Biotech Daily

Monday April 11, 2011

Daily news on ASX-listed biotechnology companies

*** ASX; BIOTECH UP: ADVANCED SURGICAL UP 19%; PRIMA DOWN 9%**

*** ANTISENSE'S ATL1103 TO TARGET CANCER**

*** RALLIES FOR RESEARCH**

*** CELLMID MIDKINE REDUCES CARDIAC CELL DEATH 27% IN RATS**

*** FDA APPROVES 20 MORE SUNSHINE HEART AORTA PUMP PATIENTS**

*** SIRTEX CLAIMS QUARTER DOSE SALES UP 21%**

*** PHOSPHAGENICS 'BODYSHAPER AOP9604 CREAM REDUCES FAT 40%'**

*** GENETIC TECHNOLOGIES SETTLES ORCHID CELLMARK DNA DISPUTE**

*** BENITEC $8m 4-FOR-5 RIGHTS ISSUE TO CLOSE LA JOLLA COVE NOTE**

*** US SCREENING PATENT FOR PHYLOGICA**

*** JAPANESE COMPOSITION PATENT FOR PRANA'S PBT2**

*** HEARTWARE AGM TO RATIFY $144m NOTE, PAY, ELECT DIRECTORS**

*** PHYLOGICA $5.2m PLACEMENT EGM**

*** CORRECTION: QRX**

*** MASSACHUSETTS MUTUAL INCREASES, DILUTED TO 15.5% OF TYRIAN**

MARKET REPORT

The Australian stock market was up 0.62 percent on Monday April 11, 2011 with the S&P ASX 200 up 30.6 points to 4971.2 points. Nineteen of the Biotech Daily Top 40 stocks were up, eight fell, 10 traded unchanged and three were untraded. All three Big Caps fell.

Advanced Surgical was best, up four cents or 18.6 percent to 25.5 cents with 7,200 shares traded, followed by Cathrx up 17.65 percent to 20 cents with 12,751 shares traded and Cellmid up 16.7 percent to 2.8 cents with 52.6 million shares traded. Genetic Technologies climbed 15.3 percent; Benitec was up 12.9 percent; Phosphagenics rose 11.5 percent; Uscom was up 8.7 percent; Phylogica was up 6.45 percent; Antisense was up 5.6 percent; Circadian, Pharmaxis and Virax were up more than three percent; Acrux, Impedimed and Sirtex rose more than two percent; with Starpharma up 1.5 percent.

Prima led the falls, down 3.5 cents or 8.9 percent to 36 cents, with 55.1 million shares traded followed by Clinuvel down 4.8 percent to $2.00. Alchemia and Viralytics lost more than three percent; Bionomics and Sunshine Heart shed more than two percent; with Cochlear, CSL and QRX down more than one percent.

ANTISENSE THERAPEUTICS

Antisense says it will investigate ATL1103 which targets the growth hormone receptor as a treatment for cancer prevention and therapy.

Antisense said ATL1103 reduced levels of growth hormone and insulin-like growth factor I (IGF-I) for diseases include acromegaly, diabetic retinopathy and nephropathy and some forms of cancer.

The company said previous studies it had conducted showed ATL1103 inhibited the growth hormone receptor and suppressed serum IGF-I levels in both mice and primates.

Antisense said it was consulting with the chief of diabetes and endocrinology and the University of California Los Angeles' Mattel Children's Hospital Prof Pinchas Cohen to establish an appropriate experimental program.

The company said the initiative followed a recent publication co-authored by Prof Cohen on the role of growth hormone and IGF-I in preventing diseases related to ageing, namely cancer and diabetes.

The paper entitled 'Growth Hormone Deficiency is Associated with a Major Reduction in Pro-Ageing Signalling, Cancer, Diabetes in Humans' was published in Science Translational Medicine in February 2011.

An abstract is available at: http://stm.sciencemag.org/content/3/70/70ra13.abstract.

The article reported on a study of a patient population with Laron syndrome who carry a genetic mutation that silences their growth hormone receptor and consequently had depressed levels of growth hormone and IGF-I.

Antisense said people with Laron syndrome had short stature due to the genetic mutation, but the authors found that over the 22 that they were observed, the study population of 99 subjects experienced only one case of (non-lethal) cancer and no cases of diabetes, which contrasted with a prevalence of 17 percent for cancer and five percent for diabetes in the control subjects who were relatives unaffected by growth hormone receptor deficiency.

The company said that the authors tested serum samples from the population who had the growth hormone receptor defect and found that the samples induced higher levels of cellular protection and resulted in decreased proliferation and reduced expression of specific pro-growth signaling genes, which regulated growth, promoted ageing and led to activation of processes that might lead to cancer progression.

Antisense said the authors concluded by saying that their results led them to consider testing medications that block growth hormone activity in ways that might protect against diseases of ageing, in particular cancer.

Antisense cited other articles including an editorial in Cell Metabolism entitled 'Is Growth Hormone Resistance/IGF-I Reduction Good for You?' which said the study findings supported the concept that reductions in growth hormone and IGF- I signaling could be important in protecting against the development of cancer.

Antisense said the results "provide further validation for the rationale for development of ATL1103, and in particular its potential as a cancer therapeutic … [and] opens up the very exciting potential new application of ATL1103 in the prevention of certain forms of cancer in high risk individuals".

"I have for some time had a professional interest in the role of [growth hormone] and IGF-I in age-related diseases such as cancer and in addition to the scientific paper that I contributed to on this topic, there have been a number of other publications suggesting a key role for [growth hormone receptor] suppression in disease modification," Prof Cohen said.

Antisense was up 0.1 cents or 5.6 percent to 1.9 cents with 71.1 shares traded.

RALLY FOR RESEARCH

The Walter and Eliza Hall Institute for Medical Research says rallies for research funding will be held in Australia's capital cities this week.

Last week, WEHI said it believed that cuts of up to $400 million in the Australian research budget were expected in the May Federal Budget (BD: Apr 8, 2011).

Rallies will be held tomorrow at 12.45pm at the State Library, Swanston Street, Melbourne; at 12.45pm at Belmore Park, Hay Street, Haymarket, Sydney; at 12.30pm at the John Curtin School of Medical Research at the ANU, Canberra; at 12.30pm (ACST) at Parliament House, North Terrace, Adelaide; and on April 14, at 12pm (AWST) at Forrest Place, Murray Street Mall, Perth.

CELLMID

Cellmid says it has completed preclinical studies into the efficacy of midkine for the treatment of acute myocardial infarction.

Cellmid said that in the study conducted by Pharmahungary's specialist cardiovascular research facilities, a total dose of 0.18 mg/kg of its midkine performed best and reduced the area of heart muscle damage by approximately 27 percent compared to untreated animals undergoing the same procedure.

The company said midkine was given to rats intravenously in single doses and in follow up intravenous infusions.

Cellmid said midkine was safe and well tolerated, with no difference in adverse events between MK treated and untreated controls.

Pharmahungary chief executive officer Dr Peter Ferdinandy said "a reduction of around 27 percent in infarct size is very encouraging".

Pharmahungary evaluated midkine in dose-ranging and acute safety and tolerability studies and the dose-ranging studies showed that midkine was effective at significantly reducing heart muscle death with doses between 0.1mg/kg and 1.0 mg/kg and was safe and well tolerated at doses 16 times greater than the most effective dose of 0.18 mg/kg, with no cardiovascular toxicities observed.

Cellmid said that midkine was a multifunctional growth factor highly expressed during embryonic development that was part of a natural defence mechanism activated during cardiac arrest.

The company said that heart cells under stress from a lack of oxygen produced midkine to prevent cell death but the amount produced was very limited and the time taken was slow.

Cellmid said the administration of its midkine was expected to directly reduce cell death from myocardial injury and improve immediate and long term survival of patients.

The company said midkine modulated many important biological interactions such as cell growth, cell migration and cellular adherence, which were relevant to ischemia, cancer, inflammation, autoimmunity, nerve growth/repair and wound healing.

Cellmid said midkine was barely detectable in healthy adults and high expression levels only occurred as a consequence of the pathogenesis of a number of different disorders, making midkine an important early marker for diagnosing cancers and autoimmune diseases.

The company said the Pharmahungary studies confirmed its earlier research findings that midkine reduced heart damage due to ischemia and reperfusion injury.

Cellmid said the demonstrated significant improvement meant that large animal trials could commence and manufacturing of good manufacturing practice-quality midkine could proceed in preparation for clinical trials.

Cellmid was up 0.4 cents or 16.7 percent to 2.8 cents with 52.6 million shares traded.

SUNSHINE HEART

Sunshine Heart says the US Food and Drug Administration has approved the implanting of its C-Pulse aorta cuff pump in an additional 20 patients and add two new study sites.
Sunshine Heart said its investigational device exemption supplement for the C-Pulse heart assist system for class III and ambulatory class IV or moderate to severe heart failure had been approved.
A Sunshine Heart spokesman told Biotech Daily the C-Pulse pumps cost about $US54,000 each and the company was reimbursed by insurance companies for each implantation.
The spokesman said that Sunshine Heart earned $648,000 in revenue in 2009-'10.
In a media release Sunshine Heart chief executive officer Dave Rosa said the company was pleased to be able "to offer this therapy to additional patients that meet the appropriate criteria while we collect the follow-up data from our initial 20 patients".
"This will allow not only existing centers to continue to offer the therapy but it will also enable us to add two additional sites that have expressed interest in participating," Mr Rosa said.
Sunshine Heart said all 20 patients in the pilot trial had been implanted by March 31, 2011 and required six months follow up prior to applications to the FDA for a pivotal trial and to European authorities for Conformité Européenne (CE) mark approval (BD: Apr 4, 2011).
Sunshine Heart closed down 0.1 cents or 2.38 percent to 4.1 cents.

SIRTEX MEDICAL

Sirtex says dose sales of its SIR-Spheres liver cancer treatment were up 20.7 percent for the three months to March 31, 2011 compared with the same quarter last year.
Sirtex said in its report for the six months to December 31, 2010 that dose sales were its "key metric of business growth" and they were up 16.5 percent to 2,325 units, compared to 1,996 for the same period last year (BD: Feb 23, 2011).
Today the company said that year-to-date dose sales had increased 18 percent, which compared favorably with the 14.7 percent increase for the first nine months of the previous financial year.
Sirtex said "the acceleration in demand highlights the growing awareness among patients and clinicians alike for the SIR-Spheres microsphere technology in liver cancer".
Sirtex said it had "reported 27 consecutive quarters of positive dose sales growth worldwide" with Europe the fastest growing market up 23 percent for the three months to march 31, 2011 compared with the previous corresponding period, while US dose sales were up 20 percent for the three months and up 15 percent for the nine months to March 31, 2011 compared to eight percent for the corresponding three quarters.
Sirtex said Asia Pacific sales were up 13 percent for the three months.
Sirtex chief executive officer Gilman Wong said the result "demonstrates that our marketing strategies to improve short term growth are resulting in a greater number of patients receiving SIR- Spheres microspheres to treat their liver cancer and we are confident dose sales growth will remain strong into the future".
Sirtex said its dose sales were less than one percent of the addressable global market of people diagnosed worldwide each year with liver cancer and more than 18,000 liver cancer patients have been treated with SIR-Spheres at more than 400 medical centres.
Sirtex was up 13 cents or 2.4 percent to $5.45.

PHOSPHAGENICS

Phosphagenics says it will launch its Bodyshaper Cellulite Contour Crème in Australia by the end of the month after US studies “produced stunning results”.

Phosphagenics said the anti-cellulite product used its tocopheryl phosphate mixture or TPM technology carrying Calzada’s AOD9604 compound.

Phosphagenics said the US trials demonstrated a reduction in the appearance of cellulite of up to 40 percent after four weeks as well as improving skin elasticity and hydration.

Phosphagenics chief executive officer Dr Esra Ogru said the company had built a solid reputation in pharmaceutical product delivery, but wanted to enter the multi-billion dollar market for cellulite reduction products using its platform technology.

“Our cosmetic products have been developed by scientists using the unique and patented Phosphagenics’ proprietary platform TPM technology,” Dr Ogru said.

“We have repeatedly demonstrated the versatility of this technology with pharmaceutical, dermatological and cosmetic preparations,” Dr Ogru said.

Dr Ogru said the phosphorylated vitamin E or tocopheryl phosphate mixture was a scientific technology that enabled active ingredients “to be delivered into the skin effectively, safely and non-invasively”.

Dr Ogru told Biotech Daily the compound formerly known as anti-obesity drug 9604 (AOD9604) would be relabeled anti-obesity peptide 9604 (AOP9604) as it was not a drug.

In the media release Dr Ogru said the Bodyshaper product combined TPM with AOP9604 and two other fat-busting molecules, caffeine and forskolin.

Phosphagenics said AOP9604 was a 16-amino acid cyclical peptide that was discovered at Monash University by Prof Frank Ng and co-workers and had undergone several years of testing to characterize its ability to promote lipolysis, which was the breakdown and release of fat stored in fat cells.

The company said the compound had been “rigorously established over many years, as has its ability to reduce the size and contents of human fat cells in vitro”.

In oral trials of 536 subjects conducted by Metabolic (now Calzada) in 2007, AOD9604 failed to reach its endpoints in patients compliant with US Food and Drug Administration exercise and diet requirements (BD: Feb 21, 2007).

Phosphagenics said today that cellulite was a condition where bulging fat cells gave the appearance of bumps on the body, commonly referred to as the orange-peel effect.

Phosphagenics said its current study of 30 women was being conducted by AMA Laboratories Inc in New York, with the women applying the cream morning and night to the upper thigh of a single leg, which would be assessed over an eight week period for quantifiable changes in the visible appearance of cellulite using advanced digital photographic techniques, as well as skin hydration and elasticity, with the untreated leg used as a control for all measurements.

Phosphagenics said participants would also record their subjective assessments of any perceived improvements at regular intervals.

The company said that after 28 days of application, the visible appearance of cellulite was quantifiably reduced by as much as 40 percent at the sites of application.

Phosphagenics said the improvements were visibly noticeable to the participants, with 86 percent of women reporting a perceived improvement to the visible appearance of the bumps and dimples of their cellulite.

The company said 96 percent of the trial participants observed an improvement to skin firmness and smoothness, while 93 percent saw an increase in skin tightness.

Measurable skin hydration was increased by 20 percent and elasticity increased by five percent over the course of the four weeks, the company said.

Phosphagenics rose 1.5 cents or 11.5 percent to 14.5 cents with 9.1 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has settled its dispute with Orchid Cellmark relating to its non-coding patents.
Genetic Technologies said the Princetown New Jersey-based company executed a settlement agreement following the patent infringement suit filed in the US District Court, Western District of Wisconsin last year (BD: Feb 16; May 3, 5; Aug 26; Nov 30, 2010)..
Genetic Technologies said Orchid was one of nine parties originally sued and the commercial terms were covered by confidentiality provisions and could not be disclosed.
The company said Orchid was granted non-exclusive rights to a number of patents, including non-coding analysis, gene mapping and internal standards patents.
Genetic Technologies was up 1.3 cents or 15.3 percent to 9.8 cents.

BENITEC

Benitec hopes to raise up to $8,012,879 through a fully-underwritten, renounceable four-for-five share rights issue at two cents a share.
Benitec said one free attaching option exercisable at four cents by December 31, 2013 would be issued with every four shares acquired.
Benitec said the record date for the rights issue was April 19, 2011, the offer opens on April 13 and closes on May 12, 2011.
The company said it would use the funds primarily to close its convertible note draw-down equity facility with La Jolla Cove.
Benitec chief executive officer Dr Peter French said the capital raising was “effectively a relaunch of Benitec following the favorable decision from the US Patent and Trademark Office’s board of appeal late last year”.
“Benitec has secured its position as a leader in the field of gene silencing and has engendered new confidence by the investment community in the renewed prospects for Benitec,” Dr French said.
“For the first time in many years, Benitec will now be in a position to realize value from our gene silencing technology,” Dr French said.
“This is a truly transformational approach to treating diseases and the company is extremely excited about capitalizing on this opportunity,” Dr French said.
“Benitec appreciates the support given … by La Jolla Cove Investors Inc when funds were difficult to obtain, given the uncertainty at the time of the company’s US Graham patent reexamination,” he said.
“The funds received from La Jolla Cove Investors Inc enabled the company to continue its key projects and to support its key patents,” Dr French said.
Dr French said that with the reissue of the patent, Benitec had more conventional funding options available.
Benitec was up 0.4 cents or 12.9 percent to 3.5 cents with 8.8 million shares traded.

PHYLOGICA

Phylogica says the US Patent and Trademark Office has granted it a patent for “innovative methods of screening molecular libraries against interactions between disease-associated proteins inside cells”.
The company said the patent was filed by the US-based Fox Chase Cancer Centre and exclusively licenced to Phylogica.
Phylogica was up 0.4 cents or 6.45 percent to 6.6 cents with 3.6 million shares traded.

PRANA BIOTECHNOLOGY

Prana says the Japanese Patent Office has granted a composition of matter patent for its lead clinical asset PBT2 and other selected 8-hydroxyquinoline compounds.
The patent entitled '8-Hydroxyquinoline derivatives' also covers pharmaceutical compositions containing PBT2 and selected 8-hydroxyquinoline compounds and the use of the compounds for the treatment of Alzheimer's Disease.
Prana executive chairman Geoffrey Kempler said the decision to grant a claim to PBT2 "completes a suite of core patent rights protecting this asset in key markets including the United States, Europe, Japan and Australia, further bolstering our commercialization plans in both Huntington's and Alzheimer's disease".
Prana said the Japanese patent had a 20 year term expiring on July 16, 2023, with a possible extension of term of up to five years under pharmaceutical protection provisions.
The company said that in 2010, it announced the grant of similar claims in Europe and the decision of the US Patent Office to extend the term of the patent.
Prana was unchanged at 23 cents.

HEARTWARE

Heartware annual general meeting will vote on resolutions on executives pay, directors options, the issue of $US143,750,000 convertible notes and re-elect directors.
Heartware said shareholders would vote to ratify last year's issue of the 3.5 percent convertible notes (BD: Dec 14, 2010) as well as advisory notes on executives remuneration, the issue of 22,450 'restricted stock units' to chief executive officer Douglas Godshall along with the issue of 1,000 restricted stock units and 1,000 options to directors Robert Thomas, Dr Seth Harrison, Timothy Barberich, Dr Christine Bennett, Charles Raymond Larkin Jr, Robert Stockman and Dr Denis Wade.
The meeting will also vote on the reelection of directors Mr Barberich, Mr Larkin Jr and Mr Thomas.
The meeting will be held at the Fairmont Turnberry Isle Hotel, 19999 West Country Club Drive, Miami, Florida, on May 12, 2011 at 4.30pm (US EST); May 13 at 6.30am (AEST).
Heartware was up one cent or 0.45 percent to $2.22.

PHYLOGICA

Phylogica shareholders will vote to ratify the placement of 88,135,594 shares at 5.9 cents each and 44,067,797 attaching options to raise $5,200,000 (BD: Mar 25, 2011).
The placement is over two tranches and shareholders will also be asked to approve the participation of directors Dr Paul Watt and Nicholas Woolf in the placement.
The Phylogica meeting will be held in the Seminar Room, Telethon Institute for Child Health research, 100 Roberts Road, Subiaco, Western Australia on May 10, 2011, at 9.30am (AWST).

TYRIAN DIAGNOSTICS

Massachusetts Mutual Life Insurance has increased its substantial holding in Tyrian and has been diluted through the recent share issue.
Massachusetts Mutual Life increased and was diluted from 93,888,166 shares (18.87%) to 157,879,432 shares (15.52%).
Tyrian raised $3.98 million at the end of last year (BD: Dec 15, 2010)
Tyrian fell 0.1 cents or 11.1 percent to 0.8 cents with 23 million shares traded.

CORRECTION: QRX PHARMA

On April 8, 2011 Biotech Daily reported that Orbis Investment Management sold 745,684 QRX shares for $1,400,007 or an average price of $1.88 a share.
QRX has not traded above $1.74.
The mistake was made it calculating values based on buy and sell trades, whereas the average sale price appears to be $1.61 a share, giving Orbis an 89.4 percent profit on the shares mostly acquired in a placement at 85 cents a share and not 121 percent profit as reported.
The calculations sub-editor has been severely reprimanded and will in future use his toes as well as his fingers for counting.
QRX fell three cents or 1.8 percent to $1.66.