Biotech Daily

Wednesday August 10, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH FLAT: MEDICAL DEVELOPMENTS UP 8%, PRANA DOWN 17%**

*** CELLMID: 'MIDKINE IMPROVES OSTEOPOROSIS IN MICE'**

*** PSIVIDA STUDY: 'SMALLER INSERT NEEDLE SUPERIOR'**

*** IMPEDIMED, SCRIPPS SOZO HEART FAILURE DEVICE STUDY**

*** BIODIEM RAISES $1m**

*** NOXOPHARM TO BEGIN NOX66 CANCER TRIALS IN TBILISI**

*** PHARMAUST INVESTIGATOR MONEPANTEL DOG CANCER TRIALS**

*** PRANA PLEADS SCHULTZ TO ASX 45% QUERY, ASX MISSES 16%**

*** BENITEC GREG WEST CEO, DR CLIFF HOLLOWAY, BRYAN DULHUNTY**

*** OVENTUS APPOINTS SCIENTIFIC ADVISORY COMMITTEE**

*** NUHEARA APPOINTS BRUCE BORENSTEIN HEAD OF SALES**

*** PRIMA BELOW $US1 NASDAQ COMPLIANCE, AGAIN**

MARKET REPORT

The Australian stock market was down 0.16 percent on Wednesday August 10, 2016 with the ASX200 down 8.8 points to 5,543.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell and 15 traded unchanged.

Medical Developments was the best, up 42 cents or 7.9 percent to $5.72 with 99,443 shares traded, followed by Cochlear up 7.6 percent to $134.51 with 467,368 shares traded and Universal Biosensors up 7.4 percent to 29 cents with 79,301 shares traded. Impedimed climbed 6.2 percent; Mesoblast was up 4.55 percent; Atcor and Osprey were up more than three percent; Antisense and Psivida rose two percent or more; Actinogen, Admedus, Anteo, CSL and Nanosonics were up more than one percent; with Clinuvel up 0.4 percent.

Yesterday's 55.9 percent best, Prana, led the falls, down 2.5 cents or 17.2 percent to 12 cents with 1.4 million shares traded. IDT lost 6.4 percent; Bionomics fell 5.3 percent; Opthea and Reva were down three percent or more; Living Cell shed 2.5 percent; Factor Therapeutics, Pharmaxis and Polynovo were down more than one percent; with Pro Medicus, Resmed, Sirtex and Starpharma down by less than one percent.

CELLMID

Cellmid says research by the Ulm Medical Centre shows that midkine antibodies improve bone quality and fracture healing in a mouse model of osteoporosis.

The research article, entitled 'Inhibition of Midkine Augments Osteoporotic Fracture Healing' was published in the US Public Library of Science in July 2016, and was available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4943649/.

The article said that the researchers investigated whether the inhibition of midkine using a midkine antibody improved compromised bone healing in osteoporotic mice that had their ovaries removed, known as OVX or overiectomized mice.

"We demonstrated that [midkine] serum levels were significantly enhanced after fracture in both non-OVX and OVX-mice, however, the increase was considerably greater in osteoporotic mice," the article reported.

"Systemic treatment with the [midkine antibody] significantly improved bone healing in osteoporotic mice by increasing bone formation in the fracture callus," the article said.

"On the molecular level, we demonstrated that the OVX-induced reduction of the osteoanabolic beta-catenin signaling in the bony callus was abolished by [midkine antibody] treatment," the article said.

"Furthermore, the injection of the [midkine antibody] increased trabecular bone mass in the skeleton of the osteoporotic mice," the research reported.

"These results implicate that antagonizing [midkine] may be useful for the therapy of osteoporosis and osteoporotic fracture-healing complications," the article concluded.

Cellmid said that the study was led by University Medical Centre's Dr Astrid Liedert and a previous publication from her group showed that midkine antibody treatment accelerated bone fracture healing in otherwise normal rodents (BD: June 24, 2016).

Cellmid said that the amount of bone deposited in the fracture site was reduced and the healing bone was weaker in mice that lack oestrogen.

The company said that treatment with a midkine antibody improved the rate of fracture healing evidenced by mechanical strength and bone volume in both normal and osteoporotic animals ($p < 0.05$) and the loss of bone mineral density and volume in otherwise intact but osteoporotic bones some distance away from the fracture site was reversed following midkine antibody treatment ($p < 0.05$).

Cellmid said that bone within the fracture site in the femur was examined, as well as the corresponding site in the other leg, which was undamaged and in addition to restoring bone quality in the femur, the midkine antibodies improved bone parameters in osteoporotic vertebrae ($p < 0.05$) a result that was "relevant for many aged patients as weakened spines have a major impact on quality of life and mobility".

The company said that molecular analysis within the healing bone at the fracture site showed that a regulator of bone formation and integrity called beta-catenin was dramatically reduced in osteoporotic animals and after 10 days of treatment beta-catenin was restored to levels seen in normal animals ($p < 0.05$) showing the ability of midkine to modulate the action of this critical factor involved in bone biology.

Cellmid said that the findings demonstrated that midkine antibodies were effective in accelerating bone healing in osteoporotic mice and might benefit elderly patients with fragile bones who were prone to debilitating and sometime fatal fractures.

The company said that "especially at risk" were post-menopausal women with more than 30 percent experiencing osteoporotic fractures after the age of 50 years.

Cellmid said that apart from the reduced quality of life and extra health care costs associated with recuperation, immobility due to fractures could cause severe, sometimes life-threatening, complications in the elderly.

Cellmid was unchanged at 3.3 cents with 1.5 million shares traded.

PSIVIDA CORP

Psivida says a 38-eye utilization study has shown its new 27-gauge inserter for Medidur for posterior uveitis was superior to the larger 25-gauge inserter.
Psivida said that 66 percent of injections using the 27-gauge inserter achieved a satisfactory rating of routine, easy or very easy, compared to 46 percent for the 25-gauge inserter used in the first phase III trial of the Medidur sustained release 0.18mg corticosteroid fluocinolone acetonide.
A 25-gauge needle is about 0.51mm in diameter compared to 0.41mm for a 27-gauge.
The company said that the study results would form part of its planned US Food and Drug Administration new drug application and application for EU marketing authorization for Medidur for posterior uveitis.
Psivida chief executive officer Dr Paul Ashton said the superiority of the smaller gauge needle was “an excellent result for the new Medidur inserter”.
“The design of the new inserter with its smaller diameter needle was shown in the study to facilitate the ease of administration of Medidur and we expect it to be more popular with physicians than the earlier, larger needle model,” Dr Ashton said.
“By comparison, Iluvien for diabetic macular oedema uses a larger diameter 25-gauge inserter, and Ozurdex for posterior uveitis, [diabetic macular oedema] and retinal vein occlusion uses an even larger diameter 22-gauge inserter,” Dr Ashton said.
“We plan to use the smaller 27-gauge needle in the inserter in our [tyrosine kinase inhibitor] insert for wet age-related macular degeneration,” Dr Ashton said.
Psivida said that the multi-centre, randomized, controlled, single masked utilization and safety study the 27-gauge inserter and the safety of the Medidur insert from the day of treatment through seven days following administration.
The company said that the study’s primary endpoint required the proportion of procedures with the new inserter scored as routine or easier to be at least as high as the corresponding proportion of procedures with the 25-gauge inserter.
Psivida said that patients would be followed for 12 months.
Psivida was up 10 cents or two percent to $5.10.

IMPEDIMED

Impedimed says Scripps Health will use its Sozo bio-impedance spectroscopy device in a validation study for monitoring patients with heart failure.
Impedimed said that patients were currently being tracked using pulmonary artery pressure monitoring and the study would provide data necessary for the final design of the pivotal trial.
The company said the study of the Sozo body composition diagnostic for congestive heart failure would be led by the La Jolla, California-based Scripps Health’s Dr J Thomas Heywood and Dr Andrew Accardi, both of whom were members of its advisory board.
Impedimed was up nine cents or 6.2 percent to $1.54 with 1.8 million shares traded.

BIODIEM

Biodiem says it has raised $1,148,940 through an entitlement offer at eight cents a share and the conversion of preference shares.
Biodiem said that the funds would be used for its live attenuated influenza vaccine and its anti-microbial BDM-I and following the entitlement issue it would have 174,734,060 shares and 14,392,433 convertible preference shares on issue.
Biodiem is a public unlisted company.

NOXOPHARM

Noxopharm says it expects to begin clinical studies of NOX66 for cancer at two clinical sites in Tbilisi, Georgia before the end of 2016.

Noxopharm said it chose Georgia for the progressive phase Ia/Ib/IIa trials “because of the speed with which the study can be recruited, and therefore completed”.

The company said that the Isle of Man, UK-based Clinical Accelerator had been appointed as the contract research organization to manage the study, with data management and statistics to be conducted by Sydney’s Datapharm Australia.

Noxopharm said the study would begin with a phase Ia study of NOX66 alone, a 15-patient phase Ib study of dosage combinations of NOX66 and carboplatin, followed by a phase IIa trial of a specific dosage combination of NOX66 and carboplatin in specific cancer types, in the 15 phase Ib patients, with an additional 20 patients.

The company said the trials would investigate patients with solid cancers that were unresponsive to standard cytotoxic chemotherapy.

Noxopharm said that the primary objectives of the three progressive studies were to determine the safety and tolerability of NOX66 alone and in combination with carboplatin, to determine if NOX66 was able to reverse resistance to carboplatin in heavily drug-resistant cancers and to determine if NOX66 would allow the dosage of carboplatin to be lowered to a safer level without compromising its efficacy.

The company said that NOX66 was “an innovative dosage formulation of idronoxil, a compound that down-regulates pro-survival mechanisms in cancer cells”.

Noxopharm was up half a cent or 2.7 percent to 19 cents with 3.1 million shares traded.

PHARMAUST

Pharmaust says Dr Angela Frimberger will evaluate monepantel as a monotherapy or in combination with chemotherapy in dogs that have failed standard care.

Pharmaust said that in the only previous studies evaluating monepantel, formerly known as PPL-1 with carboplatin, neither of the two dogs treated had any adverse events despite both had advanced cancers and few treatment options.

The company said it would provide capsules newly formulated by Juniper Pharma Services for evaluation by Dr Frimberger’s team at Sydney’s Veterinary Oncology Consultants.

Pharmaust executive chairman Dr Roger Aston said that “combining chemotherapy with [monepantel] in a target species is a critical component of our development strategy both in canines and humans, as chemotherapy is usually a first line treatment of cancer”.

“Previous studies in rodent models showed highly significant synergy between chemotherapy and [monepantel] without apparent enhancement of side-effects,” Dr Aston said.

Dr Frimberger said that her studies had shown that monepantel was safe and had biological activity in dogs and carboplatin had been given to two dogs with late stage, resistant cancers without any enhancement of side effects.

Pharmaust said dogs would be recruited in Cambridge UK and Sydney and possibly other Australian sites.

The company said the US pet market sales were about $US14 billion a year, while cancer therapies were estimated at $US550 million at about $US1,500 per treatment.

Dr Aston said that monepantel was approved for veterinary use and “if successful in this trial [it] will be able to be approved quickly for the treatment of dog cancers following a further pivotal study”.

Pharmaust fell 0.3 cents or 3.3 percent to 8.7 cents.

PRANA BIOTECHNOLOGY

Prana has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 4.2 cents or 45.2 percent from 9.3 cents on august 8 to 13.5 cents on August 9, 2016 and noted a significant increase in trading volume.
Yesterday, Prana climbed 5.7 cents or 61.3 percent to an intra-day high of 15 cents, closing last night up 5.2 cents or 55.9 percent at 14.5 cents.
In June, Prana gave a similar response to an ASX query following a share price rise of 3.3 cents or 37.9 percent to 12 cents on June 10, 2016 (BD: Jun 14, 2016).
Prana retreated 2.5 cents or 17.2 percent to 12 cents with 1.4 million shares traded.

BENITEC BIOPHARMA

Benitec says Greg West has been confirmed as chief executive officer, with Dr Cliff Holloway chief business and operating officer and Bryan Dulhunty chief financial officer.
Benitec said that Mr West was appointed interim chief executive officer in December 2015 following the sudden departure of Dr Peter French ahead of the termination of its phase I/II trial of TT-034 for hepatitis C (BD: Dec 9, 16, 2015; Feb 26, 2016).
The company said that Mr West had been its chief financial officer and company secretary since 2011.
Benitec chairman Peter Francis said Mr West had "done a terrific job helping drive the improvement of the business in a very challenging environment over the past six months".
"Following an extensive executive search in the United States and Australia, we firmly believe he is exactly the right CEO to move the company forward," Mr Francis said.
Benitec said that Dr Holloway would be based in the US and join the company on August 24, 2016.
The company said that Dr Holloway was previously the chief executive officer of Sienna Cancer Diagnostics, Immune System Therapeutics and Biosceptre International and was formerly the head of business development at Arana Therapeutics, which was acquired by Cephalon, now Teva Pharmaceuticals.
Benitec said that Dr Holloway held a Bachelor of Pharmacy and a Doctroat of Philosophy from the University of Nottingham, UK.
The company said that Mr Dulhunty started as chief financial officer on July 1, 2016, had 20 years' experience in the sector and was previously executive chairman, a director, managing director, chief financial officer and company secretary of companies including Viralytics, Analytica and Cosa company secretarial services.
Benitec said that Mr Dulhunty held a Bachelor of Economics from the University of Sydney.
Benitec was unchanged at 11.5 cents.

OVENTUS MEDICAL

Oventus says it has appointed a four member scientific advisory committee for its sleep apnoea and snoring mouth guard product.
Oventus said that the committee would aim to meet twice a year and would be consulted during the product development cycle in preparation for clinical trials.
The company said the committee was composed of Prof Bill Coman, Prof Peter Eastwood, Prof Jeremy Goldin and Dr Karen McCloy.
Oventus fell three cents or 4.3 percent to 67 cents.

NUHEARA

Nuheara says it has appointed the New York-based Bruce Borenstein as head of sales.
Nuheara said that Mr Borenstein had more than 30 years' experience in consumer electronics sales with a record of launching innovative consumer brands including Bluetooth headsets.
The company said that since 2011, Mr Borenstein had been Aftershokz chief executive officer where he built a presence for the Bluetooth headphone company using bone conduction technology.
Nuheara said that Mr Borenstein was a board member of the accessories division of the Arlington, Virginia-based Consumer Technology Association and was a trustee of the CTA Foundation board.
Nuheara fell 0.1 cents or 1.7 percent to 5.9 cents with one million shares traded.

PRIMA BIOMED

Prima says it has been notified by the Nasdaq that it is non-compliant with the rule that listed securities maintain a minimum bid price of $US1.00 per share.
Prima received a similar notice in March and regained compliance with the Nasdaq regulation in June (BD: Mar 7, Jun 7, 2016).
Today, the company reported the Nasdaq saying that from June 24 to August 5, 2016, the closing bid price of its American depositary shares, had not been maintained at the minimum required closing bid price of at least $US1.00 per share and it had 180 days, until February 6, 2017, to regain compliance for at least 10 consecutive business days.
Prima was unchanged at four cents with 1.3 million shares traded.