



# Biotech Daily

Tuesday October 28, 2008

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECHS DOWN: PRANA UP 21%, OPTISCAN DOWN 25%**
- \* **ALCHEMIA SLASHES 60% OF STAFF TO REDUCE CASH BURN**
- \* **PROF ALAN TROUNSON'S \$US3bn STEM CELL INSTITUTE**
- \* **LIVING CELL: '3-5 YEARS TO MARKET'**
- \* **VENTRACOR TIGHTENS BELTS; \$12m PLACEMENT, SHARE PLAN**
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- \* **ELLEX REPLACES CFO, COMPANY SECRETARY**
- \* **VIRALYTICS APPOINTS GAVIN CLARK TO BUSINESS DEVELOPMENT**

## MARKET REPORT

The Australian stock market fell another 0.3 percent on Tuesday October 28, 2008 with the All Ordinaries down 12.9 points to 3,755.4 points. Five of the Biotech Daily Top 40 stocks were up, 26 fell, three traded unchanged and six were untraded.

Prana was best, up seven cents or 21.21 percent to 40 cents on small volumes, followed by Starpharma up 3.5 cents or 14.58 percent to 27.5 cents, Peplin and Psivida both up more than eight percent and Cellestis up 1.01 percent.

Optiscan led the falls, down 1.7 cents or 25.37 percent to five cents, followed by Antisense down 14.29 percent to 4.2 cents, Viralytics down 11.11 percent to four cents and Arana down 10.13 percent to 71 cents. Chemgenex lost 9.09 percent; Avexa fell 8.33 percent; Cathrx, Mesoblast, Proteome and Sunshine Heart fell more than seven percent; Circadian lost 6.82 percent; Alchemia, Biota and Pharmaxis fell more than five percent; Clinuvel fell four percent; Neuren, Progen and Ventracor lost more than three percent; Cochlear, Genetic technologies and Novogen shed more than two percent; with Acrux, Bionomics, CSL, Phosphagenics, Polartechnics and Resmed down more than one percent.

## ALCHEMIA

Alchemia says it has “with immediate effect, implemented steps to significantly reduce its cash burn”.

“These measures are designed to guarantee that the company maintains sufficient funding to finance its near term projects until receipt of revenues from sales of its lead drug, generic fondaparinux,” Alchemia said.

On October 20, 2008 Alchemia reported a cash burn for the three months to September 30, 2008 of \$3,311,000 and cash at the end of the quarter of \$12,309,000.

Alchemia said today that “a broad program of cost reduction initiatives involving the suspension of various projects, principally around the company’s Vast drug discovery platform, have been implemented”.

Alchemia said the measures would result in a 60 percent reduction, equating to 30 staff members, at the company’s Brisbane and Melbourne operations, leaving the company with 20 employees.

Alchemia’s chairman Mel Bridges said that “given the unprecedented events we are witnessing in the global capital markets, we have made these difficult decisions to ensure Alchemia has sufficient cash reserves to survive these challenging economic times”.

“The steps we are taking will also include a restructuring of our board of directors,” Mr Bridges said.

Alchemia chief executive officer Dr Pete Smith said that “in the present funding environment we believe that the reduction in activities, while deeply regrettable, is both necessary and prudent”.

“We continue to explore a number of strategic alternatives with these programs that will enable us to realize value from the pipeline,” Dr Smith said.

“A number of financing initiatives were considered, but the recent events in both credit and equity markets have made third party funding either unlikely or unattractive,” he said.

“Considerable progress has been made with fondaparinux [generic heparin] this year and Alchemia remains focused on its [US Food and Drug Administration] approval and sales to follow shortly thereafter,” Dr Smith said.

Alchemia fell one cent or 5.41 percent to 17.5 cents.

## PROF ALAN TROUNSON

The president of the California Institute for Regenerative Medicine, Prof Alan Trounson, says stem cell research will lead to therapies for a diverse range of indications.

Prof Trounson gave the Prof Nancy Millis Oration at Ausbiotech’s 2008 Conference in Melbourne and said opposition to embryonic stem cell research by US President George W Bush encouraged Californians to support Proposition 71 on “the right to conduct research not supported by Federal funding”.

Prof Trounson said 60 percent of Californian voters supported the Proposition and his Institute was the holder of a \$US3 billion stem cell research fund.

“People now return my calls, which is an experience I didn’t always have,” Prof Trounson said.

He said his Institution had a mission statement to take stem cell research from discovery to the clinic.

He said stem cell research could lead to therapies for glioblastoma, Alzheimer’s disease, Parkinson’s disease and motor neuron disease, along with spinal cord repair, retinal epithelial repair, beta islet cells for diabetes and cardiac muscle progenitors.

He said the Institute was providing grants and loans and expected a three-fold return from successful development to fund future work, with no intellectual property ownership.

## LIVING CELL TECHNOLOGIES

Living Cell Technologies says that if its xeno-transplant trials were successful, US registration could be as close as three to five years away.

Living Cell's chief executive officer Dr Robert Caspari and chief operating officer Dr Paul Tan told Biotech Daily at Ausbiotech's 2008 Melbourne conference that the path to registration was likely to include trials in countries other than New Zealand.

Living Cell's Russian phase I/IIa trial has delivered some promising results and a phase II trial of the porcine islets of Langerhans has been approved in New Zealand.

Dr Tan said the last approved xeno-transplant trial was more than five years ago and trials were halted when a moratorium was initiated in 2002 following concerns over porcine endogenous retrovirus in the genetic sequence of pigs.

Dr Tan said the concerns raised proved to be "baseless".

"That was one theoretical report subsequently shown to be unsubstantiated," Dr Tan said. He said the US Food and Drug Administration and other regulators "did their job and took it seriously" and produced "very stringent requirements".

He said the FDA rules for xeno-transplant trials were about 1cm thick.

Dr Caspari said the FDA had specific guidelines and Living Cell met those guidelines "like any other endeavor".

To win New Zealand approval, Dr Tan said Living Cell had to be approved by six committees and people on those committees spoke with the US FDA as well as other international advisers.

"The international scientific regulatory community is starting to accept that the concerns have been addressed," Dr Caspari said.

The trial expected to begin in New Zealand in February 2009 will dose one patient a month with 10,000 islet equivalents/kg until four patients are dosed with a second group of four patients then being dosed with 15,000 islet equivalents/kg.

The Russian trial used 5,000 islet equivalents/kg, with one patient receiving 10,000 islet equivalents/kg.

Dr Tan said that Living Cell had "a long list" of potential patients for the trial of up to 100 people.

"In Brisbane at a diabetes fair, 86 type 1 diabetes families approached us," Dr Tan said. Apart from reducing or eliminating the need for insulin dependence, Dr Tan and Dr Caspari said that the porcine islets of Langerhans also produced glucagon and reduced the swings in blood sugar levels, thereby improving the lives of diabetics.

"The swings are much less and they feel better," Dr Caspari said. "The ability to avoid hypoglycaemia is as important if not more important and the islets produce glucagon as well as insulin. Insulin is one thing, but stability is important," he said.

Dr Caspari said parents of children with type 1 diabetes had to wake and test their children's blood sugar levels at night to ensure they didn't die of hypoglycaemia.

"It's a terrifying thing to live with and insulin use increases the risk of hypoglycaemia," Dr Caspari said. "The better you control the sugar levels the better," he said.

Dr Tan said the company had informal advice that it would need results from 40 patients to file an application to the FDA.

Dr Caspari said that should the New Zealand trial be successful the company would need about 30 patients for a "phase III pivotal trial" and it would not be necessarily in New Zealand. He said the company needed to scale up for larger trials and although its specialist pig herd in New Zealand was about 50 animals, there were hundreds of pigs on Auckland Island.

Dr Caspari said about five million Americans had type 1 diabetes.

Living Cell was unchanged at 19.5 cents.

## VENTRACOR

Ventracor has announced a share purchase plan and says it will cut costs and conserve cash, reducing capital requirements to beyond June 30, 2009.

The company said that "in light of current economic and financial market conditions" cost reduction steps taken include, but are not limited to the deferral of research and development on advanced products, including the fully implantable Ventrassist left ventricular assist device (LVAD) until additional capital is available or until the research and development can be funded from current income; reduction of some marketing activities to allow focus on the highest priority of achieving US Food and Drug Administration approval; ongoing monitoring of manufacturing ramp-up and reduction of finished goods stock and work-in-progress; and further deferral of some capital equipment expenditure, such as some items needed for advanced preparation for increased manufacturing capacity.

Ventracor said that at September 30, 2008 it had cash reserves of \$11.8 million.

The company said it needed to raise funds of \$10 million to meet its revised expenditure and cash requirements to June 30, 2009 based on assumptions concerning US trial enrolment rates, European and Australian sales, foreign exchange rates and other factors. Further funding will be required to continue commercialization of the Ventrassist LVAD beyond June 30, 2009.

The company said it was assessing an optimal future capital raising program to fund its business and was continuing to explore strategic partnering opportunities.

Separately, Ventracor said it would place up to 45 million shares or up to 15 percent of the company's total share issue with institutional and other investors "at a price to be determined ... following a book-build process".

A share plan offering up to \$5,000 of shares at 8.1 cents a share will open on November 11, 2008 and close on December 2, 2008 with a record date of November 5.

Ventracor chief executive officer Peter Crosby said that the company hoped to raise up to \$12 million from the combined share plan and placement.

Ventracor fell 0.3 cents or 3.66 percent to 7.9 cents.

## TISSUE THERAPIES

Tissue Therapies shareholders will vote on convertible notes equating to 17.6 million shares and 500,000 options in lieu of cash to chief executive officer Dr Steven Mercer.

Shareholders will also consider the issue of a convertible note converting to up to 5,865,950 shares to Roger Clarke, a convertible note converting to up to 5,862,810 shares to Queensland University of Technology and a convertible note converting to up to 5,907,067 to Asia Union Investments.

The meeting will also consider the prior issue of 4,625,000 placement shares and 77,000 shares to Trevor Baldock in part payment for consultancy services.

The company's shareholders will consider "the granting of 500,000 performance based options for which Dr Steven Mercer who has volunteered to forgo a cash based incentive payment".

Shareholders will vote on the re-election of directors Gregory Baynton and David Gardiner.

The meeting will be held the office of McCullough Robertson, Level 11, Central Plaza Two, 66 Eagle Street, Brisbane on November 27, 2008 at 10.30am.

Tissue Therapies was up 1.5 cents or 15.79 percent to 11 cents.

### METABOLIC

Metabolic shareholders will vote on issues relating to the acquisition of Polynovo from Xceed Capital and the Commonwealth Scientific and Industrial Research Organisation. The annual general meeting will vote on the name change to Polynovo, an increase in non-executive directors' remuneration from \$300,000 to \$400,000.

Shareholders will vote on an employee option plan and the re-election of chairman Rob Stewart and the election of directors Iain Kirkwood, Franklyn Brazil and Paul Lappin.

The meeting will be held the offices of Minter Ellison at Level 23, Rialto North Tower, 525 Collins Street, Melbourne on November 27, 2008 at 2pm.

Metabolic was unchanged at 2.9 cents.

### RESONANCE HEALTH

Resonance shareholders will vote on the issue of \$10,000 worth of shares for managing director Liza Dunne "in recognition of her past services to the company".

The annual general meeting will vote on an executive share incentive plan with Ms Dunne as the sole initial participant and will also consider an employee incentive option scheme.

Shareholders will vote on the re-election of directors Ian Anderson and Liza Dunne.

The meeting will be held at University of Western Australia Boat Shed, Carpark 23, 35 Stirling Highway, Crawley, Western Australia on November 26, 2008 at 10am.

Resonance was unchanged at one cent.

### SOLBEC PHARMACEUTICALS

Solbec shareholders will vote on the Vista Laser Eye Centre acquisition, a name change to Freedom Eye and a 50 percent increase in the non-executive directors pay.

A series of resolutions relate to the acquisition of the Vista Laser Eye Centre including the company name change, the issue of \$100,000 of shares to the Vista Vendors and the issue of shares to raise up to \$1.5 million to fund the acquisition.

Shareholders will consider increasing the non-executive director's remuneration pool from \$200,000 to \$300,000 and the issue of shares under the company's employee share plan.

The meeting will vote on the issue of up to 11,000,000 shares to director Dr William Ardrey and 4,500,000 shares each to Prof John Papadimitriou and Grant Bennett, with 5,500,000 shares to director Russell Barnett.

Shareholders will vote on the re-election of directors Dr Ardrey and Russell Barnett.

The meeting will be held at Level 8, Exchange Plaza, 2 The Esplanade, Perth, Western Australia on November 26, 2008 at 10.30am.

Solbec was untraded at 1.1 cents.

### PORTLAND ORTHOPAEDICS

Portland Orthopaedics says John Brassil resigned as managing director and chief executive officer effective from October 24, 2008.

Portland said Mr Brassil cited personal reasons for his resignation.

The company's chief financial officer Ralph Stonell has been appointed acting-CEO.

Portland said Mr Brassil would remain available "to advise the company on strategically critical matters during the next three months and to assist with the transition".

Portland is progressing the appointment of an additional non-executive director.

Portland was untraded at 1.1 cents.

### ELLEX MEDICAL LASERS

Ellex Medical Lasers has replaced chief financial officer and company secretary Tony Mitchell with Melanie Young as CFO and director Giuseppe Canala as company secretary.

Ellex said Ms Young joined Ellex in 2005 as group accountant.

She previously worked for the Growth Solutions division of Deloitte Australia and holds a Bachelor of Commerce from Deakin University, Victoria.

Mr Canala's appointment as company secretary follows his recent appointment as a non-executive director of the Ellex board.

Ellex appointed Simon Luscombe as group chief executive officer on October 22, 2008 replacing Kevin McGuinness who was appointed to the position in June 2008.

Ellex fell one cent or 5.0 percent to 19 cents.

### VIRALYTICS

Viralytics has appointed Gavin Clark as its business development manager.

Viralytics said Mr Clark was based in the United Kingdom and had "a prolific record in international partnering, including licencing, collaborations and merger and acquisitions".

Mr Clark co-founded the Dublin-based Procela Partners and since 2002 has provided strategic business development support for biotechnology companies including Acumen Pharmaceuticals, Pintex, Pliva dd, Powdermed, Physiomics Plc, Neurocure Maxthera Inc and Affimed Therapeutics.

He was director of global licencing for infectious diseases at Glaxowellcome and head of business development at Tibotec until its acquisition by Johnson & Johnson.

Viralytics fell half a cent or 11.11 percent to four cents.