Biotech Daily

SPECIAL SUMMER CATCH UP EDITION

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*** NEUREN'S PHASE III GLYPROMATE TRIAL FAILS**

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*** SHANE HICKEY RETRENCHED FROM BIO-MELBOURNE NETWORK**

The following articles appear in date order

ITL

ITL announced on December 23, 2009 that Brian Andrews would be appointed chief executive officer, from January 5, 2009.
ITL said Mr Andrews had more than 20 years experience with medical devices and had marketed a broad range of technologies from in vitro diagnostics to high technology endo-surgical devices used in a range of minimally invasive surgical procedures.
Mr Andrews was formerly the managing director of Sun Biomedical.
ITL manufactures medical devices, procedure packs and medical equipment.

NEUREN

Neuren announced on December 24, 2008 that lead product Glypromate equaled placebo in its phase III trial for neuro-protection in cardiac surgery.
Neuren said that in the pivotal clinical trial of Glypromate to reduce cognitive impairment in cardiopulmonary bypass surgery patients "Glypromate had no observable effect".
In contrast to the incidence of deficits reported in the published literature, among the 325 patients who completed the study, only a small proportion (about 20 percent) evidenced any degree of cognitive decline at 12 weeks and, among those with decline, the average change was small.
About 80 percent of patients in both the placebo and Glypromate groups showed improvement in cognitive function.
Neuren said "there was no evidence of impairment in ability to perform activities of daily living in either group at baseline or 12 weeks".
No significant difference was noted between patients receiving the active drug and those receiving placebo on either change in composite cognitive score or activities of daily living from baseline to 12 weeks.
Neuren's chief medical officer Dr Douglas Wilson said the company was "very disappointed with the outcome of the trial" but at the centres where the study was conducted, the surgery had little negative impact on cognition and activities of daily living, in contrast to most reports in the literature.
"To the contrary, our data suggest that these types of cardiac surgery result in improved cognitive function although the study does not shed any light on the factors that may be responsible for this observation," Dr Wilson said.
He said the data was similar to August 2008 findings from Allon Therapeutics, which reported no significant cognitive impairment in 234 coronary artery bypass graft patients.
"These discouraging results for Neuren may, in fact, be good news for patients," he said.
Neuren chief executive officer Larry Glass said the company would "discontinue development of Glypromate, focusing its efforts on the other molecules in its pipeline".
Mr Glass said Neuren had "an extremely promising portfolio of highly differentiated compounds addressing unmet needs in neurology, psychiatry and oncology and we will now be turning our full attention to developing these assets".

LIVING CELL TECHNOLOGIES

Living Cell announced on December 29, 2008 that to reduce costs, Dr Paul Tan would return as chief executive officer replacing Dr Robert Caspari.
Dr Caspari was appointed CEO on July 29, 2008 and remains a director.
Living Cell chairman Simon O'Loughlin said the company would focus on its New Zealand and Russian trials "rather than expand its operations internationally".

STEM CELL SCIENCES

Stem Cell said on December 29, 2008 that it had received a £200,000 ($A441,000) secured loan for working capital purposes.
The company said the third party lender was granted a period of exclusivity to conduct further due diligence of its business and assets.
Stem Cell said it was not in discussions with any third parties that might lead to a potential offer and was "no longer in an offer period under the rules of the United Kingdom Takeover Code". The company is suspended from trading on London's AIM and the ASX.
Stem Cell also announced on the same day that "pioneering research describing a technique for creating authentic embryonic stem cells from rats" was published in the peer-reviewed journal, 'Cell' (Buehr et al., 'Capture of Authentic Embryonic Stem Cells from Rat Blastocysts', 2008.12.007)
The company said the publication was "believed to be the first in which germ-line transmission from rat [embryonic stem] cells has been definitively demonstrated" using technology licensed from the University of Edinburgh and developed by Prof Austin Smith at Cambridge University.
Stem Cell said the technique was expected "to allow the generation of consistently pure and stable rat [embryonic stem] cells, from which drug discovery assays as well as genetically modified animals can be created for academic, medical and pharmaceutical research".

VIRALYTICS

Viralytics said on December 31, 2008 that it raised $720,000 through the allotment of 18 million shares to shareholders.
The additional capital will be used to fund the ongoing clinical evaluation of the lead product Cavatak, which is in phase I trials.

IMUGENE

Imugene said on December 31, 2008 that the UK-based Merial would develop vaccine candidates from its portfolio through to commercial sales.
The Company said the contract was worth more than $30 million over the first seven years with additional revenue from sublicence and registration milestone fees for additional vaccine candidates, as well as royalties from sales.
Imugene has received an initial payment of $US2 million ($A2.9 million) for reimbursement of past research fees.

VENTRACOR

Ventracor told the ASX on January 2, 2009 that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose from 4.9 cents on December 30, 2008 to 7.1 cents on December 31, 2008, along with an increase in trading volume.
Ventracor said it was "seeking expressions of interest from parties wishing to acquire the company or take a strategic stake" to provide further capital.
The company said expressions of interest were "not due to be received for several weeks". Ventracor said it has $9.3 million in cash at December 30, 2008.
Ventracor closed up 3.8 cents or 56.72 percent at 10.5 cents with 5.8 million shares traded on January 2, 2009.

EASTLAND MEDICAL SYSTEMS

Eastland Medical announced a non-renounceable rights issue on January 2, 2009.
Eligible shareholders can subscribe for one ordinary share and attaching option for every eight shares held on January 12, 2009 at 10 cents a share.
Eastland said that if all shareholders take up their full entitlement the rights issue would raise up to $2,490,897. The raising is not underwritten.

AGENIX

Agenix said on January 5, 2009 that the preliminary settlement deed (BD: Dec 9, 2008) resolving its Shanghai acquisition had lapsed.
Agenix refrained from taking legal action subject to conditions including concluding the final settlement deed and the acquisition parties obtaining finance by December 31, 2008 at which time Agenix reverted to its original rights. Agenix said the final settlement and finance measures were not achieved prior to December 31, 2008.
Agenix said it hoped to settle the deal before January 26, 2009 so that the second and third installments due under the lapsed agreement could be paid by January 31, 2009.

STEM CELL SCIENCES

Stem Cell said on January 5, 2009 that it had a further licencee for its internal ribosome entry site (IRES) technology.
The company said the undisclosed licencee was “a major research-based international pharmaceutical company in the top 20 by market capitalization and annual sales” and would use the technology in its own research and development activities.
Financial terms were not disclosed for the fully paid-up licence.

MESOBLAST

Mesoblast said on January 6, 2009 that it won the 2009 Frost & Sullivan emerging company award in the US Soft Tissue Repair market.

PHOSPHAGENICS

Phosphagenics said on January 6, 2009 that it completed its transdermal insulin human trial demonstrated that its TPM-insulin formulation safely delivered insulin into patients with type 1 diabetes.
Phosphagenics said the protocols were designed to meet the primary end point of evaluating the glucose lowering efficacy of transdermal insulin in patients with type 1 diabetes and the secondary end point of safety and tolerability.
The company said the clinical results met both end points.

ELLEX MEDICAL LASERS

Ellex said on January 6, 2009 that the rights issue of 34,265,420 shares was undersubscribed by 28,872,000 shares.
The rights issue was partially underwritten by Taylor Collison up to $1,400,000 or 14,000,000 shares.
In total, Ellex will issue 16,379,506 shares raising $1,637,950.60 but “does not intend to place the remaining shortfall shares at this time”.

PRIMA BIOMED

Prima Biomed said on January 7, 2009 that its share purchase plan raised $198,000 representing 39,600,000 ordinary shares.

ANTEO

On January 7, 2009 Anteo (formerly Biolayer) and New Zealand Diagnostics agreed to an assay development project for female ovarian monitoring.
Anteo said the potential market was $US670 million ($A1 billion).
Anteo said the terms included immediate cash and future royalty payments based on the commercial success of the assay and commercialization strategy.
Anteo estimated revenue of $400,000 from the project in 2009 with the collaboration providing access to further assay development opportunities in New Zealand.

METABOLIC

On January 8, 2009 Metabolic said its place of business and contact details would be Unit 2, 320 Lorimer Street, Port Melbourne, Victoria.
The new telephone number is +613 8681 4053 and facsimile is +613 8681 4099.

NOVOGEN

Novogen said on January 8, 2009 that US subsidiary Marshall Edwards had an investigative new drug approval for clinical studies of triphendiol as a chemo-sensitizing agent in combination with gemcitabine.
The US Food and Drug Administration approval will enable a phase Ib study of triphendiol in combination with gemcitabine in patients with unresectable, locally advanced or metastatic pancreatic and bile duct cancers.

PEPLIN

On January 8, 2009, Peplin said it had “positive results” for PEP005 (ingenol mebutate) Gel in its phase IIb actinic keratosis dose-ranging trial.
The trial was for the treatment of lesions on the face and scalp.
Peplin said actinic keratosis was a common pre-cancerous skin condition caused by sun exposure with the face the most common area for sun damage and the most common area for actinic keratoses, which can develop into skin cancers if left untreated.
Peplin said that “as in previous trials, this study demonstrated a clear dose response relationship with four out of the six treatment groups achieving statistically significant clearance of [actinic keratosis] lesions when compared with vehicle”.
The company said that complete clearance rates ranged from 15.6 percent to 42.3 percent across the six active treatment groups.
At all concentrations, for both the two-day and three-day treatments, the PEP005 Gel demonstrated a favorable safety profile and was well tolerated.
Peplin said that side effects were primarily transient, short term, local skin responses at the treatment site which peaked at Day 4 and returned to baseline by Day 15 and no drug-related serious adverse events were reported.
In the highest treatment group of 0.015% PEP005 Gel for three consecutive days, the complete clearance rate was 42.3percent (p=0.005 compared to vehicle) and the median reduction in lesion count was 84.5 percent.

XENOME

Xenome said on January 8, 2009 that it had executed a research licence agreement with Astrazeneca subsidiary Medimmune.
Xenome said Medimmune would gain access to its X-discover venom peptide library to exclusively screen for drug candidates against two undisclosed targets involved in key pain pathways.
Xenome said the financial terms were confidential, but it would receive an up-front cash payment for access to the X-discover library.
The partnership allows for Medimmune to fund research at Xenome relating to structure activity relationship studies on hits from the Xenome library.
The agreement provides Medimmune an option for product licences on selected peptides from the Xenome library, which would trigger undisclosed milestone and royalty payments.
Xenome said the X-discover library was a proprietary collection of more than 2000 primarily venom-derived peptides and was the result of a genomics capability that allowed for the discovery of novel peptides from cone snail venom tissue.

CIRCADIAN TECHNOLOGIES

On January 9, 2009 Circadian said the US Food and Drug Administration approved Ark Therapeutics' patient recruitment for a phase III trials of Trinam for kidney dialysis patients.
Circadian said Trinam was a gene-based compound to prevent blood vessels from blocking in kidney dialysis patients who have undergone vascular access graft surgery.
The product is an adenovirus-mediated VEGF-D gene delivered with a novel biodegradable local delivery device.
Ark reported in March 2007 that a phase II trial showed the access grafts of patients given Trinam remained functional for dialysis up to three times longer than in untreated controls.
Ark has licenced the rights to the VEGF-D gene in Trinam from Circadian's wholly-owned subsidiary, Vegenics. Vegenics is entitled to milestone payments and royalties.
Circadian chief executive officer Robert Klupacs said the phase III approval was "a significant milestone for Trinam".

TYRIAN DIAGNOSTICS

Tyrian said on January 9, 2009 that it had completed the fourth milestone of a feasibility study in collaboration with Becton, Dickinson and company.
Tyrian said the study would determine the suitability of its tuberculosis (TB) protein markers for the development of rapid diagnostic tests to detect active TB disease.
The company said the study demonstrated detection of selected proprietary TB proteins in sputum, along with the development of methods for sample preparation and testing suitable for use in the field.
Tyrian said it identified a lead marker which might be suitable for a diagnostic test because it was an essential TB protein, always present when there was active TB.
For the fourth milestone, the lead TB marker was detected in clinical strains of the bacteria responsible for TB as well as clinical sputum samples; however, the desired levels of sensitivity and specificity have not yet been achieved in a protein assay.
Tyrian said this would require further technical development of the assay as well as analysis of a greater number of clinical samples.
In an adjunct study, Tyrian demonstrated that this same marker could also be developed as a molecular diagnostic assay.

PROGEN

On January 9, 2009 the Progen Shareholders Group failed in its bid to spill the board of the company.
A poll showed that about 19 million votes opposed the spill resolutions with about 11 million votes in favor of the resolutions. Progen has 60,469,511 shares on issue.
The resolutions proposed to replace directors Dr Mal Eutick, Robert Williamson, Stephen Jun Chi Chang, Patrick Burns and CEO Justus Homburg with Robert (Bob) Moses, Alison Coutts and Dr Woei-jia Jiang.
Progen's planned merger with Avexa will proceed with shareholder meetings of both companies expected in late February 2009.

AVITA MEDICAL

Avita said on January 9, 2009 that the British Association of Dermatologists described its Recell wound treatment "as a key technology enabling the effective treatment of Vitiligo".
In an article entitled 'Guideline for the diagnosis and management of vitiligo' authored by nine British dermatologists published in the British Journal of Dermatology (2008 vol 159, pp1051–1076), the therapy enabled by Avita Medical's Recell was identified as "a very effective and most promising approach for the treatment of vitiligo".
A difficult to treat depigmentation disease, vitiligo affects about two percent of people.

GENERA BIOSYSTEMS

Genera said on January 9, 2009 that and Australian patent had been granted for its Ampasand bead multiplexing technology.
The patent, entitled 'Methods for detecting aneuploidy using microparticle multiplex detection' provided protection for Genera's microsphere multiplexing technology in its current and future molecular diagnostic products.

ACRUX

On January 9, 2009 7.2 million Acrux shares were transferred from Queensland Investment Corporation to IB Australian Bioscience Fund.
The fund holds slightly less than five percent of Acrux and is co-owned by Intersuisse and the UK-based International Bioscience Managers.
On January 12, Acrux told the ASX that trading following the transfer was probably the reason for a share price jump from 48 cents on January 8, to 69 cents on January 9.

VENTRACOR

A group of Ventracor shareholders are hoping to spill the board but retain the services of chief executive officer Peter Crosby.
Ventracor shareholders group representative Michael Fox told Biotech Daily on January 12, 2009 that he had the support of more than five percent of Ventracor's issued capital and if a support target was met he would call a meeting to spill the board at the end of January for a meeting at the end of February.
The group wants to remove directors John Ward, Ross Harricks, Elizabeth Nosworthy, Jeffrey Goodman and William Curran and replace them with Vijay Kakani, Mr Fox and Anthony Davis. The group sent a proposal of cost-cutting measures and other activities detailed in a letter to Ventracor shareholders.

SELECT VACCINES

The Australian Securities and Investments Commission has begun action against former Select Vaccines managing director Dr Martin Soust over alleged improper share transactions.

On January 13, 2009 ASIC said it had commences proceedings seeking civil penalty orders against Dr Soust in Melbourne's Federal Court.

Dr Soust was the managing director and chief executive officer of Select Vaccines and is a director and shareholder of Martin Soust & Co Pty Ltd.

ASIC alleged that on December 31, 2007, shortly before the close of the market for the calendar year, Dr Soust instructed a stockbroker to purchase Select Vaccines shares in his mother's name.

ASIC said the purchase had the effect of increasing the price of the company's shares from 2.0 cents to 2.5 cents, a 25 percent increase.

ASIC alleged it was Dr Soust's intention to increase the share price to secure a performance bonus from Select Vaccines for Martin Soust & Co.

ASIC said it was seeking declarations that the purchase created an artificial price … in breach of s1041A of the Corporations Act 2001 and a false and misleading market regarding the price for trading in Select Vaccine shares in breach of s1041B of the Corporations Act.

ASIC said it sought declarations that Dr Soust breached his duties as a director, improperly used his position and failed to act in good faith in not informing the board and remuneration committee of Select Vaccines of his involvement in the purchase of the shares on December 31, 2007.

ASIC said it was also seeking pecuniary penalty orders from the Court and an order disqualifying Dr Soust from managing corporations.

The matter is currently scheduled for a directions hearing on January 30, 2009.

Dr Soust resigned as chief executive officer and managing director of Select Vaccines effective August 31, 2008.

Biotech Daily sought a response from Dr Soust but at the time of publication of this edition had not received a reply.

KARMELSONIX

Karmelsonix says its flagship product the Personal Wheezometer has passed the European Union regulatory audit process, the Conformitée Européenne Audit.

Karmelsonix said on January 13, 2009 that receipt of European regulatory approval meant it was able to sell the Personal Wheezometer in the European Union.

The company said it would "immediately commence the process to obtain Australian approval" from the Therapeutic Goods Administration.

TISSUE THERAPIES

Tissue Therapies said on January 13, 2009 that the US Patent and Trademark Office granted the core Vitrogro would care patent 'Growth Factor Complex'.

Tissue Therapies said the US core patent grant followed the prior granting of Vitrogro patents in Australia, New Zealand and South Africa.

AVITA MEDICAL

Avita Medical announced on January 14, 2009 that, following an independent quality audit it had been granted ISO 9001:2000 Quality Management System Certification for its Class III medical devices and ISO 13485:2003 Medical Devices Certification.

Avita said successful ISO certification marked the completion of the merger of the Clinical Cell Culture and Visiomed quality and manufacturing processes.

IM MEDICAL

IM Medical told the ASX on January 14, 2009 that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 0.2 cents on 8 January 2009 to 0.7 cents on January 14, along with an increase in trading volume.

USCOM

Uscom said on January 14, 2009 that it had been granted a new US patent for a hand-held device, "much like a stethoscope".

The company said the patent recognized the novelty and inventiveness of the method and provided protection for development of the Echoscope by Uscom.

Uscom said the miniaturization of devices was "an important trend in medicine" and the Echoscope would lead to increased portability, utility and application. The device could be used in the treatment of trauma, sepsis, heart failure and hypertension.

BIO-MELBOURNE NETWORK

On January 14, 2009, Bio-Melbourne Network chief executive officer Michelle Gallaher told Biotech Daily that promotions and membership manager Shane Hickey had been retrenched.

Ms Gallaher said the "difficult decision" was primarily a cost-cutting measure and staff at Bio-Melbourne Network would share the workload.

Biotech Daily would like to thank Mr Hickey for his generous help for this publication

IMMURON

And one we missed due to technical problems beyond everyone's control. Immuron (formerly Anadis) said on December 15, 2008 that the US-based Avalan Consumer Healthcare will distribute its diarrhoea treatment Travelan and has taken a strategic stake in the company of $US300,000 ($A446,000) in shares.

BIOTECH DAILY

Biotech Daily resumes normal daily publication from Monday January 19, 2009, including the revised Top 40 Index.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053
email: editor@biotechdaily.com.au www.biotechdaily.com.au