



Biotech Daily

Friday November 1, 2013

Daily news on ASX-listed biotechnology companies

- * **OCTOBER BDI-40 UP 2.5%, ASX200 UP 4%; BIG CAPS UP 5%**
 - **ALLIED HEALTH UP 102%, BENITEC 65%, PHOSPHAGENICS 61%**
 - **7-YEAR ADJUSTED BDI-40 UP 160.7%, ASX200 6.9%**
- * **TODAY - ASX DOWN, BIOTECH EVEN: ALCHEMIA UP 11%, PRANA DOWN 17%**
- * **MRCF \$2m FOR PROTEGO STERNUM PROTECTOR**
- * **ALLAN GRAY TAKES 6.75% OF ACRUX**
- * **LIVING CELL: 'DIABECCELL REDUCES HYPOGLYCAEMIC EVENTS'**
- * **ALCHEMIA: DR REDDY'S STRONGER IN NORTH AMERICA**
- * **PERPETUAL TAKES 12% OF SIRTEX**
- * **FRANKLIN RESOURCES, AFFILIATES TAKE 5% OF COCHLEAR**
- * **AUSTRALIAN ETHICAL TAKES 10% OF ELLEX**
- * **DR BERNARD HOCKINGS REDUCES TO 5.8% OF PHYLOGICA**
- * **AUSBIOTECH ELECTS DIRECTORS JULIE PHILLIPS, DR ANDREA DOUGLAS**

MARKET REPORT

The Australian stock market fell 0.27 percent on Friday November 1, 2013 with the S&P ASX 200 down 14.4 points to 5,411.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and four were untraded.

Alchemia was the best, up 5.5 cents or 10.5 percent to 58 cents, with 433,148 shares traded. Anteo and IDT climbed more than seven percent; Antisense and Compumedics were up more than six percent; Bionomics was up five percent; Pharmaxis and Reva were up four percent or more; Viralytics was up three percent; Starpharma rose 2.2 percent; with Nanosonics and Universal Biosensors up more than one percent.

Prana led the falls, retreating nine cents or 16.5 percent to 45.5 cents with 3.4 million shares traded, following yesterday's 43.4 percent rise. Genetic Technologies and Impedimed lost more than five percent; Cellmid fell 4.65 percent; Allied Health, Atcor, Benitec and Ellex were down more than three percent; GI Dynamics and Prima shed more than two percent; with Acrux, CSL and Living Cell down more than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

October was unusually volatile for The Biotech Daily Top-40 Index (BDI-40) with six large rises offsetting a greater number of companies falling.

The BDI-40 climbed 2.5 percent in October compared to the S&P ASX200 up 4.0 percent, while the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed a collective 5.3 percent.

The deepest fall in October was Acrux's curious loss of \$104 million or 18.9 percent to a market capitalization of \$446 million, following a 15 percent fall in Axiron sales for the three months to September 30, 2013 compared to the previous quarter, but 150 percent above the previous corresponding period.

The Acrux loss was easily offset by Mesoblast's \$286 million (15.8%) rise to \$2,095 million; with Allied Health up 102.1 percent or \$95 million to \$188 million; Benitec (64.5%); Phosphagenics (60.5%); IDT (57.9%); Cellmid (55.6%); Neuren (34.5%); Prana (23.2%); and Osprey (17.8%).

Psivida led the October falls, down \$47 million (40.5%) to \$69 million; followed by Acrux and Universal Biosensors both falling 18.9 percent; Tissue Therapies (16.9%); Bionomics (14.5%); Atcor (13.8%); Starpharma (13.0%); Viralytics (12.1%); and Reva (11.1%).

* * * *

In October, Biotech Daily presented at the Canary Network 'Investing in Biotechnology' seminar and re-calibrated the Biotech Daily Top 40 Index (BDI-40) to reflect the methodology used in the S&P ASX indices.

When companies depart and enter an S&P ASX index, the index does not change but is adjusted to remain constant. So if the ASX200 was at 5,400 points and both BHP and Rio went off-shore, reducing the market capitalization-based chart by \$122 billion and \$28 billion, respectively, and XYZ and RST worth \$100 million were promoted, the index would remain at 5,400 points.

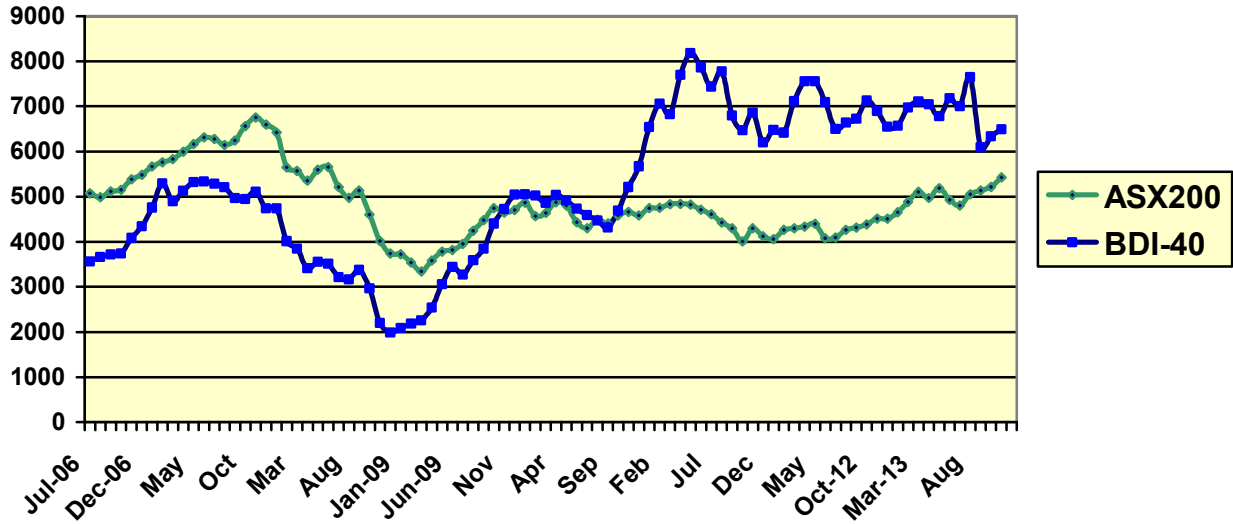
To compare a similarly constant BDI-40 to the ASX200, the companies that have either been acquired or have departed the ASX have been reinstated into the index at the value at their departure.

Companies Departing the BDI-40

Company	Date	Value/Price	Cumulative Value
Arana	Jun 2009	\$318m	\$318m
Peplin	Nov 2009	\$348m	\$666m
Cytopia	Jan 2010	\$11m	\$677m
Chemgenex	Jun 2011	\$225m	\$902m
Cellestis	Aug 2011	\$365m	\$1,267m
Biota	Oct 2012	\$107m	\$,1374m
Sunshine Heart	Apr 2013	\$57m	\$1,431m
Heartware	Sep 2013	\$1,365m	\$2,796m

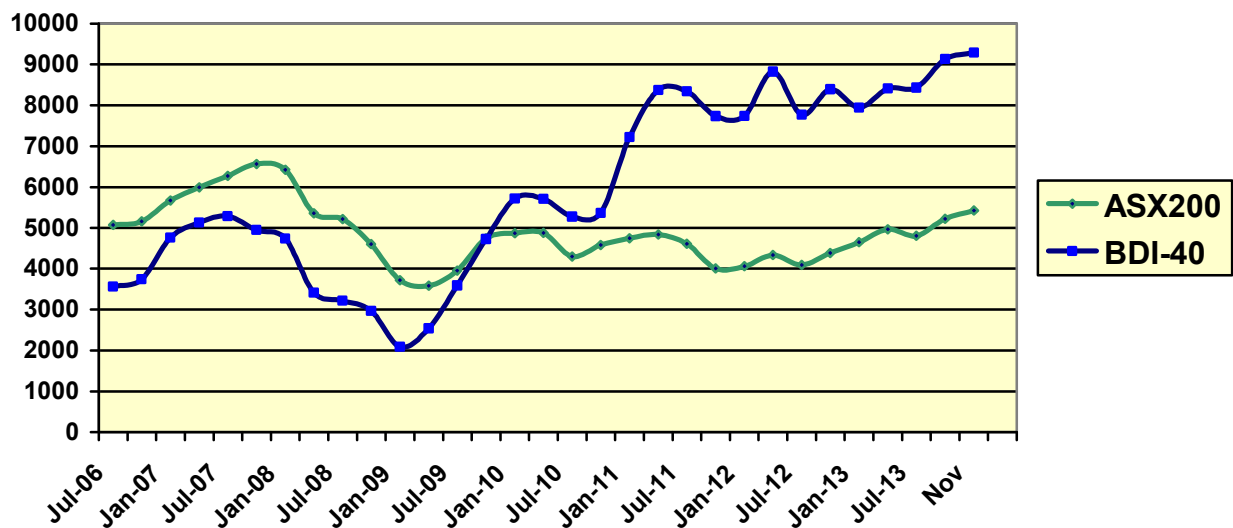
The raw data shows that since inception on June 30, 2006 the BDI-40 climbed 82.2 percent to October 31, 2013, compared to the ASX200 climbing 6.9 percent.

BDI-40 v ASX200 Jun 30, 2006 to Oct 31, 2013



But the adjusted chart, better comparing like with like, shows that the BDI-40 was up 160.7 percent over the seven years.

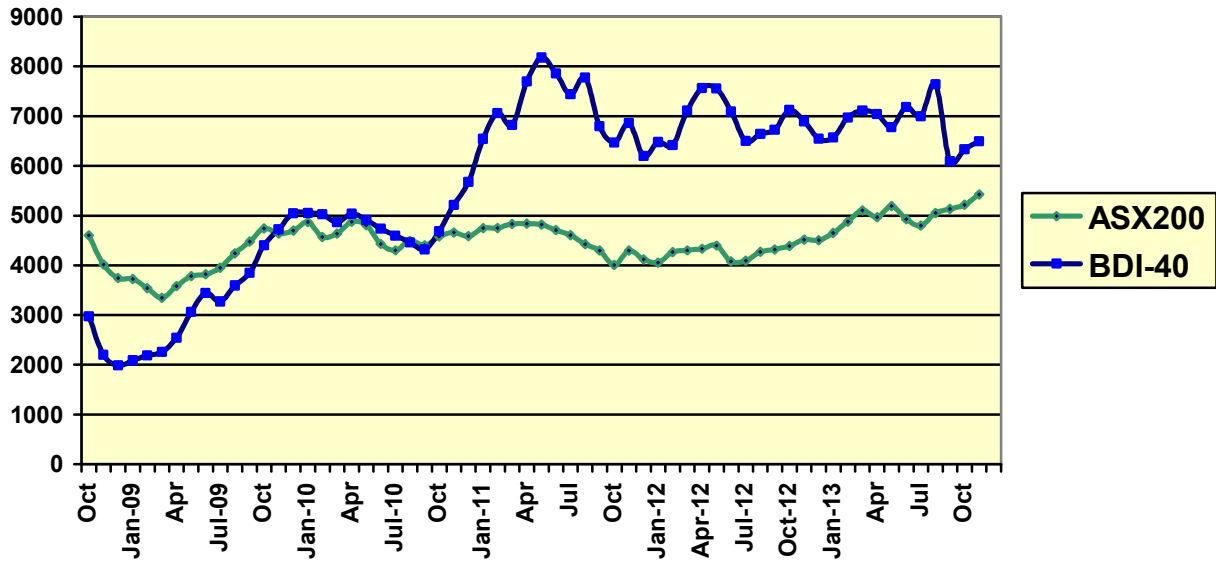
BDI-40 v ASX200 Jun 30, 2006 to Oct 31, 2013 - Adjusted



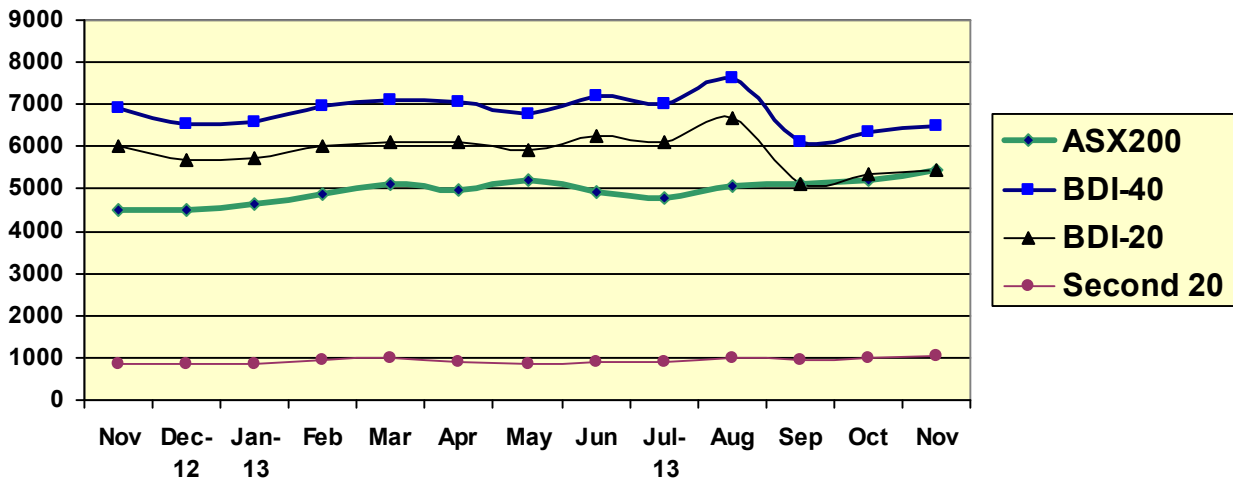
Outside the BDI-40, Invion was up 86.7 percent in October to \$56 million and up 194.7 percent for the year to October 31, 2013; Pharmaust jumped 46.7 percent for the month following the Pitney acquisition; Novogen was up 33.3 percent; and Progen returned to the fray, announcing an Australian phase I cancer trial.

On the Nasdaq, Biota fell a further 9.4 percent to \$115 million, Heartware slipped 2.2 percent to \$1,262 million and Sunshine Heart fell 10.1 percent to \$187 million.

BDI-40 v ASX200 Oct 31, 2008 to Oct 31, 2013 (Five Year Data)



BDI-40 (\$m) v S&P ASX 200 – Oct 31, 2012- Oct 31, 2013



[PROTEGO, MEDICAL RESEARCH COMMERCIALISATION FUND](#)

Protego Medical says it will develop its device for sternal protection during cardiac surgery, with \$2 million from the Medical Research Commercialisation Fund.

Protego said that the Medical Research Commercialisation Fund was managed by Brandon Capital with investment manager Dr Ingmar Wahlqvist a director of Protego.

The company said that Pablo Solis had been appointed as chief executive officer.

Protego said that the sternal protection technology was developed originally by cardiothoracic surgeon Dr Randall Moshinsky.

A spokesman for Protego told Biotech Daily that Dr Moshinsky operated at the Monash Medical Centre but developed the technology privately.

The company said that the \$2 million was expected to provide funding for two years to take the technology into a preliminary clinical trial in the coming year and a wider international trial program in the following year.

Dr Moshinsky said the device was "intended to overcome an unmet need in cardiac surgery: bleeding from the divided sternum which results in increased morbidity and complication rates".

"The device will also reduce trauma to, and fractures of the sternum from the sternal retractor," Dr Moshinsky said.

"This in turn will result in less post-operative pain," Dr Moshinsky said.

"The device may also reduce the risk of sternal wound infection by reducing the risk of inoculation by bacteria," Dr Moshinsky said.

Mr Solis said that 1.2 million cardiac operations took place each year in the US and Europe and sternal bleeding and trauma could impede the recovery of patients.

"This simple technology has excellent potential to both reduce blood loss and also protect the sternum during heart operations," Mr Solis said.

Dr Wahlqvist said that Protego was "precisely the kind of investment opportunity that the MRCF was established to support".

"This addresses a significant market opportunity and will ultimately also improve patient outcomes," Dr Wahlqvist said.

Protego said the initial clinical study would be under the direction Alfred Hospital cardiac surgeon and principal investigator Dr Silvana Marasco in mid-2014.

The company said that Mr Solis held leadership roles at Fisher & Paykel, Resmed, Ventracor and Finisar in project management, manufacturing engineering, research and development and regulatory affairs.

Protego said that Mr Solis was responsible for the preparation of the US Food and Drug Administration pre-market approval for an active implantable device approved in Europe and Australia with more than 400 people implanted.

The company said that Mr Solis Pablo held a degree in industrial engineering from the University of Costa Rica and a Master of Business Administration from Sydney's Macquarie Graduate School of Management.

Protego is a private company.

[ACRUX](#)

Allan Gray Australia (formerly Orbis Investment Management) has increased its substantial holding in Acrux from 9,302,949 shares (5.58%) to 11,246,933 (6.75%).

Allan Gray said that between October 23 and 29, 2013 it bought 1,943,984 shares for \$5,385,311 or an average price of \$2.77 a share.

Acrux fell four cents or 1.5 percent to \$2.64 with 550,136 shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says that its eight-patient, phase I/IIa trial of Diabecell for type 1 diabetes reduced unaware hypoglycaemic events and average daily insulin doses.

Living Cell said that the DIA-09 open label, study of the porcine islets of Langerhans was conducted at the Buenos Aires, Argentina-based Hospital Eva Perón by principal investigator Dr Adrián Abalovich.

The company said eight patients were divided into two groups, with four patients receiving two 5,000 islet equivalent per kilogram (IEQ/kg) doses of Diabecell and the second group of four patients receiving two 10,000 IEQ/kg doses, with the second dose implanted 12 weeks after the first and endpoints assessed 52 weeks after the second implant.

Living Cell said that overall unaware hypoglycaemic events were reduced by 57 percent, with all four patients in the higher dose group reduced by more than 40 percent without an increase in the blood glucose measure HbA1c and three of four patients in the lower dose group reduced by more than 30 percent without an increase in HbA1c.

The company said that HbA1c fell 1.5 to 2.0 percent in the group receiving the bigger dose and three of four patients in this group maintained HbA1c of less than 7.0 percent.

Living Cell said the average daily insulin dose was reduced in seven of the eight patients, with the frequency and severity of hypoglycaemic events significantly reduced in the higher dose group

The company said that analyses were underway to measure levels of porcine insulin and pro-insulin in recipients and correlate these with the clinical improvements observed.

Living Cell said that all participants had minor side effects from the implantation of Diabecell such as abdominal pain and fever and these quickly resolved, with one recipient having a severe adverse event from the implantation, namely lack of bowel movement, and this settled with intravenous medication.

Living Cell managing director Dr Andrea Grant said that there was “a genuine opportunity to develop an improved formulation of Diabecell and a revised regulatory pathway for this improved formulation is currently in preparation”.

Living Cell said the results had been accepted for presentation at the International Xenotransplantation Society meeting in Osaka from November 10 to 13, 2013.

Living Cell fell 0.1 cents or 1.1 percent to 8.9 cents with 1.6 million shares traded.

ALCHEMIA

Alchemia says marketing partner Dr Reddy's Laboratories claims North American revenue growth was driven partly by “significant traction” for its generic fondaparinux.

Alchemia said Dr Reddy's released the results on October 31, 2013 and said it expected to launch fondaparinux in Canada in the coming months.

The company said that Dr Reddy's had received a notice of compliance from Health Canada for 2.5mg, 5.0mg, 7.5mg and 10mg strengths, which are sufficient to address the whole fondaparinux market in Canada, which had total sales of fondaparinux for the year to December 31, 2012 of about \$US3 million.

The company said that Dr Reddy's had filed generic applications for fondaparinux with local regulatory authorities in two additional emerging markets and expected to file for approval in up to four additional territories in 2014, with total fondaparinux sales of about \$US10 million for the year ending December 31, 2012.

Alchemia said that Dr Reddy's would conduct additional technical work and resubmit its application based on feedback from European regulators, which could result in an EU approval in late 2014 or 2015.

Alchemia was up 5.5 cents or 10.5 percent to 58 cents.

SIRTEX MEDICAL

Perpetual and its subsidiaries have increased their substantial shareholding in Sirtex from 6,325,066 shares (11.28%) to 6,979,295 shares (12.44%).

Perpetual said it bought and sold shares between August 9 and October 29, 2013 for prices ranging from \$12.18 to \$13.88.

Sirtex fell six cents or 0.5 percent to \$12.38 with 122,641 shares traded.

COCHLEAR

Franklin Resources and affiliates have become substantial shareholders in Cochlear with 2,891,369 shares (5.07%), for a range of unnamed shareholders.

In its substantial shareholder notice Franklin Resources did not specify where it was based giving addresses in the Cayman Islands, Bermuda, the US, Europe, Asia, Africa and Australia and naming the affiliates including, Balanced Equity Management, C&EE General Partner, Darby Asia, Fiduciary International, Franklin Templeton, K2, Pelagos, Riva and Templeton.

Franklin said that between July 10 and October 28, 2013 it bought and sold the shares in a large number of small trades, with the largest two trades, on October 23 and 24, the acquisition of 159,000 shares for \$9,322,615 or an average price of \$58.63 a share.

Cochlear fell 13 cents or 0.2 percent to \$58.77 with 223,940 shares traded

ELLEX MEDICAL LASERS

Australian Ethical Smaller Companies Trust has increased its substantial shareholding in Ellex from 8,794,563 shares or 9.01 percent to 9,828,397 shares (10.06%).

Australian Ethical said that between October 4 and 25, 2013, it acquired 1,033,834 shares for \$306,698 or an average price of 29.7 cents a share.

Ellex fell one cent or 3.45 percent to 28 cents.

PHYLOGICA

Perth cardiologist Dr Bernard Hockings has reduced his substantial shareholding in Phylogica from 31,462,263 shares (6.74%) to 26,999,999 (5.78%).

The substantial shareholder notice, in the name of BEF and DC Hockings said the most recent sale was 5,000,000 shares for \$100,000 or two cents a share.

Phylogica was unchanged at 2.3 cents.

AUSBIOTECH

Ausbiotech says Biodiem chief executive officer Julie Phillips and CSL head of research and development strategy Dr Andrea Douglas have been elected directors.

Ausbiotech chair Dr Deborah Rathjen that Ms Phillips had "time and time again, shown her enthusiasm and commitment to developing the industry [and] as the CEO of an emerging biotech company, her viewpoint will be well placed to reflect a major segment of Ausbiotech's membership, particularly at a policy level".

"The board and I also welcome Andrea Douglas, who brings to the board extensive experience in research and development] and product development, and a return to the board of a representative of Australia's largest biotech company, CSL," Dr Rathjen said.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Nov-12	Oct-13	Nov-13
Cochlear	4,056	3,450	3,361
CSL	23,883	31,179	33,851
Resmed	6,023	8,026	7,699
BDI-20			
Acrux	539	550	446
Alchemia	152	198	170
Allied Health	20	93	188
Benitec	15	31	51
Bionomics	115	338	289
Clinuvel	56	61	59
Impedimed	27	33	31
Mesoblast	1,641	1,809	2,095
Nanosonics	137	216	229
Neuren	50	119	160
Osprey	32	73	86
Pharmaxis	397	40	39
Prana	92	181	223
Prima	133	48	47
Psivida	33	116	69
Reva	194	199	177
Sirtex	613	764	698
Starpharma	461	292	254
Tissue Therapies	64	65	54
Universal Biosensors	146	127	103
Second 20			
Anteo	46	47	50
Antisense	20	20	22
Atcor	11	29	25
Avita	39	39	36
Cellmid	9	18	28
Circadian	17	14	12
Compumedics	10	14	13
Ellex	16	26	28
Genetic Technologies	55	41	40
GI Dynamics	172	328	320
IDT	9	19	30
Living Cell	18	31	32
Medical Dev	103	76	73
Optiscan	17	10	9
Patrys	15	15	15
Phosphagenics	158	86	138
Phylogica	11	8	10
QRX Pharma	104	113	101
Uscom	9	14	14
Viralytics	34	33	29

* Biotech Daily editor, David Langsam, owns shares in Acrux, Alchemia, Allied Health, Benitec, Biota, Mesoblast, Nanosonics, Neuren and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Acrux, Alchemia, Atcor, Avita, Circadian, Cochlear, CSL, Ellex, IDT, Neuren, Pharmaxis, Prana, Resmed, Sirtex and Universal Biosensors. These holdings are liable to change.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053
email: editor@biotechdaily.com.au; www.biotechdaily.com.au; twitter: [@biotech_daily](https://twitter.com/biotech_daily)