



Biotech Daily

Monday June 3, 2013

Daily news on ASX-listed biotechnology companies

- * MAY BDI-40 UP 6%, ASX200 DOWN 5%; BIG CAPS DOWN 1.6%
- NEUREN UP 79%, PSIVIDA UP 68%, MEDICAL DEVELOPMENTS DOWN 23%
- * TODAY: ASX, BIOTECH DOWN: PHOSPHAGENICS UP 7%, COCHLEAR DOWN 18%
- * VICTORIA'S PREMIER'S AWARD FOR MELBOURNE UNI'S DR AUNG KO WIN
- * COCHLEAR NUCLEUS 6 LAUNCH, PROFIT WARNING
- * FDA HALTS PHARMAXIS ARIDOL IMPORTS
- * BIONOMICS PHASE I RENAL, OVARIAN CANCER PROGRESS
- * ALLIED EXPECTS \$1.9m COMMERCIALISATION AUSTRALIA GRANT
- * BEIJING BESTMED INVESTS \$500k IN COMPUMEDICS
- * BANK OF NEW YORK MELLON SELLS 5% OF COCHLEAR
- * BENITEC PLANS EURO LUNG CANCER TRIAL; FUNDING TRADING HALT
- * ASIA FUND \$17m FOR NUSEP PLANT; LOSES CO SEC TOM ROWE
- * CRYOSITE APPOINTS CHRISTINA BOYCE DIRECTOR
- * GOODBYE NEURODISCOVERY, HELLO ONCOSIL MEDICAL

MARKET REPORT

The Australian stock market fell 0.78 percent on Monday June 3, 2013 with the S&P ASX 200 down 38.3 points to 4,888.3 points. Nine of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and six were untraded. All three Big Caps fell.

Phosphagenics was the best, up one cent or 7.4 percent to 14.5 cents, with 1.2 million shares traded. Allied Health, Avita, Clinuvel, Genetic Technologies and Reva climbed five percent or more; Cellmid was up 3.7 percent; Prana rose 2.1 percent; with Nanosonics up 0.9 percent.

Cochlear led the falls, down \$11.66 or 18.1 percent to \$52.88 with two million shares traded. Neuren, Pharmaxis and Phylogica fell more than nine percent; Ellex lost 7.5 percent; QRX was down 5.4 percent; Impedimed and Resmed fell four percent or more; Mesoblast was down 3.5 percent; Sirtex shed two percent; Alchemia, Heartware, Optiscan and Starpharma were down more than one percent; with Acrux, CSL and Psivida down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 index (BDI-40), climbed 5.9 percent in May, compared to the S&P ASX200 experiencing its worst monthly fall in a year, of 5.1 percent.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40), slipped 1.6 percent, with Cochlear down \$2 million to \$3,762 million, Resmed up 11.3 percent to \$7,984 million, but CSL dragged the Big Caps down, retreating \$1,490 million or 4.8 percent to \$29,690 million - its third highest level and the second retreat this year.

Among the Top 20 (BDI-20) companies, 15 were up, of which 10 were up by more than 10 percent, four companies were down, with only Prima and Starpharma falling more than 10 percent. For the broader BDI-40, 24 companies were up, 11 fell and five were unchanged.

Both Heartware and Mesoblast improved by more than \$100 million and Sirtex added \$59 million to the index, compensating for falls by Medical Developments and Starpharma.

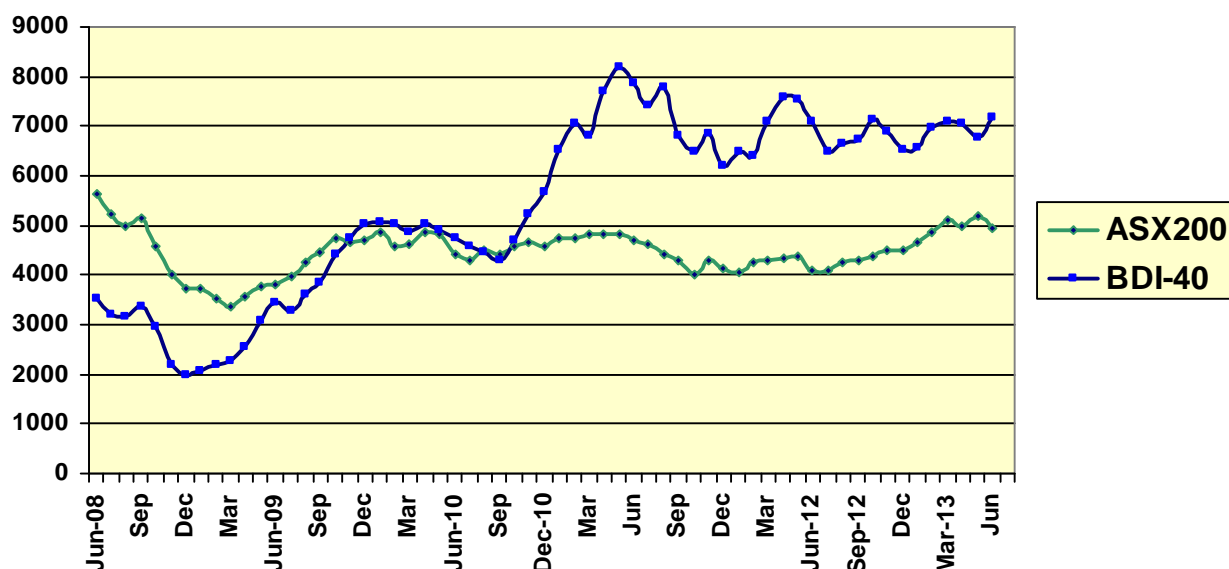
Neuren was the best in May, up 78.9 percent to \$68 million, followed by Psivida (68.1%), Phylogica (50%), Impedimed (40%), Genetic Technologies (38.9%), Allied Health (32.2%), Pharmaxis (24.4%), Benitec (21.4%) and Nanosonics (20.5%).

Medical Developments had the deepest fall, retreating \$20 million or 23.0 percent to \$67 million, followed by Compumedics (12.5%), Prima (12.1%) and Starpharma (11.9%).

For the year to May 31, 2013, the ASX200 was up 20.9 percent, the Big Caps rose 49.2 percent and the BDI-40 climbed 0.92 percent. But the five year index is instructive (see chart below). From just before the 2009 Global Financial Crisis the ASX200 is still 12.9 percent below its five year level, while the BDI-40 is up 104.5 percent, over the five years.

Outside the BDI-40, Isonex was up 233.3 percent to \$70 million in May, following a quarterly report with no revenue and a series of investor presentations. On the Nasdaq, Biota fell 6.1 percent to \$108 million and Sunshine Heart rose 21.0 percent to \$75 million.

BDI-40 v ASX200 May 31, 2008 to May 31, 2013



VICTORIA GOVERNMENT

Victoria's Minister for Innovation Louise Asher has presented the \$16,000 Premier's Award for Health and Medical Research to the University of Melbourne's Dr Aung Ko Win. Ms Asher presented the award on behalf of Premier Denis Napthine and said Dr Win was awarded the prize for his "ground-breaking research into the early detection of colorectal cancer".

"Dr Win has made some considerable breakthroughs towards developing a new genetically-based model for colorectal cancer risk prediction," Ms Asher said.

"Colorectal cancer is the second most commonly diagnosed cancer in Australia," Ms Asher said. "With around one in 20 Australians diagnosed with the disease at some stage in their lifetime, this cancer accounts for the second highest number of cancer-related deaths in Australia."

"Dr Win's discovery of applying a genetically-based prediction model will greatly assist practitioners in identifying people most at risk of developing the disease, as well as help with the discovery of new risk factors associated with the disease," Ms Asher said.

A Victoria Government media release said that Dr Win conducted his Doctorate of Philosophy research at the University of Melbourne's School of Population and Global Health (Centre for Molecular, Environmental, Genetic and Analytic Epidemiology).

The media release said that Dr Michelle Boyle, Dr Lin Wai Hung and Patricia Illing were each awarded \$8,000 commendations for their research.

Dr Boyle was a Ph D student at the Burnet Institute through the University of Melbourne's Centre of Immunology researching the *Plasmodium falciparum*, the parasite that caused the majority of malaria morbidity and mortality worldwide.

Dr Lin Wai Hung's research at the Bio21 Molecular Science and Biotechnology Institute through the University of Melbourne was in identifying a novel class of compounds effective in reducing pathology, reversing symptoms, and improving behavior in various animal models of neurodegenerative diseases.

Ms Illing is undertaking her Doctorate of Philosophy at the University of Melbourne's Department of Microbiology and Immunology, in partnership with Monash University and the Queensland Institute for Medical Research, investigating why some people develop life-threatening allergies after treatment for serious conditions such as epilepsy and AIDS.

COCHLEAR

Cochlear says it has begun the roll-out of Nucleus 6 products, with regulatory approval in Korea and Canada and expected in Europe "imminently" (BD: May 24, 2013).

Cochlear said it expected US approval "later this calendar year".

Cochlear said the Asian launch of the Nucleus 6 started at the International Federation of Oto-Rhino-Laryngological Societies in Korea in the first days of June and the North American launch of Nucleus 6 was expected to begin in Canada this month.

Cochlear said that sales since December 31, 2012 had been "weaker ahead of this much anticipated launch and slower market growth in the US".

Cochlear said it expected net profit after tax for the full year to June 30, 2013 to be in the range of \$130 million to \$135 million with an expected final year dividend of at least \$1.25 a share.

In the year to June 30, 2012, following the recall of the Nucleus CI-500 implant, Cochlear had revenue of \$779.0 million with net profit after tax \$56.8 million (BD: Aug 7, 2012).

In the six months to December 31, 2012, Cochlear posted record first half-year revenue of \$391.7 million with a net profit after tax of \$77.7 million (BD: Feb 5, 2013).

Cochlear fell \$11.66 or 18.1 percent to \$52.88 with two million shares traded.

PHARMAXIS

Pharmaxis says the US Food and Drug Administration has included Aridol on an Import Alert list, effectively stopping the import of Aridol into the US.

Pharmaxis said it had US sales of about \$99,000 for the three months to March 31, 2103, with about three months of inventory in the US.

The company said it had not received any direct communication from the FDA in relation to the listing and was seeking to clarify the reasons for the listing.

Pharmaxis said it believed the listing could relate to issues outstanding from a 2012 scheduled FDA audit of a third party contract packer and the company continued to work with the packer in its response to the audit to have Aridol removed from the Import Alert as soon as possible.

Pharmaxis fell 1.5 cents or 9.7 percent to 14 cents.

BIONOMICS

Bionomics says its phase I trial of BNC105 for renal cancer has shown "data indicative of clinical benefit" and its phase I trial for ovarian cancer has completed recruitment.

Bionomics said University of Texas Health Science Centre at San Antonio's Dr John Sarantopoulos would provide an update on the BNC105 renal cancer program at the annual American Society for Clinical Oncology meeting in Chicago, Illinois June 3, 2103 (US EST).

Bionomics said the multinational, multi-centre phase I/II clinical trial of BNC105 was in combination with everolimus (Afinitor) in patients with progressive metastatic renal cell carcinoma that have previously progressed on treatment with tyrosine kinase inhibitors. Bionomics said that Afinitor was an mTOR inhibitor used as a treatment after patients failed therapy with tyrosine kinase inhibitors such as Sutent.

The company said that Afinitor was approved by the US Food and Drug Administration for the treatment of renal cancer in 2009 and marketed by global pharma company Novartis, with sales of \$US700 million in 2012.

Bionomics said the phase I data was "indicative of clinical benefit and sustained therapy, with patients staying on therapy for up to 18 months".

The company said that the combination of BNC105 and Afinitor was well tolerated with no dose limiting toxicities or evidence of cumulative toxicity.

Bionomics said that eight of the 12 patients achieved disease stabilization, with a median treatment period across the eight patients of 11 cycles.

The company said that dose-related changes in biomarkers indicative of vascular response suggested that BNC105 reached plasma levels of pharmacological significance. Bionomics said that the phase II component of the study was ongoing at 77 US, Australian and Singaporean clinical trial sites.

Bionomics said that it had completed recruitment in the phase I component of its ovarian cancer trial.

The company said the trial was a multinational multi-centre phase I/II clinical trial to evaluate BNC105 with carboplatin and gemcitabine in patients with ovarian cancer who previously responded to, but progressed whilst on treatment, with platinum agents.

Bionomics said the study was being conducted by the Australian and New Zealand Gynaecological Oncology Group working with the National Health and Medical Research Council Clinical Trials Centre in Australia and the US-based Hoosier Oncology Group.

The company said that a poster presentation on the trial would be given by the principal investigator, the Melbourne-based Peter MacCallum Cancer Institute's Dr Danny Rischin.

Bionomics was unchanged at 39 cents.

ALLIED HEALTHCARE GROUP

Allied Health says it expects to be granted a \$1.9 million Commercialisation Australia to commercialize and launch its Cardiocel heart tissue.

Allied said the grant would “partially fund additional key resources in Europe and the US and build up global manufacturing capabilities”.

The company said that the grant funding would begin immediately.

Allied said it was pursuing approval for Cardiocel through a Conformité Européenne (CE) mark in Europe and a 510(k) application to the US Food and Drug Administration.

Allied Health was up 0.2 cents or five percent to 4.2 cents with 11.1 million shares traded.

COMPUMEDICS

Compumedics says its China distributor Beijing Bestmed has invested \$500,000 in the company becoming a top 10 shareholder with 2.9 percent of the company.

Compumedics said that Beijing Bestmed provided a combination of equity and short-term debt.

Compumedics executive chairman Dr David Burton said he welcomed Bestmed Beijing “as a strategic and significant shareholder”.

“We have had a business relationship with Beijing Bestmed for more than a decade,” Dr Burton said.

“Together we have built a significant footprint in China that we will further develop in this new chapter of our relationship, as the sleep diagnostics and neurology markets there continue to develop over coming years,” Dr Burton said.

Compumedics said the funding, together with a working capital facility with Bibby Financial Services limited to \$2.5 million and borrowing being completed, would enable it to ship “a record \$10 million of sales orders”.

The company said it expected to return to profitability by September 2013.

Dr Burton said he was “very grateful for the tireless efforts of our [chief financial officer]

David Lawson in working across the business to not only help close this funding round, but also our new facilities with Bibby Financial Services and those funding initiatives still to be completed”.

Compumedics was untraded at 4.3 cents.

COCHLEAR

The Bank of New York Mellon says it has ceased its substantial shareholding in Cochlear selling 2,689,622 shares at an average price of \$63.49.

In April, the Bank of New York Mellon returned to being a substantial shareholder in Cochlear with the acquisition of 2,863,356 shares or 5.02 percent (BD: Apr 15, 2013).

The substantial shareholder notice said the Wall Street New York bank acquired the shares on behalf of related companies, MBSC Securities, Dreyfus Corp and Walter Scott and Partners during the previous four months, but failed to disclose the purchase price.

In 2011, the Bank of New York Mellon ceased its substantial shareholding in Cochlear with the sale of 2,814,771 of the 2,847,424 shares or 5.02 percent it acquired the previous month (BD: Aug 29, 2011).

The July 2011 initial substantial shareholder notice said the bank acquired the shares on behalf of related companies, MBSC Securities, Dreyfus Corp, Walter Scott and Partners and Ankura Capital, over the previous four months but failed to disclose the acquisition prices (BD: Jul 21, 2011).

The August 29, 2011 notice said the shares were sold for \$71.87 each.

BENITEC BIOPHARMA

Benitec says it “has committed to moving its non-small cell lung cancer therapeutic Tribetarna into the clinic” following data announced in April (BD: Apr 4, 2013)

Benitec said the decision followed positive proof-of-principle data in mice, obtained in collaboration with the University of New South Wales’ Children’s Cancer Institute.

The company said it would use the Europe-based clinical research organization Clinical Trials Group to manage the initial clinical development of Tribetarna and the proposed phase I/IIa clinical trial was planned to begin by the end of 2014.

Benitec said the decision to begin Tribetarna clinical trials would be subject to obtaining appropriate funding.

Benitec said it expected to begin its US phase I/IIa trial of its DNA-directed RNA interference (ddRNAi) compound TT-034 for hepatitis C later this year (BD: March 22, 2013).

Benitec requested a trading halt “pending an announcement regarding a proposed capital raising”.

Benitec will resume trading on June 5 or on an earlier announcement.

Benitec last traded at 1.6 cents.

NUSEP

Nusep says it has a letter of intent for a \$20 million (\$16.5 million) investment in its Singapore plasma fractionation business from an Asian life sciences fund.

Nusep said it had been working with the fund for the Prime Biologics Pte Ltd plant.

Nusep said that part of the due diligence had been undertaken by a specialist equipment supplier to the plasma fractionation industry who also saw the commercial potential to replicate the Singapore facility throughout Asia.

The company said that the fund would undertake legal and technical due diligence on Prime Biologics Pte Ltd with a view to finalize the investment in the next 90 days.

Nusep said that company secretary Tom Rowe had resigned and managing director Prakash Patel would continue as company secretary.

Nusep was up 0.1 cents or 1.7 percent to six cents.

CRYOSITE

Cryosite says Christina Boyce has been appointed as a non-executive director.

Cryosite said that Ms Boyce had more than 20 years management and consulting experience and was currently a director of consulting firm Port Jackson Partners.

The company said that Ms Boyce was previously a senior executive at NBN Co (National Broadband Network) during its establishment and prior to NBN Co was a principal at McKinsey & Co.

Cryosite said that Ms Boyce held a Bachelor of Economics from the University of Sydney and a Master of Management from Kellogg Graduate School of Management.

Cryosite was untraded at 47 cents.

ONCOSIL MEDICAL (FORMERLY NEURODISCOVERY)

Neurodiscovery says that from today June 3, 2013, its name has changed to Oncosil

Medical with the ASX code of OSL, better reflecting the development of its brachytherapy for pancreatic cancer acquired with Enigma Therapeutics (BD: Apr 16, 2103).

Neurodiscovery or Oncosil closed untraded at 3.8 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Jun-12	May-13	Jun-13
Cochlear	3,571	3,764	3,762
CSL	19,265	31,180	29,690
Resmed	4,933	7,174	7,984
BDI-20			
Acrux	723	673	623
Alchemia	123	125	117
Benitec	17	14	17
Bionomics	124	156	162
Clinuvel	55	65	75
Heartware	1,151	1,459	1,571
Impedimed	57	10	14
Mesoblast	1,897	1,851	1,971
Nanosonics	129	112	135
Neuren	30	38	68
Osprey	38	39	40
Pharmaxis	354	45	56
Prana	49	74	88
Prima	160	91	80
Psivida	41	47	79
Reva	215	177	189
Sirtex	334	541	600
Starpharma	445	277	244
Tissue Therapies	86	27	27
Universal Biosensors	98	107	120
Second 20			
Allied Health	18	31	41
Anteo	50	40	46
Antisense	20	16	14
Atcor	10	12	11
Avita	49	30	34
Cellmid	8	18	18
Circadian	22	13	15
Compumedics	12	8	7
Ellex	14	15	17
Genetic Technologies	74	36	50
GI Dynamics	249	184	184
Living Cell	18	16	16
Medical Dev	44	87	67
Optiscan	13	13	12
Patrys	9	14	13
Phosphagenics	179	122	138
Phylogica	21	6	9
QRX Pharma	265	155	176
Uscom	5	13	13
Viralytics	22	25	24

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

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