Biotech Daily

Wednesday November 27, 2013

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PSIVIDA UP 12%, PRIMA DOWN 6%**

*** VICTORIA AWARDS $635k TECHNOLOGY VOUCHERS**

*** ANALYTICA 2014 LAUNCH FOR PERICOACH ANTI-INCONTINENCE TOOL**

*** CYNATA READIES FOR COMMERCIAL STEM CELL MANUFACTURE**

*** ANTISENSE ATL1103 ACROMEGALY TRIAL ON-TRACK**

*** CIRCADIAN COMPLETES PHASE Ib ENROLMENT, SAFETY REVIEW**

*** QRX, TEVA DEAL FOR MOXDUO IN ISRAEL**

*** VIRALYTICS APPOINTS PROF KEITH FLAHERTY TO SCIENTIFIC BOARD**

*** PROGEN LOSES CHAIRMAN STUART JAMES**

MARKET REPORT

The Australian stock market fell 0.45 percent on Wednesday November 27, 2013 with the S&P ASX 200 down 24.1 points to 5,332.9 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and four were untraded. All three Big Caps fell.

Psivida was the best, up 34 cents or 12.0 percent to $3.17 with 11,263 shares traded, followed by Anteo up 10 percent to 16.5 cents with 12.65 million shares traded.

Viralytics climbed 7.6 percent; Bionomics rose 6.6 percent; Living Cell was up five percent; Circadian and Tissue Therapies were up more than four percent; Antisense, QRX and Universal Biosensors were up more than three percent; Atcor, Benitec and Nanosonics rose more than two percent; Clinuvel and Compumedics were up more than one percent; with Medical Developments up 0.8 percent.

Prima led the falls, down 0.3 cents or 6.4 percent to 4.4 cents with 23.7 million shares traded.

Cellmid lost 5.6 percent; Genetic Technologies fell 4.5 percent; Admedus, Patrys and Phosphagenics were down more than three percent; Cochlear and Mesoblast shed more than two percent; Acrux, Ellex, IDT, Resmed and Sirtex were down more than one percent; with CSL, GI Dynamics, Prana and Reva down by less than one percent.

VICTORIAN GOVERNMENT

The Victorian Government says it has awarded 13 technology development vouchers each worth up to $50,000 each and totaling $635,106 as part of the $8 million program.
Victoria's Minister for Technology Gordon Rich-Phillips said companies were awarded vouchers to work with external service providers to develop new technologies and/or integrate technology into existing products or processes.
"Businesses can use their voucher to access facilities, services and expertise provided by companies and publicly-funded research organizations," Mr Rich-Phillips said.
The Victoria Government said the companies awarded vouchers included Prana Biotechnology with Industrial Research Limited to investigate scalable manufacturing; Truefield Ophthalmic Devices with Planet Innovation and the University of Melbourne to develop an ophthalmic device for the detection and management of eye diseases; Snugfit Australia with Swinburne University of Technology to design and manufacture an ergonomic support system, particularly for sleep apnoea; and Optotech with Swinburne University of Technology to develop a device for the detection of tumors.
The media release said that a directory of technology capabilities and suppliers listed more than 200 Program suppliers and businesses could apply at any time.
For further information go to: www.business.vic.gov.au/tvp.

ANALYTICA

Analytica hopes to launch its pelvic floor muscle diagnostic tool Pericoach in Australian in May 2014 and globally in October 2014.
Executive chairman Dr Michael Monsour and operations manager Geoff Daly told Biotech Daily they expected to conduct a 60-patient validation trial in January 2014, aimed at incontinence clinics in Melbourne Brisbane and Adelaide, primarily as a marketing tool.
Dr Monsour said the Pericoach had Australian Register of Therapeutic Goods approval.
Dr Monsour said that about one third of all women had incontinence issues and pelvic floor exercises could strengthen muscles, reducing incontinence.
Dr Monsour said the company was specifically targeting pre-pregnancy women between the ages of 20 and 40 years to assist in strengthening muscles prior to child-birth, when pelvic floor damage was most likely to occur.
Dr Monsour said that women undertaking fitness regimes including weight lifting also faced potential pelvic floor damage.
Mr Daly said that the company began developing the intra-vaginal Pericoach in 2007 and it had three sensors to measure muscle strength or contractility, which sent a signal to a smart-phone or wireless-enabled computer and the data was then stored in Analytica's cloud-based database.
Mr Daly said the device "directly measures the muscles that matter and can detect which muscles are being strengthened" and the data could simultaneously be sent to the patient's doctor, physiotherapist and/or incontinence nurse.
Dr Monsour said that once distribution began the company would have data that could be mined to analyze which pelvic floor programs were effective and where exercise was not relieving incontinence, the patient's doctor could explore other possible causes, including spinal issues or ovarian cancer.
"We want it used in all pre-natal classes to prevent incontinence," Dr Monsour said.
Dr Monsour said that the Pericoach would be sold like a mobile telephone contract and would cost $290 for a 12 month contract and the company hoped to have 50,000 production models manufactured in May for the Australian launch.
Analytica was unchanged at 2.7 cents with 5.8 million shares traded.

CYNATA (FORMERLY ECO QUEST)

Cynata says it hopes to resume ASX trading this week and prepare for a 2014 clinical trial to demonstrate it can create commercial quantities of high quality stem cells.
At an investor meeting hosted by stockbrokers Ord Minnett in Melbourne, Cynata chairman Dr Stewart Washer, chief executive officer Dr Ross Macdonald and company founder Prof Igor Slukvin said they aimed to begin an Australian phase I trial by the end of 2014 either in graft versus host disease or Crohn's disease, primarily to prove the safety and efficacy of the company's Cymerus technology mesenchymo-angioblast stem cells.
Dr Macdonald said that there was a need for "commercial scale stem cells" demonstrating consistency and reproducibility.
The University of Wisconsin-Madison-based Prof Slukvin said the mesenchym-oangioblast cells could be used for tissue engineering, cardiovascular disease and inflammatory disease including transplant rejection.
Prof Slukvin said there were problems obtaining pure stem cells from single donor stem cells, but the Cynata process could expand a single cell by a factor of 10^{22} times.
Prof Slukvin said that the original cells were obtained from skin or cord blood.
Dr Macdonald said the company was hoping to have a short study with a clear endpoint to demonstrate the product development was safe and working.
Dr Macdonald said the company was discussing manufacturing agreements for commercial scale manufacture.
In a slide of Cynata's proposed timeline the company said it hoped to file a US investigational new drug application and begin trials in 2016.
Dr Washer likened the stem cell manufacture and trial to a bulldozer digging a mine, not for the mine but to show that the bulldozer worked.
Dr Macdonald said the company intended to seek pharmaceutical company partnerships to market its stem cells.
Cynata last traded at a pre-consolidation 2.5 cents.

ANTISENSE THERAPEUTICS

Antisense says it has enrolled 16 of the 24 patients in its phase II trial of ATL1103 for acromegaly, with interim results expected by the end of 2013.
Antisense said that a further four patients were in "washout" of previous acromegaly medications for their potential enrolment into the trial and of the 16 patients in the trial, four had completed the three-month dosing phase as well as the two-month follow-up.
The company said the randomized, open-label, parallel group study of the safety, tolerability, pharmacokinetics and efficacy of two subcutaneous dosing regimens of ATL1103 in 24 adult patients with acromegaly was being conducted in the UK, Spain and France and to date no patients dosed with ATL1103 had withdrawn from the study nor had any serious adverse events associated with ATL1103 treatment been reported.
Antisense said that the data safety monitoring board recommended that recruitment continue and that the study proceed without modification.
The company said that ethics approval had been received for two sites in Australia.
Antisense said it expected all patients to be randomized into the trial by the end of 2013, all patients dosed by April 2014 with the results by July 2014.
Antisense said it expected to report an interim analysis assessing the percentage change from each patient's baseline serum insulin-like growth factor-I (IGF-I) levels to their levels after the completion of dosing with ATL1103, as acromegaly patients had elevated serum IGF-I levels compared to the normal population.
Antisense was up 0.5 cents or 3.2 percent to 16 cents.

CIRCADIAN TECHNOLOGIES

Circadian says it has completed enrolment and the 28-day safety review in its 24 patient phase Ib combination VGX-100 and bevacizumab solid tumor trial.

Circadian said the trial, through its subsidiary Ceres Oncology, showed that VGX-100 and bevacizumab, marketed as Avastin, was safe and well tolerated and along with phase Ia trial data of single agent VGX-100 supported progressing VGX-100 to phase II clinical studies as a combination therapy with bevacizumab for patients with relapsed brain tumors known as recurrent glioblastoma multiforme, expected to begin in mid-2014.

Circadian said a phase II trial in patients with breast cancer related lymphoedema was expected to begin by April 2014.

Royal Melbourne Hospital oncologist and the phase I trial medical monitor Dr Jayesh Desai said it was “encouraging that VGX-100 has shown an excellent safety profile when used in combination with Avastin and further phase II clinical investigation is warranted in patients with solid tumors”.

Circadian said VGX-100 was a monoclonal antibody that inhibited vascular endothelial growth factor C (VEGF-C), a member of the VEGF family of secreted glycoproteins, mediators of tumor related angiogenesis, lymphangiogenesis and vascular permeability.

The company said that the phase Ib trial was conducted at two US sites as a dose escalation study of VGX-100 alone or in combination with bevacizimab.

The trial enrolled 43 patients with advanced or metastatic solid tumors with19 patients receiving weekly intravenous administration of VGX-100 at doses ranging from 1mg/kg to 30mg/kg and a further 24 patients receiving weekly dosing of VGX-100 from 2.5mg/kg to 20mg/kg in combination with bevacizumab 5mg/kg or 10 mg/kg every two weeks.

Circadian said the primary objective was to establish the safety profile of VGX-100 while secondary objectives include determination of anti-tumor activity, biomarker levels and pharmacokinetics of VGX-100 alone and in combination with bevacizumab.

The company said that VGX-100 was safe and well tolerated by all 43 patients.

Circadian said that preliminary results showed that the VGX-100 pharmacokinetic parameters increased linearly with the dose, the half-life was consistent with once weekly dosing and the profile was similar with and without co-administration of bevacizumab.

The company said VGX-100 achieved blood concentrations expected to inhibit circulating VEGF-C and support further development for the treatment of solid tumors including recurrent glioblastoma multiforme as well as breast cancer-related lymphoedema.

Circadian was up one cent or 4.3 percent to 24.5 cents.

QRX PHARMA

QRX says it a licence agreement with Teva Pharmaceutical Industries to commercialize immediate release Moxduo in Israel.

QRX said Teva would receive exclusive rights to commercialize immediate release Moxduo in Israel and assume responsibility for all regulatory and product launch costs as well as ongoing marketing and sales efforts and QRX would receive an undisclosed up-front payment, regulatory and sales milestones and double-digit royalties on the sales, and retain rights to intravenous and controlled release formulations.

“Teva’s interest in Moxduo, together with that of Actavis, Paladin and Aspen, validate the need for safer opioids in the treatment of moderate to severe pain, and further endorse the commercial value of Moxduo,” Dr Holaday said.

QRX said it would work with Teva to submit a marketing authorization application to the Israeli health authority following approval in the US or Europe.

QRX was up two cents or 3.3 percent to 62 cents.

VIRALYTICS

Viralytics says it has appointed Prof Keith Flaherty to its scientific advisory board.
Viralytics said that Prof Flaherty was the director of the Henri and Belinda Termeer Center for Targeted Therapies at the Massachusetts General Hospital Cancer Center and a professor of medicine at Harvard Medical School.
The company said that Prof Flaherty's research focussed on melanoma with a particular expertise in targeted therapies and he had been the principal investigator "for numerous human clinical trials with a focus on novel, targeted drugs for metastatic melanoma patients".
Viralytics said that Prof Flaherty held a Bachelor of Science from Yale University and Doctorate of Medicine from Johns Hopkins University.
Viralytics was up 2.5 cents or 7.6 percent to 35.5 cents.

PROGEN PHARMACEUTICALS

Progen says that non-executive chairman Stuart James who was due to retire by rotation at tomorrow's annual general meeting will not stand for re-election.
Progen said that Mr James' decision was "due to other commitments".
The company said it would seek a replacement director and appoint a chairperson.
Progen fell one cent or five percent to 19 cents.

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