



Biotech Daily

Tuesday September 2, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECHS DOWN: OPTISCAN UP 9.5%, BENITEC DOWN 19%**
- * **STEM CELL: 'WORLD'S FIRST TRUE RAT EMBRYONIC STEM CELLS'**
- * **BIO-GUIDE BRIEF: DO WE REALLY NEED MERGERS?**
- * **VENTRACOR'S PETER CROSBY HITS THE INVESTMENT ROAD**
- * **ABSOLUTE CAPITAL SELLS 20% STAKE IN CLINUVEL**
- * **CSL APPOINTS MERCK & CO'S DAVID ANSTICE DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.1 percent on Tuesday September 2, 2008 with the All Ordinaries down 5.0 points to 5,195.0 points.

Ten of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and nine were untraded.

Optiscan was best, up two cents or 9.52 percent to 23 cents on small volumes, followed by Bionomics up two cents or 5.71 percent to 37 cents.

Biota, Pharmaxis and Phylogica climbed more than five percent; Antisense and Psivida were up four percent or more; Alchemia rose 3.45 percent; with Arana, Cochlear, CSL, Novogen and Resmed up more than one percent.

Benitec led the falls, down 1.6 cents or 19.05 percent to 6.8 cents on modest volumes, followed by Peplin down 3.5 cents or 7.07 percent to 46 cents.

Phosphagenics fell 6.1 percent; Genetic Technologies was down 5.56 percent; Arana, Chemgenex, Living Cell and Prana fell more than four percent; Clinuvel and Mesoblast were down more than three percent; Starpharma and Universal Biosensors shed two percent or more; with Heartware and Neuren down more than one percent.

STEM CELL SCIENCES

Stem Cell Sciences says laboratories in Britain and the US using its technology have achieved germ-line transmission from embryonic stem cells in rats.

Stem Cell Sciences non-executive director Dr Peter Mountford said that over the past 25 years researchers had been unable to produce germ-line transmission via embryonic stem cells into any other species other than mice.

"None have previously been able to create cells that make sperm or eggs," Dr Mountford said.

"Germ-line transmission refers to the ability of the cells to make eggs and sperm and thereby the ability of those cells to transfer the introduced genetic modification into whole animals," Dr Mountford said.

"This is the number one priority of the US National Institutes of Health in the field of rat genomics," Dr Mountford said.

In a media release to the ASX Stem Cell Sciences said the achievement in two independent laboratories, using technologies licenced to the company by Edinburgh University, was "believed to be the first time that germ-line transmission from rat [embryonic stem] cells has been demonstrated".

The company said full scientific reports on the independently verified breakthrough had been submitted to a major scientific journal for publication.

Stem Cell said that under the Edinburgh University agreement it had "global exclusive rights to commercialize the rat [embryonic stem] cells, the specific culture medium used to generate and grow the cells, and rats derived therefrom".

Stem Cell said it had licenced two important patents covering the technology from the University and would meet interested parties seeking a sublicense for the rat stem cells.

"The main advantage of this important new technology is that it allows the generation of both knockout rat models, in which the effect of gene deletion is studied, as well as the generation of knock-in models, which involves the insertion of genes," Stem Cell said. For example, in the case of knock-out models, the rat's response to drugs could provide information on safety and efficacy.

Alternatively, the insertion of genes such as those involved in drug metabolism in the human liver means that knock-in models could provide information on human safety and pharmacokinetics.

Stem Cell's chief executive officer, Dr Alastair Riddell, said the breakthrough would enable "the generation of transgenic rat models for drug discovery in a very similar manner to the already widely used transgenic mice models".

"The advantage here is that rats are viewed as more predictable human models than mice for several psychiatric, neurological and cardiovascular drug targets," Dr Riddell said.

"The ability to knock-in human genes should also enable drug metabolism studies to be undertaken with higher predictability in rats than previously available," Dr Riddell said.

"This opens the way to new and more effective drug discovery and expect there to be considerable commercial interest in access to this exciting technology," he said.

Stem Cell said the culture medium patent family, which was filed in multiple territories including the US, contained several specific enzyme inhibitors which when used in certain combinations, could be used to grow embryonic or pluripotent rat stem cells reliably in a serum-free environment.

The rat embryonic stem cell patent family, which was also filed in multiple territories including the US, gave Stem Cell the exclusive right to make and commercialize unique rat models for biopharmaceutical research and development, a market of more than \$US80 million.

Stem Cell Sciences was unchanged at 20 cents.

[MARC SINATRA'S BIO-GUIDE: MERGERS & ACQUISITIONS](#)

Everyone tells me we need consolidation in the biotech industry, we need mergers.

But, then, open The Age and I see a whole page of listed mining companies less diversified in their activities than a random sampling of 10 biotechs.

Having so many mining companies is not a recent phenomenon. I have been seeing pretty much same page in The Age since well before the recent resources boom began and the mining industry survives just fine, thank you very much.

A look at mergers that have had time to bear fruit isn't awe-inspiring.

Psivida's merger with the US-based Control Delivery Systems has failed to reap benefits for shareholders and the company now looks like the original Control Delivery Systems with Psivida's original technology, Biosilicon, seemingly moribund.

The clock is ticking on Alchemia's merger with Meditech. Despite solid clinical trial results, Alchemia has failed to do any deals based on Meditech's Hyact technology leaving that program and Alchemia's share price looking wobbly.

Finally, a few years back, AGT Biosciences merged with US-based Chemgenex, only to spit out Verva Pharmaceuticals last year because they eventually recognised that they had two distinct and incompatible product development pipelines.

The point that I am trying to make is that merging simply for the sake of increasing size or reducing the number of ASX-listed biotechs makes no sense.

The value lost by merging and reducing investor choice must be offset by synergies; such as those that ensue by merging compatible development programs.

Importantly, without synergies there will be no excess money to be ploughed back into biotech, because the merged entity will still have the same capital requirements.

Synergies are also not as easy to find as you may think. For example, a merged entity may only require one chief executive officer, but they will need to be paid more. Plus, a chief operating officer may also be needed. All of a sudden any savings are gone.

All of this is not to say we shouldn't be looking for mergers. The merger of antibody companies Peptech and Evogenix into Arana made sense with clear strategic and operational synergies.

Further mergers in the antibody therapeutic space involving a combination of Arana, Circadian, Medical Therapies and Patrys could also provide the required synergies.

But, we simply shouldn't be looking for mergers for mergers sake. For example merging Avexa with Circadian might solve some problems each company has, but there are no real synergies to give any advantage.

Marc Sinatra owns shares in Alchemia and Circadian.

VENTRACOR

Despite exponential revenue from sales of Ventracor's heart pump, chief executive officer Peter Crosby says capital raising is difficult.

In Melbourne to see investors and media, Mr Crosby told Biotech Daily the company was "actively assessing several financing options" in the quest to raise up to \$22 million to take the company to mid-2009.

Over the past three years total revenue has increased from \$1.1 million at June 30, 2006 to \$4.9 million in 2007 increasing to the \$17.3 million reported last week (see biotech Daily August 28, 2008).

"We'd be really pleased if we could double the revenues in the next 12 months," Mr Crosby said.

He said the company's third generation left ventricular assist device had approval in Australia and Europe with significant sales in both continents, but the US remained the key market.

He said that if everything went according to plan Ventracor was hoping for US Food and Drug Administration registration for the bridge-to-transplant indication by mid-2010 and the more lucrative destination therapy by mid-2013.

The bridge-to-transplant market was worth \$US300 million per year but the destination therapy was much larger at \$US4 billion a year, Mr Crosby said.

He said that to reach the mid-2010 point where revenue from the bridge-to-transplant indication was registered and retuning revenue to fund all further work, Ventracor would need a total of about \$40 million.

Mr Crosby said that when the leading supplier Thoratec passed its FDA pre-market approval in April 2008 sales of their second generation pump "took off".

He is expecting the same will happen once the Ventracor pump is approved.

"With regulatory approval we can go to everyone, not just FDA-limited centres," Mr Crosby said.

He said Ventracor would have "an early look" at the ongoing clinical trial results for the bridge-to-transplant trials, as early as December 2008.

He said the Ventracor centrifugal device was superior to its leading axial competitors and was significantly advanced compared to other centrifugal pump companies.

"It's a time to market play," Mr Crosby said.

"The first two or three will take 90 percent of the market," he said.

Mr Crosby said that with more than half of its total 325 heart pump sales in the past 12 months he expected to sell "hundreds" of pumps in the 12 months following bridge-to-transplant registration and "thousand" once the pump has been registered for destination therapy.

He also said that any development of stem cell technology to repair hearts would assist his business as the heart would require resting while the stem cells were transplanted and grown.

He said Ventracor's share price had been hit by the market turmoil, but also believed day-traders were part of the reason the price was depressed, but there was also the possibility that some investors thought that any capital raising would have to be at a discount.

He said the top 100 investors were stable or buying.

Mr Crosby said he was hoping to increase the level of US corporate investment into the company which has "the only class 3 life-saving active implantable device made in Australia".

"It's a pump. It works. And we're building a business," Mr Crosby said.

Ventracor was unchanged at 20 cents.

CLINUVEL

Clinuvel says the 60.62 million shares (20%) held by Absolute Capital Management Holdings was sold to Australian institutional and international investors today.

The sale at 25 cents a share went through on-market this morning.

Clinuvel's head of corporate development Colin Mackie told Biotech Daily that the Majorca-based and London Alternative Investment Market-listed hedge fund Absolute Capital had financial concerns for about 12 months.

"The overhang is out of the stock," Mr Mackie said.

Clinuvel said the share register was "balanced and spread evenly with no substantial shareholders".

Clinuvel said the purchase "by existing and new, international and Australian investors is welcomed by the Clinuvel board and highlights the growing breadth of investor support for Clinuvel's advances towards commercialization of its photo-protective drug afamelanotide (CUV1647).

Clinuvel's chief executive officer Dr Philippe Wolgen said Absolute Capital Management had been "a supportive shareholder over a long period of time".

"We are sorry to see them go but their circumstances and investment priorities have changed," Dr Wolgen said.

"We appreciate the support of existing and new investors for our program in the current economic downturn," Dr Wolgen said.

We welcome the increased diversity in our share register," he said.

Clinuvel fell one cent or 3.33 percent to 29 cents, with 61,066,066 shares traded.

CSL

CSL has appointed former Merck & Co executive David Anstice as a director effective from September 2, 2008.

A CSL media release said Mr Anstice retired from Merck & Co on September 1, 2008.

CSL said Mr Anstice was president of Merck Human Health for the US, Canada, Europe, Japan and Asia, in separate assignments.

The company said Mr Anstice had also been responsible for Merck's prescription drug business in Latin America, Australia and New Zealand and its joint venture relationship with Schering Plough.

CSL said Mr Anstice was a member of the board of directors and executive committee of the US Biotechnology Industry Organization and was an adjunct professor in the Faculty of Economics and Business at Sydney University.

He holds a Bachelor of Economics degree from Sydney University.

CSL said Mr Anstice would continue to reside in the US.

CSL was up 76 cents or 1.87 percent to \$41.50 with 1.4 million shares traded.