Biotech Daily

Monday August 22, 2011

Daily news on ASX-listed biotechnology companies

*** ASX UP, DOWN; BIOTECH DOWN: CATHRX UP 17%, VIRAX DOWN 23%**

*** MESOBLAST TREATS 1st STEM CELL LUMBAR DISC PATIENT**

*** IMMURON ON-TRACK FOR FDA PHASE IIb IMM-124E NASH TRIAL**

*** LIVING CELL IMPLANTS 1st ARGENTINIAN DIABETES PATIENTS**

*** PATRYS DETECTS PAT-SM6 IN TARGET TUMORS**

*** MICHAEL J FOX GRANTS $200k FOR PRANA PRECLINICAL WORK**

*** VICTORIAN GOVERNMENT $50k FOR GSK, STARPHARMA COSMETICS**

*** PHARMAXIS FILES RE-EXAM DOCUMENTS TO EUROPEAN COMMITTEE**

*** ASX ASKS IM MEDICAL EGM RESOLUTION QUESTIONS**

*** COGSTATE ACQUIRES AXON, APPOINTS RUDY CHAPA US DIRECTOR**

MARKET REPORT

The Australian stock market was up about half a percent for most of Monday August 22, 2011 but the S&P ASX 200 closed down 19.6 points or 0.48 percent to 4082.3 points. Eight of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and seven were untraded. All three Big Caps were up.

Cathrx was the best for the second trading day in a row, up two cents or 16.7 percent to 14 cents with 18,700 shares traded, followed by Patrys up 15.5 percent to 8.2 cents with 118,809 shares traded and Antisense up 14.3 percent to 0.8 cents with 4.25 million shares traded. CSL, Prima and Sunshine Heart rose more than two percent; Living Cell, Prima and Sunshine Heart were up more than one percent; with Cochlear and Sirtex up by less than one percent.

Virax led the falls, down half a cent or 22.7 percent to 1.7 cents with 780,000 shares traded, followed by Impedimed down 7.6 percent to 55 cents with 29,000 shares traded.

LBT and Starpharma lost more than six percent; Allied Health, QRX and Viralytics fell more than five percent; Acrux, Nanosonics and Phylogica were down more than four percent; Alchemia shed 2.8 percent; with Anteo, Bionomics, Biota, Circadian, down one percent or more; and Mesoblast down 0.4 percent.

MESOBLAST

Mesoblast has conducted its first of 100 minimally-invasive lumbar disc procedures in its phase II trial of its adult stem cells for lower back pain and degenerative disc disease.
Mesoblast said the outpatient procedure using its mesenchymal precursor cells was conducted at Colorado's Spine Institute and Loveland Surgery Center by Dr Kenneth Pettine and lasted less than 20 minutes, with the patient fully awake and under light sedation and the patient was discharged shortly afterwards with no complications.
Mesoblast said US Food and Drug Administration-approved phase II trial would enrol 100 patients with chronic low back pain due to lumbar disc degeneration in 15 centers across the US and Australia, comparing outcomes at six months in 60 patients receiving mesenchymal precursor cell injections against 40 patients receiving control injections.
The company said Dr Pettine was a founder of the Spine Institute and "an international leader in non-fusion surgery of the spine and the co-inventor of Medtronic's Maverick artificial lumbar disc device".
"This marks the third renaissance in spine care," Dr Pettine said.
"The first was improved diagnosis using magnetic resonance imaging, the second was end-stage replacement with artificial discs and now there is the potential widespread use of adult stem cells for disc repair and regeneration," Dr Pettine said.
Mesoblast said that up to 15 percent of people in industrialized countries had chronic low back pain lasting more than six months.
The company said that for those with progressive, severe and debilitating pain due to ongoing progression of disc degeneration, the only option is major back surgery involving artificial disc replacement or spinal fusion.
Mesoblast said that both types of surgery were associated with risks and avoiding surgery was a major objective of treatments for degenerative disease of the spine.
The company said that in preclinical trials in sheep, a single minimally invasive injection of Mesoblast's allogeneic or off-the-shelf mesenchymal precursor cells into severely damaged inter-vertebral discs resulted in significant reversal of the degenerative process, regrowth of disc cartilage and sustained normalization of disc pathology, anatomy and function for at least six months (BD: Sep 10, 2009).
Mesoblast said it aimed to show that a single minimally-invasive injection of its disc repair mesenchymal precursor cell product could regenerate damaged discs, thereby reducing pain, improving function and avoiding surgery.
Mesoblast fell three cents or 0.4 percent to $7.17 with 1.1 million shares traded.

IMMURON

Immuron says it has had "a productive meeting" with the US Food and Drug Administration for its phase IIb trial of IMM-124E for non-alcoholic steatohepatitis.
Immuron said it was preparing its trial protocol and expected to submit the investigational new drug application package to the FDA by the end of 2011.
The company said the trial was being designed with Virginia Commonwealth University's Prof Arun Sanyal who would be the principal investigator.
Immuron said the dose-ranging, placebo-controlled, double blinded multi-centre study would be conducted in the US, Israel and Australia, with enrolment to begin by June 2012.
Immuron chief executive officer Joe Baini said the meeting was "a significant milestone for Immuron and more importantly for the millions of patients suffering from NASH, as it remains one of few life threatening diseases without an approved treatment".
Immuron was up half a cent or 7.5 percent to 7.2 cents.

LIVING CELL TECHNOLOGIES

Living Cell says it has implanted the first two type 1 diabetes patients in its Buenos Aires, Argentina phase II clinical trial of Diabecell encapsulated porcine islets of Langerhans.
Living Cell said Argentina was the third jurisdiction to allow its xenotransplant trial, with Russia and New Zealand and up to eight adults with type1 diabetes, including unstable diabetes and severe hypoglycaemia would receive two implants, three months apart.
Living Cell medical director and acting chief executive officer Prof Bob Elliott said previous clinical trials had shown that Diabecell could "greatly benefit patients suffering from unstable diabetes who don't have any awareness when their blood glucose levels are low which puts their life at serious risk".
"We have a treatment that works," Prof Elliott said.
"However, during this next stage of our clinical trial we will use fewer insulin producing cells, implanted on two occasions and also utilise a different implantation technique to determine if we can provide patients with even greater benefit," Prof Elliott said.
Living Cell said that earlier clinical trials showed that lower doses had greater benefit than larger dosages (BD: Jun 6, 2011).
"We are looking for [the] most effective combination before we enter into our final stages of commercialization," Prof Elliott said.
Living Cell was up 0.1 cents or 1.75 percent to 5.8 cents.

PATRYS

Patrys says PAT-SM6 has shown activity in its nine-patient phase I clinical trial of PAT-SM6 for recurrent in-transit cutaneous melanoma at the Royal Adelaide Hospital.
Patrys said that to day the safety and tolerability trial had found no safety issues for any patients treated with the monoclonal anti-body PAT-SM6, with biopsies of melanoma tumors in two patients showed post-treatment presence of PAT-SM6.
The company said that multiple secondary endpoints were aimed at measuring the anti-tumor activity of PAT-SM6, with biopsy being taken from patients' melanoma tumors before and after treatment.
Patrys said the presence of PAT-SM6 in post-treatment tumor biopsies from two patients indicated "the strong utility of the therapy and potential for it to be an effective therapeutic for the treatment of melanoma".
Patrys chief executive officer Dr Marie Roskrow said the company was "very excited to report the detection of the PAT-SM6 product in tumors taken from patients in both the first and second dose groups".
"At this stage trial doses are substantially below anticipated therapeutic levels and the detection of PAT-SM6 in tumors is thus very encouraging," Dr Roskrow said.
"In both cases, PAT-SM6 was detectable in biopsy samples taken post-treatment," Dr Roskrow said. "Neither patient had any detectable PAT-SM6 in biopsies taken pre-treatment."
"In addition, tissue analysis to date is suggestive the PAT-SM6 leads to apoptosis in biopsies collected," Dr Roskrow.
Patrys said the dose-ranging study was of three groups of three patients with in-transit melanoma, a cancer limited to a single limb which had usually had multiple treatments.
The company said that by recruiting patients with in-transit disease, it could collect tissue samples to study the effects of PAT-SM6 on the tumors, although the primary aim was to measure the safety and tolerability of the drug.
Patrys said the Royal Adelaide Hospital was recruiting the third group of patients.
Patrys was up 1.1 cents or 15.5 percent to 8.2 cents.

PRANA BIOTECHNOLOGY

Prana says the Michael J Fox Foundation will provide $200,000 for pre-clinical studies of PBT434 for Parkinson's disease.

Prana said the funding was awarded "after a highly competitive, international, peer-reviewed process".

Prana chairman Geoffrey Kempler said he hoped that PBT434 would provide treatment "from very early diagnosis to prevent the damage to the part of brain, the substantia nigra, which is responsible for normal movement, thus preventing the loss of physical coordination and control experienced by Parkinson's disease patients".

Prana said PBT434 appeared to be able to impede the iron-induced oxidative damage and neurotoxic cascade that kills neurons.

The company's head of research Prof Robert Cherny said there was evidence to show that the onset of Parkinson's disease was associated with an increase in iron in the cells of the substantia nigra, the part of the brain that is progressively destroyed in Parkinson's disease.

"We are particularly encouraged by data that suggests that the neuroprotective effects of PBT434 are accompanied by a significant decrease in the toxic accumulation of the alpha synuclein protein, a hallmark of Parkinson's disease pathology," Prof Cherny said.

"In addition to phase II trials in Alzheimer's disease and Huntington's disease with PBT2 planned for later this year, the advancement of PBT434 for Parkinson's disease reinforces our commitment to building shareholder value through product and disease diversification," said Mr Kempler.

Prana said Parkinson's disease resulted in the loss of muscle control, speech, balance and digestive functions and could impair a patient's psychiatric and cognitive function.

The company said Parkinson's disease was the second most common neurological indication behind Alzheimer's disease.

Prana was untraded at 15 cents.

VICTORIAN GOVERNMENT, GLAXOSMITHKLINE, STARPHARMA

The Victorian Government has awarded Glaxosmithkline and Starpharma $50,000 for a dendrimer based skin treatment.

Glaxosmithkline's head of corporate affairs Lisa Maguire told Biotech Daily the Victorian Government grant was worth $50,000.

In a media release Starpharma said the grant would support the synthesis of dendrimer-based drug candidates to be tested by Glaxosmithkline subsidiary Stiefel to be developed as a skin treatment.

Starpharma chief executive officer Dr Jackie Fairley said dendrimers could be used for a wide range of drug delivery applications.

Glaxosmithkline's Australia and New Zealand general manager Deborah Waterhouse said the partnership was "an exciting step forward for Stiefel, which is committed to innovation in dermatology leading to new medicines for patients".

Starpharma said its dendrimers were precisely-defined, branched nanoparticles with applications in enhancing drug half-life, solublizing drugs and specific targeting.

Starpharma fell seven cents or 6.4 percent to $1.025.

PHARMAXIS

Pharmaxis says it has submitted detailed grounds for re-examination of its Bronchitol European Union marketing application for cystic fibrosis.

Pharmaxis said the documents were lodged with the Committee for Medicinal Products for Human Use (CHMP) which previously voted against approving Bronchitol for cystic fibrosis (BD: May 25, Jun 24, Jun 27, 2011).

The company said it had formally requested re-examination and there had been dialogue with the new rapporteurs appointed to lead the process, of which one voted for the approval of Bronchitol and one voted against the approval.

Pharmaxis said the Committee had the benefit of expert advice from a scientific advisory group appointed by the Committee, which included clinicians and experts in cystic fibrosis and patient groups could also be invited to join the advisory group.

The company said that following an initial review of the submission by the rapporteurs, the Committee could refer questions to the scientific advisory group and receive its recommendation prior to a final determination.

Pharmaxis said it expected a decision at the Committee's October meeting.

Pharmaxis chief executive officer Dr Alan Robertson said that following the appointment of the new rapporteurs discussions with them and senior cystic fibrosis clinicians, was "valuable in developing a submission which addresses the concerns that the CHMP expressed in June".

"The submission focuses on demonstrating that the improvements in lung function and reductions in exacerbation incidence are clinically relevant for cystic fibrosis patients," Dr Robertson said.

"Pharmaxis has also provided further evidence to demonstrate that the side effect profile of Bronchitol is acceptable and, in particular, that the incidence of haemoptysis is in line with that reported as the background level in this disease and that any risk of bronchospasm is low and manageable," Dr Robertson said.

Pharmaxis was up two cents or two percent to $1.025.

IM MEDICAL

The ASX has questioned IM Medical over the reasons for withdrawing a resolution relating to a proposed capital raising and sale of its radiology business (BD: Aug 17, 2011)

IM Medical said that under the radiology purchase agreement with Capitol Health, it was required to provide warranties regarding its solvency.

IM Medical said that "due to recent share market volatility, a termination clause in the underwriting agreement for the rights issue had been triggered and the company did not have certainty that the rights issue would proceed on the terms set out in the notice of meeting.

The company said the directors did not have a reasonable basis to expect that the required warranties would be met for completion of the sale of the radiology business to Capitol Health and the prudent course of action was to withdraw resolutions relating to both the sale and the rights issue to allow a replacement underwriting capital raising to be put in place.

The ASX asked a series of questions including asking IM Medical to "provide a full summary of the material terms of the management arrangements of the company's radiology business by Capitol Health" along with the progress of negotiations with the lead manager in relation to the revised rights issue.

IM Medical provided detailed answers to all ASX questions.

IM Medical was untraded at five cents.

COGSTATE

Cogstate says it will acquire the remaining 50 percent stake in Axon Sports resulting in Axon becoming a wholly-owned subsidiary.

Cogstate said Axon provided online cognitive assessment to assist in evaluating and managing sports-related concussions.

The company said it would acquire the remaining 50 percent for 7,461,831 Cogstate shares at a notional price of 17 cents per share.

Cogstate said the partners in the formation of Axon Sports, Quixote Investment principals Rudy Chapa and Patricia Eiting would retain their positions as Axon directors and Mr Chapa would be appointed as a Cogstate director.

The company said Mr Chapa was previously the global director of sports marketing at Nike, leaving the company to pursue his own entrepreneurial interests.

Cogstate was unchanged at 17 cents with 6.9 million shares traded.