

Biotech Daily

Tuesday May 5, 2015

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH EVEN: BIOTRON UP 8%, COMPUMEDICS DOWN 10%
- * VICTORIA BUDGET: BIOTECH SHARES \$200m FUTURE FUND, MORE
- * DRAWBRIDGE: 'EDITORIALS BACK RATIONALE FOR PHAXAN'
- * CLINUVEL ADDS VLRX001 FOR VITILIGO TO PIPELINE
- * NOMINATIONS OPEN FOR GSK \$80k RESEARCH AWARD
- * AMPLIPHI APPOINTS SCOTT SALKA CEO

MARKET REPORT

The Australian stock market was down just 0.02 percent on Tuesday May 5, 2015 with the S&P ASX 200 slipping one point to 5,826.5 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and one was untraded.

Biotron was the best, up one cent or 8.3 percent to 13 cents with 79,934 shares traded.

Atcor climbed 7.1 percent; Acrux, Oncosil and Starpharma were up four percent or more; Ellex and Medical Developments were up more than three percent; Clinuvel, Neuren and Pharmaxis rose more than two percent; Actinogen, Avita, Bionomics and Tissue Therapies were up more than one percent; with CSL, Impedimed, Nanosonics and Resmed up less than one percent.

Compumedics led the falls, down 2.5 cents or 10.4 percent to 21.5 cents with 143,000 shares traded.

Antisense lost 9.1 percent; GI Dynamics fell 7.4 percent; Analytica and Optiscan were down more than five percent; Admedus, Cellmid and Osprey fell four percent or more; Benitec was down 3.5 percent; Genetic Technologies shed 2.5 percent; IDT and Viralytics were down more than one percent; with Cochlear, Mesoblast, Psivida and Sirtex down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says its first Budget includes \$200 million for a Future Industries Fund investing in six sectors including medical technology and pharmaceuticals.

Victoria Treasurer Tim Pallas said "the Future Industries Fund, and it will offer grants of up to \$1 million to firms working in [the] six different sectors".

"Each of these sectors are primed for extraordinary growth," Mr Pallas said. "And the Future Industries Fund will help them lead the world."

"A \$60 million initiative for start-ups will take our most promising concepts from mind to market ... and \$12 million for a program of inbound trade missions will bring overseas investors to our soil," Mr Pallas said.

"Businesses can earn stamp duty relief if they invest in new equipment ... and they can also earn payroll tax relief if they hire retrenched workers, unemployed young people or the long-term jobless," Mr Pallas said.

Neither "innovation" not "biotechnology" featured in the Budget speech, but the Budget papers said the Government would provide \$60 million to Aikenhead biomedical engineering "funding Australia's first research and education centre for biomedical engineering [where] doctors, scientists and researchers will work together to translate medical research into life changing cures and technology."

"The Aikenhead Centre for Medical Discovery will focus on chronic conditions, such as cardiovascular disease, arthritis, cancer and diabetes, and new technology including robotic hands, heart tissue engineering and spinal cord repair," the Budget Papers said. "The project is planned to be delivered in partnership with the Commonwealth and [Melbourne's] St Vincent's Health," the Government said, but the commitment was "contingent on the Commonwealth matching funding for the project".

The Budget papers said that \$1.38 billion would be provided in extra funding for the hospitals, ambulances and health programs; \$560 million would be allocated to new hospitals and equipment; and \$200 million would go to new hospital beds and points of care and enable hospitals to admit more than 19,800 extra patients every year. In a media release from the Minister for Industry Lily D'Ambrosio, the Government said the Future Industries Fund would "play an active role in working with business experts and workers to grow our traditional industries and invest in emerging sectors" with the six high-growth sectors nominated as medical technology and pharmaceuticals; new energy technology; food and fibre; transport, defence and construction technology; international education; and professional services.

The Government said the Future Industries Fund would include a \$20 million New Energy Fund to "change Victoria's energy mix and ensure we are investing in jobs for the future". The Government said it would take advice from a Ministerial Advisory Council led by former Premier of Tasmania David Bartlett and including Swinburne University of Technology vice-chancellor Prof Linda Kristjanson, Penguin Random House chief executive officer Gabrielle Coyne, Australian Super director Nixon Apple and the Victorian Government lead scientist Dr Leonie Walsh.

In a media release from the Minister for Health Jill Hennessey, the Government said it was "investing in medical research and cutting-edge treatments to help better diagnose and treat disease and increase clinical trials".

"World-class medical research institutes, teaching hospitals and universities in Victoria will work together to develop a state-wide genomic sequencing capability thanks to a \$25 million investment in genomic testing," the State Government said.

"This will help health professionals to more quickly diagnose and treat a range of rare medical conditions and illnesses such as inherited neuropathies, epilepsy, leukaemia, cancers and childhood diseases," the media release said.

DRAWBRIDGE PHARMACEUTICALS

Drawbridge says it welcomes two editorials in the US journal Anesthesia and Analgesia calling for an alternative to the anaesthetic propofol.

Drawbridge chief executive officer Dr Anthony Filippis told Biotech Daily that along with the previously published safety and efficacy shown in its 24-patient phase I dose-ranging trial of its anaesthetic Phaxan, pre-clinical data had been published (BD: Apr 16, 2014). Dr Filippis said that Phaxan or alphaxalone dissolved in sulfobutyl ether beta cyclodextrin was an effective fast-onset short acting intravenous anaesthetic equal to propofol, with a greater safety profile than propofol and causing less depression of blood pressure and respiratory control compared with propofol (BD: Dec 16, 2013).

Dr Filippis said that Phaxan solved the problems of the previous formulation of alphaxalone formulated in Cremophor and marketed as Althesin, which was withdrawn because of hypersensitivity reactions to the cremophor.

He said that the Cremophor vehicle for the alphaxalone anaesthetic resulted in rashes and injection site pain.

Dr Filippis said that at the same time the existing gold standard for intravenous anaesthetic propofol had been associated with respiratory and cardiac depression. Dr Filippis said that the phase I trial results would be published "ahead of print in the next few weeks" and confirmed the preclinical results showing that Phaxan was as fast as propofol in onset and offset of intravenous anaesthesia with improved cardiovascular and respiratory safety.

"Ever since the analysis of the results of our survey of anaesthetists' opinions of the need for a new and safer alternative to propofol, we have been confident that Phaxan would fulfil this role," Dr Filippis said.

"Publication of the two seminal papers that signify the translation of Phaxan from concept to clinic, endorses our goals of continued commercial development of Phaxan towards widespread use in all critical care areas," Dr Filippis said.

Drawbridge said that the first editorial, entitled 'Another Steroid Hypnotic: More of the Same or Something Different?' by Prof Michael Hollmann and Prof John Sear concluded that "many anaesthesiologists in Europe and Australasia lamented the passing of Althesin ... in the interim, propofol supplanted the other [intra-venous] hypnotics and has been uniformly adopted as the [intra-venous] hypnotic of choice worldwide".

"We await further animal and human studies before seeing if a reformulated alfaxalone has a potential role in the future of anesthesia," Prof Hollmann and Prof Sear concluded. Drawbridge said that the second editorial, entitled 'Steroid Anesthesia Revisited: Again' by Prof Hollmann and Prof Evan Kharasch said that "the major problem was the formulation of these highly lipid soluble (and hence water-insoluble) compounds for [intra-venous] administration."

"Nevertheless, neurosteroids possess many characteristics of the ideal anesthetic ... [and] the search for an ideal anesthetic continues," Prof Hollmann and Prof Kharasch concluded.

"It appears that alphaxalone-cyclodextrin may be a better alphaxalone than alphaxalone-Cremophor," the editorial said.

"The more interesting question is whether alphaxalone-cyclodextrin [Phaxan] will be a better anesthetic than propofol," the editorial concluded.

"Drawbridge hopes to go straight to a phase III trial of Phaxan by the end of 2015, Dr Filippis said.

Drawbridge is a private company.

CLINUVEL PHARMACEUTICALS

Clinuvel says its Singapore subsidiary Vallaurix Pte Ltd has completed initial in-vitro development of VLRX001, a melanocortin analogue.

Clinuvel said that VLRX001 joined its product pipeline of CUV9900 and Scenesse or afamelanotide 16mg, which was recently granted marketing authorization by the European Commission for the rare disease erythropoietic protoporphyria.

The company said that VLRX001 was being developed for topical self-administration by patients as a transdermal adjuvant maintenance therapy for the depigmentation disorder vitiligo.

Clinuvel said that Scenesse was currently being evaluated as a subcutaneous medicinal product for repigmentation in vitiligo patients.

The company said that melanocortins had "a ubiquitous application in medicine" and a demand for novel melanocortin molecules had been seen in clinical research, with more than 400 peer reviewed publications on the use of melanocortins over the past 24 months. Clinuvel said that patent applications on VLRX001 had been filed in the commercially relevant jurisdictions and it would hold all rights to the final product and indications through its majority holding in Vallaurix.

The company said that formulation work would commence this year and VLRX001 was the second novel molecule to be evaluated by Vallaurix, following CUV9900, which was developed as the first reference standard for evaluating pharmacological properties such as binding affinity, potency and cellular signalling.

Clinuvel said that VLRX001 was an addition to the family of melanocortin analogues which provoked increased and prolonged cellular activity and contained a specific peptide sequence, designed to make it less susceptible to degradation than physiologic or natural alpha-melanocyte stimulating hormone.

Clinuvel was up six cents or 2.1 percent to \$2.96.

GLAXOSMITHKLINE

Glaxosmithkline says that nominations are open for its \$80,000 Award for Research Excellence and close on July 3, 2015.

A media release from Glaxosmithkline said that the award "acknowledges outstanding Australian researchers and their work".

The company said that biological chemist Prof David Craik won last year's award.

Prof Craik said that says winning the award gave his team a boost not only in funding but in morale.

"Winning the [Award for Research Excellence] in 2014 provided the funding to help us undertake our all-important blue sky research," Prof Craik said.

"It was also a great recognition of the team's efforts," Prof Craik said.

Glaxosmithkline medical director Dr Andrew Weekes said his company looked forward to the opportunity "to help support the next important Australian medical research development".

The company said that successful applicants were generally mid-career researchers with a long-standing commitment to their field.

Glaxosmithkline said that the winner would be announced on November 18, 2015.

Further information is available on the Glaxosmithkline website.

AMPLIPHI BIOSCIENCES CORP

Ampliphi says that Scott Salka has been appointed chief executive officer replacing interim chief executive officer Jeremy Curnock Cook, from May 18, 2015.

Ampliphi said that Mr Curnock Cook would continue as chairman.

Mr Curnock Cook said that Mr Salka had "experience in building biotech companies with a focus on technology development and discovery [and he] will accelerate the progress of our bacteriophage candidates towards the clinic".

The company said that Mr Salka had been the chief executive officer of Aspyrian Therapeutics since 2010 and previously was the chief executive officer Ambit Biosciences. Ampliphi said that Mr Salka would be based in San Diego, California, where he was currently a board member and professor of entrepreneurship at San Diego State University College of Business Administration and would continue as a director of Aspyrian.

The company said that Mr Salka held a degree in finance from San Diego State University and a Masters of Business Administration from Carnegie Mellon University. Ampliphi has offices in Sydney, is listed on the Nasdaq over-the-counter market, and said it was advancing three pre-clinical programs in methicillin-resistant Staphylococcus aureus, Pseudomonas aeruginosa infections in cystic fibrosis and Clostridium difficile. Last night on the Nasdaq, Ampliphi fell 1.1 US cents or 4.9 percent to 21.5 US cents.