Biotech Daily

Tuesday December 3, 2013

Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH DOWN: PRANA UP 13%, NEUREN DOWN 16%**

*** NSW CANCER CENTRE FILES FOR STAGE TWO**

*** UK TO FUND PSIVIDA, ALIMERA ILUVIEN FOR DME**

*** SIMAVITA IPO RAISES $14m FOR INCONTINENCE**

*** GI DYNAMICS: 'META-ANALYSIS SHOWS EFFICACY'**

*** PROGEN, BETA DEAL ON HEPARANASE**

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*** CIRCADIAN LOSES ROBERT KLUPACS, APPOINTS DR RUSSELL HOWARD**

MARKET REPORT

The Australian stock market fell 0.44 percent on Tuesday December 3, 2013 with the S&P ASX 200 down 23.4 points to 5,256.1 points. Ten of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and four were untraded.

Prana was the best, up seven cents or 12.8 percent to 61.5 cents, with 1.9 million shares traded, followed by Phylogica up 11.8 percent to 1.9 cents with 420,755 shares traded. Prima climbed 6.8 percent; Cellmid was up three percent; Benitec and Viralytics rose more than two percent; CSL, Mesoblast, Psivida, QRX and Resmed were up more than one percent; with Sirtex up 0.85 percent.

Neuren led the falls, down two cents or 16.0 percent to 10.5 cents with 19.3 million shares traded. Atcor and Genetic Technologies lost more than eight percent; Admedus was down 6.9 percent; Living Cell fell 5.7 percent; Acrux, Circadian, Phosphagenics and Tissue Therapies fell more than four percent; Alchemia, Antisense, Patrys and Reva were down more than three percent; Avita, Nanosonics and Starpharma shed more than two percent; with Bionomics, Cochlear, Medical Developments and Osprey down more than one percent.

NEW SOUTH WALES GOVERNMENT

The New South Wales Government says the development application has been lodged for stage two of the $79.8 million cancer centre development at Prince of Wales Hospital.
New South Wales Health Minister Jillian Skinner said that the Nelune Comprehensive Cancer Centre and Australian Advanced Treatment Centre project was scheduled for completion by mid-2016 and comprised $41.5 million funding from the New South Wales Government, $3.5 million for the Federal Government, $11 million form the University of New South Wales, $10.7 million form the Prince of Wales Hospital Foundation $7.1 from the Prince of Wales Hospital's Cancer Services and $300,000 from the Sydney Children's Hospital Foundation, with $5.7 million in funding for the linear accelerator replacements from the Health Program Grants and Prince of Wales Hospital's Cancer Services Funds.
"The Nelune Comprehensive Cancer Centre will provide an innovative, patient-centred approach to the treatment and post-care of those with cancer and blood disorders," Ms Skinner said.
"Stage one of the project is scheduled for completion in the second half of 2014," Ms Skinner said.
A media release from Ms Skinner's office said that the Nelune Comprehensive Cancer Centre would be "a world-class facility" and bring together a range of ambulatory, outpatient and radiotherapy services provided across eight sites on the Randwick hospital campus.
The media release said that the Australian Advanced Treatment Centre would be a facility of the University of New South Wales for clinical trials and provide an opportunity for fast tracking new medical discoveries.
The media release said that stage one of the project would deliver the four radiotherapy bunkers required for three linear accelerators and one additional bunker for research, as well as patient waiting area, landscaped courtyard, treatment review rooms, combined orthovoltage and brachytherapy room and special areas for adolescents and children and be physically directly linked to Prince of Wales Hospital.
The Government said that stage two of the project would include state-wide youth cancer services, a cancer genetics and thalassaemia unit, gynaecological cancer unit from the Royal Hospital for Women, ambulatory care, palliative care services and clinical research, including clinical trials.

PSIVIDA

Psivida said the UK National Institute for Health and Care Excellence has recommended funding Iluvien for post-cataract surgery patients with chronic diabetic macular oedema.
Psivida said the final recommendation was for pseudophakic patients, those who had cataract surgery, insufficiently responsive to available therapies, subject to a patient access scheme.
The company said that the Institute required clinical commissioning groups, the National Health Service and local public health authorities to comply with the recommendation in the final guidance within three months of its date of publication.
Psivida chief executive officer Dr Paul Ashton said the company was "very pleased" with the recommendation, which was "a key step in the availability of Iluvien".
The company said that licensee Alimera Sciences reported it was "communicating closely with retinal specialists, hospital pharmacists and commissioners throughout the United Kingdom with the goal of making Iluvien available to suitable patients as quickly as possible".
Psivida was up five cents or 1.6 percent to $3.15.

SIMAVITA

Simavita says its initial public offer at 41 cents a share has raised $14 million to list on the Toronto Stock Exchange Ventures market and hopes to list on the ASX.

Simavita chief executive officer Philippa Lewis said the company would have the code SV on the Toronto Stock Exchange Ventures and hoped to list on the Australian Stock Exchange by the end of 2013.

Ms Lewis said that following the public offer the company would have 57,776,494 shares available for trading.

Simavita said its Sim platform technology was “an instrumented incontinence assessment application that provides evidence-based incontinence management care plans to the residential aged care market”.

The company said that Sim was an acronym for ‘smart incontinence management’.

Simavita said Lodge Partners was lead manager for the capital raise and about half the issue was taken by existing shareholders.

The company said that new investors included Australian institutional and family office investors, high net worth investors and smaller retail investors.

Simavita said the funds would be used to build inventory and support the distribution agreement with Medline in the US, develop new products and launch in Canada and Europe.

The company said that Sim could “remotely detect multiple incontinent episodes during the 72 hour assessment period and produce accurate, evidence-based data to efficiently develop personalized incontinence plans, which are required to meet accreditation standards in aged care facilities”.

Simavita said that the technology “greatly improves quality of life for aged care residents undergoing incontinence testing and dramatically affects labor costs and efficiencies, reducing the cost of the consumables associated with ongoing daily product use”.

Ms Lewis said that Simavita supplied disposable nappies containing sensors attached to a patient-dedicated pod that transmitted data to a central point.

Ms Lewis said that patients would have multiple nappies over the period and each one clipped to the pod providing a raft of data on food and drink intake, fluid retention, patient details, medication and assessed the frequency and timing of the patient’s toilet needs.

Ms Lewis said nursing homes often changed patient or took the to the toilet on a greater frequency than required and the Sim could allow the nursing homes to more accurately direct resources.

Ms Lewis said that nursing homes would sign up for a total patient assessment costing about $250 to $300 per patient.

Ms Lewis said the company was “delighted with the strong support shown by Australian investors including the entry of a number of institutions as part of this capital raising”.

“The excellent support shown for this transaction validates our belief that Sim will be key to the transformation of incontinence management in the aged care market, both in Australia and around the world,” Ms Lewis said.

Simavita said it received US Food and Drug Administration 510(k) clearance for the Sim system in August 2013 as well as clearance to market the device as a class 1 medical device within the European Union.

The company said that Sim was being marketed in Australia with “several loyal, revenue-generating customers using it to drive labor efficiencies within their aged care facilities”.

Ms Lewis said that the Toronto listing “gives us important access to North American opportunities and investors but also allows us to remain in Australia where our technology was developed and commercialized”.

GI DYNAMICS

GI Dynamics says an analysis of 129 patients in four trials has shown its Endobarrier reduces blood glucose levels and some weight loss.
GI Dynamics said that the findings were presented at the International Diabetes Federation's World Diabetes Congress in Melbourne in an oral presentation entitled, 'Endoscopic, Duodenal-Jejunal Bypass Liner Exerts Robust Metabolic Effects: Accumulating Clinical Experience Across Four Studies' reporting on four prospective, single-arm studies with a total of 130 patients from three countries implanted with Endobarrier for a planned 12-month duration.
GI Dynamics said that among patients with type 2 diabetes, the Endobarrier showed a significant reduction in blood glucose levels reducing HbA1c by 1.3 percent from baseline, with more than half (52%) of diabetic patients achieving healthy blood glucose levels (HbA1C less than or equal to 7.0%) during the treatment period.
The US National Institutes of Health website said that a normal level of HbA1c was 5.6 percent or lower with 5.7 percent to 6.4 percent described as "pre-diabetes" and 6.5 percent or above diagnosed as "diabetes".
GI Dynamics said that patients across all studies experienced weight loss of 14.2kg from baseline and mild or moderate adverse events were mostly gastrointestinal.
The company said that mean treatment duration for the 126 patients with data available was 10.2 months.
GI Dynamics said that findings from three of the studies involving 87 obese patients with type 2 diabetes were reported in a poster entitled 'Robust Metabolic Improvement Observed with the Endoscopic, Duodenal-Jejunal Bypass Liner: 12 Month Data in Obese Type 2 Diabetes' noting improvements in glycaemia and weight.
GI Dynamics was unchanged at 72 cents.

PROGEN PHARMACEUTICALS

Progen says it will assign its know-how on novel heparanase inhibitor small molecules to Beta Therapeutics Pty Ltd.
Progen said that assignment allowed Beta to develop the know-how for use in the diagnosis, prevention or treatment and all pathologies and symptoms associated with type 1 and 2 diabetes as well as inflammation and auto-immune disorders.
Progen said it would receive a perpetual, irrevocable, royalty-free licence back from Beta to use the know-how in all other fields including oncology and that each party would retain ownership to any improvements made for use in any field such as developing the hits with medicinal chemistry into lead compounds for pre-clinical and clinical testing.
Progen said that the terms of the agreement were in line with industry standards but subject to commercial confidentiality.
Progen said that in 2011, it entered into a diabetes collaboration framework deed with the Australia National University and ANU Enterprise for the University to commercialize diabetes therapeutics based on ANU research conducted by Prof Chris Parish, Dr Charmaine Simeonovic and their research teams at the John Curtin School of Medical Research, with Beta established as a spin-off to drive the commercial development.
Progen said it formally collaborated with the ANU, held "a small stake" in Beta, consulted with the ANU and provided research and development services when required with Beta.
The company said that Prof Parish created PI-88 which was in a phase III clinical trial in Taiwan, South Korea and China for the adjuvant treatment of hepatocellular carcinoma after surgical resection by licensee Medigen Biotechnology Corporation.
Progen was up one cent or 4.55 percent to 23 cents.

AUSPHERIX, MEDICAL RESEARCH COMMERCIALISATION FUND

Auspherix Pty Ltd says the Medical Research Commercialisation Fund has provided $1 million in start-up funding to develop novel antibiotics for resistant bacterial disease.
Auspherix said it would in-licence intellectual property from the University of Technology Sydney-based Ithree Institute, which had been “exploring new ways to treat bacterial infections that have become resistance to currently available antibiotics … [using] a library screening approach to identify drugs with novel mechanisms of action as antibiotics”.
Auspherix said the initial investment by the Fund, which was managed by Brandon Capital, would be used for a lead optimization program to improve the antibiotic activity and bioavailability of drugs that identified through the screening program at Ithree and to establish initial safety and efficacy data in in-vivo models.
The company said it would adopt a virtual business model with research being undertaken by the Ithree founding scientists, as well as through partners in the UK.
Brandon Capital partner and Auspherix director Dr Stephen Thompson said that the Ithree approach “could help to bring a new class of anti-infectives to market”.
Auspherix said that the Ithree institute was launched in 2010 and joined the Medical Research Commercialisation Fund in 2011 and that subject to milestones, it would seek further investment or industry partnerships to move the novel antibiotics into pre-clinical and clinical development, potentially for broad spectrum use.
Auspherix is a private company.

UNILIFE CORP

Unilife says it will supply Novartis products from one of its platforms of injectable drug delivery systems for use with one of Novartis’ targeted early-stage pipeline drugs.
Unilife said it would supply Novartis with a customized delivery device, consisting of syringe, needle, tubing, controller and pump, to enable administration of a novel investigational Novartis drug into a targeted organ in clinical trials and had granted Novartis an option for exclusivity.
The company said that the agreement would generate revenue on the basis of the clinical product supplies and activities involved in clinical development, but the details were confidential.
Unilife was unchanged at 84 cents with 3.85 million shares traded.

COGSTATE

Cogstate says its wholly-owned subsidiary Axon Sports has formed a partnership with the GSK Human Performance Lab to use its cognition tests for “elite human performance”.
Cogstate said the partnership would drive research and development of its newest cognitive sports training programs including those for soccer, cricket and rugby.
The company said that the GSK Human Performance Lab was dedicated to deepening understanding of human performance across strength, stamina, hydration, metabolism, recovery and cognition.
Cogstate said the partnership had assisted explorer and athlete Richard Parks prepare for his solo, unassisted and unsupported 1,200km trek across Antarctica.
The company said Mr Parks completed cognitive assessment tests prior to leaving on the expedition in October 2013 and would use Axon tools for cognitive priming during his trip.
GSK Human Performance Lab head of research and development Ken van Someren, Head said that Axon was “a key strategic partner”.
Cogstate was up two cents or 5.4 percent to 39 cents.

BIOPROSPECT

Bioprospect has requested a trading halt “pending an announcement pertaining to its investment in a medical/biotechnology”.
Trading will resume on December 5, 2013 or on an earlier announcement.
Bioprospect was originally commercializing Termilone for termites but became entangled with Solagran’s pine needle extract for cancer and Alzheimer’s disease as a supplement for horses (BD: Sep 24, 2009).
In 2011, the company hoped to become an oil and gas drilling operation working with Frontier Gasfields (BD: Jun 2, 2011).
Bioprospect last traded at 0.3 cents.

CIRCADIAN TECHNOLOGIES

Circadian says that chief executive officer and managing director Robert Klupacs has resigned, effective from today.
Formerly the managing director of Circadian’s subsidiary Vegenics, Mr Klupacs was appointed chief executive officer-elect from December 3, 2007 and chief executive officer from March 1, 2008 (BD: Dec 3, 2007).
Circadian said that chairman Dominique Fisher would assume the role of interim executive chairman to oversee the transition of Mr Klupacs’ duties, including capital management.
The company said it continued to focus on its two subsidiary businesses Opthea Pty Ltd under the leadership of Opthea chief executive officer Dr Megan Baldwin and Ceres Oncology Pty Ltd under clinical research director Dr Ian Leitch.
Circadian said Dr Russell Howard had been appointed as a non-executive director.
The company said that Dr Howard had acted as a special advisor to the board since 2012 and was currently the executive chairman of the Sydney-based Neuclone developing bio-similar monoclonal antibody drugs.
Dr Howard’s Linkedin page said that he held Doctor of Science degrees from the University of Queensland and the University of Technology Sydney.
Circadian fell one cent or 4.35 percent to 22 cents.