Biotech Daily

Monday October 27, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: LIVING CELL UP 15%, ALCHEMIA DOWN 16%**

*** BIOGUIDE: VENTRACOR - A HEART BEAT AWAY**

*** STEM CELL: NEW ROUTE TO PLURIPOTENT CELLS WITHOUT EMBRYOS**

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MARKET REPORT

The Australian stock market fell a further 1.7 percent on Monday October 27, 2008 with the All Ordinaries down 63.3 points to 3,768.3 points.

Seven of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and 10 were untraded.

Living Cell was best, up 2.5 cents or 14.71 percent to 19.5 cents on small volumes, followed by Novogen up 7.5 cents or 8.29 percent to 98 cents. Proteome climbed 4.84 percent; Mesoblast and Viralytics were up more than two percent; Polartechnics was up 1.25 percent; with CSL and Sirtex up by less than one percent.

Alchemia led the falls, down 3.5 cents or 15.91 percent to 18.5 cents, followed by Ventracor down 15.46 percent to 8.2 cents, Benitec down 14.89 percent to four cents, Pharmaxis down 11.78 percent to $1.46 and Prana down 10.81 percent to 33 cents.

Cellestis and Genetic Technologies lost more than eight percent; Chemgenex fell 5.98 percent; Arana, Avexa, Labtech and Starpharma fell four percent or more; Heartware was down 3.51 percent; Acrux shed 2.86 percent; with Clinuvel and Cochlear down more than one percent.

MARC SINATRA'S BIOGUIDE: VENTRACOR

Overview: Back in mid-2003, Ventracor found blue sky and its share price rocketed to more than three dollars.

Then in a strange move, two US-based ventricular assist device (VAD) companies, Sunshine Heart and Heartware, listed on the ASX.

The signal to me was clear, Australia was significantly over-valuing VAD companies.

While avoiding these companies has proved prudent, Ventracor's share price has fallen as low as 8.0 cents.

Is it finally a good buy?

Financials: Market cap: $24 million; cash: $18 million; last half burn: $10 million.

Directors: Non-executive chairman, John Ward; CEO, Peter Crosby; non-executive directors, Ross Harricks; Elizabeth Nosworthy; Jeffrey Goodman; William E Curran.

Ventracor's board has a solid and balanced mix of individuals focusing on medical devices. In particular, CEO Peter Crosby has an exceptional knowledge of the industry.

Products on market or in development:
Ventrassist is a VAD designed to provide circulatory support for patients with severe or class IV systolic heart failure. It consists of an internal pump attached to the left ventricle and aorta via cannulae. An external controller and battery pack attaches to the pump via a percutaneous lead.

Ventrassist gained Conformitée Européenne (CE) Mark approval in December 2006. It is in two US registration directed trials; one a bridge-to-heart transplant (BTT) and the other a long-term destination therapy (DT) for transplant ineligible patients. Ventracor expects US Food and Drug Administration approval for the BTT indication in mid-late 2010 and for the DT indication in mid 2013.

In 2010, Ventracor expects to modify the Ventrassist system such that the controller and battery pack are also implanted.

Last year, Ventrassist generated revenue of $17.3 million via the sale of 189 devices. Ventrassist's US Medicare classification means Ventracor is reimbursed for the device despite its investigational status.

Significant Product Markets: Five to seven million Americans have heart failure, approximately half with systolic heart failure. Five to 15 percent or 150,000 to 450,000 patients have symptoms of class IV heart failure.

Five thousand heart transplants were performed in 2007, 1,692 in the US. About 2,700 Americans are awaiting a transplant at any one time. The BTT market is about 1000 devices a year and Millennium research estimated the 2007 BTT market to be worth approximately $US75 million.

Six VADs have CE Marking, while only two have US FDA approval for BTT. A further three devices are in the early stages of, or close to, commencing US BTT trials. Two of these are third generation devices. Many more are in development.

About 25,000 - 75,000 US patients with class IV heart failure are suitable for destination therapy. A recent review indicated VAD sales were likely to be at the lower end of this range.

All CE Marked VADs can be used in Europe for DT. No VADs are approved for DT in the US and only two, Ventrassist and Thoratec's Heartmate II, are in US trials for the indication.

The idea of using VADs as a destination therapy is not new, but the reliability of available devices has been an issue. To increase reliability, newer devices have been greatly simplified. It is thought that when VADs can perform well for two years, DT will be viable.

Opinion: When analyzing Ventracor, two major questions arise; how big will the DT market be and how big a slice of it can they grab?

I favor market size estimates at the lower end of the range above. The reasons for this are primarily the invasiveness and the high cost of the procedure. Nonetheless, the low end still equates to a US market size of $US2.5 billion alone.

Ventracor has, and should garner further, significant revenues from Ventrassist. The company is two years ahead of its third generation rivals and is likely to be the second entrant into the US BTT market, behind Thoratec's second generation Heartmate II.

Other than Thoratec, competitors may find it hard to recruit patients given Ventracor has tied up many US trial sites and the small number of patients suitable for BTT trials. BTT patients also have the option of using a good approved device rather than having to put up with the demands of a clinical trial to get one. The same situation may arise in the DT space as well.

One current disadvantage of Ventrassist is that, unlike VADs such as Jarvik Heart's Jarvik 2000 and Heartware's HVAD, the pump is placed in the abdomen, such that the cannulae must go though the diaphragm making the surgery more difficult. However, this disadvantage should vanish in the near future when fully implantable systems come into play and are likely to only be viable in the abdomen.

Ventracor's only real problem is it needs cash to ensure its strong position. When blue sky vanishes, as it does, share prices are left worse off than if it had never been found and it is happening to Ventracor in the midst of terrible market conditions.

I have calculated a discount cash flow analysis valuation for Ventracor of 38 cents a share, but this is contingent on a successful capital raising.

Ventracor fell 1.5 cents or 15.46 percent to 8.2 cents with 2.5 million shares traded.

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STEM CELL SCIENCES

Stem Cell Sciences says collaborator Prof Austin Smith has described a technique for reprogramming adult mammalian cells into authentic induced pluripotent stem cells

The technique is described in 'Promotion of Reprogramming to Ground State Pluripotency by Signal Induction' by Silva, J. et al was published by the Public Library of Science (PLoS Biology Vol. 6, No. 10, e253 doi:10.1371/journal.pbio.0060253) and was developed by Prof Smith and his team at the University of Cambridge.

Stem Cell Sciences said the reprogramming technique "features a key proprietary step" that forms the basis of a licence agreement with the University of Cambridge.

The company said the licence was "a significant addition" to its intellectual property portfolio around the development and commercialization of stem cell technologies.

Stem Cell said the technique described in the publication was a novel approach for generating pluripotent stem cells without using mammalian embryos and uses the combination of chemical inhibitors in Stem Cell Sciences' Culticell iSTEM media range with leukemia inhibitory factor.

The company said the Culticell iSTEM media range was being bought and used by researchers to establish pure and stable populations of authentic embryonic stem cells, to overcome limitations in current approaches for producing these cells.

Stem Cell said its Culticell iSTEM medium was launched earlier this year and was part of its stem cell culture media business, an important revenue source for the company.

The company said a key step for the "rapid and new approach for making [induced pluripotent stem] cells occurs at the transition point between incomplete and complete reprogramming to pluripotency".

Previous studies have indicated that progression through the transition point had been notoriously inefficient, but through the use of chemical inhibitors of the enzymes MEK and GSK3 in combination with the cell growth promoter, leukemia inhibitory factor, the inefficient process has been dramatically improved, the company said.

Stem Cell Sciences said partly-converted stem cells "complete the transition efficiently and become indistinguishable from authentic embryonic stem cells, that is, those generated from early stage embryos".

Stem Cell's chief scientific officer Dr Tim Allsopp said the proprietary technique "greatly facilitates the simple, most reliable and efficient route to obtaining authentic induced pluripotent stem cells and will form the basis for the industrialization of [induced pluripotent stem] cell production".

"This peer-reviewed publication is an important validation of the technology Prof Smith and his team have developed and Stem Cell Sciences is very pleased to be working with Cambridge University and Professor Smith's team on this important breakthrough," Dr Allsopp said.

Stem Cell's Australian operations manager Dr Paul Bello told Biotech Daily that reprogrammed adult cells into induced pluripotent stem cells (iPS) cells "are being heralded as the equivalent to embryo-derived stem cells in [their] potential to generate any cell type of the human body, minus the ethical issues".

Dr Bello said Stem Cell Sciences' already available Culticell iSTEM media has been proven in its ability to generate and maintain purer populations of authentic embryo-derived stem cells under serum-free and growth factor-free culture conditions.

Coupled with Stem Cell Sciences' cell-expansion expertise and robotic capabilities, the technology from Prof Smith's laboratory, licenced by Stem Cell Sciences, capitalizes on the iSTEM media range's utility in providing iPS cells more rapidly, efficiently, under cost-effective and defined conditions for pharmaceutical and research use, Dr Bello said.

Stem Cell Sciences was unchanged at 21 cents.

AUSBIOTECH 2008

More than one thousand delegates, sponsors and speakers have attended the first two days of the Ausbiotech 2008 Melbourne 'Building a Bio-Economy' conference.
Delegates were welcomed last night by Ausbiotech's outgoing chairman Dr Susan Pond and the conference was launched this morning by Victoria's Minister for Innovation Gavin Jennings with Ausbiotech's chief executive officer Dr Anna Lavelle.
Along with company representatives, Ausbiotech has a strong representation by State Governments including New South Wales, Victoria, Tasmania and South Australia as well as the Australian, United Kingdom, New Zealand, Korea, Canada and Pennsylvania governments.
The Queensland contingent was assisted by the State's trade commissioner to the US, former Premier, Peter Beattie.
Mr Beattie told Biotech Daily that he was proud of his achievements for the biotechnology sector when he was Premier of Queensland.
He said that if a state premier supported an initiative, such as support for the biotechnology sector, it strongly enhanced the outcome.
Victoria's Premier John Brumby is expected to attend the Ausbiotech conference.
The conference has a floor of semi-private meeting rooms and a floor of exhibitors as well as space for lectures and panel sessions.
The conference continues until Wednesday October 29, 2008.

HEALTHLINX

Healthlinx says it has received notification from the US Patent Office that the first of a family of patents relevant to regulating vascular permeability has been granted.
The patent, with a date of issue of October 28, 2008 "has broad claims that focus on inhibition of the p21 activated kinase pathway as a method for treating aberrant vascular permeability associated disorders".
Healthlinx said the patent "potentially has applications for treating multiple diseases or disorders including acute respiratory distress syndrome (Ards), ischemia, stroke and burns.
"This is a major milestone for the company," Healhtlinx said.
Healthlinx said the sales launch of the Ovplex ovarian cancer test in Australia was "imminent" through its collaborator ARL Pathology.
Healthlinx was unchanged at 5.1 cents.

XCEED CAPITAL

Xceed Capital shareholders will vote on the sale of its Polynovo holding to Metabolic (see Biotech Daily; July 18, 2008).
The annual general meeting will vote on the re-election of directors Dr Stewart Washer, Peter Francis and Dr Ian Griffiths.
The meeting will be held at QV1 Conference Centre, Training Room 2, Level 2, 250 St Georges Terrace, Perth, Western Australia on November 28, 2008 at 1.30pm.
Xceed was unchanged at four cents.

VICTORIAN GOVERNMENT

The Victorian Government says a new policy will make it easier for scientists to collect limited material from Victoria's native plants and animals to create new medicines.

At Ausbiotech's 2008 Melbourne conference Innovation Minister Gavin Jennings launched 'Biodiscovery in Victoria', a framework for managing access to and use of native biological resources

Mr Jennings said the Victorian Government was "taking action to encourage scientific research into the medicinal potential of plants and animals while ensuring our native species are protected from exploitation".

"Victoria has a biologically rich environment with at least 3140 native species of vascular plants, 900 lichens, 750 mosses and liverworts, 111 mammals, 447 birds, 46 freshwater and 600 marine fish, 133 reptiles, 33 amphibians and an untold number of invertebrates, fungi and algae," Mr Jennings said.

"These species may contain unique compounds that have the potential to aid human health or contribute to conservation of the environment," he said.

"This new framework aims to prevent over-harvesting and exploitation while allowing scientists limited access to Victoria's natural resources to create new drugs, jobs and export income," Mr Jennings said.

"Many modern drugs originally came from a molecule discovered in nature: Aspirin came from the bark of willow trees while breast cancer drug Taxol came from the North American yew tree," he said.

The director of the Monash Institute of Pharmaceutical Sciences Prof Bill Charman said the policy placed scientists "in a much stronger position because it gives assurance that our bio-discovery source material ownership and associated intellectual property is well-defined and not open to question later".

Dr Charman and a research team from the US, Switzerland and the UK have been working for the past four years on a bio-discovery project aimed at finding a cheap and easily produced drug to fight malaria, a disease which kills about 1.3 million people a year and infects many more.

Their attention has focused on the plant sweet wormwood (Artemesia annua), which has been used for centuries by the Chinese as a remedy against malaria, a Victorian Government media release said.

Knowing that artemsinin, extracted from the wormwood plant was an effective anti-malaria remedy, they use this knowledge to design two synthetic anti-malarial drugs, OZ277 and OZ439 that can trace their therapeutic history back to the natural product, the media release said.

OZ277 is progressing through clinical trials in India.

"If a chemical with potential medicinal properties is isolated from a plant or animal, ideally it should be capable of synthetic manufacture in the laboratory and optimization of its therapeutic and pharmaceutical properties," Prof Charman said.

He said bio-discovery "allows scientists to source new and useful bioactive chemical compounds which can then be fine-tuned in a laboratory to make them more effective".

The Victorian Government said the policy included benefit-sharing agreements, a compliance code and rigorous application assessment system.

The Victorian Government said the policy met internationally agreed requirements under the Convention on Biological Diversity and was consistent with the Victorian Biodiversity Strategy.

AVEXA

Avexa has sufficient cash for a further nine months of activity, according to its Appendix 4C for the three months to September 30, 2008.

In the notice to the ASX, Avexa said it net decrease in cash held was $10,391,000 with cash at the end of the quarter of $33,020,000.

A previous cash flow statement indicated the company may not have had sufficient cash, but included high start-up costs for its phase III apricitabine trial (see Biotech Daily; June 27, 2008).

Avexa fell half a cent or four percent to 12 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says the volume of biological data doubles every 14 months and companies need data management and analysis techniques

“Without effective data management and analysis techniques, researchers and clinical development teams will drown in the volumes of data they must deal with,” the Bio-Melbourne Network said.

The November 11, 2008 Bio-Melbourne Network bio-breakfast will examine the issues around information technology for the life sciences sector as well as bio-engineering.

The Network said “bio-informatics” was the application of information technology, statistics and mathematics to biology providing the foundation for much of modern biomedicine and biotechnology.

The main application for bio-informatics is in the acquisition, management and interpretation of the large data volumes generated modern by genomics techniques - the study of genes and their actions.

Melbourne University's Professor of Bio-Informatics, Justin Zobel will introduce the National ICT Australia story and why bio-informatics and bio-engineering are enabling drivers for Melbourne's life sciences industry.

Prof Zobel will talk about the strategic benefits of applied bio-engineering in generating disruptive technology platforms for new device categories and bio-informatics in assisting researchers in data driven genomic and proteomic research projects.

The Bionic Ear Institute's director Prof Rob Shepherd will talk about the Institute's research strategy and the outcomes that are being driven through new bio-engineering approaches.

Prof Shepherd will provide his observations on why successful product development is collaboration driven, the product and therapy opportunities afforded by new bio-engineering frameworks and some of the likely spin-out benefits from the research partnership with National ICT Australia.

Prof Shepherd will also comment on the relationship management and future benefits of the collaboration, as well as some advice to others considering a similar strategic approach.

The November 11 bio-breakfast will be held in the Supper Room, Melbourne Town Hall, Swanston St, Melbourne, with registration: from 7.15am and presentations from 8am.

Bio-Melbourne Network members: $55, non-members: $88.