Biotech Daily

Wednesday November 18, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRIMA UP 12%; GENETIC TECHNOLOGIES DOWN 8%**

*** REVA ROAD SHOW INTRODUCES CEO DR REGGIE GROVES**

*** ORTHOCELL IMPLANTS 1st SINGAPORE ORTHO-ACI KNEE PATIENT**

*** PRIMA PHASE I IMP321, CHECKPOINT INHIBITOR MELANOMA TRIAL**

*** ALCHEMIA COMPLETES $25m DR REDDY'S FONDAPARINUX SALE**

*** PRESCIENT SHARE PLAN RAISES $1.2m**

*** PROTEOMICS RECEIVES $309k FEDERAL R&D TAX REFUND**

*** DIRECTOR ANDREW GOODALL LENDS NUSEP FURTHER $515k**

*** SIMAVITA, HEALTH METRICS DISTRIBUTION, COLLABORATION**

*** AUSTRALIAN PATENT FOR AVITA'S RECELL**

*** IMMURON ENROLS 2 MORE PHASE IIB IMM-124E NASH TRIAL PATIENTS**

*** UP TO 20% OF BIONOMICS OPPOSE 500k DIRECTOR OPTIONS**

*** UP TO 32% OF ACRUX OPPOSE EMPLOYEE OPTIONS**

*** CLARIFICATION: SUDA - 'NO REMUNERATION REPORT 1st STRIKE'**

MARKET REPORT

The Australian stock market climbed 0.29 percent on Wednesday November 18, 2015 with the ASX200 up 14.9 points to 5,133.1 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and two were untraded.

Prima was the best, up 0.6 cents or 12 percent to 5.6 cents with 4.6 million shares traded. Universal Biosensors climbed 8.05 percent; Orthocell was up 7.1 percent; Admedus was up 5.7 percent; Antisense, Cellmid and Circadian were up more than three percent; Avita, Impedimed, Psivida, Reva and Viralytics rose more than two percent; Cochlear was up 1.8 percent; with CSL and Medical Developments up by less than one percent.

Genetic Technologies led the falls, down 0.2 cents or 8.3 percent to 2.2 cents with 2.3 million shares traded. Benitec, Biotron and Ellex lost more than six percent; Oncosil and Tissue Therapies fell five percent or more; Bionomics and Mesoblast fell more than four percent; Compumedics and Pro Medicus were down more than three percent; Acrux and Anteo shed two percent or more; Actinogen, Nanosonics and Sirtex lost more than one percent; with Starpharma down 0.6 percent.

REVA MEDICAL

Reva chief executive officer Dr Reggie Groves says the company is moving from research and development to commercialization of its bioresorbable Fantom coronary stent.

Dr Groves and Reva chairman Robert Stockman were in Melbourne as part of an investor road-show through Melbourne, Sydney and Brisbane, in part to introduce the recently-appointed Dr Groves to investors (BD: Aug 21, 2015) .

Dr Groves told Biotech Daily that she grew up in Miami, Florida, but said she went to school at the Middleburg, Virginia-based Foxcroft boarding school, of which she was currently the chairman of the school board.

Dr Groves earned her Bachelor of Science degree in Pharmacy at the University of Florida and holds a Masters of Business Administration from the Harvard Graduate School.

She said that she gained experience in business consulting and strategy development with McKinsey & Co before joining internet and technology start-up company IXL, where she rose to head of enterprise services, before joining Medtronic.

At Medtronic, Dr Groves held several senior executive roles, including as the most senior woman executive in the company, culminating as Medtronic's AF Solutions division's vice-president and general manager.

Dr Groves said she was familiar with the cardiac device market and told Biotech Daily that her mission was to plan the commercial manufacturing of Reva's Fantom stent, as well as organize sales and marketing teams and ensure that cardiologists, physicians and potential patients were aware of the bioresorbable cardiac stent option.

"We need to reach out to physicians so that they understand the product and how to use it, as well as reimbursement coverage," Dr Groves said.

Dr Groves said that the company expected to begin commercial sales in Europe by July 2017, along with other countries that accept Conformité Européenne (CE) mark approval.

She said that Boston Scientific was one of the founding investors in Reva and it had an exclusive option to negotiate distribution of its products.

Dr Groves said that engaging with Boston Scientific was central to plans for distribution.

"The key to commercial success is building the adoption and engaging with innovators, early adopters and the early majority," Dr Groves said, describing the bell-curve of new product adoption and once a company had the early majority, it "crossed the chasm" and would gain "the late majority and the laggards".

Dr Groves said Reva needed to reach interventional cardiologists and physicians so they know about the Fantom stent, its benefits and how to use it.

Reva climbed two cents or 2.5 percent to 82 cents.

ORTHOCELL

Orthocell says its autologous chondrocyte implantation (Ortho-ACI) has been applied to its first patient in Singapore for damaged articular knee cartilage.

Orthocell said that the use of Ortho-ACI in Singapore followed the treatment with Ortho-ACI of Hong Kong patients with articular cartilage damage within the knee joint.

The company said that the Ortho-ACI process involved taking cartilage cells from a patient via a biopsy, expanding the cell volume and then surgically implanting the cells back into the area of cartilage damage to regenerate the lost tissue.

Orthocell said that Singapore orthopaedic surgeon Dr Derrick Oh completed the Ortho-ACI implantation at Gleneagles Hospital, Singapore.

Orthocell said that the global regenerative medicine market has been forecast to reach $US67.6 billion in 2020.

Orthocell was up 3.5 cents or 7.1 percent to 52.5 cents.

PRIMA BIOMED

Prima says it will conduct a 24-patient phase I metastatic melanoma safety trial combining its IMP321 with a checkpoint inhibitor.

Prima said the Brisbane, Queensland-based Greenslopes Private Hospital had approved the protocol and the first patient was expected to be dosed in the 'two active immune-therapeutics in melanoma', or Tacti-mel, study by July 2016.

The company said that it was "one of the first clinical occasions in which an antigen presenting cell … activator [had] been combined with a checkpoint inhibitor".

In October, Prima said that Belgium's Federal Agency for Medicines and Health Products had approved its 211-patient phase IIb trial of IMP321 for metastatic breast cancer (BD: Oct 27, 2015).

In May, Prima said it had a pre-clinical collaboration with NEC Corporation and Yamaguchi University for IMP321 in combination with a peptide vaccine for liver cancer (BD: May 11, 2015)

Prima chief scientific and medical officer Dr Frederic Triebel said the study was "a significant development for Prima … because the future of immuno-oncology lies in combination therapies".

"If we can combine IMP321 synergistically with a checkpoint inhibitor, as the pre-clinical evidence has suggested, then we will be well positioned in this revolutionary field," Dr Triebel said.

Prima said that checkpoint inhibitors were monoclonal antibody drugs which targeted certain inhibitory checkpoints on immune cells, whose regular function was to supress an immune response, but cancer was able to exploit the checkpoints to prevent the immune system from attacking tumours.

The company said that checkpoint inhibitors, by foiling this tumor escape route, allowed a more effective immune response, leading to significant beneficial outcomes for many patients.

Prima said that three checkpoint inhibitors had gained US Food and Drug Administration approval since 2011, all initially in metastatic melanoma.

The company said that showing IMP321 to be synergistic with the checkpoint inhibitors would increase its clinical and commercial potential.

Prima said that the pre-clinical and clinical evidence to date suggested that IMP321 could treat cancer by activating antigen presenting cells to sustain an anti-cancer immune response.

The company said it was "a markedly different mechanism of action from the checkpoint inhibitors, and suggests that the two approaches can be used synergistically in combination".

Prima said that in May 2015 it filed a provisional patent application over the use of IMP321 in combination with immune checkpoint inhibitors, thereby potentially providing patent exclusivity for the product to 2035 or beyond if granted.

The company said that the Tacti-mel study would recruit 24 patients with stage III or IV metastatic melanoma being treated with an approved checkpoint inhibitor and add IMP321 to the dosing regimen.

Prima said that patients would receive ascending sub-cutaneous doses of IMP321 up to 30mg per injection fortnightly for 13 injections.

The company said that the study would mainly evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumour activity of IMP321 at the various doses as well as the nature of the immune response in the combination and the primary endpoint would be safety.

Prima climbed 0.6 cents or 12 percent to 5.6 cents with 4.6 million shares traded.

ALCHEMIA

Alchemia says it has completed the sale of fondaparinux to Dr Reddy's Laboratories and had received $US17.5 million ($A24.6 million) in payment (BD: Sep 25, 2015).
Alchemia said it would make a further announcement regarding a potential return of capital in the near future once it has finalised its cash position, which included the receipt of an expected R&D Tax Incentive refund.
Alchemia was up 0.6 cents or 6.7 percent to 9.6 cents.

PRESCIENT THERAPEUTICS

Prescient says that new and existing investors have subscribed for $1,201,500 in its share purchase plan.
Prescient said that the price would be "based on a 20 percent discount to the five-day volume weighted average price before the issue date of November 23, 2015.
The company said that the final price would be announced on the date of issue of the shares.
Prescient was unchanged at 6.8 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has received $309,101 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Proteomics said the rebate related to research and development expenditure for the year to June 30, 2015 and the funds would be used to continue to advance the application and commercialisation of [its] products and services derived from its proteomics-based technology platform.
Proteomics fell two cents or five percent to 38 cents.

NUSEP HOLDINGS

Nusep says it has a $515,000 loan from director Andrew Goodall, repayable by May 16, 2016, with an interest rate of eight percent a year.
Nusep said that a previous loan from Mr Goodall of $NZ250,000 to be repaid from the company's R&D Tax Incentive had been amended to be repaid by May 16, 2016 and the interest rate was reduced from 10 percent to 8 percent (BD: Jun 30, 2015).
The company said the loans would fund its operations.
Nusep was untraded at 4.1 cents.

SIMAVITA

Simavita says it has an agreement with aged care software provider Health Metrics to distribute its smart incontinence management software in Australia and New Zealand.
Simavita said that its system would be distributed through the Melbourne-based Health Metrics Ecase system and the two companies would collaborate to integrate the smart incontinence management (SIM) software into the Ecase system.
The company said that once completed, the integration would result in SIM being hosted as a module on the Ecase system providing access to more than 40,000 residential aged care beds in Australia and New Zealand.
Simavita said the two companies would promote and sell to common and new customers.
Simavita was untraded at 36 cents.

AVITA MEDICAL

Avita says that IP (Intellectual Property) Australia has granted a patent entitled 'Cell suspension and use thereof' which extends Recell coverage to 2033.
Avita said that the patent related to the use of its Recell cell suspension preparation device for grafting cells to treat wounds and provided coverage, including conditioned regenerative epithelial suspension (RES) and methods of preparing and using the suspension for skin treatment as well as other than skin, such as cornea and trachea.
Avita said the patent meant that "exogenous agents can be added to RES, including such items as heat shock protein, hyaluronic acid and adipose-derived stem cells".
The IP Australia website named Avita's head of research and technology Andrew Quick and former chief executive officer Dr William Dolphin as the inventors.
Avita chief executive officer Adam Kelliher said the patent was "an important step in securing the company's global footprint for our proprietary Recell technology".
"In addition, it provides further validation of the significant need for our device skin repair technology," Mr Kelliher said.
Avita said that the technology could be used to treat chronic wounds, burns, scars and a range of skin conditions, including depigmentation and acne.
Avita was up 0.2 cents or 2.1 percent to 9.9 cents.

IMMURON

Immuron says it is more than 25 percent of the way to the 120-patient target for its phase IIb trial of IMM-124E for non-alcoholic steato-hepatitis, or fatty liver disease.
Immuron said that 35 patients had been randomized to the trial and so far no significant treatment adverse events had been reported.
In July, Immuron said it had enrolled 33 of the 120 patients in the randomized, double-blind, placebo controlled study (BD: Nov 27, 2014; Jul 2, 2015).
The company said it expected to complete enrolment by June 2016.
Immuron said that patients were being randomized into groups receiving either 600mg or 1200mg dose of IMM-124E, or placebo, three times daily.
The company said that it had 22 active clinical study sites in the US, Australia and Israel, including three additional sites initiated in the past three months, with three more US sites expected to begin enrolling patients by early 2016.
Immuron said the primary endpoint was to prove safety and efficacy of IMM-124 in the reduction of fatty liver, as confirmed by magnetic resonance imaging and in the reduction of liver enzymes over a six-month treatment period.
Immuron was up six cents or 14.3 percent to 48 cents.

BIONOMICS

All Bionomics annual general meeting resolutions were passed, but with strong dissent against the issue of 500,000 options to director Dr Alan Dunton (BD: Oct 16, 2015).
The resolutions to Dr Dunton the options was opposed by 32,846,668 votes (19.7%) and supported by 133,688,558 votes (80.3%) with all other resolutions including the issue of options to chief executive officer Dr Deborah Rathjen passed overwhelmingly.
The company's most recent Appendix 3B new issue announcement said that Bionomics had 440,585,599 shares on issue, meaning that the votes against Dr Dunton's options amounted to 7.5 percent of the company, sufficient to requisition extraordinary general meetings.
Bionomics fell 2.5 cents or 4.8 percent to 50 cents.

ACRUX

All resolutions to the Acrux annual general meeting were passed but there was strong dissent against the grant of up to 2,400,000 options to about 25 employees.

The resolution, to provide the performance-linked options vesting in three tranches over three years and exercisable at a 15 percent premium to the 30-day volume-weighted average price, July 31, 2016, was opposed by 13,533,167 votes (31.7%), with 29,104,159 votes (68.3%) in favor.

The company's most recent Appendix 3B new issue announcement said that Acrux had 166,521,711 shares on issue, meaning that the votes against the options amounted to 8.1 percent of the company, sufficient to requisition extraordinary general meetings.

The remuneration report and the re-election of director Bruce Parncutt were passed by significantly wider margins.

In 2013, the grant of 600,000 options to executive chairman Ross Dobinson, exercisable at $4.30 by July 31, 2016, was opposed by 23,657,409 votes (27.9%), with 61,158,417 votes (72.1%) in favor (BD: Nov 22, 2013).

Acrux fell 1.5 cents or two percent to 74 cents.

SUDA

Suda chief financial officer Joseph Ohayon has told Biotech Daily that more than 77 percent of the company voted for the remuneration report, avoiding a "first strike".

Yesterday, Biotech Daily reported that 29,783,542 votes (26.5%) opposed the remuneration report with 82,643,059 votes (73.5%) in favor.

Mr Ohayon said that 17,161,339 votes were held at the "proxy's discretion" and although it was not disclosed clearly to the ASX, those votes were all in favour of the remuneration report, taking the votes in favour to 99,804,398 votes (77.02%) with 29,783,542 votes (22.98%) opposed.

Biotech Daily believes the correct way to count votes is to include only "for" and "against" votes, unless the resolution goes to a poll and all votes are disclosed.

Suda was up 0.1 cents or 3.45 percent to three cents with 1.6 million shares traded.