



# Biotech Daily

Thursday September 1, 2011

*Daily news on ASX-listed biotechnology companies*

- \* AUGUST CRUELS BDI-40 - DOWN 12.6%; ASX200 DOWN 2.9%
- \* TODAY: ASX, BIOTECH UP: REVA UP 17%; COMPUMEDICS DOWN 9%
- \* BIONOMICS POSTER SHOWS ANTI-ANXIETY, ANTI-DEPRESSION LINK
- \* CLINUVEL COMPLETES SCENESSE PRE-CLINICAL PROGRAM
- \* ADVANCED SURGICAL REVENUE DOWN 1%, LOSS UP 264% TO \$3m
- \* CYCLOPHARM REVENUE UP 10% TO \$3.6m, LOSS UP 99% TO \$1.5m
- \* ALLIED HEALTH REVENUE UP 63% TO \$7m, LOSS UP 3236% TO \$1.4m
- \* HELICON PLACES \$898k
- \* CHINA PATENT FOR VIRALYTICS ANTI-CANCER ECHOVIRUS EVATAK
- \* IMUGENE REQUESTS STRATEGIC ALLIANCE HALT
- \* CBIO REQUESTS CAPITAL RAISING HALT
- \* ACRUX LOSES FOUNDER, DIRECTOR PROF BARRIE FINNIN
- \* SUNSHINE HEART LOSES FOUNDER, DIRECTOR CRISPIN MARSH

## MARKET REPORT

The Australian stock market climbed 0.26 percent on Thursday September 1, 2011 with the S&P ASX 200 up 11.0 points to 4307.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and eight were untraded.

Reva was the best, up 11.5 cents or 16.7 percent to 80.5 cents with 371,070 shares traded, followed by Genetic Technologies up 13.2 percent to 21.5 cents with 3.2 million shares traded and Cathrx and Clinuvel both up 10.3 percent on modest volumes. Viralytics climbed 9.8 percent; Phylogica was up 7.9 percent; Optiscan was up five percent; Benitec climbed 4.35 percent; Starpharma was up 3.8 percent; Acrux, Bionomics, Impedimed and Resmed rose more than two percent; with Anteo and QRX up more than one percent.

Compumedics led the falls, down 0.8 cents or 8.9 percent to 8.2 cents, with 165,746 shares traded. Biota lost 5.1 percent; Allied fell four percent; Living Cell, Phosphagenics and Psivida were down more than three percent; Tissue Therapies shed 2.1 percent; with Alchemia and Heartware down more than one percent.

### [BIOTECH DAILY TOP 40 INDEX \(BDI-40\)](#)

Not falling in August 2011 was a major achievement. Twenty-seven of the Biotech Daily Top 40 Index (BDI-40) companies fell, nine were up and four were unchanged.

The BDI-40 (which does not include the Big Caps of Cochlear, CSL and Resmed) suffered its deepest one month fall since October 2008, down 12.6 percent to a cumulative market capitalization of \$6,798 million, compared to the S&P ASX200 down 2.9 percent.

The fall partly reflected the replacement of Cellestis, (see below) but Mesoblast took the biggest hit, losing \$320 million or 12.6 percent of its market capitalization, with many other companies recording significant falls.

By percentage, Alchemia fell the furthest, down \$71 million or 52.2 percent to \$65 million on news that Glaxosmithkline had a competitor synthetic heparin product, followed by Viralytics down 25 percent to \$27 million, Prima (24.9%), Bionomics (24.4%), Starpharma (23.5%), Nanosonics (23.2%), Universal Biosensors (16.9%) and Benitec (16.0%).

The best from a very low base was LBT, up 50 percent to \$6 million, but Phosphagenics' \$21 million (19.6%) improvement was more significant, followed by Advanced Surgical (16.7%), Compumedics (15.4%) and Sunshine Heart (15.4%). Biota, Circadian, Genetic Technologies and Psivida were up between two and four percent.

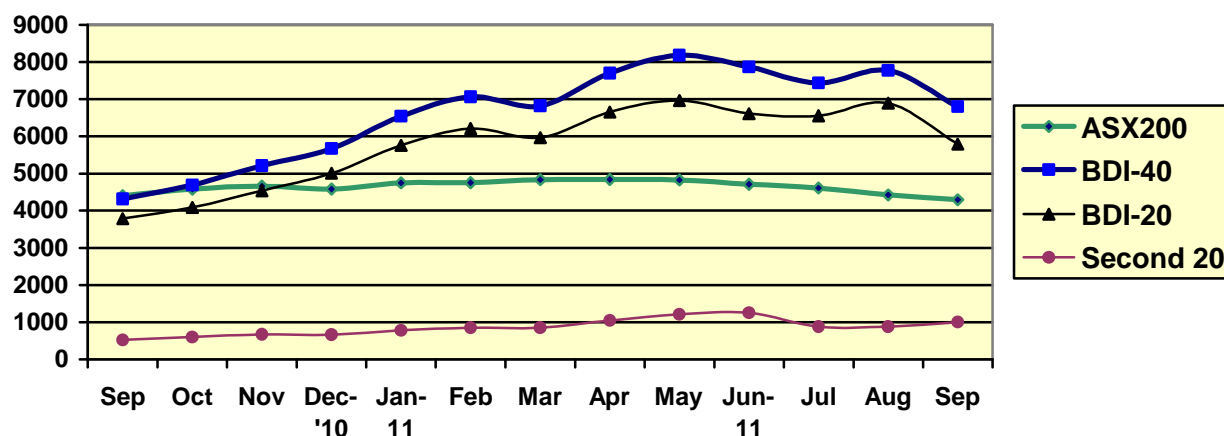
For the year to July 31, 2011, the Biotech Daily Top 40 Index (BDI-40) was up 57.5 percent, compared to the S&P ASX200 down 4.4 percent.

The three Big Caps collectively fell 3.6 percent in August and 13.3 percent for the year. Cochlear climbed 7.0 percent in August, Resmed was up 4.7 percent, but CSL fell 8.4 percent to \$14,846 million, its lowest market capitalization since March 2007.

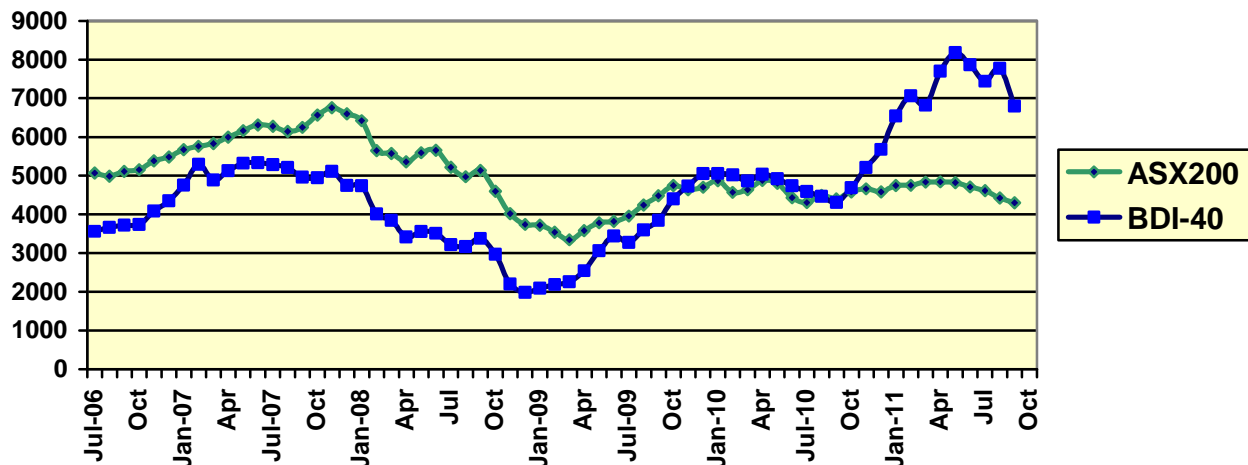
Outside the BDI-40, CBio fell 61.7 percent to \$41 million, while Neuren climbed 46.7 percent to \$22 million.

Reva has been promoted to the Second 20, replacing Virax, with Patrys promoted to the Top 20 and Genera demoted to the Second 20.

BDI-40 v ASX200 Aug 31, 2010 to Aug 31, 2011



BDI-40 v ASX200 Jun 30, 2006 to Aug 31, 2011



### BIONOMICS

Bionomics says it has demonstrated a common molecular link between the anti-anxiety and anti-depressant effects of anti-anxiety compound BNC210 in mice.

Bionomics said BNC210 showed antidepressant activity in animal models of depression and it potentially promoted neurite outgrowth, an indication of neurogenic activity and a hallmark of anti-depressants.

The company said the data would be the subject of poster presentations at the European College of Neuropsychopharmacology conference in Paris, September 3-7, 2011, along with the previously published phase Ib human clinical trial of BNC210 showing it had no side effects compared to the benzodiazepine, lorazepam (BD: Mar 30, 2011).

Bionomics said the poster entitled 'The phospholipase C inhibitors U73122, D609 and Edelfosine inhibit the activity of the novel anxiolytic and antidepressant compound BNC210' would "for the first time describe the molecular link between the neurotrophic effects of BNC210 and its anti-anxiety properties".

The company said the effect of BNC210 on neurite outgrowth was more potent than brain-derived neurotrophic factor (BDNF), one of the body's endogenous neurotrophins or nerve growth factors.

Bionomics said BNC210 intracellular signaling occurred through phospholipase C (PLC) enzymes which were important in the signal transduction pathways used by neurotrophins and the results showed that inhibitors of PLC enzymes inhibit BNC210's promotion of neurite outgrowth as well as its anxiolytic activity in a mouse model of anxiety.

The company said that the inhibitors did not inhibit the anxiolytic activity of diazepam, indicating that the action of the PLC inhibitors was specific to BNC210 signaling and not a general anti-anxiety effect.

Bionomics chief executive officer Dr Deborah Rathjen said it was a "very important step to have determined a common molecular link between the anti-anxiety and anti-depressant effects of BNC210".

"Marketed anti-depressants usually take several weeks to exert their beneficial effects," Dr Rathjen said. "BNC210 ... is faster-acting than marketed drugs such as Prozac."

The company said that both poster presentations would be given by BNC210 project leader and senior director, CNS research Dr Sue O'Connor and were available on Bionomics' website.

Bionomics was up one cent or 2.1 percent to 49.5 cents.

## CLINUVEL PHARMACEUTICALS

Clinuvel says it has completed its pre-clinical program for its ultra-violet light protection drug Scenesse or afamelanotide.

Clinuvel said completing the program was “an important regulatory milestone” for filing the marketing authorization application to the European Medicines Agency for the orphan disease erythropoietic protoporphyria.

The company said the data from the four pre-clinical studies confirmed the results from earlier trials.

Clinuvel said the studies investigated the chronic effects of afamelanotide and the effects of the drug in reproductive toxicology models and all four studies used significantly higher and more frequent levels of drug exposure compared to those used in patients.

The company said that following a review of earlier pre-clinical studies the EMA agreed that carcinogenicity studies were not required.

Clinuvel said that chronic exposure over 10 months showed that afamelanotide implants activated pigmentation as expected but had no adverse or unexpected effects on tissue toxicity, the neurological or cardiovascular systems.

The company said a placebo-controlled, six month, high-dose study showed no adverse effects and confirmed the reversal of pigmentation within a 28 day recovery period.

Clinuvel said that single and repeat dose toxicology studies, ranging from 21-90 days, had shown the drug to be safe and well tolerated in a number of pre-clinical models, with no clinically relevant histopathological changes observed.

The company said that in subcutaneous controlled-release drug formulations there was no evidence of drug accumulation.

Clinuvel said that earlier pre-clinical reproductive studies had shown the drug to have no adverse effects on reproduction in males and females at significantly elevated exposure levels compared to those used in humans and the latest data confirmed the drug had no effect on body weight or weight gain, food consumption or reproductive parameters, with no abnormalities seen in first generation off-spring.

The company said that pending clinical results from a US phase II study and a European phase III study it expected to file the EMA application before the end of 2011.

Clinuvel was up 15 cents or 10.3 percent to \$1.60.

## ADVANCED SURGICAL DESIGN & MANUFACTURE

Advanced Surgical says its net loss after tax for the 12 months to June 30, 2011 was up 264.4 percent to \$3,265,000 on revenue down 1.3 percent to \$7,370,000.

Advanced Surgical chief executive officer Dr Greg Roger told Biotech Daily that the first half of the financial year saw an increased expenditure on a strategic review with the second half implementing the new strategy.

Dr Roger said that year-on-year sales were up 19 percent and the company was “set for a good year ahead”.

Dr Roger said he expected the company to be in profit by June 30, 2012 and was “committed to pay a dividend to shareholders”.

Advanced Surgical said that net tangible asset backing per share fell 39.9 percent from 18.69 cents to 11.24 cents.

The company said diluted loss per share was 9.25 cents compared with 2.54 cents in the previous corresponding period.

Resonance said it had cash and equivalents fell from \$723,000 at June 30, 2010 to a debt of \$172,000 at June 30, 2011.

Advanced Surgical was untraded at 18.5 cents.

### CYCLOPHARM

Cyclopharm says its net loss after tax for the 12 months to June 30, 2011 was up 99 percent to \$1,533,793 on revenue up 10 percent to \$3,615,429.

Cyclopharm said the reduction in profitability was "primarily attributed to the timing of sales and the slower than expected ramp-up of Macquarie University Hospital".

The company said the volume sales of the company's key medical imaging product Patient Administration Sets were eight percent higher than the prior year, with Technegas sales constant at \$3.27 million.

Cyclopharm said that net tangible assets per share was constant at 0.6 cents

The company said its diluted loss per share up 102.2 percent to 0.91 cents.

The company said it had cash and cash equivalents of \$1,095,751 at June 30, 2011 down 28.9 percent compared to \$1,541,644 at June 30, 2010.

Cyclopharm was up 0.1 cents or 2.2 percent to 4.6 cents.

### ALLIED HEALTHCARE GROUP

Allied Health says its net loss after tax for the 12 months to June 30, 2011 was up 3,236 percent to \$1,423,000 on revenue up 63 percent to \$6,750,000.

Allied said that net tangible assets per share was 0.95 cents compared to the previous year's negative 0.24 cents.

The company said that basic loss per share increased 2,156.7 percent to 0.677 cents.

Allied said it had \$1,352,000 in cash at June 30, 2011.

Allied Health fell 0.2 cents or four percent to 4.8 cents.

### VIRALYTICS

Viralytics says China has granted a patent covering the use of Echovirus type 1 or Evatak as an anti-cancer agent in human ovarian cancer.

Viralytics said the patent covered the use of Evatak recognizing the integrin alpha2-beta1 on the surface of human ovarian cancers to infect and destroy cancer cells.

The company said the patent covered the use of a combination of Evatak and Cavatak, or Cocksackievirus type A21, in the targeted destruction of human ovarian cancer cells.

Viralytics said Cavatak used an alternative targeting mechanism to Evatak, binding to the cell surface receptor ICAM-1 to invade and destroy cancerous cells.

The company said the Chinese patent widened its protection on the use of Echoviruses in cancer patients, which already includes existing US and Australian patents covering the use of Evatak in the oncolysis of alpha2-beta1 expressing cancers.

Viralytics said it was undergoing multi-site recruitment for its US-based phase II trial of Cavatak in late stage melanoma patients under an investigation new drug application allowed by the US Food and Drug Administration.

The company said the first patient in the phase II trial was expected to be injected with Cavatak by the end of this year.

Viralytics said it was completing two phase I safety trials in Australia, focusing on the safety of both intra-tumoral and intravenous delivery of Cavatak.

Viralytics was up 4.5 cents or 9.8 percent to 50.5 cents.

### HELICON GROUP

Helicon says it has raised \$898,000 in private placement of shares at two cents each to sophisticated investors.

Helicon said that subject to shareholder approval each new share would come with an attaching option, exercisable at 2.5 cents by December 31, 2014.

Helicon was up 0.1 cents or 4.8 percent to 2.2 cents.

### IMUGENE

Imugene has requested a trading halt pending an announcement regarding a strategic alliance for its pig and poultry vaccines.

Trading will resume on September 5, 2011 or on an earlier announcement.

Imugene last traded at 3.1 cents.

### CBIO

CBio has requested a trading halt "pending the release of a material announcement concerning capital raising".

Trading will resume on September 5, 2011 or on an earlier announcement.

CBio last traded at 26 cents.

### ACRUX

Acrux says co-founder Prof Barrie Finnin has retired as a director after 12 years' service to the company.

Acrux said Prof Finnin was a co-inventor of its transdermal drug delivery technology and he played an integral role in developing the core technology and the company's corporate growth.

Acrux said it would appoint a suitably qualified non-executive director to replace Prof Finnin in due course.

Acrux was up nine cents or 2.3 percent to \$3.93 with 1.3 million shares traded.

### SUNSHINE HEART

Sunshine Heart says that founder Crispin Marsh has retired as a director.

Sunshine Heart chairman Nick Callinan said Mr Marsh worked with co-founder Dr William Peters to build the company from 2000.

Mr Callinan said Mr Marsh was a named inventor on a number of early patents, raised the first capital to fund the initial development of the C-Pulse heart assist system and won \$8 million in research and development grants which were crucial support in the early days.

Mr Callinan said Mr Marsh managed the company's intellectual property portfolio to secure important patent protection for the C-Pulse and guided the company to a public listing in Australia, raising \$14 million.

Sunshine Heart was untraded at four cents.

## BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Sep-10	Aug-11	Sep-11
Cochlear	3,915	4,022	4,302
CSL	18,124	16,203	14,846
Resmed	5,140	4,220	4,420
<b>BDI-20</b>			
Acrux	324	683	639
Alchemia	93	136	65
Bionomics	86	221	167
Biota	167	175	180
Clinuvel	67	52	44
Genetic Technologies	13	86	88
Heartware	995	892	836
Impedimed	94	102	91
Living Cell	53	20	20
Mesoblast	283	2,549	2,229
Nanosonics	140	177	136
Patrys	18	21	18
Pharmaxis	458	251	212
Phylogica	13	28	26
Prima	63	261	196
Sirtex	270	284	282
Starpharma	117	383	293
Sunshine Heart	14	39	45
Tissue Therapies	26	95	82
Universal Biosensors	239	172	143
<b>Second 20</b>			
Advanced Surgical	17	6	7
Allied Health	3	34	29
Anteo	28	56	51
Antisense	8	8	8
Benitec	10	25	21
Bioniche	105	96	89
Cathrx	25	21	21
Cellmid	6	9	8
Circadian	27	27	28
Compumedics	24	13	15
Genera	31	11	10
LBT Innovations	8	4	6
Optiscan	6	13	13
Phosphagenics	73	107	128
Prana	30	45	43
Psivida	65	88	90
QRX Pharma	91	207	192
Reva	275	238	210
Uscom	14	11	10
Viralytics	17	36	27

\* Biotech Daily editor, David Langsam, owns shares in Alchemia, Allied Health, Bionomics, Biota, Neuren, Optiscan, Pharmaxis, Sunshine Heart and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Atcor, Circadian, Pharmaxis, QRX and Tissue Therapies. These holdings are liable to change.

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