Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHOSPHAGENICS UP 15%; PRANA DOWN 3%**

*** VICTORIA'S CARTWHEEL MATCHES RARE TUMOR PATIENTS TO TRIALS**

*** COCHLEAR'S DR CHRIS ROBERTS: DESIGN YOUR FUTURE**

*** QRX PHASE III BUNIONECTOMY TRIAL 'SIGNIFICANT PAIN RELIEF'**

*** PHARMAXIS 2nd CYSTIC FIBROSIS PHASE III TRIAL COMPLETED**

*** NANOSONICS SCALE-UP 'BACK ON TRACK'**

*** GENETIC TECHNO BUYS BREAST CANCER TEST, NON-CODING DNA**

*** CIRCADIAN LOSES CFO NATALIE KORCHEV**

MARKET REPORT

The Australian stock market rebounded 0.87 percent on Wednesday April 14, 2010 with the S&P ASX 200 up 43.1 points to 4994.7 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and five were untraded. All three Big Caps were up.

Phosphagenics was best for the second day in a row, up two cents or 15.4 percent to 15 cents with 5.2 million shares traded, followed by Antisense up 11.1 percent to two cents with 3.7 million shares traded and QRX up 10.45 percent to 97 cents.

Nanosonics climbed 7.96 percent; Genera was up 6.9 percent; Phylogica was up 5.4 percent; Benitec and Bionomics were up more than four percent; CSL, Living Cell and Sunshine Heart were up more than three percent; with Circadian and Pharmaxis up more than one percent.

Cellmid and Prana led the falls, both down 3.45 percent to 2.8 cents and 14 cents, respectively; followed by Cathrx, Novogen, Starpharma, Tissue Therapies and Viralytics down two percent or more; with Acrux, Cellestis, Chemgenex and Clinuvel down more than one percent.

CENTRE OF ANALYSIS OF RARE TUMOURS

Victoria's Centre of Analysis of Rare Tumours has created Cart-Wheel.org as the world's first website matching people with rare tumors to clinical trials and research.

Formally launched at Melbourne's Walter and Eliza Hall Institute by Prof Gustav Nossal the website is the first international, ethically-approved web portal coordinating patient information, research studies and clinical trials.

Prof Nossal said that rare tumors accounted for 20 percent of cancers but received only five percent of cancer funding.

Prof Nossal said much of the data was with small sample sizes and not statistically significant and the best data was held in clinical trials and not widely disseminated.

"Cart-Wheel is a philosophical shift linking you to a personalized cancer treatment," Prof Nossal said.

"The is an international need for linking data and this is a great example of what the Parkville Comprehensive Cancer Centre can do," he said.

Cart-Wheel's principal investigator Dr Clare Scott told Biotech Daily that the matching service intended to "target therapy for specific tumors, make existing drugs more efficient and enable patients to find clinical trials that suit them".

The chair of the Biogrid Australia Board Prof Bryan Williams told the WEHI launch that his group was created as part of the Victoria Government's Bio 21 initiative and in turn created the Centre of Analysis of Rare Tumours (Cart).

Prof Williams said Biogrid's initial funding came from the Victoria Department of Innovation Industry Research and Development and with a consumer grant for Cart-Wheel from the Victorian Cancer Agency.

Dr Scott is a medical oncologist and a fellow at the Walter and Eliza Hall Institute and told the launch that Cart-Wheel.org was the first international website created for and by consumers to provide access to clinical trials.

She said the idea stemmed from Cynthia Pollock whose son Danny had the rare vascular cancer haemangioendothelioma and finding that doctors had little information on the tumor set up a website.

Ms Pollock gathered data from more than 200 participants but the task became too large and she turned to the cancer research community for help.

Cart-Wheel.org is dedicated to the memory of Danny Pollock who died in 2008.

Dr Scott said that creating the website involved issues across ethics, privacy, database and website engineers and clinical expertise and she thanked the website developer Jana Graenz for overcoming all those issues.

Dr Scott said it was a user-friendly website with four levels of privacy consent enabling the sharing of as much information as the individual patient wanted to publish, as well as linking all trials and data and hospitals.

The system can track patients and link the data by cancer type, by listed hospitals, by treatment type and by genetic tests.

Dr Scott said it would create data sets for tumor studies for researchers and provide a comprehensive matching service.

"We need researchers and clinical trial doctors to recognize the name of Cart-Wheel.org," Dr Scott said.

Media releases with the launch said there were more that 500 types of rare tumors and while numbers in each type were small, all rare cancers combined accounted for up to 20 percent of cancers diagnosed each year and 31 percent of cancer-related deaths, with increasing associated morbidity and mortality.

"The ultimate goal for Cart-Wheel is to gather enough entries over time to make clinical trials for different types of rare tumors a possibility," Dr Scott said.

COCHLEAR, DR CHRIS ROBERTS

Cochlear's chief executive officer Dr Chris Roberts says biotechnology success depends on patience and designing the future.

Speaking to a Life Sciences Lunch Club in Melbourne Dr Roberts said that research on the cochlear implant could be considered to have begun when Alessandro Volta addressed the Royal Society in London in 1800 and said he had placed electrodes in each of his ears and heard a noise. He chose not to repeat the experiment.

Dr Roberts said the more conventional beginning was when Paul Trainor created the Nucleus Group of medical device companies in 1964 to manufacture in Australia and export products, which was unusual at that time.

Dr Roberts said Dr Mike Hirshorn made the first contact between Nucleus and Cochlear. He said there were layers of development from the 1957 discovery of pitch perception to a 1961 trial of placing a single electrode into three patients for about three weeks.

Dr Roberts said scientific discovery and technological invention were more often the work of a progression of ordinarily clever people building on what went before, rather than the work of a single genius. But he gave great credit to his company's principal inventor Prof Graeme Clark, for developing the first true cochlear ear implant in 1982.

Dr Roberts said the layers of development included David Cowdery's 1971 creation of a molecular bond between the insulating ceramic and the encapsulating titanium.

He said development was a step-by-step process, but the benefit was that there were about 50 separate innovations in the Cochlear Nucleus 5 and that put the company unassailably ahead of any competitor.

"The time frames are stunning," Dr Roberts said of the development process. "And 30 years later the company still does not earn $1 billion in income".

He said the $700 million in sales for the last financial year resulted in a profit of $130 million, with spending of $96.7 million on research and development.

"We are essentially a 25 year-old start-up; we are not mature as a company," he said.

Dr Roberts said the most important driver of business was outcome, ahead of what customers wanted and what the technology might do, but life science companies would only succeed if they can get reimbursement for their products.

"You have to design the future. You can analyze the past all you like, but you have to design the future," he said.

Dr Roberts said the criticism of the company's performance, despite posting record revenue and profits seemed to come from "sell-side analysts" affected by the glass half-full or half-empty syndrome.

He said those who did not get on board at $19 a share and were still not on board at $75 would probably never understand the company.

Dr Roberts said people use data to reinforce their own ideas.

Dr Roberts said that at inception, Cochlear received what was then a very large grant from the Federal Government as there were no commercial funds for the project.

GBS Venture Partners principal Brigitte Smith said the amount was $4.4 million at the time and probably worth about $40 million today.

Dr Roberts said the first round of funding came from the Fraser Liberal Government but it was continued and supported by Labor's Senator John Button and Barry Jones when the Hawke-Keating Governments were in power.

Several people in the room commented that biotechnology and medical technology were unlikely to see that sort of funding from the present Federal Labor Government.

Asked about acquisitions, Dr Roberts said "more companies die from indigestion than starvation" and noted that some had "M&A groups larger than their R&D groups".

Cochlear was up 30 cents or 0.4 percent to $75.00.

QRX PHARMA

QRX says preliminary data from the first of two pivotal phase III studies of its Moxduo-IR immediate-release dual-opioid pain therapy has shown statistically significant results.

QRX said the combination rule study of 522 patients compared the efficacy and safety of Moxduo-IR with 12mg of morphine and 8mg oxycodone against 12mg morphine alone or 8mg oxycodone alone to reduce moderate to severe pain following bunionectomy surgery.

The company said the trial was a double-blind, randomized comparison of three fixed-dose treatment groups experiencing moderate to severe pain following surgery.

Each treatment group received the respective drug every six hours and the trial had "a high completion rate of 94 percent ".

QRX said that despite Moxduo-IR delivering twice the morphine equivalent opioid dose, its discontinuation rate (4.7%) due to adverse side effects compared favorably with morphine (2.3%) and oxycodone (4.0%) alone, reinforcing the improved safety/side effect profile of Moxduo-IR over existing opioid treatments.

The primary endpoint for evaluating the efficacy of Moxduo-IR 12 mg/8 mg versus its milligram components (morphine 12 mg and oxycodone 8 mg) was the difference in pain intensity scores from baseline for each patient over the 48-hour treatment period (SPID48).

The company said that Moxduo-IR "demonstrated statistically superior analgesic effect compared to its individual components of morphine (p=0.01) and oxycodone (p=0.01)".

Moxduo-IR also demonstrated significantly greater analgesic effect compared to its components during the first day of dosing using the SPID24 secondary endpoint (the difference in pain intensity scores from baseline for each patient over the first 24-hour treatment period).

In the media release QRX chief executive officer Dr John Holaday said that "with bunionectomy surgery, the most severe pain occurs within the first 24 hours and, accordingly, that's where we observed the greatest benefit of Moxduo-IR relative to its components in terms of pain relief".

Dr Holaday told Biotech Daily that the preliminary results were in line with previous studies.

"In previous trials we achieved about twice the amount of pain relief with the same side effects at 24 hours," Dr Holadya said.

He said he expected the 24 hour and 48 hour pain relief and side effect data from this trial to support the earlier results.

Dr Holaday said the trial was completed ahead of time and under budget and he expected the second phase III trial to be completed by the end of July 2010.

In the media release Dr Holaday said the path to commercialization was clear.

"With the successful completion of this pivotal trial, we believe we have satisfied the FDA's 'combination rule' requirement and clearly demonstrated the efficacy superiority of Moxduo-IR compared to its individual components," Dr Holaday said.

"We now shift our focus to the final Moxduo-IR registration trial, a study to evaluate the effectiveness of Moxduo-IR in patients following total knee replacement surgery," he said.

Dr Holaday said that based on data from an earlier pilot study the company was confident the second pivotal trial would also yield statistically significant results and file its application to the FDA by the end of 2010.

The company said its Moxduo product portfolio included both immediate and controlled release as well as intravenous formulations.

QRX was up nine cents or 10.2 percent to 97 cents.

PHARMAXIS

Pharmaxis has completed dosing and assessment in its 305 patient, second phase III trial of Bronchitol for cystic fibrosis.

Pharmaxis said the last participant completed the final clinical visit and the trial ran on time and on budget. The first patient entered the trial in September 2008.

Pharmaxis chief executive officer Dr Alan Robertson told Biotech Daily that concluding the trial was a milestone and he expected top line results by the end of June with the full data set to be presented at the North American Cystic Fibrosis meeting in October and hoped to complete the US Food and Drug Administration application by the end of 2010.

The company said an optional 26 week open-label Bronchitol extension was continuing.

Pharmaxis said the trial was the second of two trials, required by the FDA, before a marketing application can be submitted, involving a total of 600 cystic fibrosis patients.

In a media release, Dr Robertson said the support of the US Cystic Fibrosis Foundation was important in conducting the trial efficiently and there had been "considerable enthusiasm from patients and the clinical centres involved".

"It is hoped this trial will confirm that Bronchitol has the opportunity to impact the way people with cystic fibrosis live their lives," Dr Robertson said.

Pharmaxis said the primary efficacy end-point was change in lung function from baseline as determined by forced expiratory volume in one second, over 26 weeks.

Consistent loss of lung function was the main factor shortening the life of people with cystic fibrosis, the company said.

Based on the results of the first phase III trial reported in May 2009, Pharmaxis filed a marketing authorization application with the European Medicines Agency in October 2009.

Pharmaxis was up three cents or 1.1 percent to $2.80.

NANOSONICS

Nanosonics says its manufacturing scale-up halted by a component problem "is on track and has to date been successful".

In February Nanosonics identified "a component of a sub-assembly which is currently not meeting Nanosonics' exacting quality assurance standards" in its commercial scale-up of production of the Trophon EPR ultrasound probe disinfection system (BD: Feb 26, 2010).

At that time Nanosonics' chief financial officer Chris Grundy told Biotech Daily the component caused the system "to report a failed cycle when in fact it hasn't failed" and there was "nothing wrong with safety of efficacy" and that an earlier batch of the components from the same supplier had no problems.

Today, Nanosonics said the first trial batch of Trophon EPR devices with upgraded specifications, including the previously identified sub-assembly, had been released from production and installed in customer sites this week.

The company said the upgraded devices had been provided to customers for in-field trial evaluation and use as per the requirements of the company's quality assurance system.

Subject to evaluation of the in-field performance of the upgraded Trophon EPR units, the Nanosonics said it expected scale-up of production to commence in May 2010.

The company said that volume production would depend on feedback received from the current evaluation and it was pursuing options for an increase in production capacity.

Nanosonics said it had confirmation that a diagnostic imaging company wanted to begin the roll-out of its approximately 200 unit requirement of the Trophon EPR in May.

The company said the Trophon EPR units were to be progressively installed subject to successful completion of the evaluation of the upgraded systems.

Nanosonics was up 4.5 cents or 7.96 percent to 61 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has acquired assets from US-based Perlegen Sciences Inc. primarily the Brevagen breast cancer risk test and non-coding DNA patents.

Genetic Technologies said the suite of granted patents were valid to 2022 and augmented and extended its current non-coding patent portfolio.

The company said Brevagen was a diagnostic test that informed clinicians and patients about individual, non-familial, sporadic risk of breast cancer for women where a breast biopsy outcome is indeterminate.

Genetic Technologies said that there were 1.6 million biopsies taken every year for breast cancer in the US and about one million were indeterminate, representing a potential market of up to $US500 million.

The test combines population risk factors with validated genetic risk factors to give an integrated, personalized breast cancer risk assessment.

Genetic Technologies said it intended to launch the Brevagen test in the US and Australia between July and December 2010, followed by a worldwide rollout.

The company said it could incorporate Brevagen's non-coding patent portfolio to extend its licensing assertion program.

Genetic Technologies said Perlegen was a venture capital funded private company located in Menlo Park, California, launched in 2001 and raising more than $US300 million in equity and other funding.

In 2009, Perlegen failed to secure additional funding critical to the Brevagen product launch and as a shareholder, Genetic Technologies was "privy to information that enabled it to secure an exclusive option to purchase Perlegen's global assets".

Perlegen developed the Brevagen test using data from about 50,000 analyses across numerous studies and the company undertook a preliminary launch of the fully validated test in the US in September 2009.

Genetic Technologies was unchanged at 3.7 cents.

CIRCADIAN

Circadian says Natalie Korchev will resign as chief financial officer, head of operations and company secretary on May 14, 2010 after 10 years with the company.

Circadian said it had begun the process for identifying and recruiting a suitable candidate to fill the role.

Circadian was up one cent or 1.45 percent to 70 cents.