



# Biotech Daily

Monday February 2, 2009

*Daily news on ASX-listed biotechnology companies*

- \* **BIOTECH DAILY TOP 40: LIFE SIGNS RETURN TO LIFE SCIENCES**
  - PEPLIN UP 71%, VENTRACOR UP 45%, CYTOPIA FALLS 40%
- \* **TODAY: ASX DOWN, BIOTECH EVEN**
  - UNIVERSAL UP 8%, CYTOPIA DOWN 18%
- \* **TISSUE THERAPIES REDUCES CANADIAN DIABETIC ULCER 29%**
- \* **FIRST AUSTRALIAN INDUCED PLURIPOTENT STEM CELLS**
- \* **ACRUX AXES FENTANYL MDTs; EVAMIST KV'S SILVER LINING**
- \* **ORBIS INVESTS \$2m IN IMPEDIMED**
- \* **AUSBIOTECH CALLS FOR STIMULUS PACKAGE**
- \* **FLUOROTECHNICS REBRANDS AS GELCOMPANY**
- \* **METABOLIC, POLYNOVO CHAIRMAN ROB STEWART RESIGNS**
- \* **GIACONDA ANSWERS ASX CASH FLOW QUERY**
- \* **BIOTECH DAILY TOP 40 WITH MARKET CAP**

## MARKET REPORT

The Australian stock market fell 1.22 percent on Monday February 2, 2009 with the S&P ASX 200 down 43.3 points to 3,497.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and 11 were untraded.

Universal Biosensors was best, up 4.5 cents or 8.18 percent to 59.5 cents with 1,600 shares traded, followed by Starpharma up 5.88 percent to 18 cents. Ventracor climbed 3.45 percent; Heartware was up 2.94 percent; with Arana, Chemgenex, Impedimed, Living Cell and Progen up more than one percent.

Cytopia led the falls, down two cents or 18.18 percent to nine cents with 200,000 shares traded, followed by Genera down 9.09 percent to 20 cents and Clinuvel down 8.16 percent to 22.5 cents. Alchemia and Prana lost more than seven percent; Viralytics was down five percent; Avexa fell 4.35 percent; CSL was down 3.65 percent; Novogen and Pharmaxis shed more than two percent; with Biota, Cochlear and Sirtex down more than one percent.

## BIOTECH DAILY TOP 40 INDEX

Biotech stocks improved in January with the Biotech Daily Top 40 Index (BDI-40) up 4.2 percent compared with the S&P ASX 200 fall of 4.9 percent for the month.

The three Big Caps (which are not included in the BDI-40) were even better, up 8.5 percent for the month and 7.2 percent for the year to the end of January, with all three, Cochlear, CSL and Resmed contributing to the gain.

Statistically, the BDI-20, also fared very well, up 7.3 percent for the month, but this includes the new year changes to the constituent companies. For the year to the end of January the S&P ASX 200 fell 37.3 percent while the BDI-20 notionally outperformed it by falling 34.8 percent. The BDI-40 fell 43.1 percent.

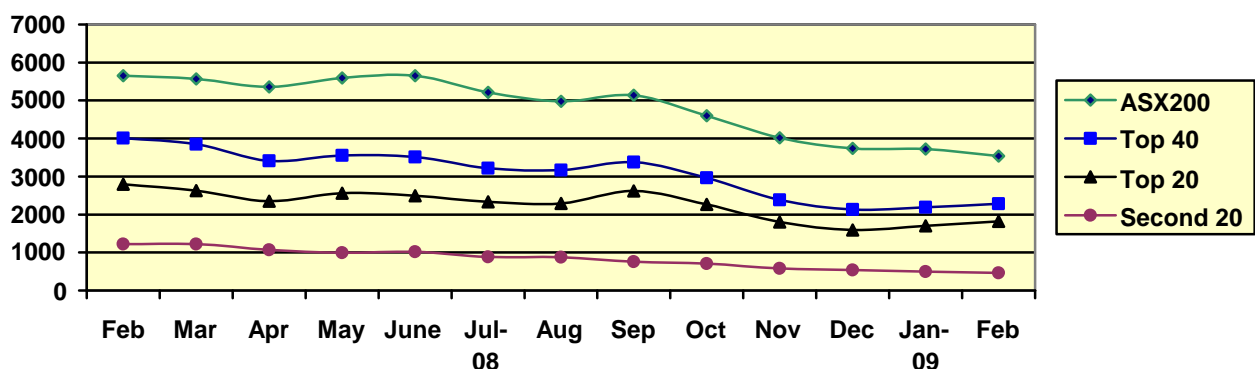
Nineteen of the Top 40 companies climbed in January, 17 fell and four were unchanged.

Peplin led the charge, increasing its market capitalization from \$59 million by 71.2 percent to \$101 million, its highest value since March 2008 (BD Dec 17, 2008). From a much lower base, Ventracor recovered \$9 million or 45 percent to a market capitalization of \$29 million, followed by Phylogica and Tyrian both up 42.9 percent to \$10 million; Sunshine Heart (33.3%), Biota (32.8%), Phosphagenics (29.4%), Pharmaxis (19.6%), Sirtex (17.0%) and Acrux all indicating it might be safe to go back into the better biotechs.

Outside the Top 40, Tissue Therapies jumped 175 percent to \$11 million, its highest market capitalization since January 2008, Uscom climbed 65 percent to \$28 million its best since January 2007 and Cogstate hit \$16 million, its highest value since listing.

Most falls were less than 10 percent with the steepest a 40 percent drop in the value of Cytopia from \$15 million to \$9 million, for no particular reason and preceding the company's bid for Progen's cash (BD Jan 28, 2009). Polartechncis retreated 28.6 percent from the previous month's sales-driven \$42 million highpoint to \$30 million followed by Impedimed (20%); Mesoblast (19.8%); and Labtech (16.7%). Outside the Top 40 the most significant fall was Solagran, which dropped as low as 14.5 cents a share and a market capitalization of \$27 million, its lowest since January 2007, having been as high as \$156 million in January 2008..

Biotech Daily Top 40 (\$m) v S&P ASX 200 2008-09



## TISSUE THERAPIES

Tissue Therapies says the first patient in its Toronto clinical trial of Vitrogro for diabetic, venous and pressure ulcers has had a 29 percent reduction in ulcer size.

Tissue Therapies said the 73 year old man with diabetes and high blood pressure continued to smoke cigarettes, but experienced the substantial reduction in the size of chronic diabetic ulcer at the base of his right big toe in six weeks, after conventional treatment for more than two years had produced no effect.

The diabetic ulcer was the site of recurrent infections for which he needed combination antibiotics and with no response, "the patient was so despondent that he was considering amputation as the only means of ridding himself of the pain, social isolation and reduced mobility," Tissue Therapies said.

The company said that following six weeks of treatment, the maximum permitted under the approved trial protocol, the ulcer had reduced in size by almost one third.

The trial protocol includes six weeks of treatment and six weeks of follow up, with no further ability to apply Vitrogro.

Tissue Therapies' chief executive officer Dr Steven Mercer told Biotech Daily that the company had not discussed compassionate post-trial use of Vitrogro with Health Canada, but said trial patients "might, continue to heal without further treatment as have the patients in the Fremantle Western Australia trial".

Dr Mercer said the diabetic ulcers were more difficult to treat than venous ulcers.

In the media release Dr Mercer said the 29 percent reduction in six weeks was "an excellent result in a patient with a severe chronic diabetic ulcer".

"This patient presents an extremely challenging combination of complicating clinical factors and in many ways represents the most challenging and ambitious type of patient for a clinical trial of Vitrogro," Dr Mercer said.

Tissue Therapies said the trial was being conducted at a Toronto wound care centre run by Prof Gary Sibbald.

Tissue Therapies said the Canadian trial followed "a successful clinical trial of Vitrogro for the treatment of venous ulcers" in Fremantle during 2008.

Tissue Therapies climbed half a cent or 2.56 percent to 20 cents.

## STEM CELL RESEARCH

The Victorian Government says researchers in Melbourne and Sydney have created Australia's first induced pluripotent stem cell line from human cells.

Innovation Minister Gavin Jennings said the Australian induced pluripotent stem (iPS) cell line was developed by Dr Paul Verma's group at the Monash Institute of Medical Research, working with Sydney Cell Therapy Foundation's Prof Bernie Tuch and was backed by a joint Victorian and New South Wales Government grant

Mr Jennings said the ability to produce human iPS cell lines locally "would greatly assist Victorian researchers to progress their research into the causes of serious diseases and to develop better treatments".

"To date human iPS cells have been imported under agreements with American or Japanese laboratories that first developed them in November 2007," Mr Jennings said.

He said iPS cell derivation did not require donated IVF embryos or human eggs and no embryos were destroyed in the process, but could be derived from adult cells, such as skin, which were reprogrammed to be more embryonic-like in behavior.

Mr Jennings said they would be able to generate iPS cells from type I diabetes patients to help understand the disease and develop better drugs to treat it.

## ACRUX

Acrux has suspended clinical development of its Fentanyl MDTs (metered dose transdermal spray) program “despite positive results in phase I clinical trials to date”. After the market closed on January 30, 2009, Acrux announced that the decision followed dialogue with the US Food and Drug Administration on the likely development requirements for Fentanyl MDTs for chronic pain to become an approvable product for the US market.

Acrux chief executive officer Dr Richard Treagus said “the regulatory environment for Fentanyl around this product has in recent times become much more onerous and further development will be both difficult and expensive”.

“Acrux’s cash and human resources will be more effectively applied to the many other valuable products in our pipeline,” Dr Treagus said.

Dr Treagus told Biotech Daily that the FDA had continued to tighten controls on opioids and narcotics making the development path more expensive.

Separately, Dr Treagus told Biotech Daily that quality and manufacturing problems facing KV Pharmaceuticals was not having an impact on sales marketing and distribution of Acrux’s Evamist, known as Ellavie outside the US, to treat menopause symptoms.

Dr Treagus said KV’s problems were with manufacturing and Evamist was manufactured by a third party pharmaceutical company in Texas, with KV providing sales, marketing and distribution.

He said that Evamist was a silver lining on KV’s black cloud, allowing KV to more closely focus on his company’s product.

“There has been no disruption to the manufacturing and supply and KV continues to market and supply Evamist,” Dr Teagus said. “Evamist is not caught up in this.”

“Under certain circumstance we could reacquire the rights to our product, but they continue to market and sell our product,” Dr Treagus said.

Apart from Evamist, Acrux’s development pipeline includes Testosterone MD-Lotion to treat testosterone deficiency in men; Testosterone MDTs for decreased libido in women; Nestorone MDTs contraceptive sprays for women; an undisclosed companion animal health product; and Nicotine MDTs for smoking cessation.

Acrux has licenced Testosterone MDTs to Vivus; the Australia and New Zealand distribution rights for Estradiol MDTs to Aspen Pharmacare; and Testosterone MDTs to CSL Limited.

Acrux has also licensed its technology to Eli Lilly and Company for veterinary healthcare products and has an exclusive commercial manufacturing alliance with Orion Corporation. Acrux was unchanged at 50 cents.

## IMPEDIMED

Impedimed has raised \$2 million through the placement of 2,857,143 shares at 70 cents a share to Orbis Investment Management.

After the market closed on January 30, 2009, the company announced that with the \$4.7 million cash it had at December 31, 2008, it had a “proforma cash position of \$6.7 million”. Impedimed said its operating plans for 2009 “project a more modest cash burn due to the new product development costs reducing significantly, meaning the company does not have near term cash pressures”.

Impedimed has 90,176,001 shares on issue.

Orbis increased its substantial shareholding in Impedimed from 10,494,044 shares (12.01%) to 13,351,187 shares (14.81%).

Impedimed was up one cent or 1.41 percent to 72 cents.

## AUSBIOTECH

Ausbiotech wants Government intervention to encourage investment and growth in the biotechnology industry.

In a media release Ausbiotech said the industry employed 40,000 people and said in its headline the Federal Government provided '\$6 billion for old industries while industries of the future are still waiting'.

The industry organization said there was "a compelling argument to recognize, support and create the next wave of growth in Australia".

Ausbiotech chief executive officer Dr Anna Lavelle said Australia's 21st century industrial "power houses will emerge from biotechnology, not wool, mining, cars or textiles".

"By all means defend existing jobs, but at the same time, we also need to defend the future of our families," Dr Lavelle said.

Dr Lavelle said "governments around the world are responding to the economic crisis by bolstering industries of the future and ... Australia must do the same".

She said that many of Australia's world-leading biotechnology companies were "fighting to survive" as funding for research and development had slowed dramatically.

"Right now, \$600 million for biotechnology probably buys more future jobs and export opportunity than the same investment in traditional industries," Dr Lavelle said.

She said that last week the Federal Government released the report from the Pharmaceuticals Industry Strategy Group (BD: Jan 30, 2009), convened to report on the state of the industry and the role that government could and should play to support it.

Dr Lavelle said the report recommendations were "sound and when implemented will benefit, not only the industry but the Australian community".

She said Ausbiotech called for the introduction of refundable tax credits for companies with operational turnover of less than \$50 million and providing competitive matched grants of up to \$750,000 to companies in proof of concept stage and \$3 million to \$10million for those moving through the clinical trial process.

Dr Lavelle said Ausbiotech supported access to strong and effective capital markets that will fund high-risk projects that have sufficient potential commercial returns and taxation arrangements that do not deter companies from investing in relatively high risk activities like research and development or complex manufacturing.

Dr Lavelle said that a refundable 50 percent tax credit was a necessary stimulant and incentive for research and development activity in Australia and was urging the Federal Government to consider this in the Federal Budget.

## FLUOROTECHNICS

Fluorotechnics says it is changing its trading name and product branding to 'Gelcompany', but the corporate holding and ASX name will remain Fluorotechnics.

Fluorotechnics supplies fluorescence and other protein detection technologies and said Gelcompany was the trading name for products from San Francisco's The Gel Company, Germany' Elektrophorese-Technik GmbH and Australia's Fluorotechnics.

Using one umbrella brand across three companies and over 300 products would help build goodwill, rationalize operations and cut costs, the company said.

Fluorotechnics chief executive officer Dr Duncan Veal said that combining the trading and brand names for the three parts of the enterprise reflected "the orientation to provide complete solutions rather than off-the-shelf products from different companies in different countries".

Fluorotechnics was unchanged at 90 cents.

## METABOLIC

Metabolic chairman Rob Stewart will resign as a director of the company from February 20, 2009.

Metabolic said Mr Stewart would also resign as a director and chairman of Polynovo Biomaterials which is 60 percent owned by Metabolic (BD: Dec 18, 2008).

Mr Stewart said that with the acquisition of the 60 percent share of Polynovo completed, "I feel that my task in helping to chart a new direction for Metabolic is done and I am therefore now in a position to move on to other things".

Mr Stewart is chairman of internet development company Melbourne IT.

Metabolic was untraded at 2.5 cents.

## GIACONDA

Giaconda has told the ASX that "is not of the opinion that it can be concluded that Giaconda only has sufficient cash to fund its activities for less than two quarters".

Giaconda said it had previously announced that chief executive officer Patrick McLean and chief medical officer Prof Thomas Borody had agreed to loan the company \$10,000 a month from October 1, 2008 to August 1, 2009.

The ASX noted a cash burn of \$63,000 for the quarter ending December 31, 2009 with cash of \$16,000 at the end of the quarter and no receipts from customers.

Giaconda said it expected to have a lower cash burn than for the three months to December 31, 2008 and was continuing "to seek alternative funding arrangements".

Giaconda was untraded at 5.5 cents.

## BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

<b>Company \$Am</b>	<b>Feb-09</b>	<b>Jan-09</b>	<b>Dec-08</b>
Cochlear	3,239	3,101	3,094
CSL	21,750	20,321	20,919
Resmed	4,635	3,887	4,072
<b>BDI-20</b>			
Acrux	86	76	74
Alchemia	23	26	23
Arana	200	190	186
Avexa	30	31	45
Bionomics	52	53	55
Biota	77	58	64
Cellestis	144	168	180
Chemgenex	96	111	99
Cytopia	9	15	14
Heartware	186	185	130
Impedimed	52	60	52
Living Cell	22	24	33
Mesoblast	97	121	106
Novogen	73	70	79
Peplin	101	59	47
Pharmaxis	281	235	233
Phosphagenics	66	51	50
Sirtex	110	94	106
Starpharma	31	35	36
Universal Biosensors	86	93	69

**Second 20**

Antisense	20	20	22
Benitec	10	11	9
Bone Medical	21	17	25
Cathrx	23	21	28
Circadian	30	26	25
Clinuvel	73	73	64
Genera	10	11	9
Genetic Tech	18	19	17
Labtech	10	12	12
Optiscan	7	7	7
Phylogica	10	7	7
Polartech	30	42	22
Prana	65	64	61
Progen	51	47	47
Psivida	12	13	15
Stem Cell Sci	5	5	5
Sunshine Heart	16	12	16
Tyrian	10	7	11
Ventracor	29	20	23
Viralytics	12	11	14

\* Biotech Daily editor, David Langsam, owns shares in Alchemia, Biota, Chemgenex, Cytopia and Stem Cell Sciences as well as non-biotechnology stocks. These are liable to change at any time.