



Biotech Daily

Monday December 1, 2014

Daily news on ASX-listed biotechnology companies

- * **NOVEMBER BDI-40 UP 3.5%, ASX200 DOWN 4%, BIG CAPS UP 4%**
- **CIRCADIAN UP 167%, OPTISCAN UP 83%, PATRYS DOWN 25%**
- * **TODAY: ASX, BIOTECH DOWN: GI DYNAMICS UP 5%, BIONOMICS DOWN 7%**
- * **EUROPE CLEARS GI DYNAMICS ENDOBARRIER FOR SALES**
- * **IMUGENE HER-VAXX RESPONSE IN MICE**
- * **PHARMAUST TREATS 1st PPL-1 CANINE CANCER COHORT**
- * **VIRAX: ALL CHANGE FOR PRESCIENT THERAPEUTICS, CONSOLIDATION**
- * **ACTINOGEN TAKES CORTICRINE FOR ALZHEIMER'S, BOARD CHANGES**
- * **CALZADA BECOMES POLYNOVO, CODE CHANGE**
- * **WESTPAC, ASSOCIATES TAKE 7% OF MAYNE PHARMA**
- * **ISONEA SWAPS ROSS BLAIR-HOLT FOR BRUCE MATHIESON – AGM**
- * **GENETIC TECHNOLOGIES LOSES PROF IAN MCKENZIE, DR MERVYN CASS**

MARKET REPORT

The Australian stock market lost 1.98 percent on Monday December 1, 2014 with the S&P ASX 200 down 105.3 points to 5,207.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 22 fell, five traded unchanged and two were untraded.

GI Dynamics was the best, up 1.5 cents or 5.3 percent to 30 cents with 218,334 shares traded. Anteo and Neuren climbed more than four percent; Atcor, Cellmid, Ellex and Universal Biosensors were up more than three percent; Clinuvel and IDT rose more than two percent; Medical Developments and Viralytics were up more than one percent; with CSL up 0.7 percent.

Bionomics led the falls, down three cents or 6.45 percent to 43.5 cents with 118,948 shares traded. Both Circadian and Patrys lost 5.9 percent; Admedus, Benitec, Compumedics and Phosphagenics fell more than four percent; Acrux, Analytica, Antisense, Nanosonics and Tissue Therapies were down more than three percent; Avita, Prana, Prima, Sirtex and Starpharma shed more than two percent; Impedimed, Mesoblast, Oncosil and Osprey were down more than one percent; with Cochlear, Psivida and Resmed down more than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top-40 Index (BDI-40) recovered 3.5 percent in November, while the S&P ASX200 shed 3.9 percent and the Big Caps climbed a further 4.4 percent.

Apart from the gaoling of four senior biotechnology executives there were no major technology failures, while several achievements pushed the index up and away from the benchmark S&P ASX200 index.

Small and not-so-small falls were offset by good news and consequent rises, including Neuren's Rett syndrome trial finding efficacy signals and Impedimed's increased US reimbursement for its lymphoedema test. Sixteen BDI-40 companies were up, 20 fell and four were unchanged. Most of the BDI-20 climbed while most of the Second 20 fell.

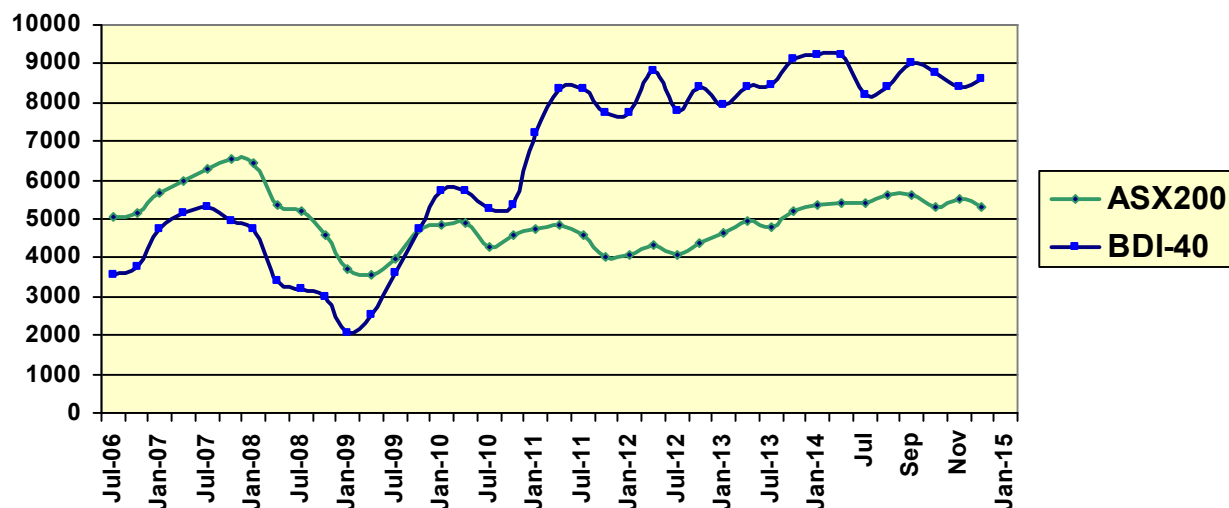
Circadian was the best, up 166.7 percent to \$24 million on a \$17.4 capital raising, followed by Optiscan up 83.3 percent to \$11 million on meeting a Zeiss microscope milestone, with Impedimed up 55.1 percent, Neuren (35.7%), Benitec (33.3%), Living Cell (23.1%), Clinuvel (22.9%), Acrux (21.0%), Biotron (16.7%), Ellex (13.3%) and Psivida (11.3%).

Patrys had the deepest fall, down 25.0 percent to \$12 million, followed by Phosphagenics down 23.8 percent to \$77 million, its lowest level since 2010 when it appointed Dr Esra Ogru co-chief executive officer and licenced AOD9604 for its alleged fat-buster crème. IDT fell 23.5 percent to \$13 million, followed by Starpharma (20.2%) and Uscom (20.0%).

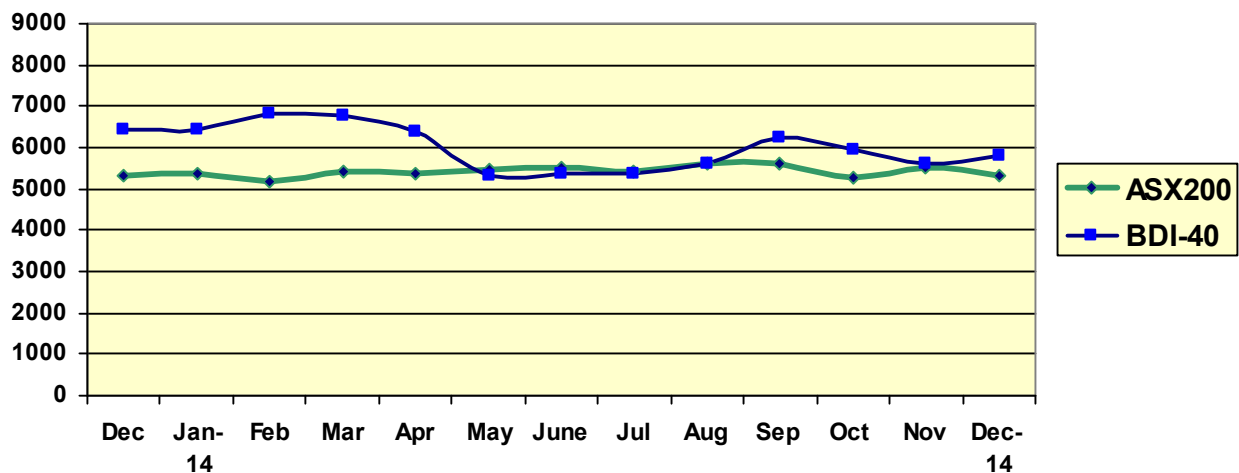
The three Big Caps (which are not included in the BDI-40) climbed a cumulative 4.4 percent in November, with Resmed the best, up 5.7 percent to \$8,707 million, the unstoppable CSL up a further 5.0 percent to \$39,442 million and Cochlear sliding 3.5 percent to \$4,013 million. For the year to November 30, 2014, the Big Caps climbed 16.8 percent, the BDI-40 fell 9.6 percent and the ASX200 slipped 0.1 percent.

Outside the BDI-40, Novogen fell to \$17 million, half the value of 12 months ago and Reva regained \$37 million or 38.1 percent to \$134 million on a \$55 million capital raising. The four formerly Australian companies in North America all fell, with Biota down 7.1 percent, Heartware (1.3%), Sunshine Heart (3.2%) and Bioniche (9.8%).

BDI-40 v ASX200 Jun 30, 2006 to Nov 30, 2014 - Adjusted



BDI-40 (\$m) v S&P ASX 200 – Nov 30, 2013- Nov 30, 2014



GI DYNAMICS

GI Dynamics says its European Union notified body has cleared the resumption of commercial shipments of Endobarrier for obesity and type 2 diabetes.

In October, GI Dynamics said that its method and timelines in reporting adverse events in clinical use caused the European Union suspension of commercial shipments of Endobarrier (BD: Oct 6, 7, 2014).

Today, GI Dynamics said that “as a result of a review of the company’s historical clinical evidence for the Endobarrier product, the company will clarify its indications for use to reflect that its obesity indication includes a restriction to patients with a body mass index [equal to or greater than] 30kg/m²”.

The company said that its revised indications meant that the Endobarrier was to be used for the treatment of obese type 2 diabetes with BMI [equal to or greater than] 30kg/m², or obese patients with BMI [equal to or greater than] 30kg/m² with one or more co-morbidities, or obese patients with BMI greater than 35kg/m².

GI Dynamics chief executive officer Michael Dale said the company was “pleased to have resolved the outstanding questions surrounding Endobarrier therapy”.

GI Dynamics was up 1.5 cents or 5.3 percent to 30 cents.

IMUGENE

Imugene says researchers have shown that high HER-2-specific antibody levels have been generated using HER-Vaxx fusion peptide antigens in mice.

Imugene said that the pre-clinical work at the Medical University of Vienna demonstrated that the HER-Vaxx fusion peptide antigens were strongly immunogenic.

The company said that its HER-Vaxx was a peptide vaccine or immunotherapy and the peptide component in HER-Vaxx was the component that caused the immune system to generate cancer-fighting antibodies.

Imugene said that the university’s Prof Ursula Wiedermann found that the generated antibodies recognised native HER-2 protein, a result critical for eventual efficacy.

Imugene chief executive officer Charles Walker said the results formed part of the preclinical testing needed to submit an investigational new drug application and begin clinical testing with HER-Vaxx in patients with gastric cancer.

Imugene was unchanged at 1.1 cents with 2.4 million shares traded.

PHARMAUST

Pharmaust says it expects to complete treatment of three dogs in the first cohort of PPL-1 for canine cancer by December 23, 2014.

In October, Pharmaust said it had begun treatment of two dogs using a soft gel formulation in its home-based, dose-ranging trial of PPL-1 in up to 36 dogs for canine cancers, following issues with the palatability of the liquid form which caused vomiting delaying the study (BD: Sep 9; Oct 2, 22, 2014).

Pharmaust was unchanged at 0.9 cents with 2.7 million shares traded.

PRESCIENT THERAPEUTICS (VIRAX HOLDINGS)

Virax board has changed and the annual general meeting has passed all resolutions including the change to Prescient Therapeutics and the 20-to-one consolidation.

Virax said that despite his re-election at the annual general meeting on November 28, 2014, Dr Brendan de Kauwe, along with Dr Wayne Millen and Dr Roland Toder would resign from the board at the conclusion of the meeting, to be replaced by chairman Steven Engle and directors Dr James Campbell and Steven Yatomi-Clarke.

Virax managing director Dr Rob Crombie told Biotech Daily that Prescient would trade on the ASX under the code PTX.

Virax said that Mr Engle was the former chairman and chief executive officer of the Berkeley, California-based Xoma and La Jolla Pharmaceuticals and was currently the chief executive officer of Averigon Consulting.

The company said that Dr James Campbell was previously Chemgenex chief financial officer and chief operating officer prior to the acquisition by Cephalon in 2011 and was currently a director of Invion, Bioprospect and Patrys.

Virax said that Mr Yatomi-Clarke was Patersons Securities director of corporate finance with more than 15 years experience in investment banking, specializing in healthcare and biotechnology and held a Bachelor of Science and a Bachelor of Commerce.

Mr Engle said that Dr Millen, Dr Toder and Dr de Kauwe "provided sound guidance as the company transitioned from its re-appointment to the ASX to the present stage of its development".

"Under their stewardship Virax raised \$5.5 million, sourced and acquired the major Pathway and Activate portfolios and commissioned the appointment of Dr Rob Crombie as managing director," Mr Engle said.

"Following shareholder approval the company will have two novel technologies targeting cancer pathways of intense interest to big [pharmaceutical companies] with two clinical trials already recruiting in the US and further trials to start in 2015," Mr Engle said.

Virax was unchanged at 0.7 cents with 10.6 million shares traded Virax

ACTINOGEN

Actinogen says it has completed the acquisition of Corticrine from the University of Edinburgh to develop UE2343 for Alzheimer's disease (BD: Aug 27, 2014).

Actinogen said that Martin Rogers and Dr Jason Loveridge had been appointed as non-executive chairman and non-executive director, respectively.

The company said that Daniel Parasiliti had resigned as a non-executive director and Dr Brendan de Kauwe had stepped down from executive chairman to non-executive director.

Actinogen said that it had received a Federal Government R&D Tax Incentive refund of \$103,500 for the year to June 30, 2014.

Actinogen was unchanged at 4.4 cents.

POLYNOVO (FORMERLY CALZADA)

Polynovo, which was formerly Calzada and before that Metabolic, says it has formally changed its name and ASX code and is trading under the code PNV.

Polynovo was untraded at 9.3 cents.

MAYNE PHARMA

Westpac Banking Corp and associates have increased their substantial holding in Mayne Pharma from 36,723,857 shares (6.26%) to 43,081,975 shares (7.33%).

Westpac said shares were bought by Advance Asset Management, Asgard Capital Management, BT Funds Management, BT Investment Management ANZ Bank, the National Australian Custodial Services, National Nominees and National Australia Bank. Westpac said that BT Investment Management bought the largest number of shares for the National Australia Bank between September 4, and November 27, 2014, acquiring 6,358,118 shares at an average price of about 73.2 cents a share

Mayne fell four cents or 6.15 percent to 61 cents with 1.25 million shares traded.

ISONEA

Isona says director Bruce Mathieson's nomination for re-election was withdrawn before the annual general meeting and Ross Blair-Holt will be appointed to fill the vacancy. Isona said that Mr Blair-Holt was a was a director of the Bruce Mathieson Group and until recently senior executive in the Woolworths Group as chief operating officer of the Australia Leisure and Hospitality joint venture which operates poker machines, hotels and liquor shops.

The company said that Mr Mathieson's "international business interests are taking a considerable amount of his time" but as the company's major shareholder he would continue to support the company.

Isona said that 10 other resolutions to the annual general meeting were passed overwhelmingly, except for two issuing shares and options to former chief executive officer Stephen Tunnell, which were defeated with up to 69,077,086 votes (83.2%) against and 13,914,718 votes (16.8%) in favor.

The company's most recent Appendix 3B new issue announcement said that Isona had 281,588,816 shares on issue, meaning that the votes against Mr Tunnell's options amounted to 24.5 percent of the company, sufficient to requisition extraordinary general meetings.

Isona was up 0.1 cents or 1.4 percent to 7.3 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says that directors Prof Ian McKenzie and Dr Mervyn Cass have filed Appendix 3Z Final Director's Interest Notices.

Genetic Technologies said that the notices were filed "following recent changes to the board".

In sentencing founder Dr Mervyn Jacobson in the Supreme Court of Victoria, on Friday, Justice Stephen Kaye described Dr Cass as "a lifelong friend" who gave character evidence on Dr Jacobson's behalf (BD: Nov 28, 2014).

Dr Cass was appointed a director on September 30, 2011 and Prof McKenzie was appointed on November 29, 2013 (BD: Oct 3, 2011; Nov 29, 2013).

Genetic Technologies was unchanged at 1.5 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Dec-13	Nov-14	Dec-14
Cochlear	3,381	4,157	4,013
CSL	33,613	37,561	39,442
Resmed	7,657	8,236	8,707
BDI-20			
Acrux	418	181	219
Alchemia	193	31	28
Admedus	188	188	166
Benitec	42	66	88
Bionomics	330	225	198
Biotron	20	24	28
Clinuvel	50	153	188
GI Dynamics	280	133	135
Impedimed	47	107	166
Mesoblast	1,974	1,335	1,368
Nanosonics	222	256	283
Neuren	186	129	175
Osprey	86	70	68
Pharmaxis	34	16	16
Prima	54	49	48
Psivida	84	133	148
Sirtex	673	1,446	1,526
Tissue Therapies	51	83	74
Universal Biosensors	94	30	26
Viralytics	31	57	57
Second 20			
Analytica	19	29	26
Anteo	123	112	96
Antisense	24	17	15
Atcor	27	15	15
Avita	32	32	30
Cellmid	23	19	21
Circadian	12	9	24
Compumedics	15	18	18
Ellex	32	30	34
Genetic Technologies	35	13	11
IDT	34	17	13
Living Cell	39	26	32
Medical Developments	78	75	66
Oncosil	36	37	31
Optiscan	10	6	11
Patrys	27	16	12
Phosphagenics	128	101	77
Prana	216	103	90
Starpharma	242	198	158
Uscom	11	20	16

* Biotech Daily editor David Langsam owns shares in Acrux, Alchemia, Admedus, Benitec, Biota, Mesoblast, Nanosonics, Neuren and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Alchemia, Avita, Circadian, Cochlear, CSL, Ellex, IDT, Impedimed, Innate, Pharmaxis, Resmed, Sirtex and Universal Biosensors. These holdings are liable to change: <http://www.australianethical.com.au/who-we-invest-in>.

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