Biotech Daily

Tuesday July 9, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BENITEC UP 14%, PRIMA DOWN 9%**

*** ARC $47m FOR 17 LAUREATE FELLOWSHIPS**

*** ARC $10m FOR MONASH, MELBOURNE BIONIC EYES**

*** WEHI BH3 MIMETICS STUDY SHOWS BREAST CANCER EFFECT IN MICE**

*** CALZADA'S POLYNOVO 40/60 NOVOPLASTIQ JV FOR FACIAL SURGERY**

*** MAYNE LAUNCHES US DORYX AUTHORIZED GENERIC**

*** PROGEN: 'US STUDY BACKS PG545 FOR PANCREATIC CANCER'**

*** NUSEP CONVERTS $1.7m DEBT TO 7c, 40% PREMIUM NOTES**

*** ANTISENSE PLEADS SCHULTZ, 'CHAT ROOMS' TO ASX 27% QUERY**

*** CANADA HEALTH, BIONICHE TALK UROCIDIN FILINGS**

*** ALLAN GRAY TAKES 12% OF QRX**

MARKET REPORT

The Australian stock market climbed 1.5 percent on Tuesday July 9, 2013 with the S&P ASX 200 up 72.2 points to 4,881.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and five were untraded.

Benitec was the best, up 0.2 cents or 14.3 percent to 1.6 cents, with 1.9 million shares traded.

Patrys climbed eight percent; Antisense and Impedimed were up more than seven percent; Viralytics was up four percent; Anteo, Medical Developments, Pharmaxis and Tissue Therapies were up three percent or more; CSL, Heartware, Mesoblast and Starpharma were up more than two percent; with Psivida up 0.5 percent.

Prima led the falls, down 0.9 cents or 9.3 percent to 8.8 cents with 6.5 million shares traded. Bionomics and Cellmid lost more than six percent; Prana fell five percent; Circadian and GI Dynamics were down more than three percent; QRX shed 2.9 percent; Allied Health, Clinuvel and Resmed were down one percent or more; with Cochlear, Nanosonics and Sirtex down by less than one percent.

FEDERAL GOVERNMENT, AUSTRALIAN RESEARCH COUNCIL

The Federal Government, through the Australian Research Council, has awarded $47 million in Australian Laureate Fellowships to 17 “outstanding” researchers.

A media release from the Minister for Innovation, Industry, Science and Research, Senator Kim Carr, said the fellowships would assist research in child health, language learning, harvesting energy from seabed soils and microbiology.

Senator Carr noted two women Laureates, the University of Sydney’s Prof Glenda Sluga who won the Kathleen Fitzpatrick Fellowship and the University of Adelaide’s Prof Tanya Monro who won the Georgina Sweet Fellowship.

The media release said that Prof Monro’s Fellowship was for controlling light to understand and drive nanoscale processes, aiming to develop a suite of light-based sensing technologies capable of quantifying the dynamic environment within a living cell, extending the capacity to harness light-matter interactions at the nanoscale.

The University of Melbourne’s Prof Lloyd Hollenberg was awarded a fellowship for a project based on the quantum properties of diamond, to answer problems in biology, from how cells differentiate at the beginning of life, to understanding brain function.

The media release said the project would “directly benefit society through the development of new technology for nano-medicine and drug discovery”.

Monash University’s Prof Trevor Lithgow was awarded a fellowship for his work on molecular machines and bacterial cell biology to deliver a detailed understanding and visual rendering of molecular machines at work on the surface of bacteria.

Other Fellowship winners were: Monash University’s Prof Arthur Lowery; the Australian National University’s Prof Nicholas Evans, Prof Hugh O’Neill, Prof Kim Sterelny and Prof Xu-Jia Wang; Griffith University’s Prof Mark Finnane; the University of Adelaide’s Prof Ian Reid; the University of Melbourne’s Prof Peter Taylor; the University of New South Wales’ Prof Michelle Simmons; the University of Queensland’s Prof Hugh Possingham; the University of Western Australia’s Prof Mark Cassidy; and the University of Wollongong’s Prof Richard Roberts.

FEDERAL GOVERNMENT, AUSTRALIAN RESEARCH COUNCIL

The Federal Government says it will provide an additional $8 million to the University of Melbourne Bionic Vision Australia and $1.9 million to the Monash Vision Group.

Innovation Minister Senator Kim Carr said the funding was in addition to $50 million provided for the project and meant the program could be extended for another year.

The Federal Member for Chisholm and Speaker of the House of Representatives Anna Burke said the work was “progressing with astounding success and remarkable speed”.

“Bionic Vision Australia has successfully performed the first human implantation of an early prototype bionic eye and here in my own electorate, Monash Vision Group recently unveiled its bionic eye prototype, with trials to commence next year,” Ms Burke said.

In March, the Monash Vision Group chief investigator and the head of Monash University’s Department of Surgery and Clinical Sciences Prof Jeffrey Rosenfeld said his group had expended most of the initial $8 million Australian Research Council funding and required funding for a further three years to trial its device on seven to 10 patients ahead of an application to the US Food and Drug Administration (BD: Mar 14, 2013).

Today Prof Rosenfeld said he was “very grateful to the Australian Reesearch council for the $1.9 million bridging grant” which would help maintain staff levels on the project.

Prof Rosenfeld said the Group was applying for a National Health and Medical Research Council a $5 million three-year grant to implant bionic eyes in seven to 10 patients in preparation for FDA and Australian Therapeutic Goods Administration applications.

WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers have discovered that compounds in trials for leukaemia could be used to treat the most common type of breast cancer.

The Institute said that its researchers, led by Prof Geoff Lindeman, Prof Jane Visvader, Dr François Vaillant and Dr Delphine Merino, found that BH3 mimetics were effective in treating aggressive oestrogen receptor-positive (ER-positive) breast cancers when combined with the breast cancer drug tamoxifen in mouse models.

The Institute said that about 70 percent of breast cancers were ER-positive.

WEHI said that the hoped their results would lead to clinical trials of BH3 mimetics for treating ER-positive breast cancers in the next few years.

The study, entitled 'Targeting BCL-2 with the BH3 Mimetic ABT-199 in Estrogen Receptor-Positive Breast Cancer' was published in the journal Cancer Cell and an abstract is available at http://www.cell.com/cancer-cell/abstract/S1535-6108%2813%2900278-X.

Prof Lindeman, a Royal Melbourne Hospital oncologist, said that BH3 mimetics worked by neutralizing the BCL-2 protein in cancer cells, making them more susceptible to dying.

Prof Lindeman said that up to 85 percent of ER-positive breast cancers had high levels of BCL-2, which was a 'pro-survival' protein that helped cancer cells to become immortal, and could help them survive chemotherapy and other treatments.

Prof Lindeman said that Dr Vaillant and Dr Merino looked at the effect of adding BH3 mimetics to the standard hormone treatment, tamoxifen, used for a subtype of ER-positive cancers called luminal B cancers, which had high levels of BCL-2.

"They found that a BH3 mimetic … ABT-199/GDC- 0199 improved the effectiveness of hormone therapy by stopping or delaying the growth of these aggressive tumors," Prof Lindeman said. "In one of the tumor models, the combined treatment caused complete disappearance of the tumor, while standard treatment had only a partial and unsustained benefit."

Prof Visvader said there was a need to improve treatments for luminal B breast cancers, which were a more aggressive type of ER-positive breast cancer, associated with a poorer prognosis.

Prof Visvader said the study used preclinical models of breast tumor samples donated by Melbourne women undergoing cancer surgery to understand how real human cancers would respond to the treatment.

"We are excited by these results and what they could mean for women with breast cancer," Prof Visvader said.

"ER-positive breast cancers are the most common type of breast cancer, so even a small improvement could have a substantial impact if more effective upfront treatment could prevent relapse," Prof Visvader said.

"It is very early days, however, and the findings will need to be rigorously tested in clinical studies," Prof Visvader said.

WEHI said that a landmark discovery in the late 1980s by its scientists that BCL-2 promoted cell survival "fuelled more than two decades of global research that has culminated in the design of BH3 mimetics".

WEHI said that the investigational compound, ABT-199/GDC-0199, was discovered by scientists at Abbott (now Abbvie) and was being developed by Genentech, a member of the Roche group, and Abbvie.

Professor Lindeman said he hoped the Centre for Translational Breast Cancer Research could contribute to future clinical trials of the novel combination treatment.

"Australian women who donated their tumor samples for research helped make this discovery possible," Prof Lindeman said. "It would be great to see Australians among the first to benefit from clinical trials, should they proceed."

CALZADA, POLYNOVO BIOMATERIALS

Calzada's Polynovo says it has created a US joint venture Novoplastiq LLC to commercialise and distribute Novosorb devices for facial implant and aesthetic surgery.
Polynovo is a wholly owned subsidiary of Calzada and its chief executive officer Laurent Fossaert told Biotech Daily that Polynovo's 40 percent contribution was through the provision of the Novosorb technology and the US investors' contribution was financial, but at this stage was "commercial in confidence".
Calzada said that the Novosorb polymer technology had many medical applications involving human tissue repair, including wounds and burns treatment.
The company said that the significant market opportunity for Novosorb in facial implants was "a further example of the diversity and versatility of the Novosorb platform".
Calzada said that aesthetic facial surgery included nasal, chin, cheek and lip augmentation where existing treatments involved short-lasting dermal fillers, non-biodegradable implants and autologous transplants.
The company said that Novosorb had demonstrated "excellent biocompatibility, tissue incorporation, reduction in the risk of infection and biodegradability".
Calzada said Novoplastiq would target opportunities in the aesthetic facial surgery market and Shawn Huxel had been appointed chairman and chief executive officer.
Calzada said that Mr Huxel had "decades of prior experience and expertise … exclusively dedicated to the development and commercialization of biomaterial based [products] for the medical device implant industry".
The company said that Mr Huxel had worked for Johnson & Johnson Ethicon and founded, financed and exited startup companies and had worked in Europe and Asia.
Calzada said that Novoplastiq had global marketing and distribution rights to Novosorb devices in the field of aesthetic facial surgery, Polynovo would co-develop, manufacture and supply the Novosorb devices and Novoplastiq would be responsible for raising working capital, regulatory approvals, marketing and distribution of the finished devices.
The company said Polynovo would receive manufacturing revenues and royalties on product sales in addition to the value of its equity ownership.
Calzada said Novoplastiq aimed to have the first device approved by the US Food and Drug Administration within 12 months and be marketed within four months of approval.
Mr Huxel said that "the advantages of Novosorb over existing polymers, as well as its versatility and biodegradability, make it ideal for use in facial surgery procedures".
"The regulatory path is well defined and our 510(k) submission for Novosorb to enter the US market is well supported based upon the preclinical and clinical data," Mr Huxel said.
Calzada was up 1.1 cents or 16.4 percent to 7.8 cents with 952,712 shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says it has launched doxycycline hyclate delayed-release 75mg and 100mg tablets, in the US, through its generic products division.
Mayne said that doxycycline hyclate delayed-release tablets, 75mg and 100mg, had sales of about $US24 million for the 12 months ending April 30, 2013 and were authorized generic versions of the Doryx 75mg and 100mg products.
Mayne's chief executive officer Scott Richards said the company was "very excited about the launch of these products which will be the first revenue synergies to materialize from the Metrics Inc acquisition completed in November 2012".
"These products will add to Mayne Pharma's growing portfolio of generic products marketed in the US," Mr Richards said.
Mayne was up 4.5 cents or nine percent to 54.5 cents with 5.5 million shares traded.

PROGEN PHARMACEUTICALS

Progen says a US study supports its heparan sulfate mimetic with dual anti-angiogenic and anti-metastatic properties PG545.
Progen said the study was featured on the cover of the July 2013 print edition of the peer-reviewed journal Molecular Cancer Therapeutics.
The company said that pre-clinical experiments evaluated the therapeutic potential of PG545 in three different experimental pancreatic ductal adenocarcinoma mouse models compared to a control or Gemcitabine, a deoxycytidine nucleoside analog chemotherapy which is a standard treatment for advanced and metastatic pancreatic ductal adenocarcinoma.
The article, entitled 'PG545, an angiogenesis and heparanase inhibitor, reduces primary tumor growth and metastasis in experimental pancreatic cancer' was published in Molecular Cancer Therapeutics.
An abstract is available at: http://mct.aacrjournals.org/content/12/7/1190.
Progen said pancreatic ductal adenocarcinoma was characterized by rapid tumor growth, late presentation, early metastasis and significant resistance to conventional treatments.
The company said that data from the models showed that PG545 inhibited primary tumor growth and metastasis and prolonged survival.
Progen said that the anti-tumor effects of PG545 were accompanied by inhibition of vascular function within the tumor and increased tumor hypoxia, PG545 inhibited collagen deposition and promoted tumor cell differentiation in the setting of hypoxia.
The company said that the effects of PG545 on tumor growth inhibition were comparable to Gemcitabine but PG545 had better anti-metastatic activity which resulted in prolonged survival in an implant mouse model of human pancreatic cancer.
Progen said that PG545 was being re-assessed in non-clinical safety studies following a change from subcutaneous to intravenous infusion and, subject to positive results from the safety studies, it intended to begin a phase I trial in advanced cancer patients this year.
Progen was untraded at 20 cents.

NUSEP

Nusep says it will convert about $1.7 million of its long term debts, including director loans, into convertible notes.
Nusep said it would seek shareholder approval to issue the convertible notes, converting at seven cents a share, a 40 percent premium to the current five cent share price.
Nusep was unchanged at five cents.

ANTISENSE THERAPEUTICS

Antisense has told the ASX that, apart from chat room posts, it is not aware of any information it has not announced which, if known, could explain recent share trading.
The ASX said the company's share price climbed from 1.1 cents on July 5, to 1.4 cents, a 27.3 percent increase, on July 8, 2013, and noted an increase in trading volumes.
Antisense said that it periodically monitored social media including internet forums and chat rooms and was aware of "a very recent increase in postings on certain of these forums including postings on share price movements and relativities between the company and its technology collaboration partner Isis Pharmaceuticals and speculation on the progress of the company's phase II clinical study of ATL1103".
The company said its policy was "to offer no specific commentary on individual postings".
Antisense was up 0.1 cents or 7.1 percent to 1.5 cents with 19.3 million shares traded.

BIONICHE LIFE SCIENCES

Bioniche says it met Health Canada in late June to discuss the filing of a regulatory submission for its Urocidin phase III bladder cancer product.

Bioniche said that Health Canada advised that the data from the first phase III clinical trial with Urocidin might be sufficient to qualify for filing under the Notice of Compliance with Conditions policy.

The company said the regulator asked it "to submit a clinical assessment package addressing some clinical questions as part of the request to file a new drug submission under the … policy".

Bioniche said it was expected that all materials could be submitted to Health Canada before the end of 2013, with about one year of review to follow.

The company said that approval of Notice of Compliance with Conditions could follow by the end of 2014 and an early registration in Canada would generate revenues from commercial sales to offset the cost of additional clinical trial work that may be required for the US and other jurisdictions.

Bioniche said it would seek a meeting with the US Food and Drug Administration to discuss a clinical development plan to achieve US registration.

Bioniche was untraded at 30 cents.

QRX PHARMA

Allan Gray Australia has again increased its substantial holding in QRX, from 16,198,173 shares (11.20%) to 17,683,669 shares (12.21%).

Allan Gray said it bought 1,485,496 shares between December 5, 2012 and July 5, 2013 for $1,569,057 or an average price of $1.056 cents a share.

QRX fell three cents or 2.9 percent to $1.01.