Biotech Daily

Wednesday June 29, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ANTISENSE UP 12.5%, HEARTWARE DOWN 7%**

*** STARPHARMA DEVELOPS DENDRIMER DOCETAXEL FOR CANCER**

*** BIOMD BECOMES ALLIED HEALTH CARE**

*** INNOVATION MINISTER BACKS BIO DELEGATION**

*** ONDEK DEVELOPING EDIBLE H PYLORI-BASED VACCINES**

*** FDA CLEARS MESOBLAST FOR PHASE II DEGENERATIVE DISC TRIAL**

*** OVERSUBSCRIBED AVITA SHARE PLAN RAISES $2.8m**

*** QRX DETAILS EQUI-DOSE TRIAL DETAILS**

*** ANTISENSE DOSES ATL1103 PHASE I ACROMEGALY; CANCER PROGRAM**

*** EMA ORPHAN DESIGNATION FOR PROGEN'S PI-88**

*** QUEENSLAND GIVES $2m FOR IMAGING CENTRE**

*** CBIO UPSET AT REGISTER REQUEST OVER 9.1m SHARE EGM**

*** HELICON TO ACQUIRE OZPHARMA'S LANGUET BUCCAL DELIVERY**

*** US APPROVES WAIVER FOR BLUECHIIP FREQUENCY BAND**

MARKET REPORT

The Australian stock market climbed 1.2 percent on Wednesday June 29, 2011 with the S&P ASX 200 up 55.2 points to 4,529.5 points. Seventeen of the Biotech Daily Top 40 stocks rose, nine fell, eight traded unchanged and six were untraded. All Big Caps rose.

Antisense was the best, up 0.1 cents or 12.5 percent to 0.9 cents with 2.7 million shares traded, followed by Starpharma up 10.9 percent to $1.425 with 603,198 shares traded. Cellmid climbed 8.7 percent; QRX was up 6.9 percent; Alchemia was up 5.3 percent; Impedimed and Universal Biosensors were up more than three percent; Acrux, Cellestis, CSL, Genetic Technologies, Phylogica and Prana rose more than two percent; with Circadian, Mesoblast, Optiscan and Viralytics up more than one percent.

Heartware led the falls, down 15 cents or 6.85 percent to $2.04 with 5,000 shares traded. Living Cell and Virax lost more than five percent; Pharmaxis fell 4.7 percent; Anteo shed 2.7 percent; with Prima and Tissue Therapies both down 1.7 percent.

STARPHARMA

Starpharma says anti-cancer drug docetaxel will be the lead dendrimer candidate in its cancer drug delivery program following encouraging early results.

Starpharma said docetaxel was an important chemotherapy drug to treat breast, lung and prostate cancer and last year generated sales of EUR2.122 billion ($A2.89 billion).

The company said that it had been applying its dendrimer technology to the reformulation of existing cancer drugs and following pre-clinical studies, would advance a dendrimer-docetaxel formulation to further pre-clinical studies as a lead candidate in its drug delivery cancer program.

Starpharma said that docetaxel reformulated with a suite of its dendrimers showed a 2000 to 8000-fold improvement in water solubility, potentially allowing for the development of a novel, improved formulation of the drug.

The company said it hoped that the increased water solubility would allow the development of a formulation which would not require pre-medication with high doses of cortisone and would avoid the need for inclusion of formulation components thought to cause the severe allergic reactions and fluid retention experienced by some patients.

Starpharma compared its docetaxel strategy with the US-based Abraxis “highly successful water-soluble formulation of paclitaxel, [Abraxane] a very similar molecule to docetaxel”.

The company said Abraxis was acquired for $US2.9 billion by Celgene in 2010.

Starpharma chief executive officer Dr Jackie Fairley said the “success seen with Abraxane highlights the significant commercial opportunity of reformulated proprietary chemotherapy agents which can result in improved patient outcomes, significant product sales, and extended commercial life through new intellectual property filings”.

“We believe a proprietary docetaxel-dendrimer formulation has a similar potential and as a result we are expanding our internal drug delivery program to fully explore this opportunity,” Dr Fairley said.

Starpharma said its earlier work with other closely-related cancer drugs demonstrated similar solubility improvements and other significant benefits including markedly reduced toxicities and lengthened half-life and its internal program would run in parallel with its drug-delivery partnering program which includes a growing list of pharmaceutical companies including Glaxosmithkline and Eli Lilly.

Starpharma said it had filed a new patent application with the US Patent and Trademark Office incorporating recent Docetaxel data, building on extensive filings already held and captured the potential uses of a class of dendrimers in a range of applications related to drug delivery, laying the groundwork to secure further intellectual property in this area.

Starpharma’s lead dendrimer product Vivagel has been trialed in a range of vaginal and sexually transmitted diseases and is being refined as a condom coating for Durex and is also conducting research for agricultural uses of dendrimers (BD: Mar 3, 2011).

Starpharma was up 14 cents or 10.9 percent to $1.425.

ALLIED HEALTHCARE GROUP

Biomd says its name has formally been changed to Allied Healthcare Group and it will trade under the ASX code AHZ from Friday July 1, 2011.

Allied managing director Lee Rodne told Biotech Daily that the Australian Securities and Investments Commission formally approved the change today.

Allied Medical acquired Biomd in a reverse takeover and has incorporated the company’s Adapt cardiac tissue treatment with DNA vaccine development by subsidiary Coridon along with its existing profitable medical distribution business.

Allied fell 0.2 cents or 2.5 percent to 7.8 cents.

BIO 2011

The Minister for Innovation Industry Science and Research Senator Kim Carr is at BIO 2011 in Washington DC with representatives from industry, research and government.
A Department of Innovation media release said some of Australia's most innovative firms would showcase their wares at the event and Senator Carr was supporting "the continued push to promote Australian products and services in markets overseas".
"Our biotech sector has recovered strongly from the global financial downturn due largely to its strong research base and valuable intellectual property," Senator Carr said.
"Australia's skills, world class research institutions and regulatory environment make it an ideal place to invest in biotechnology research and development and manufacturing," he said. "Our national assessment of university research capability exceeds world class standards in the fields of ecology, evolutionary biology, genetics, microbiology and plant biology."
"Australia's biotech industry is world class and the high regard with which it is held internationally is on show at BIO 2011," Senator Carr said.
He said the Federal Government had "made a significant investment in the biotechnology sector, recognizing its potential to treat major diseases, improve food production and reduce the impacts of climate change".

ONDEK

Ondek says clinical trials have identified strains of Helicobacter pylori bacteria which are safe to use in humans as the basis for edible vaccines.
An Ondek media release said the Perth Australia trial of 30 subjects showed that some strains of Helicobacter pylori (H pylori) were safe and well tolerated in humans.
Ondek's chief scientist Dr Barry Marshall said the results, released at the World Vaccine Congress Asia in Singapore "demonstrated that some strains of H pylori are well tolerated in humans and can provide an oral delivery platform for vaccines and biologics".
The company said the research showed which strains of the bacteria had the most benign effect on the human stomach while still inducing an immune response.
Dr Marshall said Ondek would seek approval for clinical trials in which an influenza virus gene would be attached to the bacteria.
Dr Marshall said the next step was to submit the data with an application to the Australian Therapeutic Goods Administration and US Food and Drug Administration for the next trial.
Ondek said the Perth trial injected five strains of the bacteria Helicobacter pylori into five groups of six participants to find out if they would cause any side-effects.
The company said the bacteria were collected from elderly people in Sweden who had carried them all their lives but never showed any symptoms.
Ondek said the bacteria easily infected the trial participants, who suffered none or only minor side-effects such as occasional stomach upsets, with three strains lasting longer than three months, while the other two disappeared in the same period.
The company said the results suggested the bacteria were safe to attach vaccines for delivery through the wall of the stomach instead of via a syringe.
Ondek said the next trials would give participants one dose of the edible vaccine, possibly in the form of a yoghurt which Dr Marshall said was for people to eat as a vaccine.
Dr Marshall said there was huge potential for edible vaccines and they would be an easy way of providing booster vaccines for hepatitis B, malaria and swine influenza.
Dr Marshall won a Nobel Prize in 2005 for discovering Helicobacter caused stomach ulcers.
Ondek is a private company.

MESOBLAST

Mesoblast says it has US Food and Drug Administration clearance to begin a phase II trial of its adult mesenchymal precursor cells for degenerative disc disease.

Mesoblast said the adult stem cell biologic disc repair therapeutic was a non-surgical treatment for the number one cause of chronic lower back pain.

The company said that the multi-center phase II trial in the US and Australia would enroll 100 patients with chronic lower back pain due to lumbar disc degeneration.

Mesoblast said 60 patients would be injected with the allogeneic or off-the-shelf mesenchymal precursor cells into a damaged disc, using one of two doses combined with a hyaluronic acid carrier.

The company said the endpoints of safety and efficacy would be compared at six months against 40 control patients injected with either hyaluronic acid or saline alone.

Mesoblast said the trial would build on preclinical results in sheep which showed that six months after a single low dose injection of the cells into severely damaged intervertebral discs there was dramatic reversal of the degenerative process, regrowth of disc cartilage, and sustained normalization of disc pathology, anatomy and function (BD: Sep 10, 2009).

Mesoblast said the control discs were either not injected or were injected with hyaluronic acid and continued to demonstrate significantly reduced disc height ($p < 0.01$), disordered disc structure ($p < 0.01$), disrupted histopathology ($p < 0.01$) and reduced cartilage content ($p < 0.05$) compared with healthy non-degenerated discs over six months.

The company said that up to 15 percent of people in industrialized countries had chronic back pain lasting more than six months and short-term benefits could be obtained by bed rest, analgesics, physiotherapy, and steroids, but many patients progressed to unremitting, severe and debilitating pain due to ongoing disc degeneration.

Mesoblast said the only current option was major back surgery involving artificial disc replacement or spinal fusion.

Mesoblast chief executive Prof Silviu Itescu said the company had developed a novel therapeutic approach to reverse disc degeneration and address the number one cause of chronic low back pain.

“There is a clear need for a product to reverse the degenerative process and regenerate the disc back to a healthy state,” Prof Itescu said.

“We believe our allogeneic adult stem cell product may represent a major breakthrough into this unmet market segment,” Prof Itescu said.

Mesoblast was up 16 cents or two percent to $8.26.

AVITA MEDICAL

Avita says it received applications for $4.1 million worth of shares at 10 cents shares in its plan to raise $2 million.

Avita said the applications would be scaled back to $2.8 million on a pro-rata basis.

Avita chief executive officer Dr William Dolphin said that “following the successful completion of the placement which raised $9 million, it is pleasing that the opportunity to invest in the [share purchase plan] has been strongly supported by our existing shareholders”.

“The additional capital raised from the [plan] along with the funds already raised from the placement will be primarily directed to expansion of sales and marketing efforts and secondarily to research and development related to the Company’s regenerative medicine product line,” Dr Dolphin said.

Avita was unchanged at 11.5 cents.

QRX PHARMA

A detailed study of QRX's equi-analgesic trial of Moxduo against morphine and oxycodone focuseson oxygen desaturation as a key side effect measure (BD: June 14, 2011).

The company said on June 14 that the Study 022 primary endpoint of respiratory depression as measured by oxygen desaturation was less severe and of shorter duration in patients receiving Moxduo immediate release (12mg morphine and 8mg oxycodone) compared to those receiving either 24mg morphine or 16mg oxycodone alone and respiratory depression was the leading cause of death from high doses of opioids.

QRX said at that time that Moxduo was superior to Oxycodone for blood oxygen desaturation but not significantly so for morphine.

QRX said Moxdua was significantly superior to oxycodone for moderate to severe vomiting but was comparable for morphine.

Today QRX said episodes of oxygen desaturation were of shorter duration and less intensity in patients receiving Moxduo immediate release (IR) compared to those receiving either morphine or oxycodone alone, with Moxduo patients 4:1 to 5:1 times less likely to suffer a potentially life threatening severe desaturation event compared to those receiving the other opioids.

QRX said it believed Moxduo IR was the first opioid product to demonstrate a lower risk of respiratory depression in a clinical study comparing equi-analgesic doses and said 40 percent of the study were subjects aged 60 years or older, a group at enhanced risk of opioid induced respiratory impairment.

QRX said the double-blind, randomized, fixed-dose trial enrolled 375 patients with moderate to severe pain following bunionectomy received equi-analgesic doses every six hours of either Moxduo IR 12mg/8mg, morphine 24mg or oxycodone 16mg.

The company said the primary objective was "to explore, as the primary end point, the performance of Moxduo IR relative to morphine and oxycodone comparators with respect to oxygen desaturation, a direct measure of respiratory depression".

The company said the results were intended to support the European Marketing Authorisation Application and be submitted to the US Food and Drug Administration as a safety update after the August 2011 new drug application filing.

QRX said it analyzed data from patients experiencing the worst (10th percentile) of all observed desaturations, which demonstrated that the risk of the occurrence of such potentially dangerous desaturations was significantly greater in patients receiving morphine ($p < 0.009$) or oxycodone ($p < 0.002$) alone than in those receiving MoxDuo.

The company said that the median area-under-the-curve of each individual desaturation for the Moxduo patients were 20 percent to 45 percent smaller than those of morphine alone and oxycodone alone, with the latter difference being statistically significant ($p=0.018$).

QRX said that an evaluation of the more extreme desaturations showed that Moxduo patients had significantly less severe desaturations than morphine or oxycodone.

QRX said that SPID48 pain scores showed comparable analgesic effects among the treatment groups but with no statistically significant differences, with the Moxduo group scoring 14 percent better than morphine and four percent less than oxycodone.

The company said the FDA required the administration of anti-nausea rescue medication only to patients that vomited and not to those only exhibiting nausea, which significantly limited the interpretation and comparative value of nausea and vomiting measurements, but the occurrence rate of moderate to severe vomiting was significantly ($p < 0.04$) reduced 32 percent to 42 percent in Moxduo treated subjects compared to patients receiving oxycodone alone.

QRX was up 11 cents or 6.9 percent to $1.70.

ANTISENSE THERAPEUTICS

Antisense says it has begun dosing human subjects in its phase I trial of the growth hormone receptor (GHr) targeting drug ATL1103.

Antisense said the 36-subject, randomized, placebo-controlled, double-blind study of single ascending doses and multiple doses of ATL1103 in healthy adult male subjects aged between 18 and 45 years was being run by Nucleus Network at their dedicated clinical trial unit co-located at the Austin Hospital, Heidelberg, Victoria.

The company said the primary objective was to assess the safety, tolerability and pharmacokinetics of ATL1103 administered by subcutaneous injection, with a secondary, objective to obtain key data on the effect of ATL1103 on IGF-I levels in the blood of the trial subjects.

Antisense said reducing elevated levels of serum IGF-I to normal was the therapeutic endpoint in the treatment of the growth disorder acromegaly, and reducing the effects of IGF-I had a potential role in the treatment of diabetic retinopathy, nephropathy and certain forms of cancer.

The company said the Royal Children's Hospital's director of endocrinology Prof George Werther, an Antisense non-executive director, would be a member of the data monitoring committee.

Antisense said University of California Los Angeles' Prof Shlomo Melmed would also consult on the trial.

Prof Melmed said there was a need for improved therapies for treatment of the growth disorder, acromegaly.

"ATL1103's effects in suppressing serum IGF-I levels in previous studies combined with its potential safety advantages over existing treatments and more convenient dosing regimen make ATL1103 an excellent clinical candidate," Prof Melmed said.

The company said dosing was expected to be completed before the end of the year with results early next year.

Antisense said would conduct its ATL1103 cancer experimental program in parallel with the phase I acromegaly clinical trial, established with Mattel Children's Hospital at UCLA head of diabetes and endocrinology Dr Pinchas Cohen.

The company said Prof Cohen co-authored a study that found that patients with Laron syndrome who carry a genetic mutation that silences their growth hormone receptor thereby having depressed levels of growth hormone receptor and IGF-I, were protected from developing cancer.

Antisense said Prof Cohen's team will look at ATL1103's effect on exploratory markers of cellular activity relevant to cancer from the subjects who received multiple doses, to assist in determining the potential of ATL1103 in the new application of preventing certain forms of cancer in high risk individuals.

Antisense was up 0.1 cents or 12.5 percent to 0.9 cents with 2.7 million shares traded.

PROGEN PHARMACEUTICALS

Progen says the European Medicines Agency has granted licensee, Taiwan's Medigen Biotechnology Corp, orphan drug designation for PI-88 for hepatocellular carcinoma.

Progen said the designation was to advance the development of drugs intended to treat, prevent or diagnose life-threatening or very serious conditions that are rare and affect not more than five in 10,000 persons in the European Union.

The company said that Medigen would have market exclusivity in the EU for 10 years should PI-88 receive marketing approval for hepatocellular carcinoma.

Progen was up one cent or 3.85 percent to 27 cents.

QUEENSLAND GOVERNMENT

Queensland Premier Anna Bligh says her Government will invest $2 million in the University of Queensland's Centre for Advanced Imaging.

A media release from the University said the funding was announced by premier Bligh at Bio 2011 in Washington DC as part of the Smart State funds to strengthen the state's research capacity.

University of Queensland vice-chancellor Prof Paul Greenfield said the funding would go towards establishing an international-class research facility that would support major research into Alzheimer's disease, stroke, arthritis and cancer.

“Advanced imaging is integral to earlier diagnosis and to personalized, patient-specific treatments for diseases that cause high levels of disability and distress in Australia,” Prof Greenfield said.

The media release said the investment was in support of a $40.2 million grant awarded to expand the National Imaging Facility under the Federal Government's Education Investment Fund which has a total project value of $107 million.

CBIO

CBio executive chairman Stephen Jones says he is concerned that two shareholders have requested copies of the shareholders register relating to a general meeting next month.

Mr Jones said the register included names, addresses and other details of all shareholders.

He said the requesting parties told the company that their intentions were to write to shareholders concerning resolutions to be put to the July 15, 2011 meeting.

Mr Jones said the Corporations Act allowed the company to refuse access to the register for certain “prescribed purposes” but the purpose did not qualify as a prescribed purpose.

Shareholders are entitled to request registers of companies in which they hold shares at no cost, while non-shareholders may have to pay for the privilege.

Mr Jones said “it appears that there is no legal avenue available to the company to prevent these parties from obtaining a full copy of the register of members”.

Mr Jones did not explain why he would want to stop them having copies of the register.

He said the company wanted drafts of the correspondence the two parties intend to send to shareholders, but was refused.

Mr Jones said the company “has therefore been unable to determine what the contents are, whether all or only some members will be communicated with, the frequency of any communication, whether different shareholders receive the same message or not, whether any proposed correspondence contains factual errors, inaccuracies, confidential information, defamatory remarks or is unreasonable in length”.

“As a result, I apologize in advance for any inconvenience with respect to this matter,” Mr Jones said.

He said it was “regrettable that the Corporations Act permits one or two shareholders to contact some or all shareholders with potentially unwelcome correspondence, containing personal views on matters relating to the company”.

After the ASX closed on Friday June 10, CBio announced an extraordinary general meeting to issue 9.1 million free performance rights to executives and directors, exercisable, pending conditions, at no charge for seven years (BD: June 14, 2011).

CBio shareholders will be asked to ratify the prior issue of 15,350,616 shares and 2,169,109 shares to Springtree Special Opportunities Fund along with approval for director Dr Michael Monsour to subscribe for rights offer shortfall shares.

CBio was up 1.5 cents or 2.7 percent to 57 cents.

HELICON GROUP

Helicon says it will acquire all the intellectual property associated with Ozpharma's Linguet buccal technology for $50,000, shares and roaylties.

Helicon managing director Fabio Pannuti said his company looked forward to working with the Ozpharma to complete the development the asset.

"We have now completed our restructuring of Helicon and put in place a strategy and a team capable of identifying, acquiring and building a drug delivery technology portfolio that will deliver shareholders strong returns over multiple licensing opportunities," Mr Pannuti said.

Helicon chairman Rod Tomlinson said Linguet had "some real advantages over the existing buccal technologies".

"Having successfully developed buccal technologies at Soltec, we are well placed to understand the potential for a technology like this and more importantly, how it can add significant value to a licensing partner," Mr Tomlinson said.

Pending conditions Helicon said it had the right to acquire the Linguet by paying $50,000, 15 percent of Linguet royalties paid to Helicon, 1,370,000 Helicon shares and a call option over the new subsidiary company that Helicon would form to hold the technology.

Helicon was up 0.4 cents or 17.4 percent to 2.7 cents with 2.3 million shares traded.

BLUECHIIP

Bluechiip says the US Federal Communications Commission has granted a waiver, allowing its technology to operate in specified restricted frequency bands.

Bluechiip said the waiver removed a potential roadblock in the path to the company commercializing its wireless tracking technology in the U.S.

The company said the device transmitted in the frequency band 1.5MHz-4.2MHz, which included narrow frequency windows that are normally restricted and reserved for military or government use.

Bluechiip said that its technology offered improvements in tracking of genetic, stem cell and other biological materials stored under extreme temperature conditions.

Bluechiip was up one cent or 7.1 percent to 15 cents.