Biotech Daily

Tuesday August 9, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRANA UP 56%, ONCOSIL DOWN 7%**

*** MESOBLAST PHASE II RHEUMATOID ARTHRITIS SAFETY, EFFICACY**

*** COCHLEAR RECORD REVENUE UP 22% TO $1,131m, PROFIT UP 30%**

*** MACH7 APPOINTS SOLITON UK DISTRIBUTOR**

*** DORSAVI VIMOVE FOR ADOLESCENT IDIOPATHIC SCOLIOSIS**

*** MEDICAL DEVELOPMENTS FDA PENTHROX TRIAL, US SPACER DEAL**

*** BIONOMICS REVENUE UP 31% to $22m, GRAEME KAUFMAN GOES**

*** NOXOPHARM $6m IPO, OPENS DOWN 10%**

*** IMPEDIMED: 'FDA GUIDES ON DIGITAL HEALTH, LOW RISK DEVICES'**

*** GARY GOETZKE REPLACES IMPEDIMED'S DR MICHAEL PANACCIO - DAVID ADAMS EXECUTIVE**

*** RACE APPOINTS DR DANIEL LEVY, DR KALIDAS KALE CONSULTANTS**

MARKET REPORT

The Australian stock market was up 0.27 percent on Tuesday August 9, 2016 with the ASX200 up 14.7 points to 5,552.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and three were untraded.

Prana was the best, up 5.2 cents or 55.9 percent to 14.5 cents with 3.5 million shares traded, on no news, but following a 30 percent increase on the Nasdaq last night. Impedimed and Mesoblast climbed more than six percent; Genetic Technologies was up 5.9 percent; Antisense rose 4.65 percent; Bionomics, Cellmid and Nanosonics were up more than three percent; Pro Medicus and Reva rose more than two percent; Avita, Orthocell and Viralytics were up more than one percent; with Resmed and Sirtex up less than one percent.

Oncosil led the falls, down one cent or 7.1 percent to 13 cents with 2.4 million shares traded. Osprey fell 5.9 percent; Actinogen and Atcor lost more than three percent; Cochlear and Prima shed more than two percent; Admedus, CSL, Factor Therapeutics, Neuren and Universal Biosensors were down one percent or more; with Acrux and Starpharma down by less than one percent.

MESOBLAST

Mesoblast says its 48-patient, phase II, rheumatoid arthritis trial has shown safety and statistically significant efficacy for its mesenchymal precursor cells over placebo.

Mesoblast said that the study randomized the patients into three groups of 16 patients each, receiving either placebo, 1,000,000 mesenchymal precursor cells (MPCs) per kilogram of body weight, or 2,000,000 MPCs/kg in a single infusion, including 30 patients who had failed one or two prior biologic treatments, of which nine were controls, 10 received 1,000,000 MPCs and 11 received the 2,000,000 MPC dose.

In a presentation and teleconference, Mesoblast chief executive Prof Silviu Itescu said that the trial of the MPC-300-IV product resulted in “compelling” efficacy data, particularly for the sub-group of patients who had failed prior use of biologic drugs.

Prof Itescu said there had been a clear dose response with statistical significance on two separate measures of efficacy as well as improvement on a third measure of efficacy, despite the small numbers in the trial.

One of the efficacy endpoints, the American College of Rheumatology improvement criteria measured changes in swollen joints, as well as a pain scale and disability rating described as ACR20 for a 20 percent improvement, ACR50 for a 50 percent improvement and ACR70 for a 70 percent improvement.

Prof Itescu said that ACR20 was a very low bar but ACR70 was a high bar, which was not met by any of the control patients, while 20 percent of the 1,000,000 MPC dose reached ACR70 at 12 weeks ($p = 0.043$), with 27 percent of the higher 2,000,000 MPC dose reaching ACR70 at 12 weeks ($p = 0.043$).

The data showed of the sub-group that failed prior biologic drugs four of the 11 on the 2,000,000 MPC dose reached ACR70 as did two of 10 on the 1,000,000 MPC dose.

The Mesoblast data showed that more patients on both MPC doses reached ACR50 improvement than controls, as well as improvements on two other efficacy measures the health assessment questionnaire disability index (HAQ-DI) and the disease activity score 28 (DAS28-CRP).

The company said that all infusions were well-tolerated without any acute infusion reactions or adverse events reported during infusion or in the six-hour post-infusion monitoring period, with no serious adverse events reported during the 12 week primary study period and the safety profile was comparable for the placebo and treatment groups.

Prof Itescu said the results showed “potential as a first line treatment for those who had failed biologics” and about 30 percent of rheumatoid arthritis patients failed current therapies.

Prof Itescu said the results were positive for a phase III trial partnership and the MPC-300-IV product “should be very clearly a partnering product in the rheumatoid arthritis space”.

Prof Itescu said that other treatments for rheumatoid arthritis carried “black box” warnings if adverse events including infections and cancers in one to five percent of cases, requiring large phase III trials.

He said that with the safety profile shown by the mesenchymal precursor cells, the US Food and Drug Administration might not require such a large phase III trial.

Prof Itescu compared the single infusion of MPCs to the current treatment of daily oral tablets or fortnightly sub-cutaneous injections of biologic drugs.

The New York-based Weill Cornell Medical College’s Prof Allan Gibofsky said the safety and efficacy results were “very encouraging and suggest that Mesoblast’s cell therapy has the potential to fill the major unmet medical need of the biologic refractory[rheumatoid arthritis] population, where agents that provide consistent durable effects without the risk of opportunistic infections or malignancies are sorely needed”.

Mesoblast was up 7.5 cents or 6.6 percent to $1.21 with 1.3 million shares traded.

COCHLEAR

Cochlear says total revenue for the 12 months to June 30, 2016 was up 22.1 percent to $1,130,600,000 with net profit after tax up 29.6 percent to $188,900,000.
Cochlear chief executive officer Chris Smith told a teleconference that along with an increase in sales and revenue in all regions, net profit after tax guidance for the year to June 30, 2017 would be a further 10 to 20 percent to $210 million to $225 million.
Mr Smith said the company had introduced five new products in the previous 12 months, established an innovation fund and said “we wake up every morning to win market share”.
Mr Smith said that revenue from the Americas was up 29 percent, with the Europe, Middle East and Africa up 13 percent and revenue from the Asia-Pacific up 31 percent.
Mr Smith said that sales in each of Germany, France and the UK were up more than 10 percent, but the company needed to increase its footprint in Central and Eastern Europe and had opened an office in Vienna to service Central and Eastern Europe.
Cochlear’s chief financial officer Neville Mitchell said the company had filed its first ‘Tax Contribution Report’ a voluntary requirement in the May 2015 Federal Budget to ensure tax transparency for larger companies.
Mr Mitchell told Biotech Daily that although the company earned two percent of its revenue in Australia, it paid 75 percent of its taxes, here.
In the Report, Mr Mitchell said the company invested $140 million or 12 percent of sales revenue in research and development and that the Federal R&D tax offset was “critical to Cochlear continuing this level of investment in research and development in Australia”.
“Cochlear continues to strongly advocate for the retention of the tax offset at current levels and the lifting of the $100 million cap on eligible R&D expenditure,” Mr Mitchell said.
“Cochlear has been at the forefront of transparency reporting in Australia.”.
Cochlear’s accounts said that record sales of $1,158.1 million had been impacted by $27.5 million in foreign exchange losses, providing the record revenue of $1,130.6 million.
Cochlear said the investment in research and development was up 15.1 percent to $143,100,000 or 12.7 percent of total revenue, down from 13.8 percent for the year to June 30, 2015 and 15.85 percent for the year to June 30, 2014.
The company said the final 100 percent franked dividend was up 20.0 percent to $1.20 to be paid on September 29, 2016, based on a record date of September 8, 2016, taking the full year dividend to $2.30 compared to the previous year’s $1.90 and $2.54 in 2014.
Cochlear said that net tangible assets per share increased 76.4 percent to $3.92 from $2.222 at June 30, 2015 and diluted earnings per share climbed 29.5 percent to $3.30, compared to the previous year’s $2.548.
The company said it had reduced net debt by $22.6 million to $117.9 million.
Cochlear said it held $75,417,000 in cash and cash equivalents at June 30, 2016, compared to $72,208,000 at June 30, 2015.
Cochlear fell $3.59 or 2.8 percent to $125.00 with 598,420 shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has appointed the London-based Soliton IT as a non-exclusive distributor of its enterprise imaging products in the United Kingdom.
Mach7 said that Soliton would promote, market and distribute the Mach7 suite of products and provide user training and customer support.
The company said that Soliton had an extensive installation base and leading market share in UK radiology information systems market, managed and supported software installations in more 100 healthcare sites and was an approved NHS supplier.
Mach 7 was up 0.2 cents or 5.6 percent to 3.8 cents with 1.2 million shares traded.

DORSAVI

Dorsavi says its Vimove wearable sensors could be used to identify adolescent idiopathic scoliosis.

Dorsavi said that a study by Wake Forest Baptist Medical Center research engineer Dr Michael De Gregorio, entitled 'Seated postural differences between children with and without adolescent idiopathic scoliosis: a pilot study' found that the Vimove sensors could identify lower back movement patterns and differences between adolescents with scoliosis and those without.

The company said the research was presented at the American Society of Biomechanics meeting in Raleigh, North Carolina, August 2 to 5, 2016.

Dorsavi said the findings "present opportunities for both early identification and potential prevention of adolescent idiopathic scoliosis", an abnormal curvature of the spine that can lead to life-long pain and disability affecting seven million children in the US.

The company said that the key to preventing severe deformity in adolescent idiopathic scoliosis was early diagnosis and the current treatment for moderate and severe scoliosis was long-term bracing and surgery.

Dorsavi said that understanding the differences between adolescents with and without scoliosis allowed the opportunity to study possible early stage posture treatments as an intervention.

The company said that data from a chronic low back pain study showed the Vimove system could modify patient's movement patterns and lead to sustained long term improvements in pain and function.

Dorsavi said it was "excited to be working with world leading medical researchers in this important project aiming to improve the health outcomes and quality of life for adolescents with this challenging spinal condition".

Dorsavi was up one cent or 2.6 percent to 39 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says the US Food and Drug Administration has required a phase III trial for acute trauma pain to register its analgesic Penthrox in the US.

Medical Developments said it had received a written response to its meeting request by the FDA and it had "a clearer understanding of the steps required and data needed to get Penthrox approved for sale".

Medical Developments chief executive officer John Sharman said that "nothing in the response received from the FDA was unexpected, which is encouraging".

Mr Sharman said that the company had completed two phase III pivotal trials, invested in its clinical program and had sufficient clinical data for approval in the UK, France, Ireland, Belgium, Singapore and South Africa.

Mr Sharman said the company's advisors were "working through the details of how best to gather the data needed to submit a new drug application to the FDA".

Separately, Medical Developments said it had appointed the Dublin, Ohio-based Cardinal Health as a US distributor of its range of Space Chamber anti-static respiratory devices.

Mr Sharman said the distribution agreement complemented the appointment of Amerisource Bergen which was completed in May 2016 (BD: May 25, 2016).

"We have delivered our first shipment of product to Cardinal Health and these two distribution deals will be an excellent platform for growth in the USA for our respiratory business," Mr Sharman said. "We now have one of the largest distribution networks in North America distributing our range of respiratory products."

Medical Developments was unchanged at $5.30.

BIONOMICS

Bionomics says revenue for the year to June 30, 2016, was up 30.76 percent to $21,727,915 reducing net loss after tax by 2.01 percent to $16,608,757.
Bionomics said that receipts from customers reflected funds from Merck Inc, contract services and sales of libraries by wholly-owned subsidiaries Neurofit and Prestwick.
The company said that net tangible assets per share was up 47.7 percent to 6.5 cents.
Bionomics said it had $45,450,382 in cash and cash equivalents at June 30, 2016.
Separately, Bionomics said that chairman Graeme Kaufman would retire at the end of August 2016, with director Dr Errol De Souza appointed as chairman.
In March, the Sydney-based CVC has called for the removal from the board of Mr Kaufman and director Trevor Tappenden and in June, the company appointed David Wilson and Peter Turner as directors (BD: Mar 16; Jun 16, 2016).
Bionomics was up one cent or 3.6 percent to 28.5 cents with 1.2 million shares traded.

NOXOPHARM

Noxopharm opened on the ASX down 10 percent from its $6 million initial public offer price of 20 cents, under the code NOX to develop NOX66 for cancer.
Noxopharm's chief executive officer and Novogen founder and former executive chairman Dr Graham Kelly said Noxopharm was "focused on commencing the first clinical trial with its drug candidate NOX66 which we believe has the potential to produce the first major change in cytotoxic chemotherapy for the past 20 years".
"The purpose of NOX66 is to eliminate the ability of a cancer cell to develop and maintain its drug-resistance mechanisms, something that leads to many cancer patients eventually running out of treatment options," Dr Kelly said.
The company said that NOX66 was "an innovative dosage formulation of idronoxil, a compound that down-regulates pro-survival mechanisms in cancer cells, including the cell's ability to establish and maintain a range of drug-resistance mechanisms".
"The primary target of idronoxil is tumor-specific external NADH oxidase 2, or ENOX2, the protein responsible for maintaining the transmembrane electron potential in the cancer cell's plasma membrane," Noxopharm said.
"Loss of this potential inhibits the ability of the cancer cell to maintain a wide range of pro-survival mechanisms," the company said. "NOX66 has been developed specifically to protect idronoxil from phase 2 metabolism in the human body and in so doing to increase the bio-availability of idronoxil to cancer cells."
In the prospectus, Dr Kelly said the company had four key assets including his more than 20 years' "experience … in the field of isoflavonoid drug development, access to talented scientists and key collaborators who will provide the scientific inspiration for the company; a product ready to enter a phase Ia/Ib trial … [by the end of] 2016 and potentially a phase IIa trial in 2017; and a core of supportive seed investors".
Noxopharm said its non-executive chairman was Peter Marks, a current director of Prana, Armadale Capital and Efemcy and a former executive director of Peregrine Corporate, with Cynata founder Dr Ian Dixon a non-executive director and Phillip Hains of the CFO Solution as company secretary.
Noxopharm said the offer was completed by lead manager Asia Pacific Prudential Securities.
Noxopharm climbed as high as its offer price of 20 cents in early trade and closed down 1.5 cents or 7.5 percent at 18.5 cents with 6.1 million shares traded.
According to Commsec data there were 6,483 individual trades, the overwhelming majority for a single share at a time.

IMPEDIMED

Impedimed says that two US Food and Drug Administration guidance documents could benefit its digital health and low-risk device business.

Impedimed said the documents were entitled 'Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices' and 'General Wellness: Policy for Low Risk Devices'.

The company said that the former document allowed manufactures of medical devices to use real-world evidence to support applications for clearance and/or approval and included evidence of a product's performance and outcomes in settings outside clinical trials, such as in hospitals, doctors' offices, and patients' homes.

Impedimed said that the latter policy document stated that the agency did "not intend to examine low risk, general wellness products … [such as] devices and software which monitor health information" along with devices and applications marketed to promote healthy behaviors.

The company said that the FDA would continue to regulate devices and applications that made disease-specific claims.

Impedimed chief executive officer Richard Carreon said the documents "could significantly impact those companies already in, or about to enter, the digital health space".

Impedimed was up 8.5 cents or 6.2 percent to $1.45 with one million shares traded.

IMPEDIMED

Impedimed says that Gary Goetzke has been appointed a non-executive director, replacing directors Dr Michael Panaccio and David Adams, effective August 8, 2016.

Impedimed said that Mr Adams had been appointed as the company's head of ventures, licencing and corporate development.

The company said that Mr Goetzke had worked in management positions of three medical device companies for 15 years, "where he led efforts in pursuing global coverage and payment policy for a variety of medical device therapies" for cardiology, neurology, urology, pelvic health, wound care, orthopaedics, ear, nose and throat and sleep.

RACE ONCOLOGY

Race says it has appointed Dr Daniel Levy and Dr Kalidas Kale as consultants for its Bisantrene development program.

Race said that Dr Levy was previously was a research scientist for Scios, Cor Therapeutics, Advanced Medicine and Ligand Pharmaceuticals and would coordinate manufacturing from active pharmaceutical ingredient to final packaging and release for sale.

The company said that Dr Levy held a Doctorate of Philosophy in organic chemistry from Massachusetts Institute of Technology.

Race said that Dr Kale was a US-based chemist, who had experience with Bisantrene and previously worked as a research scientist at Bristol-Myers Squibb, Barr Laboratories and Lederle Laboratories, the company that originally developed Bisantrene.

Race fell one cent or 4.2 percent to 23 cents.