



Biotech Daily

Thursday October 4, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: SIRTEX UP 10%, PRIMA DOWN 10%**
- * **NZ CLEARS LIVING CELL PIG-TO-HUMAN BRAIN CELL TRANSPLANT**
- * **\$55m MAYNE TO PAY \$120m FOR US GENERIC COMPANY METRICS INC**
- * **3-MONTH SIRTEX DOSE SALES UP 37%, BREAKS THROUGH \$10**
- * **PRIMA COMPLETES PHASE II OVARIAN CANCER TRIAL**
- * **BLUECHIIP GRANTED US TAGGING METHODS, APPARATUS PATENT**
- * **PHARMAUST TO LOSE FOUNDER BRYAN MCLARTY**
- * **ACUVAX EX-CEO DR WILLIAM ARDREY BAILED TO NOVEMBER**

MARKET REPORT

The Australian stock market was up 0.31 percent on Thursday October 4, 2012 with the S&P ASX 200 up 13.8 points to 4,452.4 points.

Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and six were untraded.

Sirtex was the best, breaking the \$10 barrier and up 95 cents or 10.3 percent to \$10.18 with 279,465 shares traded.

Alchemia and Genetic Technologies climbed more than nine percent; Bioniche and Cellmid were up more than six percent; Bionomics and Biota were up more than four percent; Phylogica was up 3.85 percent; Ellex and QRX rose more than two percent; with CSL, Pharmaxis and Starpharma up by less than one percent.

Prima led the falls, down two cents or 10.3 percent to 17.5 cents with 15.2 million shares traded, followed by Optiscan down 10 percent to nine cents with 5,000 shares traded.

Allied Health lost 8.3 percent; Benitec was down 6.7 percent; Antisense and Viralytics fell more than five percent; Anteo and Impedimed were down more than three percent; Prana, Reva and Sunshine Heart shed more than two percent; Cochlear, Living Cell, Nanosonics, Tissue Therapies and Universal Biosensors were down more than one percent; with Mesoblast and Resmed down by less than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says New Zealand's Minister of Health has authorized phase I clinical trials of NTCell for Parkinson's disease, involving a pig-to-human brain cell transplant.

Living Cell said the phase I open label investigation of the safety and clinical effect of NTCell, encapsulated pig choroid plexus cells, in people with Parkinson's disease was expected to begin by April 2013 and would last up to 60 weeks.

The company said that the trial would enroll patients that have been diagnosed with Parkinson's disease for at least four years.

Living Cell chief executive officer Dr Andrea Grant told Biotech Daily that in 1996, a US company previously transplanted non-encapsulated, embryonic pig stem cells into humans, but without success.

Living Cell owns a pig herd formerly isolated on Auckland Island and said the treatment involved transplanting choroid plexus cells into the patient's brain.

Living Cell said that choroid plexus cells were naturally occurring support cells for the brain and when transplanted could help protect the brain and repair damaged nerve tissue.

The company said the cells were encapsulated to prevent the immune system from rejecting them as foreign.

Living Cell said the trial patients would receive either NTCell treatment or the current gold standard of treatment for their symptoms, deep brain stimulation.

The company said that the principal investigator would be the Auckland Movement Disorders Clinic's Dr Barry Snow.

"Parkinson's is a disorder which clinicians can help manage but can't reverse, so this represents an exciting new potential option for patients," Dr Snow said.

"These clinical trials will also help raise public awareness of the disorder, which in turn helps improve the way the disorder is looked after generally," Dr Snow said.

Dr Grant said that regulatory approval for the clinical trials was "a critical step in developing a treatment for this debilitating condition".

"The unprecedented results of our preclinical studies suggest that NTCell can protect brain tissue which would otherwise die, potentially delaying or even preventing the effects of Parkinson's," Dr Grant said.

The company said that its pre-clinical studies showed an increase in dopamine-producing neurons, improvements in movement and neurological defects, together with good tolerance with no evidence of inflammation or other adverse reaction.

Living Cell said that the improvements were seen within two weeks and lasted for at least six months, the trial endpoint.

The company said that Parkinson's disease was the second most common neurodegenerative disorder after Alzheimer's disease and affected up to six million people worldwide.

Living Cell said that reduced dopamine levels in the brain lead to movement-related symptoms such as tremor, rigidity and slowness of movement, with patients later developing cognitive and behavioral symptoms.

The company said that the effectiveness of current treatments, which focused on dopamine replacement, declined as the disease progresses and were symptomatic, failing to reverse or slow the degeneration of the brain.

Living Cell fell 0.1 cents or two percent to five cents.

MAYNE PHARMA

Mayne Pharma chief executive officer Scott Richards says his company will acquire the Greenville, North Carolina based Metrics for up to \$US120 million.

Mayne had a market capitalization of \$55 million at the close of business last night.

In 2009, the then \$29 million Halcygen acquired Mayne Pharma, valuing it at more than \$300 million at that time, but paying only \$US15 million (BD: Sep 25, 2009).

In a teleconference and documents to the ASX today, Mr Richards said Mayne would raise \$65 million through a fully underwritten equity raising at 20 cents a share and a \$US48.5 million debt funding commitment.

Mr Richards said Metrics was a privately-owned pharmaceutical company with 300 employees, developing and manufacturing generic drugs and was also a provider of contract development services to the pharmaceutical industry.

Mr Richards said that with one product in the market Doryx and one in development, Subacap, the deal would be "transformational" with the merged entity having 14 products in the market and 14 in development.

Mr Richards said Metrics had an established direct distributions service so Mayne "won't have to partner with third party pharmaceutical companies and lose significant value".

Mr Richards said that four of the Metrics products were "first generics" and company was targeting niche market and difficult to formulate drugs, lessening potential competition.

He said that Metrics founder Phil Hodges would join the Mayne board

Mr Richards said that a US phase III trial could be required for Mayne's super-generic anti-fungal drug Subacap, formerly Suba-itraconazole a super-generic form of Sporanox. Despite the delays with Subacap, Mr Richards said he was "feeling very very good about this product".

He said Mayne also had an extended release pain product targeting the US market and a hypertension product in development.

In a media release, Mr Richards said that Metrics was "highly complementary to Mayne Pharma's existing business in term of its products, services and the markets in which it operates".

"In addition to providing scale in the US market, Metrics brings additional technical capabilities and material upside from cross-selling revenue opportunities," Mr Richards said.

Mayne said the underwritten \$65 million would be raised through a \$30.4 million one-for-one pro-rata accelerated non-renounceable entitlement offer; a \$9.1 million unconditional placement to institutional investors; a \$19.0 million conditional placement; and conditional placements to certain Metrics shareholders to raise up to \$3.1 million; Mayne director and gambling machine operator Bruce Mathieson and related investment entities to raise \$3.0 million; Mayne chairman Roger Corbett to raise \$300,000; and \$500,000 from Mr Richards.

Mayne said that all shares in the capital raising would be at 20 cents a share.

The company said the entitlement offer and placements were underwritten by Credit Suisse Australia and UBS AG Australia and the conditional placements were subject to shareholder approval.

Mayne said that the institutional offer opened on October 4, the retail entitlement offer had a record date of October 10, would open on October 12 and close on October 29, 2012.

Mayne called a trading halt prior to the announcements, which were reported in Fairfax newspapers this morning, and last traded at 36 cents.

SIRTEX MEDICAL

Sirtex says dose sales of its SIR-Spheres microspheres grew 37 percent for the three months to September 30, 2012 compared to the previous corresponding period.

Sirtex did not disclose the values of the sales but In August, said that dose sales for the year to June 30, 2012 amounted to \$83 million in revenue (BD: Aug 29, 2012).

Sirtex previously reported that for the year to June 30, 2011 it sold 4,977 doses earning revenue of \$70.3 million, with dose sales priced at \$8,500 in Australia, EUR12,000 in Europe and \$US15,000 in the US (BD: Aug 25, 2011; Feb 29, Apr 11, 2012).

Today, Sirtex said that dose sales of the liver cancer treatment increased in all regions with the US up 42 percent, Europe, Middle East and Africa up 26 percent and Asia Pacific was up 33 percent.

The company said that dose sales were a key measure of the company's business performance and it had reported 33 consecutive quarters of sales growth.

Sirtex chief executive officer Gilman Wong said the dose sales were "a pleasing set of numbers".

"When we measure Sirtex's growth in unit number terms, the last three quarters have been the largest in our history with this quarter being our best," Mr Wong said.

"However we should remember in Europe during the first quarter last year we experienced some issues that impacted negatively on our progress," Mr Wong said.

"These issues are resolved and we have returned to positive growth," Mr Wong said.

Sirtex chief financial officer Darren Smith told Biotech Daily that reimbursement issues in Germany had been resolved as well as industrial issues and competitor pricing issues in Turkey.

"We are confident, barring unexpected events, that sales of Sirtex's SIR-Spheres microspheres will continue to grow," Mr Wong said.

"The implementation of our '2020 vision' strategy is the prime focus with appropriate investments being made by the company in sales and marketing, clinical studies and research which should ensure Sirtex achieves its future potential," Mr Wong said.

Sirtex was up 95 cents or 10.3 percent to \$10.18 with 279,465 shares traded.

PRIMA BIOMED

Prima says that the last patient in its phase II trial of CVac for ovarian cancer is due to receive the final dose this month, with early data to be reported on October 15, 2012.

Prima said patient enrollment began in July 2010, was completed in September 2011 and the 63 patients in first or second remission would be followed until at least October 2013.

The company said that Royal Brisbane and Women's Hospital's Dr Jeffrey Goh would present interim safety and progression-free survival data from the phase II (CAN-003) trial at the International Gynecologic Cancer Society meeting in Vancouver, Canada on October 15, 2012.

Prima said that the first seven patients were all assigned to receive CVac and the subsequent 56 patients were randomized to either receive CVac or to standard of care observation.

The company said that in total, 36 patients received treatment with CVac and 27 patients were assigned to the observation group.

Prima said that to date, 16 patients have been randomized in the phase III 1000-patient 'CANVAS' trial in the US and Australia.

The company said the trial had been approved by regulators in the US, Australia, Belarus, Belgium, and Ukraine.

Prima fell two cents or 10.3 percent to 17.5 cents with 15.2 million shares traded.

BLUECHIIP

Bluechiip says it has been granted a US patent entitled 'Tagging Methods and Apparatus'. Bluechiip said the patent covered a method of tagging and sterilizing items including surgical instruments using a device based on its micro-electro mechanical systems (Mems) or micro technology.

The company said that the patent was for items which had to undergo physical sterilization using ionizing radiation or autoclaving.

Bluechiip said that a Mems-based mechanical device provided an opportunity to overcome limitations of assigning unique serial numbers using barcodes, electronic radio frequency identification and other methods such as etching.

The company said that the invention covered items such as surgical instruments, prostheses and other medical and healthcare items.

Bluechiip said that its tagging system allowed such items to be identified in a non-line-of-sight manner and without human intervention and could facilitate automated item management and tracking of orthopaedic loaner kits.

Bluechiip chief executive officer Brett Schwarz said the patent "underlines the platform nature of Bluechiip's technology".

"Whilst our technology is initially being used in the bio-banking industry to track high value specimens such as stem cells, tissue and blood, it has a broad range of market applications," Mr Schwarz said.

"The tracking of surgical instruments, including specialist areas such as orthopaedics, is one such use," Mr Schwarz said.

"The US Food and Drug Administration recently issued its proposed rules for unique device identifiers for medical devices," Mr Schwarz said. These rules will require the labelling and packaging of most medical devices to contain a [unique device identifiers] for tracking purposes."

"In some cases the [unique device identifiers] must appear on the device itself, which is where Bluechiip can play a significant role," Mr Schwarz said.

Bluechiip said it had a portfolio of 15 patents over seven patent families, including six granted in US and Europe.

Bluechiip was untraded at 26 cents.

PHARMAUST

Pharmaust founder and executive chairman Bryan McLarty will retire on or about December 7, 2012.

In the notes to the resolutions for the company's annual general meeting, Pharmaust said that Mr McLarty's employment would be terminated one month after the meeting.

The company said that, subject to shareholder approval, it would issue shares worth \$135,000 in lieu of a termination payout under his executive services agreement.

Pharmaust said the shares would be issued at the five-day volume-weighted average price prior to the date of the meeting.

Other resolutions include the remuneration report, the re-election of director Sam Wright, the reduction of capital through an in specie distribution of 16,500,003 Diashi Mining shares and the placement of 100,000,000 shares at one cent a share.

Pharmaust has sold its interest in Pela Resources to Diashi and said it would focus on its Epichem business (BD: Sep 10, 2012).

The meeting will be held at Steve's Wine Cellar, 30 The Avenue, Nedlands, Western Australia on November 7, 2012 at 12pm (AWDT).

Pharmaust was unchanged at one cent.

ACUVAX

Former Acuvax chief executive officer Dr William Ardrey has been remanded to reappear at the Perth Magistrates Court on November 28, 2012, on undisclosed bail conditions.

Dr Ardrey has been charged with 22 counts of gaining benefit through fraudulent means (BD: Feb 28, Apr 20, Jul 20, 2012).

Western Australia Police previously told Biotech Daily that Dr Ardrey had appeared at the Perth Magistrates Court for a committal hearing and bail conditions had been set but were undisclosed.

Western Australia Police said the complainant in the matter was Phoenix Eagle a company described as a small biotechnology company involved in therapeutic cosmetics. In 2006, Dr Ardrey was appointed chief executive officer of Avantogen, which later became Acuvax, and prior to that was the chief executive officer of Regenera, which later became Advanced Ocular (BD: Aug 29, 2006).

In January, with new investors and new management, Acuvax said it would acquire an Israeli diagnostic company (BD: Jan 25, 2012).

In May, Acuvax said it had a controlling stake in Biohealth Pty Ltd, which was focused complementary medicines comprising natural non-toxic ingredients and its first product Provent had been listed by the Australian Therapeutic Goods Administration on the Register of Therapeutic Goods as a complementary medicine with the claim: 'Helps Maintain Healthy Respiratory Function' (BD: May 18, 2012).

Acuvax was untraded at 0.1 cents.