Biotech Daily

Thursday October 31, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH FLAT: PRANA UP 43%, NEUREN DOWN 8%**

*** FDA APPROVES TEVA, MESOBLAST PHASE III CARDIAC TRIAL**

*** PRANA PBT2 REVERSES MEMORY LOSS IN OLD NORMAL MICE**

*** REVA IMPLANTS 87th REZOLVE2 STENT LIVE TO CONFERENCE**

*** HATCHTECH RAISES $13m, DR RICHARD TREAGUS DIRECTOR**

*** AGENIX TO SELL AGX-1009 FOR HEP B TO CHINA FOR $2m**

*** UBS AG TAKES 6% OF NEUREN**

*** DR ESRA OGRU, PHOSPHAGENICS DEED; ROBERT GIANELLO TO COURT**

*** TISSUE THERAPIES HAS ONE QUARTER CASH; RAISING TRADING HALT**

*** UNILIFE HAS ONE QUARTER CASH**

*** CEO DR NEIL FRAZER TAKES 8% OF ONCOSIL**

*** IAN FRAZER, ALLIED, NANOSONICS WIN AUSBIOTECH JANSSEN GONGS**

MARKET REPORT

The Australian stock market slipped 0.1 percent on Thursday October 31, 2013 with the S&P ASX 200 down 5.4 points to 5,425.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and five were untraded.

Prana was the best, up 16.5 cents or 43.4 percent to 54.5 cents with 7.3 million shares traded. Benitec and Patrys climbed more than 11 percent; Mesoblast was up 9.6 percent; both Antisense and Living Cell rose 7.1 percent; IDT was up 5.3 percent; Cellmid and Phylogica were up more than four percent; Nanosonics was up 3.6 percent; Prima rose 2.7 percent; with Bionomics, Cochlear, CSL and Sirtex up more than one percent.

Neuren led the falls, down one cent or 8.3 percent to 11 cents with 15.6 million shares traded. Allied Health lost 6.25 percent; Anteo, Genetic Technologies, Psivida and Universal Biosensors fell more than four percent; Pharmaxis and QRX were down more than three percent; Alchemia, Atcor and GI Dynamics shed more than two percent; with Osprey down 1.4 percent.

MESOBLAST

Mesoblast says the US Food and Drug Administration has approved a phase III trial of its mesenchymal precursor cells for congestive heart failure.

Mesoblast said that the FDA cleared the investigational new drug filing by partner, the Israel-based Teva Pharmaceutical Industries, for the phase III trial in patients with chronic congestive heart failure and patient recruitment was expected to begin “shortly”.

The company said that the multi-center trial would be conducted by Teva and was planned to enrol about 1,700 patients, with two interim analyses of efficacy and/or safety.

Mesoblast said the clinical protocol was designed after initial consultation with both the FDA and the European Medicines Agency.

The company said that the phase III trial design was a double-blinded, one-to-one randomized, placebo-controlled study evaluating a single dose of 150 million mesenchymal precursor cells (MPCs) delivered via trans-endocardial injection catheter to the left ventricle of heart failure patients with New York Heart Association class II or III disease and an ejection fraction of less than or equal to 40 percent.

Mesoblast said that the primary efficacy endpoint of the trial is a time-to-first event analysis of heart failure-related major adverse cardiac events, defined as a composite of cardiac related death or resuscitated cardiac death, or non-fatal decompensated heart failure events.

The company said that nonfatal decompensated heart failure events required the use of intravenous diuretics or aquapheresis during an in-hospital stay or during an outpatient visit.

Mesoblast said that adjudication of heart failure-related major adverse cardiac events would be performed by an independent, blinded clinical endpoint committee.

The company said that the dose for the phase III trial was chosen on the basis of results from its 60-patient phase II trial which showed that heart failure patients treated with the 150 million MPC dose had not experienced any heart failure-related major adverse cardiac events over the three-year follow-up period compared with an heart failure-related major adverse cardiac events incidence of approximately 30 percent for the control group over the same period (BD: Nov 15, 2011).

In the phase II trial, one patient in the 45-patient Revascor adult stem cells active group died, compared with three patients in the 15-patient control group dying.

Last year, the delay in confirmation of the trial fueled speculation, primarily from Macquarie Equities analyst Dr Craig Collie, about the relationship between Mesoblast and Teva and that Teva might not support the phase III trial (BD: Nov 19, Dec 12, 2012).

Today, Mesoblast chief executive Prof Silviu Itescu said that “Mesoblast’s proprietary mesenchymal lineage cells have the potential to offer long-term beneficial outcomes to the millions of patients suffering from heart failure worldwide”.

“Importantly, in 2014 we plan to have products in active phase III clinical trials in all four of our core major therapeutic areas of focus: cardiovascular medicine, congestive heart failure; inflammatory/immune diseases, Crohn's disease; orthopedics, spinal fusion and intervertebral disc repair; and oncology, acute graft versus host disease, and cord blood expansion in bone marrow transplantation,” Prof Itescu said.

Mesoblast climbed 58 cents or 9.6 percent to $6.60 with 2.1 million shares traded.

PRANA BIOTECHNOLOGY

Prana says its PBT2 creates neurones and reverses the memory and learning losses associated with the aging process, in normal, non-transgenic, old mice.

Prana said a research paper, entitled 'A Novel Approach To Rapidly Prevent Age-Related Cognitive Decline' was published in the journal Aging Cell.

The article is available at: http://onlinelibrary.wiley.com/doi/10.1111/acel.12178/pdf.

Prana said the article's authors were led by the Florey Institute of Neuroscience and Mental Health's head synaptic neurobiology laboratory Prof Paul Adlard, with co-authors including former Prana consultant Prof Ashley Bush and the company's head of research Prof Robert Cherny.

Prana said that PBT2 had an effect on neurogenesis, or the creation of neurons and in reversing the memory and learning losses associated with the aging process, in normal, non-transgenic, old mice.

Prana said that mice typically lived for 24 to 30 months, developing progressive cognitive impairment from 16 to 18 months.

The company said that age-related cognitive decline was associated with measurable structural and biochemical changes in the brain, which were significantly improved by PBT2.

Prana said that in the study 22-month-old mice were treated with PBT2 for a total of 12 days and PBT2 restored learning and memory.

The company said that old mice treated with PBT2 performed learning and memory tasks to the same level exhibited by young mice and significantly better than untreated old mice ($p < 0.01$).

Prana said that PBT2 increased markers of neurogenesis and neuron number: increasing the number of mature neurons by up to 27 percent in the hippocampus; increasing markers of cell proliferation by 67 percent and markers of numbers of immature neurons by 130 percent in the hippocampus; and neuronal proliferation markers were elevated around the lateral ventricles by 214 percent.

The company said that atrophy of peri-ventricular tissue was a feature of Huntington's disease.

Prana said PBT2 increased the number of synapses in the hippocampus with synaptophysin levels increased by 38 percent and dendritic spine density increased by 15 percent; increased glutamate receptor levels in the hippocampus and protein phosphotase 2a in the hippocampus, while phosphorylated tau levels decreased by 81 percent.

Prana chief scientific advisor Prof Rudy Tanzi said that it was "very exciting to discover that PBT2 not only helps clear amyloid from the brain, but is promoting the birth of new nerve cells in a part of the brain that is particularly affected by Alzheimer's disease, the hippocampus … [adding] to the predicted beneficial properties of PBT2 for the treatment and prevention of Alzheimer's disease."

Prana said that age-related cognitive decline occurred in humans and all other mammals and this data described how PBT2 reversed both memory and cognitive loss in aged mice.

The company said the findings were in normal old mice that had not been genetically modified and did not form amyloid.

"These data help explain why other Alzheimer's therapies that solely target Abeta or tau pathology may, at best, be only partially effective," Dr Tanzi said. "PBT2, by addressing metal induced oligomer formation, restoring metal balance in affected brain regions, and by promoting new neuronal cell growth, elicits a distinct set of disease modifying effects."

"PBT2 may not only ameliorate Alzheimer's pathology, but perhaps other detrimental aspects of aging on the brain," Dr Tanzi said.

Prana climbed 16.5 cents or 43.4 percent to 54.5 cents with 7.3 million shares traded.

REVA MEDICAL

Reva says the implanting of the eight-seventh patient in its 125-patient trial of the Rezolve2 bioresorbable scaffold was transmitted live from hospital to a conference.

Reva said the implant at the Sao Paulo, Brazil Institute Dante Pazzanese of Cardiology, was performed by invasive cardiology director Dr Alexandre Abizaid and study co-investigator Dr J Ribamar Costa and transmitted to the Transcatheter Cardiovascular Therapeutics conference in San Francisco, California.

Earlier this year Reva initiated the 125-patient Conformité Européenne (CE) mark-directed trail of the Rezolve2 bioresorbable sirolimus-eluting stent, evaluating its safety and performance at centers in Australia, Brazil, Europe and New Zealand (BD: Apr 2, 2013).

Today, the company said that the Rezolve2 scaffold was implanted in a patient that presented with a blockage of the left anterior descending artery of the heart.

Reva said the lesion was about 80 percent blocked and had evidence of moderate calcium and the stent was delivered to the heart through the radial artery of the wrist.

Dr Abizaid said the hospital “achieved a very successful acute result from this implant”.

“The scaffold was easily delivered, and the procedure was aided by the complete visibility of the scaffold under x-ray and the ability to achieve the desired implant diameter with a single inflation,” Dr Abizaid said.

Reva chief executive officer Bob Stockman said the follow-up data from the case, along with data from up to 125 patients enrolled in the trial, will be used for the CE mark application expected by the end of 2014.

Reva said that 12-month data on patients in the Restore pilot clinical trial was prewetned to the conference.

The company said that 12-month angiographic follow-up was conducted to evaluate the change in the lumen area between the time of treatment when blood flow was restored and the time of follow-up, referred to as late lumen loss or ‘late loss’.

Reva said that permanent drug-eluting stents historically exhibited late loss values of 0.20mm to 0.40mm, which generally corresponded to positive long-term outcomes.

The company said that in patients treated with Rezolve who remained event free after treatment, imaging results demonstrated a mean in-stent late loss of 0.29 mm, which was within the range of safety and performance of drug-eluting metal stents and bioresorbable scaffolds used today.

Reva said that when imaging results for patients who had undergone re-treatment for focal in-stent re-stenosis, or re-narrowing of the artery at the implant site were taken into consideration, the mean in-stent late loss was 0.69 mm.

The Institute’s Dr Ricardo Costa said that “the positive late loss results seen in the majority of patients demonstrates the platform’s ability to successfully treat coronary artery disease, before resorbing from the body, and returning the patient’s artery to its natural function”.

“To reduce the incidence of retreatment, Reva developed Rezolve2, which is a lower profile scaffold with an approximate 30 percent increase in radial strength when compared to the original Rezolve device,” Dr Costa said.

“Our center is now enrolling patients in a larger clinical trial with Rezolve2, and positive 30-day data was presented on the first 65 patients … earlier this week,” Dr cost said.

“The data from the patients treated with our first generation scaffold has been instrumental in advancing our product platform,” Mr Stockman said.

“The current performance of Rezolve2, along with the additional advantages that will be realized by Reva’s pipeline bioresorbable scaffolds that are now in development, position Reva very strongly for the future,” Mr Stockman said.

Reva fell half a cent or 0.9 percent to 53.5 cents.

HATCHTECH

Hatchtech says it has raised $12.6 million capital raise for a phase III trial and US regulatory application of its Deovo head lice treatment.
Hatchtech said the funds were expected to see it through to the submission of a new drug application to the US Food and Drugs Administration.
The company said that capital raising was led by Oneventures Innovation Fund and supported existing investors including the University of Melbourne, the Queensland Biotechnology Fund and Uniseed, with new investors including private sophisticated investors and the Brisbane-based Blue Sky Alternative Investments.
Hatchtech said it expected to complete the trial by July 2014, file the completed application by the end of 2014 and, if approved, target US product launch by July 2016.
The company said that Neuren executive chairman and former Acrux chief executive officer Dr Richard Treagus had been appointed as an independent director.
Hatchtech said that its chief executive officer Hugh Alsop had been appointed as an executive director.
The company said that Dr John Kurek and Dr Ross Macdonald would retire from the board.
Hatchtech said that Deovo was a single dose, single treatment, prescription product addressing a significant unmet need for safer and more effective head lice treatments.
The company said that unlike other products Deovo had been shown through clinical and in-vitro studies to kill both live lice and their eggs, in a single 10 minute treatment.
Hatchtech is a public unlisted company.

AGENIX

Agenix says that an unnamed Chinese pharmaceutical company has agreed to buy its AGX-1009 hepatitis B drug for $US2 million ($A2,106,500)
Agenix said it had a binding term sheet with the unnamed Chinese pharmaceutical company to divest the AGX-1009 tenofovir prodrug for hepatitis B, which had completed pre-clinical trials, with a definitive agreement to be completed within 10 days.
Agenix executive chairman Nick Weston said the deal “enables us to crystallize the value of this project with the $US2 million payable in three tranches timed with the transfer of intellectual property … and expected to be completed by December 31, 2013”.
Agenix was up half a cent or 23.8 percent to 2.6 cents with 2.8 million shares traded.

NEUREN PHARMACEUTICALS

UBS AG and related companies have become substantial shareholders in Neuren with 90,539,390 shares or 6.24 percent of the company.
The UBS substantial shareholder notice filed from Singapore said that UBS Securities Australia was the beneficial owner of 15,313,000 shares (1.06%) and UBS AG, Australia Branch had an interest in 74,356,825 shares (5.12%) held as “borrowing right in respect of shares pursuant to a prime broking agreement”, with UBS AG London Branch holding 869,565 shares (0.06%) also as a “borrowing right”.
UBS said it bought and sold shares, mainly in small parcels shares from July 2 to October 28, 2013, with six purchases on October 28 acquiring 56,655,000 shares for $6,515,324 or 11.5 cents a share, the same price as the $21.5 million placement (BD: Oct 22, 2013).
Neuren fell one cent or 8.3 percent to 11 cents with 15.6 million shares traded.

PHOSPHAGENICS

Phosphagenics says that former chief executive officer Dr Esra Ogru, her husband and mother have entered into a deed of settlement relating to stolen funds.
In July, Phosphagenics said that Dr Ogru had sold her shares and the company would receive about $570,000 as the first restitution of misappropriated funds (BD: Aug 5, 2013).
In July, Dr Orgu was first suspended in her role as chief executive officer pending an investigation into “irregular transactions in relation to its invoicing and accounting records”, she later resigned as a director and when Deloitte Forensic quantified the amount at $5.7 million was sacked as chief executive officer (BD: Jul 1, 22, 24, 2013).
Today Phosphagenics said that Dr Ogru had agreed to pay the misappropriated funds plus a fixed amount in respect of interest and costs.
The company said that the amount of funds it would recover depended on the realizable value of the family assets.
Phosphagenics said that the deed of settlement was “a better outcome … than would have been achieved through court proceedings”.
The company said it continued to pursue repatriation of funds from other parties involved.
In a separate announcement, Phosphagenics said it had issued proceedings in the Supreme Court of Victoria against former employee Robert Gianello to recover misappropriated funds.
The company said that the writ named his spouse and an associated private company.
Phosphagenics said in August that it had “taken steps to secure other assets of persons referred to in its announcement of July 24, 2013 and remains confident of recovering a substantial proportion of the misappropriated funds”.
Phosphagenics was unchanged at 13.5 cents with 2.6 million shares traded.

TISSUE THERAPIES

Tissue Therapies says its net operating cash burn for the three months to September 30, 2013 was $2,248,800 with cash at the end of the quarter of $2,630,400.
Tissue Therapies requested a trading halt pending the completion of a capital raising.
Trading will resume on November 4, 2013 or on an earlier announcement.
Tissue Therapies last traded at 25 cents.

UNILIFE

Unilife says its net operating cash burn for the three months to September 30, 2013 was $US9,414,000 ($A9,914,000) with cash at the end of the quarter of $9,452,000.
In September, Unilife said it had a deal with the Paris, France-based Sanofi worth up to $15 million in milestone payments, with the contract involving payment and royalties for its retractable pre-filled syringe sales (BD: Sep 10, 11, 2013).
The company first announced the deal without naming Sanofi in May but the signing was delayed (BD: May 14, Jun 17, 2013).
Unilife said it had a loan facility with $US22,471,000 available.
Unilife fell 1.5 cents or 2.6 percent to 55.5 cents.

ONCOSIL

Oncosil chief executive officer Dr Neil Frazer has become a substantial shareholder in his company with 26,265,632 shares or 7.80 percent.
The substantial shareholder notice said that Dr Frazer acquired 20,000,000 shares for $2,000,000 or 10 cents a share.
Oncosil was unchanged at 12.5 cents.

AUSBIOTECH

Ausbiotech says that Prof Ian Frazer, Allied Healthcare and Nanosonics are this years winners of the Janssen industry excellence awards.
Ausbitoech said that the inventor of the Gardasil vaccine, chief executive officer of Brisbane's Translation Research Institute and the founder of Allied Health's 60 percent owned Coridon anti-viral DNA vaccine business Prof Ian Frazer won the industry leadership award, Allied Health won the emerging company of the year award and Nanosonics was named the company of the year.
Ausbiotech chief executive officer Dr Anna Lavelle said that Prof Frazer's "leadership has demonstrated exceptional success in navigating the research, clinical trial and commercialization pathways that are essential for success in this industry".
"Prof Frazer is an excellent ambassador for Australia's biotechnology sector and is actively supporting the growth of Australia's bio-economy, which is a central focus for this year's conference," said Dr Lavelle.
Ausbiotech said that Allied Health won the Janssen emerging company of the year award in recognition of its accomplishments in commercializing its Adapt tissue engineering for regenerative medicine, its investment in Coridon and its share price more than doubling in the past 12 months.
The industry organization said that Nanosonics won the company of the year award for its Trophon EPR ultrasound probe cleaning system breaking ground in international markets, with "outstanding sales" and gaining the interest of investors.
Janssen-Cilag managing director Chris Hourigan said this year's award recipients were at the forefront of thriving biotech, innovation and healthcare sectors in Australia.
"These award recipients are actively improving the lives of people across the globe, which is a very noble mission," Mr Hourigan said.
"They are doing so with a commitment to world class research, industry collaboration and commercial acumen, which will support a healthy pipeline of novel medicines, medical devices and other new technologies for the community in years to come," Mr Hourigan said.