Biotech Daily

Friday June 1, 2012

Daily news on ASX-listed biotechnology companies

*** MAY BDI-40 DOWN 6.1%, ASX200 DOWN 7.34%:**
GENETIC TECHNO UP 68%; PRIMA DOWN 30%; MESOBLAST DOWN $237m

*** TODAY: ASX, BIOTECH DOWN: CIRCADIAN UP 8%, PHYLOGICA DOWN 10%**

*** UK COMMITTEE REBUFFS PHARMAXIS BRONCHITOL REIMBURSEMENT**

*** CE MARK BODY ASKS TISSUE THERAPIES FOR MORE VITROGRO INFO**

*** HEARTWARE AGM DISSENT ON DIRECTOR SHARES, OPTIONS**

*** LIVING CELL LOSES R&D HEAD DR OLGA GARKAVENKO**

*** BIONOMICS POSTERS BNC105 FOR KIDNEY CANCER, MESOTHELIOMA**

*** DR STEFAN GEHRIG WINS VICTORIA PREMIER'S RESEACH AWARD**

MARKET REPORT

The Australian stock market fell 0.3 percent on Friday June 1, 2012 with the S&P ASX 200 down 12.4 points to 4,063.9 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and four were untraded.

Circadian was the best on an updated presentation, up four cents or 8.3 percent to 52 cents with 49,969 shares traded.

Antisense, Prima and Viralytics climbed more than six percent; Allied Health, Anteo and Optiscan were up more than four percent; Genetic Technologies, Impedimed and Prana were up more than three percent; Acrux and Heartware rose more than two percent; with Cochlear up 1.5 percent.

Phylogica led the falls, down 0.5 cents or 10.4 percent to 4.3 cents with 1.6 million shares traded, followed by Living Cell down 9.4 percent to 4.8 cents, with 113,816 shares traded.

Patrys, Pharmaxis and Starpharma lost eight percent or more; Phosphagenics fell 5.7 percent; both Neuren and Sunshine Heart fell four percent; Avita, Bionomics, Psivida and Sirtex shed more than two percent; with Alchemia, Mesoblast and QRX down more than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) fell 6.1 percent in May 2012 to $7,098 million, a slightly smaller fall than the S&P ASX200, which lost 7.3 percent.

For the year to May 31, the BDI-40 (which does not include the Big Caps of Cochlear, CSL and Resmed) was down 9.5 percent, compared to the ASX200 falling 13.4 percent.

Over the longer term, the BDI-40 has continued to outperform the ASX200, up 99.2 percent above the June 30, 2006 initiation point, compared to the ASX200 falling 19.7 percent in the 71 months (see charts below).

CSL defied the trend in May, up 2.1 percent to $19,265 million, taking the collective value of the three Big Caps up 0.3 percent for the month, despite Cochlear easing 4.4 percent to $3,571 million and Resmed down 3.1 percent to $4,933 million. For the 12 months to May 31, 2012 the Big Caps were up 1.9 percent.

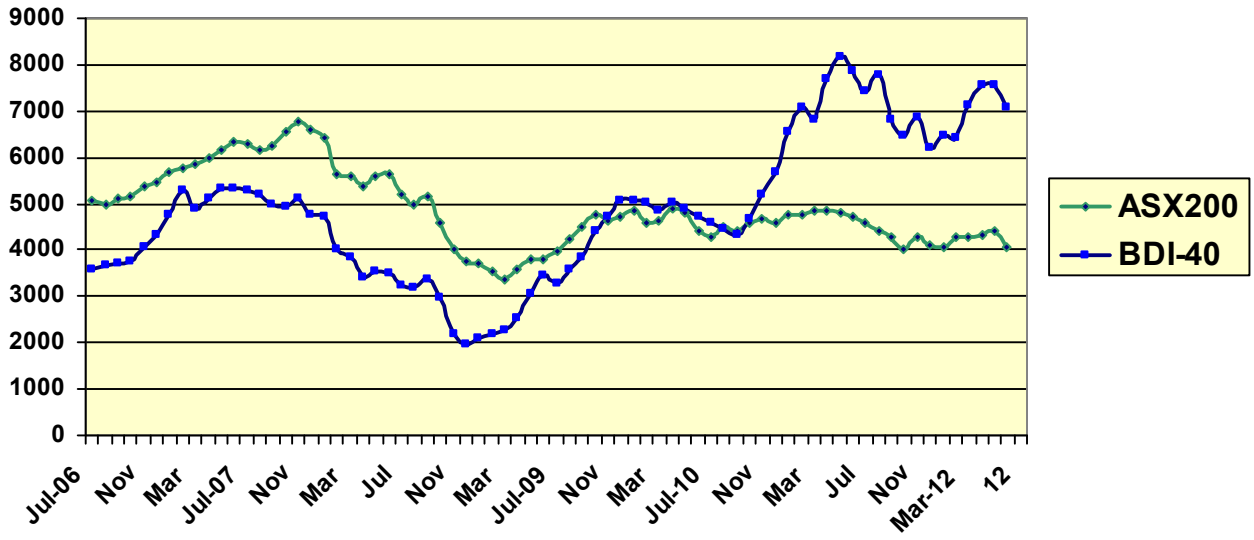
There was little good news, with just nine of the BDI-40 stocks up, 27 down and four unchanged, with 17 companies falling between 10 and 20 percent.

Genetic Technologies closed the month up 68.2 percent at $74 million, followed by Antisense up 17.6 percent to $20 million; Prana (14.0%); Nanosonics (9.3%); Heartware (8.7%); and Acrux (8.2%).

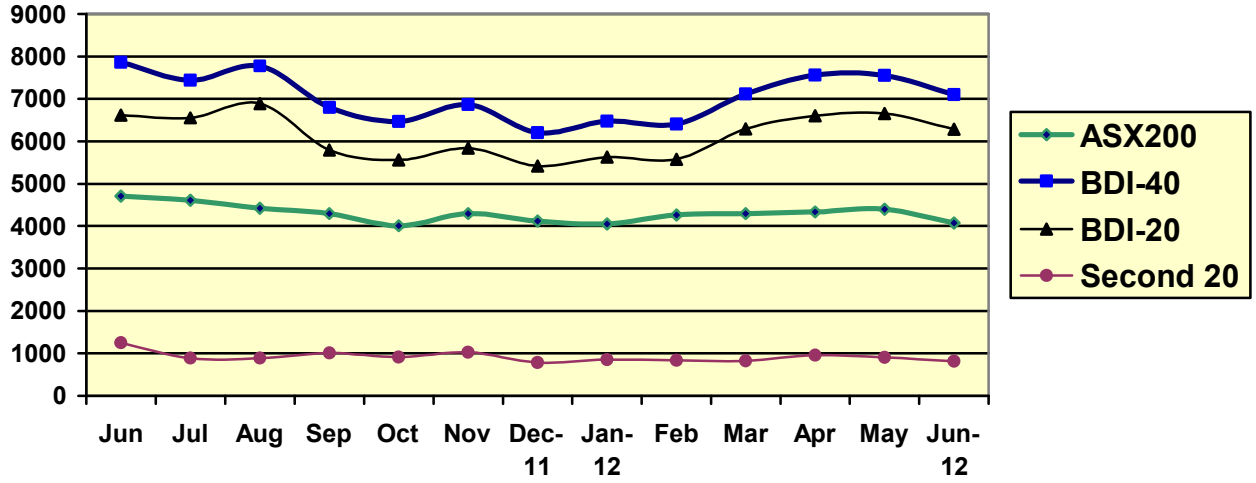
Mesoblast's 11.1 percent fall to $1,897 million wiped $237 million from the BDI-40 index and Starpharma's 14.4 percent fall was a $75 million loss. The deepest relative fall was Prima, down 30.1 percent to $160 million; followed by Patrys down 25 percent to $9 million; Bioniche (22.8%); Anteo (19.4%); Optiscan (18.75%); Psivida (18.3%); Alchemia (17.8%); Universal Biosensors (17.6%); Sunshine Heart (16.7%); and Bionomics (15.6%).

Biotech Daily has discovered a discrepancy in the ASX and data services reporting of Reva Medical and the 8.4 percent understatement will be adjusted in next month's index.

BDI-40 v ASX200 Jun 30, 2006 To May 31, 2012



BDI-40 v ASX200 May 31, 2011 To May 31, 2012



PHARMAXIS

Pharmaxis says a UK advisory committee has rejected the reimbursement cost-effectiveness of Bronchitol for cystic fibrosis, despite its market approval and availability.

Pharmaxis chief executive officer Dr Alan Robertson told Biotech Daily that Bronchitol was available in the UK and that in the near future local authorities could decide whether to reimburse patients, regardless of the UK National Institute for Health and Clinical Excellence review.

In a media release, Pharmaxis said the Institute's opinion was not its final guidance on whether Bronchitol should be funded by the National Health Service and the recommendations could change following consultation and stakeholder comment.

The company said that Bronchitol was available in the UK at a retail price of GBP16.55 ($A26.28) per day and the UK Department of Health ruled that the price was acceptable.

Pharmaxis said that in Germany the price was EUR35.65 ($A45.45) per day.

Pharmaxis said that the UK National Institute for Health and Clinical Excellence (NICE) appreciated that cystic fibrosis was a multi-faceted condition, with a complex treatment pathway needing to be tailored to the needs of the individual patient.

The company said the quality of its phase III clinical studies were acknowledged and the committee accepted clinical and patient expert evidence on the advantages of a choice of treatments and that Bronchitol had the potential to ease the disease burden.

Pharmaxis said that the committee's view was that the calculation of cost effectiveness had considerable uncertainty and was dependent on a variety of imputed assumptions.

Dr Robertson said that "the cost effectiveness ratios in our submission are correctly positioned to gain a positive recommendation from NICE".

Dr Robertson said that draft opinion comments closed on July 3, 2012, a second appraisal meeting was likely to be held in September and the process finalized this year.

Dr Robertson said that no cystic fibrosis drugs available in the UK other than Bronchitol had been reviewed by the Institute.

"The decision to fund Bronchitol remains in the hands of the local health authorities with whom we have been liaising over recent months," Dr Robertson said

"Bronchitol is now available in pharmacies and we will be pursuing the negotiations with local payers to fund treatment for … patients in their area," Dr Robertson said.

Dr Robertson said Bronchitol would be launched at the European Cystic Fibrosis symposium in Dublin on June 6 to 9, 2012.

Pharmaxis fell 9.5 cents or 8.2 percent to $1.06.

TISSUE THERAPIES

Tissue Therapies says the body assessing the Vitrogro extracellular matrix (ECM) application for Conformité Européenne (CE) marking has requested additional information.
Tissue Therapies chief executive officer Dr Steven Mercer said the company had planned for requests for additional data in a range of critical areas, particularly manufacturing and compliance with the essential requirements for devices sold in the European Union.
"Additional requests for information during the CE mark review process are considered routine and are not surprising to us or our regulatory advisors," Dr Mercer said. "In anticipation of this type of request we have completed additional work to ensure we could promptly respond to likely enquiries during the examination process."
"We remain confident that CE mark will be granted in time for the planned start of sales in the UK and Europe at the end of June 2012," Dr Mercer said.
Dr Mercer said the CE mark submission was based on the strong clinical results of the pivotal EU study in hard-to-heal wounds, primarily venous leg ulcers, as well as validation of manufacturing processes.
Dr Mercer said the nature of the information required indicated that significant progress had been made to bring Vitrogro to market and the review was moving to the final phase.
Tissue Therapies was unchanged at 51 cents.

HEARTWARE

Heartware shareholders passed most annual general meeting resolutions overwhelmingly but there was significant dissent against the incentive award plan
Heartware investors re-elected directors Cynthia Feldman and Denis Wade unopposed.
The greatest dissent at the meeting was on the 2012 incentive award plan resolution, in which 5,729,692 proxy votes (64.8%) were cast in favor, with 3,109,759 proxy votes (35.2%) against.
Heartware has 14,169,799 shares of common stock on offer, with 10,650,200 described as validly appointed proxies, meaning the largest no vote was about 21.9 percent of the company's shares.
The issue to chief executive officer Doug Godshall of 36,000 restricted stock units was supported by 7,272,884 proxy votes and opposed by 1,569,242 proxy votes.
Seven resolutions providing shares and/or options to directors were passed easily with about 205,000 proxy votes against, but more than 8.6 million proxy votes in favor.
Heartware was up six cents or 2.6 percent to $2.38.

LIVING CELL TECHNOLOGIES

Living Cell says it has restructured with medical director and founder Prof Robert Elliott assuming the role head of research and development replacing Dr Olga Garkavenko.
Living Cell said that Prof Elliott would hold the single position of chief science and medical officer in an acting capacity, while the company conducts a search for a successor.
The company said that at that time Prof Elliott would focus on his governance role as founder and non-executive director on the Living Cell and Diatranz Otsuka boards.
Living Cell said that Dr Garkavenko was appointed head of research and development in June 2011 and was previously the company's head of molecular diagnostics and virology and "played a key role in demonstrating that the Auckland Island Pigs, which are used as a source herd for [its] cell therapies, are free from common pig viruses and disease".
Living Cell said that Dr Garkavenko would leave the company.
Living Cell was down half a cent or 9.4 percent to 4.8 cents.

BIONOMICS

Bionomics says clinical trial data shows that BNC105 is safe with everolimus in patients with metastatic renal cancer and well-tolerated as a second-line therapy for mesothelioma

Bionomics said the data from its ongoing US trial of BNC105 in patients with metastatic renal cancer and the completed Australian trial in patients with mesothelioma would be presented at the American Society for Clinical Oncology meeting in Chicago, Illinois, June 1 to 5, 2012.

Last year, Bionomics discontinued its planned 60-patient trial of BNC105 for mesothelioma and earlier this year published data from its 12-patient renal cell carcinoma trial (BD: Aug 3, 2011; Feb 3, 2012).

Bionomics said BNC105 was being studied in a US multi-centre phase II clinical trial in combination with everolimus (Afinitor) in patients with progressive metastatic renal cell carcinoma.

The poster presentation, entitled 'Phase I results of a phase I/II trial of BNC105P with everolimus in metastatic renal cell carcinoma (mRCC) patients previously treated with VEGFR tyrosine kinase inhibitors' would be given by the principal investigator Dr Thomas Hutson of the Texas Oncology Cancer Center on June 3, 2012.

Bionomics said the phase II component of the study was underway and more than 30 US-based clinical trial sites had been activated.

The company said that the primary objective of the phase I component of the trial was to examine the safety and tolerability BNC105 in combination with Afinitor.

Bionomics said that 12 patients were enrolled in the phase I component, five patients completed more than 10 cycles of treatment and two patients remained on treatment.

The company said the results indicated that the recommended dose of Afinitor was well tolerated when combined with the previously identified phase II dose level of BNC105 of 16mg/m2, supporting the use of both Afinitor and BNC105 at their full dose levels.

Bionomics said that pharmacokinetic analysis of drug levels indicated no interaction between BNC105 and Afinitor, confirming the compatibility of the drug combination.

The company said that single arm phase II mesothelioma trial enrolled patients progressing after first line chemotherapy with pemetrexed (Alimta) and cisplatin.

Bionomics said the poster, entitled 'Phase II trial of BNC105P as second-line chemotherapy for advanced malignant pleural mesothelioma (MPM): Australasian Lung Cancer Trials Group and NHMRC Clinical Trials Centre Collaboration' would be presented on June 2, 2012 and 30 patients were enrolled in the trial, with one patient showing an objective response and 13 patients classified as having stable disease.

Bionomics said that BNC105, at a dose of 16mg/m2 was well tolerated, a finding consistent with clinical experience to date.

The company said the poster described for the first time the measurement of a number of candidate plasma biomarkers and that statistically significant changes were observed in candidate biomarkers which are consistent with the vascular activity of BNC105, including changes in MIP-1beta ($p = 0.0023$), IL-8 ($p = 0.0007$), IL-10 ($p = 0.0018$), TNFR2 ($p = 0.0001$) and IL-16 ($p = 0.0037$).

The company said that mesothelin levels, a potential marker for mesothelioma, in the patient showed an objective response and achieved a decrease to less than 75 percent of baseline after one treatment cycle.

Bionomics said the two additional patients with stable disease similarly achieved decrease in mesothelin to less than 75 percent of baseline.

The company said that objective tumor response, safety profile and tolerability of BNC105 warranted further research into its integration with established chemotherapy regimens.

Bionomics fell one cent or 2.8 percent to 35 cents.

VICTORIA GOVERNMENT

Victoria Premier Ted Baillieu and Health Minister David Davis have awarded Dr Stefan Gehrig the $16,000 Premier's Award for Health and Medical Research for 2012.

A Victoria Government media release said the award "recognized and honored the achievements of Victoria's early career health and medical researchers".

Mr Baillieu said Dr Gehrig won the award from a highly competitive field of young Victorian researchers for his far-reaching investigation into Duchenne muscular dystrophy.

"Dr Gehrig discovered that increasing levels of a specific protein in muscles has the potential to treat [Duchenne muscular dystrophy] a severe and progressive muscle wasting disease," Mr Baillieu said.

The media release said that Dr Gehrig found that increasing levels of heat shock protein 72 in the muscles of mice could help treat Duchenne muscular dystrophy.

"Dr Gehrig discovered that increasing this protein in muscles improved the function of a pump responsible for controlling calcium levels, confirming it as a target for future therapeutic drugs for the disease," Mr Davis said.

"Dr Gehrig also discovered that administering the drug BGP-15 improved overall muscle function and increased the lifespan of mice," said Mr Davis.

"This is promising news for boys with [Duchenne muscular dystrophy] who at the moment are treated with corticosteroids, which come with significant side effects," Mr Davis said .

"We anticipate that these findings could serve as the basis for future clinical trials within the next five to ten years," Mr Davis said.

The media release said that the University of Melbourne's Department of Physiology, where Dr Gehrig conducted his research, received the $30,000 Jack and Robert Smorgon Families Award.

Dr Gehrig's research was performed in collaboration with the Baker IDI Heart and Diabetes Institute, Deakin University and the University of Oxford.

The media release said that three commendees were presented with $8,000 each for their outstanding contribution in the field of health and medical research:

Turning Point Alcohol and Drug Centre researcher Michael Livingston was awarded $8,000 for his work on the availability of alcohol and its effect on consumption, health and social problems, which led to changes in alcohol regulation in Victoria.

Murdoch Children's Research Institute researcher Dr Elena Tucker was awarded $8,000for her work on mitochondrial disease, characterized by an inability to generate the energy required for normal bodily functions and often with fatal consequences.

The media release said that Dr Tucker's research, using next generation sequencing technology, had the potential to diagnose the disease in children using a blood sample.

The University of Melbourne Department of Microbiology and Immunology's Dr Sophie Valkenburg was awarded the commendation for her research on the role of T-cells to recognize and protect against different influenza viruses.

The media release said that her research raised possibilities for the design of new universal vaccines.

The Victoria Government and the Australian Society for Medical Research present the Premier's Award for Health and Medical Research each year during Medical Research Week.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company $Am	Jun-11	May-12	Jun-12
Cochlear	4,527	3,737	3,571
CSL	18,046	18,861	19,265
Resmed	4,653	5,089	4,933
BDI-20			
Acrux	614	668	723
Alchemia	132	146	123
Bionomics	241	147	124
Biota	216	155	139
Clinuvel	56	56	55
Genetic Technologies	101	44	74
Heartware	963	1,059	1,151
Impedimed	94	67	57
Living Cell	30	25	18
Mesoblast	2,257	2,134	1,897
Nanosonics	184	118	129
Pharmaxis	260	407	354
Phylogica	29	22	21
Prima	286	229	160
QRX Pharma	263	263	265
Sirtex	284	361	334
Starpharma	391	520	445
Sunshine Heart	55	35	30
Tissue Therapies	83	79	86
Universal Biosensors	167	119	98
Second 20			
Allied Health	9	21	18
Anteo	72	62	50
Antisense	10	17	20
Avita	16	48	49
Benitec	31	19	17
Bioniche	107	57	44
Cellmid	11	8	8
Circadian	30	23	22
Compumedics	15	12	12
Ellex	16	16	14
Genera	18	16	15
Neuren	12	34	30
Optiscan	6	16	13
Patrys	32	12	9
Phosphagenics	119	219	179
Prana	48	43	49
Psivida	81	50	41
Reva	335	198	198
Uscom	14	5	5
Viralytics	56	26	22

* Biotech Daily editor, David Langsam, owns shares in Alchemia, Allied Health, Biota, Neuren, Pharmaxis and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Atcor, Avita, Circadian, Pharmaxis and QRX. 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