Biotech Daily

Thursday November 22, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH FLAT: NEUREN UP 18%, PATRYS DOWN 8%**

*** MINISTER ASHER AWARDS $50k VICTORIA PRIZES, $18k FELLOWSHIPS**

*** LIVING CELL PHASE I/IIa DIABECELL EFFICACY, PHASE IIb TRIAL BEGINS**

*** NEUREN PHASE I SHOWS ORAL NNZ-2566 SAFE, RETT SYNDROME IND**

*** ALCHEMIA EARNS $1.4m FROM FONDAPARINUX, SALES UP 30%**

*** PHYLOGICA UPGRADES PHYLOMER LIBRARY '47-FOLD'**

*** UNIVERSAL BIOSENSORS REQUESTS CAPITAL RAISING TRADING HALT**

*** VIRALYTICS 36.5% AGM DISSENT AT DIRECTORS FEES POOL HIKE**

*** STARPHARMA EXPECTS $6m R&D TAX PAYMENT**

*** AGENIX EGM TO LICENCE TYRIAN ASSETS, ISSUE FORTREND SHARES**

*** ALCHEMIA TO LOSE CHAIRMAN DR MEL BRIDGES IN 2013**

*** SMALL TECHNOLOGIES CLUSTER BBQ ON VICTORIA'S IMPACT**

MARKET REPORT

The Australian stock market climbed 1.0 percent on Thursday November 22, 2012 with the S&P ASX 200 up 43.6 points to 4,413.1 points. Eight of the Biotech Daily Top 40 stocks were up, 10 fell, 15 traded unchanged and seven were untraded. All Big Caps rose.

Neuren was the best, up 0.6 cents or 18.2 percent to 3.9 cents with 10.1 million shares traded, followed by Psivida up 15.4 percent to $1.50, with 2,325 shares traded and Avita up 12.5 percent to 13.5 cents, with 876,618 shares traded. Phylogica climbed 4.8 percent; Acrux and Mesoblast were up more three percent; Cochlear, QRX and Resmed were up more than one percent; with Clinuvel and CSL up by less than one percent.

Patrys led the falls, down 0.3 cents or 7.9 percent to 3.5 cents with 2.8 million shares traded. Benitec and Heartware lost more than six percent; Prima was down 3.85 percent; Ellex shed 2.3 percent; Anteo and Tissue Therapies were down more than one percent; with Alchemia, Pharmaxis and Sirtex down by less than one percent.

VICTORIA PRIZE FOR SCIENCE AND INNOVATION

Minister for Innovation, Services and Small Business Louise Asher says Walter and Eliza Hall Institute Prof Terence Speed and Monash Water Prof Ana Deletic have won the 2012 Victoria Prize for Science and Innovation.

A Victoria Government media release said that Prof Deletic was the first woman scientist to be awarded the Prize in its 14 year history.

The media release said that Prof Deletic won her $50,000 Victoria Prize for Science and Innovation in Physical sciences for work on storm-water management

The Victorian Government said that Prof Speed received the $50,000 Victoria Prize for Science and Innovation in Life Sciences “for his dedication to helping increase understanding of infectious disease, the immune system, heritable human diseases and cancer”.

The media release said that Prof Speed and his team developed methods of analysis, now in daily use in research laboratories, underpinning many of the recent advances in medical research.

The media release said that Prof Speed’s work, described as a shield against bad science, helped to identify areas of the human genome that contribute to cancer, genes that are vital for embryonic development and pinpointing malaria proteins responsible for initiating infection in human red blood cells.

Ms Asher said the Victorian Government was committed to supporting science and innovation and had awarded two $50,000 Victoria Prizes this year instead of one, as well as increasing the number of $18,000 Victoria Fellowships from six to 12.

“The Coalition Government has invested $1.7 million in Victoria’s innovation researchers since 2011, and has committed to treble this investment over the next three years to $4.8 million,” Ms Asher said.

“We firmly believe that supporting research in Victoria is vital to our state continuing to lead Australia and the world in medical and scientific research,” Ms Asher said.

“It is important to provide opportunities for our scientists working here in Victoria’s leading research institutions, rather than seeing them leave for overseas never to return, so they can foster the next generation of Victorian scientists,” Ms Asher said.

“The 12 recipients of the Victoria Fellowship are all early-career researchers and innovators who will receive $18,000 to enhance their career with international study missions and return to Victoria to apply their new skills to an Australian company or research organization and hopefully emulate the success of Professors Deletic and Speed as they progress their careers,” Ms Asher said.

Fellowships winners included David Ascher for a cancer drug development program targeting cellular proteins which appear to be able to overcome drug resistance; Emma Burrows to study touchscreen technology to assist in human brain disorders such as dementia, autism spectrum disorders and schizophrenia; Dr Peter de Cruz to further his work in intestinal failure in order to establish Australia’s first intestinal failure and transplant service and Dr Dion Stub to research cardiac emergency care and treatment strategies.

Non-biomedical winners included Dr Everson Kandare, Dr Rachel Kilmister, Dr Colin Scholes and Dr Sharath Sriram, Nicholas Tobias Dr Hai L Vu, Dr William Gee and Dr Mohsen Kalantari.

LIVING CELL TECHNOLOGIES

Living Cell says an interim analysis of its Argentinian phase I/IIa trial of Diabecell for unstable type 1 diabetes show significant efficacy and a phase IIb trial has begun.

Living Cell said the eight-patient trial of the encapsulated porcine islets of Langerhans showed reductions in blood glucose level measured by HbA1c, insulin dose and unaware hypoglycaemia, with greater benefit shown in the patient group receiving the higher of two doses.

The company said that the ongoing trial split the patients into two groups of four, one receiving two 5,000 IEQ/kg doses of Diabecell (islet equivalents per kilogram of body weight) and the other receiving two 10,000 IEQ/kg doses.

Living Cell said that the second dose was implanted 12 weeks after the first.

The company said that at the time of the interim analysis, group one patients were at 24 weeks follow-up after the second transplant, and group two patients were at 12 weeks follow-up after the second transplant.

Living Cell said that in the second group of patients, those receiving the higher dose of two implants of 10,000 IEQ/kg, the most significant clinical benefits were and average insulin dose reduced by 20 percent; a reduction of HbA1c from a pre-transplant average of 8.6 percent to an average of 6.7 percent at 12 weeks following the second implant and an up to 70 percent reduction in unaware hypoglycaemic events.

Living Cell founder and chief scientific and medical officer Prof Bob Elliott said that “most type 1 diabetic patients who cannot attain reasonable control of their disease by conventional intensive insulin treatment would welcome the degree of control achieved with two doses of Diabecell”.

“The reduction in both average daily insulin dose and HbA1c is clear demonstration of the positive effect of the Diabecell transplant,” Prof Elliott said.

Living Cell said that Diabecell was the first islet transplant treatment that did not require ongoing administration of immuno-suppression drugs.

The company said that Diabecell was owned by the joint venture company Diatranz Otsuka, in which it and Otsuka Pharmaceutical Factory both had a 50 percent interest.

Living Cell chief executive officer Dr Andrea Grant said the interim analysis would “inform our 20 patient phase IIb study, the start of which has also been announced today”.

“With each trial analysis we grow increasingly confident that Diabecell will bring many benefits to patients with unstable type 1 diabetes and we remain intently focused on reaching the market by 2016,” Living Cell said.

In a separate announcement Living Cell said it had begun patient recruitment in Argentina for a 20-patient phase IIb trial of Diabecell.

The company said that the trial was designed to demonstrate the clinical benefits of Diabecell in unstable type 1 diabetes and 20 patients would receive two implants of 10,000 IEQ/kg, with the second implant occurring 12 weeks after the first.

Living Cell said that principal investigator of the phase IIb trial was Dr Adrián Abalovich of Hospital Eva Perón in San Martin, Buenos Aires.

“We are using an adaptive trial design for our pivotal studies and so the data generated in this 20 patient trial will likely form the foundation data for our registration package,” Dr Grant said.

“We remain on track to meet our goal of completing clinical trials of Diabecell by 2015 and having a product commercially available by 2016,” Dr Grant said.

Living Cell was unchanged at five cents.

NEUREN PHARMACEUTICALS

Neuren says it has completed a phase I safety study of oral NNZ-2566 and applied to the US Food and Drug Administration for a phase II trial of the drug for Rett syndrome.
Neuren said the study was successful and the oral solution of NNZ-2566 appeared to be safe and well-tolerated when administered at the highest dose in the phase I trial of 100 mg/kg twice daily for five days.
The company said that the availability of an oral formulation opened the way for a number of studies in autism spectrum and neuro-developmental disorders and brain injury.
Neuren said the first trial would be a safety and efficacy study of NNZ-2566 in adolescents and adults with Rett Syndrome, with patient screening and enrolment beginning following investigational new drug application approval by the FDA and approval by the clinical study site institutional review board.
Neuren said that the lead phase II study site would be the Blue Bird Circle Rett Center at Texas Children's Hospital and the Baylor College of Medicine, led by director Dr Daniel Glaze and assistant director Dr Jeffrey Neul.
The company said that part of the cost of the phase II trial in Rett syndrome patients was being underwritten by a grant from the International Rett Syndrome Foundation to Baylor.
The company said that once the application for NNZ-2566 in Rett Syndrome was open, expected within 30 days, it would support additional studies of the oral solution in other autism spectrum and neuro-developmental disorders.
Neuren said it planned to begin a phase II trial in paediatric patients with Rett syndrome in 2013 and was planning studies in additional disorders.
The company said that the completed phase I study of oral NNZ-2566 supported the initiation of the phase II study in concussion for which there already was an open investigational new drug application in place.
Neuren said that the concussion study was part of the clinical studies program supported by the US Army and will make NNZ-2566 the only proprietary drug in development for all traumatic brain injury patients irrespective of the severity of the injury.
The company said that concussion or mild traumatic brain injury was a significant problem in both civilian and military populations, including athletes.
Neuren was up 0.6 cents or 18.2 percent to 3.9 cents with 10.1 million shares traded.

ALCHEMIA

Alchemia says it will receive $US1.5 million ($A1.44 million) for generic fondaparinux sales, with net sales up 30 percent to $US12 million.
Alchemia said its share of the profits from fondaparinux sales for the three months to September 30, 2012 from marketing partner Dr Reddy's Laboratories was $US2.0 million, but this was reduced to $US1.5 million after the contribution of $US500,000 by Alchemia to activities to improve yields and cost of goods.
Alchemia said that the average market share in the retail segment for the three months to September 30, 2012 was 41 percent with a six percent share in the hospital or institution segment, compared with 39 percent and three percent, respectively, for the three months to June 30, 2012.
Alchemia chief executive officer Dr Pete Smith said the "full benefit of our joint investment in process improvement, which has resulted in significant reductions in the cost of active pharmaceutical ingredient, will start to be realized from the December quarter onwards".
Alchemia fell half a cent or 0.85 percent to 58 cents.

PHYLOGICA

Phylogica says it has completed “a major upgrade to its proprietary Phylomer libraries of peptides derived from bio-diverse bacterial genomes”.
Phylogica said the improvements should enable the discovery of higher quality peptide drug candidates with enhanced drug-like characteristics, which could shorten the timelines for lead optimization.
In a media release Phylogica said that initial results showed that the new Phylomer libraries were 47-fold larger than the former versions completed in 2009, containing more than 126 billion unique peptide sequences in aggregate.
The company said that the upgraded libraries comprised a broader range of natural biological molecules, capturing more structures from the evolutionary diversity encoded by each respective genome.
Phylogica said the libraries were being integrated with a comprehensive upgrade to the discovery platform, incorporating automated processes to enhance the efficiency and scalability of screening.
Phylogica chief executive officer Dr Paul Watt said that the next generation libraries were “a clear advancement in the field” of peptide drug discovery.
“The new libraries are now an integral part of our peptide drug discovery platform and are expected to further enhance the level of interest from prospective [pharmaceutical company] partners,” Dr Watt said.
Phylogica was up 0.1 cents or 4.8 percent to 2.2 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors has requested a trading halt “pending an announcement in relation to a capital raising”.
In its Appendix 4C statement for the three months to September 30, 2012, Universal Biosensors said that it had $13,935,110 in cash with a three month cash burn of $421,482.
Trading will resume on November 26, 2012 or on an earlier announcement.
Universal Biosensors last traded at $1.01.

VIRALYTICS

Viralytics annual general meeting saw significant dissent against increasing the directors feel pool by 42.9 percent from $350,000 a year to $500,000 a year.
Viralytics said that 2,770,625 proxy votes (36.5%) opposed the resolution with 4,814,387 proxy votes (63.5%) in favor.
Resolutions to issue 200,000 options to director Dr Leonard Post and the re-election of director Dr Post, were passed by wider margins.
The remuneration report was passed with 1,444,698 proxy votes (15.5%) opposed and 7,849,688 proxy votes (84.5%) in favor
The company’s most recent Appendix 3B said that Viralytics had 75,212,123 shares on issue meaning that the votes against the increased directors fee pool amounted to 3.7 percent of the company, not sufficient to requisition extraordinary general meetings.
Viralytics was untraded at 36 cents.

STARPHARMA

Starpharma says the Federal Government's Ausindustry has approved a research and development tax rebate of about $6 million for overseas activities.

Starpharma said it made the submission for an advance finding in relation to Vivagel activities in June 2012, and Ausindustry responded today that its offshore activities satisfied 45 percent Research and Development Tax Incentive Program criteria.

The company said the submission supported the Vivagel bacterial vaginosis program and the finding covered certain overseas activities over a three-year period from July 1, 2011.

Starpharma said that about $3.3 million of the total $6 million cash refund related to the 2011-'12 financial year and that in addition to the cash refund for eligible overseas expenditure, it expected a further $2.0 million of research and development tax incentive from eligible Australian activities and expenditure.

Starpharma said it was expected that following the submission of its 2011-'12 tax return, a $5.3 million cash refund would be received in the current financial year, whereas the 2012 annual report estimated a tax incentive of $1.3 million for the 2011-'12 financial year.

Starpharma chief executive officer Dr Jackie Fairley said that "we all agree on the critical importance of innovation to the growth and diversification of the Australian economy".

"This cash refund program is an excellent example of how Government initiatives can support the development of successful companies like Starpharma in innovation based sectors such as biotechnology," Dr Fairley said.

The Research and Development Incentive Program is jointly administered by Ausindustry and the Australian Taxation Office.

Starpharma was unchanged at $1.57.

AGENIX

Agenix says shareholders will vote to approve the issue of 10,000,000 shares to Tyrian Diagnostics and up to 60,000,000 shares to Fortrend Securities.

In October, Agenix said it would licence Tyrian's rapid point-of-care human diagnostic technology for $500,000 in shares to be paid over two years (BD: Oct 25, 2012).

Both the ratification of a prior issue to Fortrend and permission to issue shares to Fortrend relate to the potential use of draw down equity facilities.

The meeting will be held at the BDO Melbourne Ballroom, Level 14, 140 William Street, Melbourne, on December 20, 2012 at 10am (AEDT).

Agenix was up 0.1 cents or 2.3 percent to 4.4 cents.

ALCHEMIA

Alchemia says chairman Dr Mel Bridges will retire as both chairman and a director in 2013.

Dr Bridges told the Alchemia annual general meeting that he intended to retire in the approach to the end of the financial year.

Alchemia quoted Dr Bridges saying that with the approval of fondaparinux and the subsequent launch in the US, coupled with the demerger of its oncology assets, Audeo Oncology, and intended US listing, the time was right for a new chairman.

Alchemia said that the transition would be orderly and professionally managed.

Director and founding chief executive officer Dr Tracie Ramsdale thanked Dr Bridges "for his outstanding contribution and leadership … over the past nine years".

"We especially appreciate his decision to remain until after the successful completion of the proposed Audeo Oncology Nasdaq listing," Dr Ramsdale said.

SMALL TECHNOLOGIES CLUSTER

The Small Technologies Cluster says it will host a December 6, 2012 barbecue discussing Victorian Government support for small technologies.

The Small Technologies Cluster general manager Dr Buzz Palmer told Biotech Daily that the Cluster was an independent Victoria-based technology hub administering the Technology Voucher Program and the afternoon would feature presentations from three past Small Technology Industry Uptake Program (STIUP) on how the State Government's program helped them to absorb new technologies into their products, processes and services and improve their business.

Dr Palmer said that the afternoon program would include a panel chaired by Minifab chief executive officer Erol Harvey with the Department of Business and Innovation Science and Technology Programs executive director Amanda Caples

University of Melbourne Engineering professor Prof Robin Batterham, Small Technologies Cluster director Clive Davenport and Monash University pro-vice-chancellor of research and research infrastructure Ian Smith.

The afternoon will hear a presentation from Arrayware's Paul Savage on a robotically steerable micro-guidewire for surgeons to use in coronary angioplasties, as well as presentations on automotive technologies and surveillance systems

The Small Technologies Cluster said the Victorian Government launched the Technology Voucher Program in September after the success of the Small Technology Industry Uptake Program.

The Cluster said that the presentations would be held between 3pm and4pm, with the barbecue at 4pm on December 6, 2012 at STC, 1 Dalmore Drive, Caribbean Business Park, Scoresby, 3103.

The Cluster said the event was free, but registration is necessary

To register, email: nicole@stc-melbourne.com by November 23, 2012.