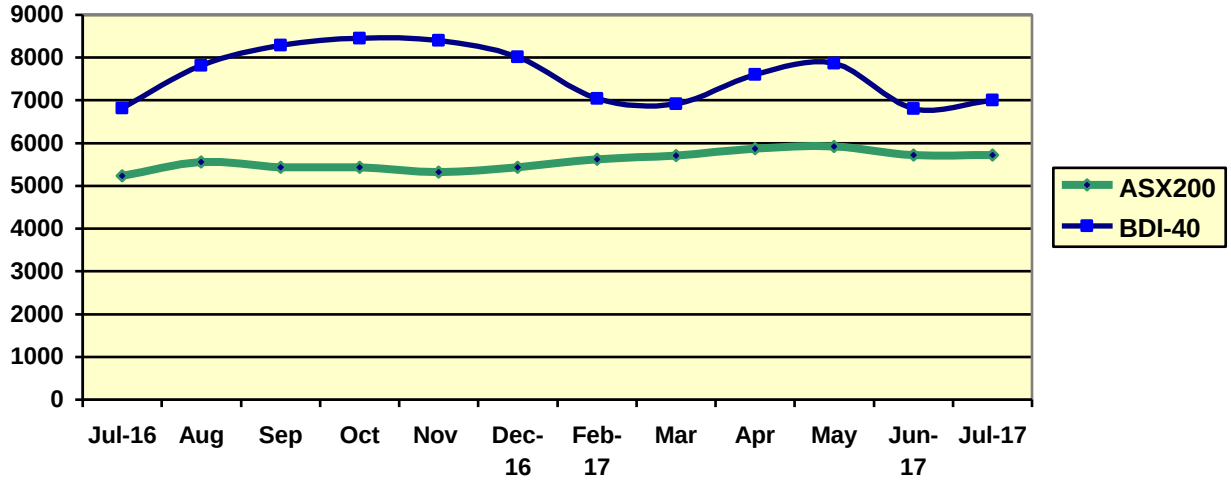
The June BDI-40 was marked by mainly small rises and falls, with Compumedics the best, up 64.7 percent to $112 million, followed by Sirtex (35.5%), Impedimed (24.7%), Dimerix (20.0%) and Universal Biosensors (15.9%).

The June falls were led by Psivida, down 23.1 percent to $93 million, down 6.1 percent from the $99 million of 10 years ago, followed by Benitec (16.1%), Acrux (14.3%), Oncosil (13.0%) and Viralytics (12.1%).

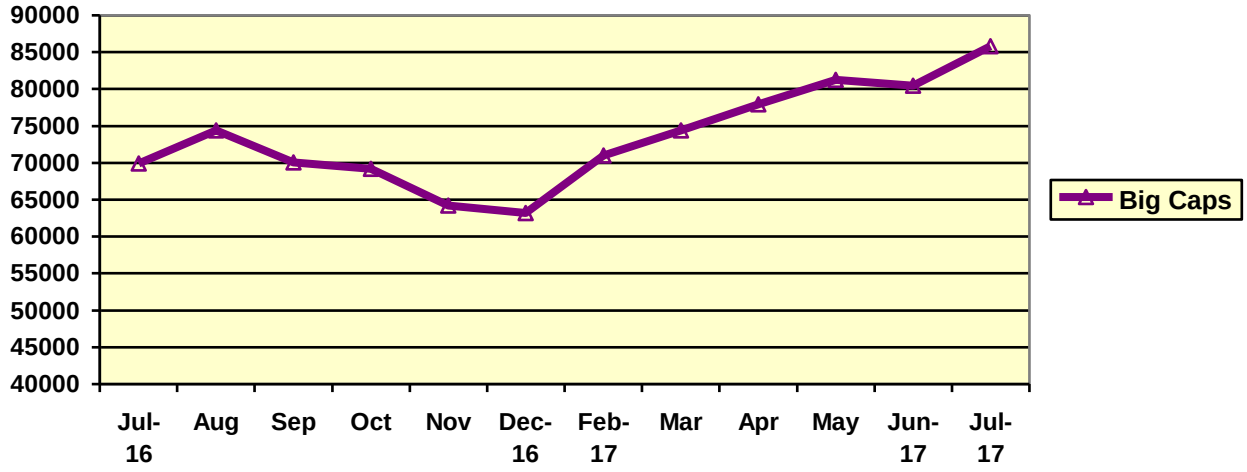
BDI-40 v ASX200 Jun 30, 2006 to June 30, 2017- Adjusted



BDI-40 ($m) v S&P ASX 200 – June 30, 2016 – June 30, 2017



Big Caps $m (Cochlear, CSL, Resmed) June 30, 2016 – June 30, 2017



OSPREY MEDICAL

Osprey says its Dyetect automated contrast monitoring system has been approved in Europe and the US, expanding its addressable market by 40 percent.

Osprey said the Dyetect system had Conformité Européenne (CE) mark and US Food and Drug Administration 510k approval, had its first clinical use at the University of Michigan Health System and the University Health System in Texas, with commercial release expected by the end of 2017.

The company said that Dyetect incorporated technologies from the Dyevert Plus system "and more than doubles the number of patients who can benefit from Osprey's portfolio of kidney protection devices".

Osprey said the Dyetect system was intended for non-chronic kidney disease heart patients and would continue to sell the Dyevert Plus for patients with poor kidney function where dye minimization was recommended.

The company said that Dyetect was targeted for patients without chronic kidney disease, as it did not minimize the amount of dye used.

Osprey said that patients with chronic kidney disease needed Dyevert Plus because it reduced the amount of dye indicated for patients with compromised kidneys.

The company said that the addressable market for Dyetect was 3.5 million procedures a year in the US and Western Europe and the list price for the consumable components was expected to be $US149 ($A193.90) per procedure making the addressable market worth about $US526 million a year.

Osprey said the total addressable market for its product portfolio was expected to be 6.7 million procedures per year, or a $US1.8 billion a year market opportunity.

Osprey's chief executive officer Mike McCormick said that the development of Dyetect was "a direct response to customer requests for the benefits of Dyevert Plus contrast monitoring for non-chronic kidney disease patients".

"This exciting new product increases our addressable market and further supports our long-term company vision: to lower kidney damage in all heart imaging procedures," Mr McCormick said.

Osprey was up two cents or five percent to 42 cents.

INVITROCUE, GARVAN INSTITUTE OF MEDICAL RESEARCH

Invitrocue says it has raised $685,087 and has approval for a Garvan Institute of Medical Research study to validate its personalized cancer drug screening.

Invitrocue said that Sydney's St Vincent's Hospital human research ethics committee had approved the trial of its oncology patient-derived organoid technology and followed a collaboration agreement with the Garvan (BD: Feb 23, 2017).

The company said that clinical trials would evaluate the potential of patient-derived organoids for testing potential anti-cancer therapies before their administration.

Invitrocue said it had raised $685,087 through a private placement of 8,563,583 shares at eight cents and 2,057,563 options exercisable at eight cents within one year to fund development of the Onco-PDO business and for working capital.

Invitrocue executive director Dr Steven Fang said the ethics approval was a "milestone [which] allows us to advance our engagement further and explore the potential of our technology in determining the right treatment for each patient, at the right time".

"Ultimately, we will work towards having Invitrocue technology as a clinical service, improving patient outcomes with a more personalized approach to the treatment of cancer," Dr Fang said.

Invitrocue was up one cent or 16.7 percent to seven cents with 1.2 million shares traded.

PRANA BIOTECHNOLOGY

Prana says it hopes to begin a phase I human safety trial of PBT434 for Parkinson's disease this year.

Prana said that in-vitro and in-vivo pre-clinical research showed that PBT434 prevented: the formation of toxic alpha synuclein fibrils, the formation of insoluble alpha synuclein in animals and alpha synuclein mediated oxidative stress that induced cell death.

The company said that PBT434 protected against cell death and preserved neuronal circuitry in mouse models of Parkinson's disease, improved motor behavior in Parkinson's disease mouse models and normalized brain iron distribution.

In previous announcements, Prana has noted the impact of PBT434 in models of Parkinson's disease (Mar 16, 2011; Aug 30, 2012; Mar 6, Jun 20, 2013; Mar 30, 2017).

Today, the company said that research, entitled 'The novel compound PBT434 prevents iron-mediated neurodegeneration and alpha-synuclein toxicity in multiple models of Parkinson's disease' had been accepted for publication in the journal Acta Neuropathologica Communications and an abstract was available at: https://actaneurocomms.biomedcentral.com/articles/10.1186/s40478-017-0456-2.

Prana said the publication was "the culmination of 10 years of research" at Melbourne's Florey Institute of Neuroscience Health investigating compounds from its library.

The company said that PBT434 was "the first of a new generation of small molecules from the quinazolinone class of drugs that was specifically designed to block the accumulation and aggregation of alpha-synuclein, … [a] brain protein widely believed to be involved in the pathogenesis of Parkinson's disease and related disorders".

"Not only was PBT434 shown to block alpha-synuclein accumulation, but it also prevented loss of nerve cells in the region of the brain primarily affected in Parkinson's disease, called the substantia nigra," Prana said.

Prana said that if the findings were observed in patients with diseases caused by alpha-synuclein, PBT434 could address a significant unmet need in preventing progression.

Prana chief medical officer Dr David Stamler said that an agent which slowed disease progression could have a great impact on reducing disease burden and quality of life.

Prana was up 0.8 cents or 15.7 percent to 5.9 cents with 1.0 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says its 20-patient, open-label, phase I study of BTX1503 for acne showed "an excellent safety profile, with little to no skin irritation and no severe adverse events".

Botanix said that the safety, tolerability and pharmacokinetic study used topical cannabidiol BTX1503 solution as a single dose either once or twice on day-1 followed by a washout period, then starting on day-8, either once or twice daily for 14 days.

The company said the study showed that its Permetrex delivery technology ensured that majority of BTX1503 was delivered across the outer layer of the skin and into skin tissue, with only small amounts of drug being delivered into systemic circulation.

Botanix said it would take BTX1503 into a follow up phase Ib acne patient pilot study, to begin by October 2017, subject to ethics approval.

Botanix executive director Matt Callahan said the company was "pleased with the safety and tolerability profile of BTX1503, which for dermatology products, is often a significant hurdle to further development and commercialization".

The company said the study achieved its primary objective of identifying a safe dose for further clinical development, but did not disclose the dose.

Botanix was unchanged at 4.3 cents with 4.2 million shares traded.

CELLMID

Cellmid says a Spanish mouse study shows that midkine “is a crucial agent in the promotion of melanoma metastasis”.
Cellmid said that the paper, entitled ‘Whole-body imaging of lymphovascular niches identifies premetastatic roles of midkine’, by Prof Marisol Soengas and her group at Madrid’s Centro Nacional de Investigaciones Oncológicas (Spanish National Cancer Research Centre) was published in Nature, with an abstract available at: https://www.nature.com/nature/journal/v546/n7660/full/nature22977.html.
The company said that the article described how midkine drove the often-fatal metastatic spread of melanoma cells from the primary tumor in the skin to distant organs such as liver, lung, bone and brain.
Cellmid said the study was “highly significant” because it provided “strong validation for [its] cancer therapeutic and diagnostic programs”, added to the data on the prognostic value of detecting midkine in different cancer types, where elevated midkine levels in various tissues corresponded with poor therapeutic outcomes, significantly increased visibility and credibility of the cancer therapeutic programs targeting midkine and the company held “the most significant intellectual property and antibody assets around midkine” placing it “in a unique position for partnerships”.
Cellmid said its midkine antibodies had shown promise in reducing tumor growth and restricting new blood supply to different solid tumors (BD: Oct 3, 2013; Oct 5, 2016).
The company said the discoveries around metastasis as well as inhibiting midkine for better treatment of melanoma made for “a compelling drug development program”.
Cellmid said that conventional anti-cancer treatments aimed to kill tumor cells, but the ability to stop the spread of metastatic tumor cells “would be of immense benefit for many advanced cancer patients with diverse tumor types”.
The company said that lymphatic vessels were often the escape route for cancer cells to spread initially to lymph nodes, followed by metastasis to more distant organs and the sprouting of new lymphatic vessels from the tumor into surrounding lymph nodes was thought to facilitate the metastatic spread through lymph-angiogenesis.
Cellmid said the Madrid group used a mouse model to demonstrate that the primary tumor induced aberrant lymph-angiogenesis in lymph nodes and organs distant from the tumor, producing a pre-metastatic niche in which tumor cells could lodge.
The company said that midkine released from the tumor was found to stimulate distant lymph-angiogenesis, producing a route for cancer cells to colonize sites throughout the body independent of local spread into lymph nodes adjacent to the primary tumor.
Cellmid said that midkine enhanced the ability of tumor cells to adhere to lymphatic vessels, promoting lymph-angiogenesis and tumor cell colonization in newly formed lymphatic vessels.
The company said that, with previous studies, the findings provided a rationale for its oncology program targeting midkine with therapeutic antibodies.
Cellmid was up 0.2 cents or eight percent to 2.7 cents.

BARD1 LIFE SCIENCES

Bard1 has requested a trading halt “pending an announcement to the market regarding a proposed capital raising that is material to the company”.
Trading will resume on July 5, 2017 or on an earlier announcement.
Bard1 last traded at one cent.

NOVITA HEALTHCARE (FORMERLY AVEXA)

Novita says it has completed a trial roll-out of Tali Train for paediatric attention deficit and finalized a clinical trial of primary school students.

Novita said the roll-out of a beta version of the game-based training technology for attention deficit was through 18 child development clinics and enrolment of a Victorian school in the beta version allowed the company to trial an additional distribution channel.

The company said it had increased user licences to clinics and training courses and had begun the final stage of software development with Grey Innovation and Torus Games and was “on schedule for near-term commercialization”.

Novita said it had received a $50,000 Innovation Connection Grant from the Federal Department of Industry, Innovation and Science to fund Tali research trials.

Novita executive chairman Iain Kirkwood said the company was “encouraged by the strong performance of Tali Train and our progress towards commercialization”.

Novita fell 0.1 cents or 3.45 percent to 2.8 cents with 3.3 million shares traded.

AVITA MEDICAL

The Sydney-based Pengana Capital says it has reduced its holding in Avita from 89,332,147 shares (13.27%) to 82,041,700 shares (12.19%).

A Pengana spokesperson told Biotech Daily that the company was the result of the recent merger of Pengana Capital and Hunter Hall International.

The Pengana substantial shareholder notice said that the Avita shares were held by Pengana Capital, Pengana Capital Group, Hunter Hall Investment Management and Hunter Hall Global Vlaue.

Pengana said it sold shares between May 24 and June 28, 2017, with the single largest sale 1,331,286 shares for $111,108 or 8.3 cents a share.

Avita was unchanged at 7.7 cents.

OVENTUS MEDICAL

Thorney Technologies says it has become a substantial shareholder in Oventus with 13,929,019 shares (15.49%).

The Melbourne-based Thorney said it acquired 9,029,000 shares on June 29, 2017 at 36 cents a share.

The company said that the shares were held by Thorney Technologies, Thorney Investment Group, Tiga Trading Pty Ltd and Jasforce Pty Ltd.

Oventus was up 1.5 cents or 4.55 percent to 34.5 cents.

PSIVIDA CORP

Psivida says it has appointed Kristine Peterson as a director.

Psivida said that Ms Peterson had “extensive pharmaceutical experience” and was Valeritas chief executive officer from 2009 to 2016 and previously Johnson & Johnson’s group chair of biotechnology groups, where she oversaw the research, development, manufacturing and commercialization of oncology, immunology and other therapeutics.

The company said that Ms Peterson had received an initial grant, subject to shareholder approval, of an option to buy 40,000 US shares, which would vest and become exercisable in three equal instalments on the first, second and third anniversaries of grant.

Psivida was untraded at $2.36.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JUNE 30, 2017

Company $Am	**Jul-16**	**Jun-17**	**Jul-17**
Cochlear	6,936	8,418	8,927
CSL	51,323	58,725	62,639
Resmed	11,651	13,342	14,235
BDI-20			
Admedus	64	71	68
Airxpanders	219	228	186
Bionomics	137	173	193
Clinuvel	203	326	333
Compumedics	61	68	112
Ellex	109	121	129
Impedimed	353	227	283
Medical Developments	354	278	292
Mesoblast	410	903	890
Nanosonics	648	840	756
Neuren	94	116	122
Opthea	74	160	150
Pharmaxis	81	85	80
Polynovo	156	124	118
Prima	85	64	58
Pro Medicus	482	534	546
Psivida	139	121	93
Reva	470	377	369
Sirtex	1,464	692	938
Viralytics	235	265	233
Second 20			
Acrux	120	42	36
Actinogen	44	43	38
Atcor	25	9	8
Avita	49	49	49
Benitec	14	31	26
Cellmid	31	27	27
Cyclopharm	58	56	56
Dimerix	10	15	18
Factor Therapeutics	25	46	45
Genetic Signatures	37	41	40
ITL Ltd	15	52	50
LBT Innovations	17	34	36
Living Cell	37	66	63
Oncosil	64	54	47
Orthocell	19	27	27
Osprey	34	93	103
Prana	53	25	27
Starpharma	237	243	269
Universal Biosensors	56	63	73
Uscom	27	21	21

* Biotech Daily editor, David Langsam, owns shares in Acrux, Admedus, Benitec, Mesoblast, Nanosonics, 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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