Biotech Daily

SPECIAL SUMMER CATCH UP EDITION

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December 20, 2010

PHYLOGICA IN $136m PFIZER COLLABORATION

PHYLOGICA

Phylogica says it has a potential $136 million collaboration and licencing agreement with Pfizer to discover novel peptide-based vaccines.

Phylogica said its Phylomer drug discovery platform would be used to identify Phylomer peptides suitable for further evaluation.

The company said Pfizer would have an option to licence any resulting Phylomers for further research, development and commercialization of novel peptide-based vaccines derived from the Phylomers.

Phylogica said it would receive an upfront payment of $US500,000 and was eligible for a commercial licence payment and to receive preclinical, clinical and other milestone payments of up to US$134 million ($A135.7 million) as well as royalties on worldwide sales.

Phylogica founder and chief executive officer Dr Paul Watt said his company had created three alliances with global pharmaceutical companies within the last 12 months.

PHARMAXIS EURO APPROVAL DELAYED UP TO THREE MONTHS

PHARMAXIS

Pharmaxis says the review of its European marketing application of Bronchitol for cystic fibrosis would be delayed by up to three months to April 2011.

Pharmaxis previously said the review was expected to conclude by December 31, 2010.

The company said the Committee for Medicinal Products for Human Use agreed that Bronchitol would be the subject of an oral explanation at the January 2011 meeting and the review was expected to conclude in the first three months of 2011.

Pharmaxis chief executive officer Dr Alan Robertson said the Bronchitol marketing application for Europe was “well into its review cycle, however, predicting the conclusion of these processes is notoriously difficult”.

“Bronchitol is an important new treatment option for patients with cystic fibrosis and we are looking forward to completing the European marketing review,” Dr Robertson said.

Dr Robertson said that two long term trials of Bronchitol in patients with cystic fibrosis demonstrated a clinically important improvement in lung function as well as an improvement in a variety of other measures.

Loss of lung function is the principal reason for reduced life expectancy for people with cystic fibrosis, Pharmaxis said.

LANGLEY WALKER REDUCES 1.5% IN ACRUX

ACRUX

Langley Walker and related parties have reduced their substantial holding in Acrux from 11,855,866 shares (7.44%) to 9.760,599 shares (5.90%).

The substantial shareholder notice said 2,881,388 shares were acquired in 2008 and 2009 at an average price of 89.8 cents a share with sales between 90 cents a share and $3.59 a share.

FLUOROTECHNICS SELLS GERMAN ASSETS FOR $196k

FLUOROTECHNICS

Fluorotechnics has sold its Gel and HPE Tower technology to Germany's Serva Electrophoresis GmbH for EUR150,000 ($A195,620).

Fluorotechnics said it was continuing to scale back its operations and selling some or all of its assets and had appointed the Heidelberg-based Serva as its global sales and marketing partner for its electrophoresis gels and hardware product lines.

Fluorotechnics said Serva's EUR150,000 was payable by January 31, 2011.

The company said that based on receiving ongoing orders from Serva, Fluorotechnics German subsidiary, Gelcompany GmbH would continue to manufacture electrophoresis gels for the short to medium term.

Fluorotechnics said all other activities in Germany have been closed.

The company said it would continue to manufacture the fluorescent stain products from Sydney and sell these products directly and through overseas distributors, including Serva and the US-based Gel Company.

Fluorotechnics said it was reviewing other opportunities for the sale of the remaining operations and assets and was looking at new investment opportunities.

NZ APPROVES 2 LOW-DOSE LIVING CELL DIABETES TRIAL PATIENTS

LIVING CELL TECHNOLOGIES

Living Cell says New Zealand has approved two more patients for its phase II trial of its Diabecell encapsulated pig islets of Langerhans for type 1 diabetes.

Living Cell said the patients were in addition to the 12 patients approved for the trial, of which 11 had been dosed.

The company said the trial expansion would allow it to build its dose-ranging data set.

Living Cell said the first four patients received one implant of Diabecell at a dose of 10,000 islet equivalents per kilogram body weight (IEQ/kg).

A second group of four patients received a higher dose of 15,000 IEQ/kg.

In the third group of two patients, a high dose of 20,000 IEQ/kg was administered. The fourth group of four patients will receive a dose of 5,000 IEQ/kg.

Living Cell chairman and medical director Prof Bob Elliott said that "as often happens in medicine, we see a threshold zenith where there appears to be little additional therapeutic response to higher doses of Diabecell and it is currently thought that this threshold may have been reached in this clinical trial".

"We believe reducing the dose may increase the clinical benefit of this treatment and will also mean we will require fewer islet cells to treat each patient," Prof Elliott said.

"If this is proven true, it will be a very good outcome for the commercialization of Diabecell, Prof Elliott said.

PATRYS US MANUFACTURING PATENT

PATRYS

Patrys says it has filed a provisional US patent application to protect its internally developed downstream manufacturing processes for natural human antibodies.

Patrys said it was the first biotechnology company to report the ability to produce natural human antibody therapeutics at a commercial scale and the most recent patent filing covered newly developed and proprietary methods for purifying and formulating natural human antibodies.

The company said the critical manufacturing processes were applicable to all natural human antibody products in Patrys' pipeline.

SBC RESEARCH QUESTIONS FERMISCAN 'ERRORS AND OMISSIONS'

FERMISCAN, SYDNEY BREAST CLINIC

The Sydney Breast Clinic and SBC Research have published a media release entitled 'Errors and omissions in Fermiscan Holding Limited's Notice of Annual General Meeting'.

SBC Research said it had told Fermiscan "whose shares are currently suspended from trading on ASX, of its concerns that the notice of annual general meeting issued … on October 29, 2010 appears to SBC Research to contain errors and omissions".

SBC Research said the major concerns were that Fermiscan "intends to embark on a program to have its shares reinstated to trading on ASX and to raise additional capital to complete French and Italian clinical trials of the 'technology' and 'recommence commercialization of the technology', without having made it clear to shareholders and the market that it does not in fact own or have contractual rights to use all of the patents or intellectual property rights which comprise 'the technology'".

Fermiscan paid $5.5 million to acquire the Sydney Breast Clinic in 2008 (BD: May 28, Jun 16, 2008), but sold it in 2009 for $1 million (BD: Oct 2, 2009).

In 2010, Fermiscan's administrators Woodgate & Co sold the company's intellectual property and other assets to the Sydney Breast Clinic-related company SBC Research for $250,000 plus GST to SBC Research (BD: May 4, 2010).

The Clinic's managing director Ron Phillips told Biotech Daily at that time that people associated with the Sydney Breast Clinic held a minority share of SBC Research, but no one associated with Fermiscan was involved in SBC Research.

Fermiscan's core intellectual property was the x-ray diffraction of hair test for breast cancer acquired from inventor Prof Veronica James. Fermiscan raised and spent tens of millions of dollars on the test.

SBC said the explanatory memorandum for the Fermiscan meeting did not mention that on March 18, 2010 Fermiscan sold all of the patents, patent applications and other intellectual property rights owned by it and its wholly owned subsidiaries, Fermiscan Australia Pty Ltd, Fermiscan Pty Ltd, Fiberscan Pty Ltd (all in liquidation), regarding the 'technology' to SBC Research and Fermiscan no longer owned any rights in relation to the 'technology' and therefore had no rights to commercialize that 'technology'.

SBC quoted Fermiscan saying its "objective in the short term [was] to complete the French and Italian trials of the Technology", but SBC said it owned all intellectual property rights relating to those trials, including trial worksheets and trial images.

"It is unclear to SBC Research what rights Fermiscan has to undertake or complete the trials of the Technology in France or Italy utilizing any of the results or materials connected with those trials, or any patents owned by SBC Research," SBC said.

SBC said the meeting papers also indicated that Fermiscan aimed to "negotiate key commercial relationships so as to commercialize the technology in all legally available jurisdictions, including, China, India, Russia, Israel, Egypt and Thailand".

SBC said Fermiscan did not own the technology and although there were no current patents in the countries mentioned, including China and India, SBC had a number of pending patent applications in a number of these countries, including China and India..

SBC said that Fermiscan's financial report for the year ended December 31, 2009 suggested that on completion of the French and Italian trials it proposed to negotiate with "the purchaser of the Fermiscan patents to move to the commercialization of the technology".

"To date, SBC Research as the purchaser of the Fermiscan patents has not received a formal approach from, nor had any negotiations with, Fermiscan or any of its related entities regarding commercialization of the technology," SBC said.

SBC said it had asked Fermiscan to supplement the information provided with updated information to its shareholders and ASX, regarding the patents and intellectual property.

ATCOR $US250k DIABETES TRIAL CONTRACT

ATCOR MEDICAL

Atcor says it has a $US250,000 contract for its Sphygmocor system which measures central blood pressures and arterial stiffness non-invasively for a US diabetes study.

Atcor chief executive officer Duncan Ross said that multi-center research in pharmaceutical trials and publicly funded studies "continues to be an expanding foundation for Atcor Medical's long term diversification and growth".

"This is one of a number of emerging applications for Sphygmocor technology beyond current clinician utilization in early cardiovascular disease identification and drug therapy management," Mr Ross said.

NEOPEC APPOINTS DIRECTORS DR CREES, DR ROGER, DR THORBURN

NEOPEC

Neopec has appointed Dr Owen Crees, Dr Greg Roger and Dr Lyndal Thorburn as directors.

The Melbourne-based Neopec is developing breast regrowth technology.

Neopec said Dr Crees was the chief executive officer of Research Laboratories of Australia and had extensive business contacts in Europe, the US and Japan.

The company said Dr Roger was the founder and director of Advanced Surgical Design & Manufacture, a medical practitioner and a director of Ausbiotech, as well as an adjunct associate professor of biomedical engineering at the University of Sydney.

Neopec said Dr Thorburn has been involved with the commercialization of about 30 new technologies and business concepts and was an adjunct professor in biotechnology commercialisation at the University of Canberra and was a former senior policy adviser at the Commonwealth Scientific and Industrial Research Organisation.

Neopec said the three would join directors Gillian Franklin, O'Brien Institute director Prof Wayne Morrison and Research Australia chief executive officer Rebecca James and the appointments were made as clinical trials were due to begin for the device and surgical technique that uses a woman's own regenerative capacity to grow a living fat tissue substitute for a breast removed by mastectomy.

December 21, 2010

ATCOR $1.3m SUPPLY DEAL

ATCOR MEDICAL

Atcor says it has signed a $US1.28 million ($A1.27 million) agreement to supply Sphygmocor systems and trial support services to an unnamed pharmaceutical company.

Atcor said the million contract was with an existing customer and would expand the use of Sphygmocor in a current trial.

MARK CANSDALE REPLACES AARON FINLAY AS MAYNE CFO, CO SEC

MAYNE PHARMA GROUP

Mayne says Mark Cansdale has been appointed chief financial officer and company secretary replacing Aaron Finlay.

Mayne said Mr Cansdale was formerly the chief financial officer and company secretary at McMillan Shakespeare and prior to that, Vision Systems.

FLUOROTECHNICS PLACES $210k; NOTES RAISE $500k; BOARD CHANGES

FLUOROTECHNICS

Fluorotechnics says it has completed a placement for $210,000 at three cents a share and raised $500,000 through the issue of convertible notes.

Fluorotechnics said it had been reviewing “a number of potential investment opportunities over the last month or so and it is our expectation to focus for a period on one of these opportunities. This opportunity is in the bioscience industry”.

Fluorotechnics said that in parallel and as part of the placement, it had appointed Richard Trevillion as chairman and Dr Brian Damian Pethica as a non-executive director.

The company said Mr Trevillion was the founder of financial investment and corporate consulting businesses Amity Partners and Adillion Pty Ltd.

Fluorotechnics said Dr Pethica worked for Ciba-Geigy in Basel, Switzerland, as a group head in the medical department, pharmaceutical division, then as medical director in New Zealand and was medical director of Novartis New Zealand.

The company said Dr Pethica was educated at Oxford University (mathematics) and London University (medicine) and was a Fellow of London’s Royal College of Physicians and a member of the Medicines Assessment Advisory Committee, New Zealand.

Directors Peter Bergquist, John Fletcher, Lars Eric Utterman and David Weber resigned.

Fluorotechnics said the notes were convertible at any time over the 18 month term at three cents a share and automatic conversion would occur at the earlier of six, nine, 12 or 15 months after issue if the 10-day, volume-weighted, average price was at least three cents, subject to shareholder approval.

The company said there were 47,147, 777 shares on issue and there were 7,000,000 additional shares issued in the placement, with a further 16,666,667 ordinary shares and 16,666,667 options expected to be issued from the conversion of the notes.

Fluorotechnics said the funds would discharge liabilities and provide working capital.

SOLAGRAN CLAIMS ROPREN REDUCES LIVER FIBROSIS IN 4 WEEKS

SOLAGRAN

Solagran says a preliminary report of its over-the-counter cure-all Ropren shows it is effective for liver cirrhosis and reduces fibrosis in four weeks.

Solagran said the trial was conducted under the supervision of Prof Oleg N Minushkin.

Entitled ‘Results of Application of Ropren in Treatment of Liver Alcohol Cirrhosis’ the report said that “when used at the dose of 144mg per day for a period of four weeks, Ropren is effective in treatment of alcohol liver cirrhosis”.

Solagran said this was “confirmed by reliable positive data of trail making test, biochemical parameters of the blood, fibrosis index and vitality (as per the SF-36 questionnaire)”.

The company said improvement was registered during evaluation of neuropathy symptoms as per the NSC and Young’s scales …however, the differences were statistically unreliable”.

Solagran said the data suggested that “an increase in duration of the therapy might improve or stabilize the clinical neuropathic condition”.

The company said that no side effects were registered and tolerance to the conifer green needle extract was “excellent for all patients”.

Solagran said the report was presented on December 4, 2010 at the Siberian Forum of Gastroenterology at the Novosibirsk State Medical University and the preliminary results were from observations at four weeks of a minimum 12 week course of treatment.

Solagran said it was “particularly encouraged that Ropren has again indicated statistically significant changes in all main liver parameters including the cirrhosis index”.

Solagran said the trial was due to be completed in February 2011.

December 22, 2010

OPTISCAN, ZEISS EXPAND COLLABORATION

OPTISCAN

Optiscan says Carl Zeiss will expand and intensify their collaboration following successful neurosurgery trials at the Barrow Neurological Institute in Phoenix, Arizona.

Optiscan said the agreement would pave the way to commercialization of its confocal microscopes in neurosurgery.

The company said the agreements with Zeiss were commercial in confidence, but it would "receive significant immediate and near term cash payments flowing from these new arrangements boosting cash reserves beyond $2 million by December 31, 2010".

Optiscan said the expansion of activities with Zeiss was "validation of our technology and our ability to take that technology to product".

The company said that as well as entering further medical applications with Zeiss, the progress with Zeiss complemented the development of its second generation technology for use in other established applications such as gastroenterology.

NOVOGEN, MARSHALL EDWARDS COMPLETE $US4m ASSET SALE

NOVOGEN

Novogen's 70 percent US subsidiary Marshall Edwards has acquired Novogen's isoflavone-based intellectual property portfolio for $US4 million in preferred stock.

Novogen chairman William Rueckert said that over the past 15 years, Novogen had "conducted the largest and most comprehensive isoflavone-based research program in the world".

"We believe these assets are now better served in the hands of a company equipped with the drug development expertise and capital required to execute a clinical strategy and fully realize their value," Mr Rueckert said. "Meanwhile, this transaction serves to bolster our ownership stake in Marshall Edwards, a significant value driver for our company."

Marshall Edwards chairman Prof Bryan Williams said the agreement was "the culmination of a watershed year at Marshall Edwards".

"Now armed with a hand-selected management team, world-class oncology drug development expertise and the flexibility to develop these valuable assets, we are poised to enter the clinic with two next-generation drug candidates in the coming year," he said.

"This strategic acquisition will enable us to explore other potential candidates and indications within the portfolio while enhancing our ability to partner," Prof Williams said.

Novogen said that using the isoflavone-based technology platform, it had generated more than 400 new chemical structures, including compounds showing anti-tumor activity.

Previously, Marshall Edwards licenced rights from Novogen for oncology drug candidates phenoxodiol, triphendiol, NV-143 and NV-128.

Novogen said the asset agreement canceled prior licencing agreements between the two companies, including any potential royalty payments.

Each share of the 1,000 shares of class A preferred stock was convertible into a minimum of 4,827 shares of Marshall Edwards common stock valued at US$4 million based on the 20-day, volume-weighted, average price.

Should any of the acquired assets achieve a statistically significant result in a phase II clinical trial or the first patient was enrolled in a phase III clinical trial, each share of class A preferred stock not already converted would convert into 9,654 of Marshall Edwards common stock.

The transaction has been unanimously approved by directors of both companies, but was subject to shareholder approvals and an independent expert report.

XCEED SELLS BORON FOR $1.5m

XCEED CAPITAL, BORON MOLECULAR

Xceed says that, subject to shareholder approval, it has sold its wholly owned subsidiary Boron Molecular for $1.5 million in cash.

On settlement, Xceed said it would have about $3 million cash.

Xceed said that it had sold Boron to an undisclosed private group to be disclosed when the deal was completed.

USCOM CASHED UP, NEW BOARD, SHARE PLAN

USCOM

Uscom says its revamped board has been installed and the company raised the hoped-for $3 million (BD: Dec 2, 2010).

Uscom said the former managing director of Oracle Corporation Phil Kiely was appointed as executive chair "to reshape the company into a global leader in the biotechnology sector".

The company said the placement at 30 cents a share raised $3 million with $2.9 million committed and $100,000 contingent and up to 15 percent of the capital of the company or $1.88 million would be issued immediately with the balance being issued subject to shareholder approval early in the New Year.

Uscom said it would also offer shares at 30 cents each to existing shareholders through a share purchase plan.

The company said the capital would be directed "at implementing a new sales culture … and strengthening a new and invigorated sales distribution channel to achieve global sales success for the … cardiac output monitor, the USCOM 1A".

Uscom said Jochen Bonitz had been appointed a director effective from January 4, 2011, replacing Roman Zwolenski, who was retiring after eight years with the company.

The company said Mr Bonitz was a former director at KPMG Corporate Finance with more than 20 years experience in the technology sector.

Outgoing executive chairman and founder Rob Phillips will remain an executive director and Bruce Rathie will remain as a non-executive director.

VETERANS NAMED FOR LIFE SCIENCES QUEENSLAND COMMITTEE

LIFE SCIENCES QUEENSLAND

Life Sciences Queensland says some of the State's most respected and experienced industry leaders have joined its steering committee.

Confirmed members include Queensland Clinical Trials Network president Tony Webber; Queensland Clinical Trials Network chief executive officer Mario Pennisi; Queensland Biocapital Fund chief executive officer Dr Cherrell Hirst; James Cook University vice-chancellor Sandra Harding; Boeing Research and Technology Australia vice-president William Lyons; Alchemia chief executive officer Dr Peter Smith; Vicibio director and founder Peter Riddles; Fusidium managing director Stuart Hazell; and Jay Hetzel.

Life Sciences Queensland steering committee chairperson Dr Peter Riddles said the committee would help steer Queensland from a State recognized as a strong resource exporter to a State known for its diversified knowledge-based industries and world class resourcefulness.

AUSBIOTECH APPOINTS DR GREG ROGER DIRECTOR

AUSBIOTECH

Ausbiotech has appointed Advanced Surgical Design & Manufacture founder Dr Greg Roger as a director, to increase and sustain the medical technology industry.

Ausbiotech chair Dr Deborah Rathjen said Dr Roger was previously an elected director.

"After Dr Roger's years of committed service to Ausbiotech and Ausmedtech, the board is especially pleased to welcome him back, in the knowledge that his extensive experience in the biotechnology and medical technology sectors will complement the skills and expertise of the current board," Dr Rathjen said.

IDT PROFIT GUIDANCE UP TO $1.2m

IDT

IDT chairman Dr Graeme Blackman says the clinical services company expects to post profit after tax for the six months to December 31, 2010 of $1.0 million to $1.2 million.

Dr Blackman said the company had "a pleasing first half [year] in which the underlying business had performed well in a difficult environment'.

He said the profit was driven by the strong demand for phase I clinical services and while the Boronia, in Melbourne's eastern suburbs, manufacturing performance was subdued there were "good signs for recovery in the second half".

SELECT VACCINES COMPLETES $500k CAPITAL RAISING

SELECT VACCINES

Select Vaccines says it has completed the second tranche of its $500,000 placement issuing 187,500,000 shares at 0.2 cents a share to raise $375,000.

The company said it had also issued 93,750,000 free attaching options exercisable at 0.2 cents each by July 13, 2013. Patersons Securities was lead manager to the placement.

December 23, 2010

COMPUMEDICS GERMANY'S $1.3m CHINA CONTRACT

COMPUMEDICS

Compumedics says it has a EUR1 million ($A1.3 million) agreement to supply the Beijing-based Beike Digital Medical Technology with its ultrasonography products to in 2011.

Compumedics said the contract was through its German brain blood-flow ultrasonography division, Compumedics Germany GmbH.

The company said Beike was a neurology company with more than 20 years experience and had collaborated with Compumedics Germany for more than 10 years to develop the Chinese brain blood-flow ultrasonography market.

TACERE PAYS BENITEC $158k DIVIDEND

BENITEC

Benitec says that California-based licencee Tacere Therapeutics will pay it a dividend of $US161,674 ($A158,070).

Benitec said the dividend came from its equity stake in Tacere and it had licenced its gene-silencing DNA-directed RNAi technoloy for treating hepatitis C to Tacere in return for upfront and milestone payments and future royalties, along with the equity stake.

CEPHALON TAKES 12% OF MESOBLAST
MESOBLAST
Cephalon has taken a 12.2 percent stake in Mesoblast with a holding of 31,083,750 shares.

HEALTHLINX LOSES WHITE KNIGHT DIRECTOR STEPHEN COPULOS
HEALTHLINX
Healthlinx says Stephen Copulos has resigned as a non-executive director effective from January 1, 2011, due to increased workload from his expanding business interests.
Healthlinx said Mr Copulos had been a director since June 2007, in which time he, with his fellow directors, helped achieve significant milestones, including capital raising to fund scientific programs, the launch for the Ovplex ovarian cancer diagnostic and the expansion of jurisdictions in which was sold.
In 2009 the Copulos Group provided a $3 million funding facility to Healthlinx. The Group is Healthlinx's largest shareholder (BD: May 25, 2009).

FERMISCAN CLAIMS AGREEMENT TO CONTINUE BREAST CANCER TRIALS
FERMISCAN
Fermiscan says it has an agreement with the Milan-based Synchrotron Diagnostics to continue trials of Prof Veronica James x-ray diffraction of hair diagnostic for breast cancer.
The Sydney Breast Clinic-related SBC Research has previously said that Fermiscan does not own the intellectual property related to the test, which it acquired in 2010 (see above).
Fermiscan said Synchrotron Diagnostics (SD) conducted research for epithelial cancer and would arrange the trials.
"Any new intellectual property developed by Fermiscan or SD during the conduct of the trials is to be jointly owned by Fermiscan and SD," Fermiscan said.

REVA CLOSES UP 14% AT $1.25
REVA MEDICAL
Reva opened on the ASX at $1.145 fell to $1.12 and ended the day up 15 cents or 13.64 percent at $1.25 with 1.2 million shares traded.
Reva Medical raised $85,000,003 through the initial public offering of 77,272,730 CHESS depositary interests or CDIs at $1.10 each
Reva closed at $1.25 on December 24, 2010.

December 24, 2010

CHINA PAYS AGENIX LAST $2.8m INSTALLMENT
AGENIX
Agenix has received the final installment of RMB18 million ($2.78 million) relating to its failed Chinese bio-pharmaceutical acquisition (BD: Feb 14, Jun 6, 2007; Jul 24, 2008).
Agenix said the recovery efforts produced total payments of RMB44 million ($A7.2 million).

FDA REJECTS PSIVIDA'S ILUVIEN FOR DIABETIC MACULAR OEDEMA

PSIVIDA

The US Food and Drug Administration cannot approve Psivida's new drug application for Iluvien (fluocinolone acetonide intravitreal insert) for diabetic macular oedema.

Psivida told the ASX that the application to the FDA contained safety and efficacy data to month 24 of its 956 patient phase III trial of Iluvien and the FDA granted priority review on August 30, 2010.

Psivida said the FDA complete response letter asked for analyses of safety and efficacy data through to month 36 of the Study, including exploratory analyses in addition to those previously submitted, to further assess the relative benefits and risks of Iluvien.

Psivida said its partner for Iluvien, Alimera Sciences, had completed month 36 of the study and reported that it was preparing the analyses that the FDA has requested.

Psivida said Alimera further reported that it had requested a meeting with the FDA to clarify the path to regulatory approval.

The FDA did not ask for any new clinical studies.

Psivida said the FDA letter sought additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of Iluvien, which Alimera was in the process of compiling.

Psivida said the FDA "observed deficiencies in current good manufacturing practices during facility inspections of two of Alimera's third-party manufacturers, which were completed in August and September of 2010 and that all facilities and controls will need to comply with cGMP".

Psivida said Alimera had reported that its third-party manufacturers were in the process of resolving these deficiencies.

HEALTHLINX SPRINGTREE, 50m SHARE PLACEMENT EGM

HEALTHLINX

Healthlinx shareholders will vote on resolutions relating to its $7,230,000 equity draw-down facility and the issue of up to 50,000,000 shares and 10,000,000 options.

Healthlinx said the draw-down facility was with the New York-based Springtree Special Opportunities Fund.

The company said the meeting would also vote on the issue of shares in lieu of work done by Allen & Caron Inc and RM Research Pty Ltd.

Healthlinx said it intended to place up to 50,000,000 shares and 10,000,000 options to fund a range of its activities.

NARHEX ISSUES 160m SHARES

NARHEX LIFE SCIENCES

Narhex says it has issued 160,000,000 shares at 0.3 cents a share raising $480,000.

Narhex is the subject of a deed of company arrangement and hopes to return to trading on the ASX to continue developing its anti-HIV drug candidate DG17 and its China investments (BD: Oct 7, Nov 5, 2010).

December 28, 2010

HEARTWARE APPLIES FOR HEART PUMP FDA PRE-MARKET APPROVAL

HEARTWARE INTERNATIONAL

Heartware says it has applied for pre-market approval from the US Food and Drug Administration for its ventricular assist system for bridge-to-heart transplantation.

Heartware said the submission included data from its pivotal, 140-patient, FDA-approved investigational device exemption clinical trial.

The company said the trial was conducted between August 2008 and February 2010 with the final implant performed in February 2010 and the last follow-up evaluation at 180-days in August 2010.

Heartware said the trial showed that 92 percent of the investigational device patients met the per protocol primary endpoint of the trial, which was defined as alive on the originally implanted device, transplanted or explanted for recovery at 180 days.

The trial showed that 94 percent of patients achieved a survival endpoint at 180 days.

Results for the comparator arm of the study, derived from 499 contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support showed a 90 percent success of the primary endpoint at 180 days.

Heartware said that based on the results for the primary endpoint of the study, non-inferiority of the investigational device was established [$p<0.0001$].

December 31, 2010

LIVING CELL $5.75m SPRINGTREE FACILITY

LIVING CELL TECHNOLOGIES

Living Cell says it has signed a share purchase and convertible security agreement with New York's SpringTree Special Opportunities Fund for up to $5,750,000.

Living Cell said it would issue up to $5,250,000 worth of shares over an 18-month period from the date of the agreement and the provision of a $500,000 convertible security, for total funding of up to $5,750,000.

The company said the funds were for the further development and commercialization of its lead product, Diabecell encapsulated porcine islets of Langerhans for type 1 diabetes and general operations.

GENETIC TECHNOLOGIES LICENCES NON-CODING DNA TO QIAGEN

GENETIC TECHNOLOGIES

Genetic Technologies says it has executed a non-coding DNA settlement and licence agreement with Netherlands-based Qiagen NV.

Genetic Technologies said Qiagen had been granted non-exclusive rights to a number of its patents, including non-coding analysis, gene mapping and internal standards.

The company said commercial terms of the agreement were covered by confidentiality provisions and could not be disclosed.

Genetic Technologies said it was continuing discussions with several other biotechnology companies in the US and Europe.

January 4, 2011

PRANA LOSES DIRECTOR PAUL MARKS

PRANA BIOTECHNOLOGY

Prana Biotechnology says Paul Marks has resigned as non-executive director "in order to focus on his other commitments".

Prana said the resignation was effective immediately.

Mr Marks was appointed a director on January 14, 2010 and his most recent director's interest statement said he owned 8,589,361 shares (3.55%) in the company.

CHEMGENEX EGM FOR 4.6m CEO GREG COLLIER OPTIONS

CHEMGENEX PHARMACEUTICALS

Chemgenex will hold an extraordinary general meeting to approve the issue of 4,578,667 options exercisable at 47.5 cents a share to chief executive officer Dr Greg Collier.

The meeting will be held at RBS Morgans, Port Philip Room, Level 27, 367 Collins Street, Melbourne on February 10, 2011 at 11am (AEDT).

January 5, 2011

CHEMGENEX T315I EURO APPLICATION REPLACED, DELAYED

CHEMGENEX PHARMACEUTICALS

Chemgenex says that following discussions with its European partner Hospira it will "align the European regulatory strategy for omacetaxine with the approach … in the US".

Chemgenex chief executive officer Dr Greg Collier told Biotech Daily that the European application for the T315i mutation was previously expected to be filed by July 2011 and if approved Hospira could have begun marketing Omapro by the end of 2011.

Dr Collier said on January 5, 2011 that aligning the two regulatory timetables meant the filing would be expected to be completed by December 2011 with a further six months before the regulators responded.

Chemgenex met resistance from the US Food and Drug Administration over its new drug application for Omapro (omacetaxine mepesuccinate) for chronic myeloid leukemia (CML) patients with the T315I mutation, with the FDA raising serious questions about trial management and also requiring a diagnostic test for that indication (BD: Feb 9, Mar 23, Apr 12, 2010).

Following discussions wit the FDA Chemgenex said Omapro for patients who failed therapy with two or more tyrosine kinase inhibitors could be approved by the FDA as early as mid-2011.

Chemgenex said it had informed the European Medicines Agency that it wanted to withdraw its marketing authorization application for CML patients who had failed imatinib (Gleevec) therapy and had the T315I mutation.

The company said it had told the Agency that it intended to submit a new application for CML patients who have failed therapy with two or more tyrosine kinase inhibitors and it was expected the submission would be made by the end of 2011.

Chemgenex said the new application would use combined data from its two pivotal studies, which were designed to evaluate the safety and efficacy of subcutaneously administered omacetaxine in patients who had failed imatinib and had the T315I mutation, or were intolerant to two or more TKIs.

In the media release Dr Collier said that "harmonization of the regulatory strategies in the US and Europe offers significant operational and potential commercial benefits".

DR BURWOOD CHEW REPLACES SIRTEX'S DR MARIUS VAN DEN BERG

SIRTEX MEDICAL

Sirtex has appointed Dr Burwood Chew as chief executive for the Asia Pacific region, effective from January 10, 2011.

Sirtex said that Dr Chew was previously a senior executive with Bayer Healthcare.

The company said Dr Chew would be responsible for increasing the sales of Sirtex's therapy for liver cancer SIR-Spheres microspheres in the Asia Pacific market.

Sirtex said Dr Chew had "a strong oncology background" and previously held senior positions with Wellcome and Sanofi.

Sirtex said Dr Chew would be based in its Singapore office and he replaces Dr Marius van den Berg.

January 6, 2011

GENERA UNDISCLOSED MILESTONE PAYMENT FROM UNNAMED PARTNER

GENERA BIOSYSTEMS

Genera says it has received a milestone payment from its unnamed research partner, following successful tests on two alternative human papillomavirus test designs.

Last year Genera announced "a major collaboration agreement with one of the world's leading diagnostic equipment and test manufacturers" (BD: May 24, 2010).

Genera chief executive officer Dr Allen Bollands told Biotech Daily at that time that he could not disclose the identity of the "top 10" company but said the research and development agreement for the Paptype human papillomavirus would not conflict with Genera's distribution arrangements with Healthscope and Sonic Health.

On January 6, 2011 Genera said the research and development program involved a redesign of Genera's Paptype test for use on the partner's instrumentation.

The company said two alternative designs had been developed, which incorporated more than 70 target design criteria.

Genera said both designs had been tested, both in Genera's Melbourne laboratory and in the laboratories of the partner organization.

Genera said that all target criteria have been met in both laboratories and the company had received "a substantial milestone payment".

Genera chairman Fernando Careri said it was "an important milestone for us to hit".

"We now know that we can design tests that will function effectively on our partner's platform and we think that this bodes well for the prospects of a licencing agreement for Paptype, or something more substantial, in the coming months," Mr Careri said.

Genera said it was manufacturing two more batches of tests for the partner to conduct a 300 patient clinical study in conjunction with a major university teaching hospital, expected to be completed near the end of March 2011.

Genera said it was in discussions with the partner over a commercial transaction for the test and the broader Ampasand bead technology, with an agreement expected about the same time.

SELECT APPOINTS GARY SEABROOKE, CHERIE LEEDEN DIRECTORS

SELECT VACCINES

Select Vaccines has appointed Gary Seabrooke and Cherie Leeden as non-executive directors with retiring director Philip Warren appointed joint company secretary.

Richard Wadley continues as joint company secretary, with Ian Macliver as chairman.

CALZADA'S POLYNOVO WINS $400k NOVOSORB STUDY EXTENSION
CALZADA, POLYNOVO
Calzada says the Polynovo feasibility study of its Novosorb technology with a medical device company yielded promising results, leading to an extension of the collaboration.
Calzada said its wholly owned subsidiary Polynovo Biomaterials started the study with the unnamed partner in December 2009 and the 12 month extension included a $100,000 up front fee along with a further $300,000 in milestone payments.
Calzada said the Polynovo collaboration would include several animal studies to further prove both safety and efficacy of the device.
The company said the agreement included an exclusive right to negotiate a licence to the Novosorb technology in the fieldand on the basis of the earlier animal trial results Polynovo was "confident the proposed studies will be successful".
Polynovo chief executive officer Laurent Fossaert said his company had "found the right partner to work on a well defined application".
"Successful completion of this collaboration may well result in a licence involving a large market opportunity, with the potential for Polynovo to generate significant revenues," Mr Fossaert said.

January 10, 2011

PRIMA CLOSES SPRINGTREE EQUITY DRAW DOWN FACILITY
PRIMA BIOMED
Prima has agreed with New York's Springtree Special Opportunities Fund to termination the convertible loan funding facility by March 29, 2011.
Prima said it entered into the funding agreement for up to $25.5 million with Springtree in July 2009.
Prima said Springtree had provided a total of $12.2 million on a fixed schedule, allowing it to issue the majority of the shares at significantly higher prices than the prices that prevailed at the time the agreement was entered into in July 2009.
The company said the funds provided by Springtree were "invaluable … and have been an appropriate and vital source of funding for Prima during a phase of significant growth".

XCEED VOTES ON BORON SALE
XCEED CAPITAL
Xceed will hold a general meeting to vote on the sale of 100 percent subsidiary Boron Molecular.
The meeting will be held on February 8, 2011 at the Holiday Inn, Perth City Centre, 788 Hay Street, Perth, Western Australia at 3pm (WST).

January 11, 2011

CANADA ISSUES STIRLING AN ESTABLISHMENT LICENCE
STIRLING PRODUCTS
Stirling Products says Health Canada has issued an 'establishment licence' to its Canadian subsidiary, Stirling Pharma for its pharmaceutical plant in Cape Breton, Nova Scotia.

MESOBLAST: 'REVASCOR REDUCES CARDIAC EVENTS, MORTALITY'

MESOBLAST, CEPHALON

Mesoblast says patients in its phase II trial of Revascor for congestive heart failure had fewer cardiac events, deaths and hospitalizations than control patients.

In a joint statement with partner Cephalon, Mesoblast said patients who received a single injection into damaged heart muscle of the Revascor off-the-shelf adult stem cell product or mesenchymal precursor cell had a significant reduction in cardiac events.

Mesoblast said the number of patients who developed any severe adverse cardiac events over the follow-up period was reduced from 93.3 percent in the control group to 44.4 percent in the treated patients (p=0.001).

Mesoblast said Revascor significantly reduced the number of patients who developed any major adverse cardiac events, defined as the composite of cardiac death, heart attack, or coronary revascularization procedures, from 40 percent to 6.7 percent (p=0.005).

The company said that a single injection of Revascor reduced the overall monthly event rate of a major adverse cardiac event by 84 percent compared with controls (p=0.01) and every dose tested demonstrated a similar protective effect.

Mesoblast said death from cardiac causes was reduced from 13.3 percent to zero over the follow-up period (p=0.059) and the overall monthly rate of cardiac-related hospitalizations was reduced by 48 percent (p=0.07).

Mesoblast said the randomized, placebo-controlled, trial in 60 patients with moderate to severe congestive heart failure would evaluating Revascor's safety and efficacy.

A single injection of Revascor at one of three progressively increasing doses was administered to 45 patients randomized to receive cell therapy in addition to standard-of-care, while 15 control patients received standard-of-care alone, the company said.

Mesoblast said the trial would be completed when all available patients had been followed-up for 12 months but a scheduled interim analysis of safety and of time-dependent hard efficacy endpoints was performed when the last of the 60 enrolled patients had completed six months of follow-up in December 2010.

The company said the Revascor 45 patients had been followed for a mean of 18.5 months per patient and the 15 controls had been followed for a mean of 18 months per patient.

Mesoblast said there were no cell-related adverse events in any of the 45 patients treated with Revascor, showing that all three doses were safe over the short and medium term.

Mesoblast chief executive officer Prof Silviu Itescu said the interim results "show for the first time that our proprietary technology can impact both quality of life and survival".

"If these long-term beneficial outcomes from a single dose of our adult stem cells are sustained they will translate into significant improvements to the quality of life and longevity of patients who are struggling with debilitating congestive heart failure," Prof Itescu said.

Cephalon chief executive officer Kevin Buchi said his company would "look to progress clinical development of Revascor for the treatment of congestive heart failure towards a phase III or pivotal trial".

CATHRX APPOINTS NY'S OPPENHEIMER FOR US PARTNER ADVICE

CATHRX

Cathrx says it has engaged New York investment bank Oppenheimer & Co as its financial advisor to identify strategic catheter transactions with US partners.

Cathrx chief executive officer Jeff Goodman said his company's focus was "to identify a partner with the network, market and product requirements that fit our own strategic ambitions" and Oppenheimer was well-placed to assist Cathrx to do that.

CEO LUSIA GUTHRIE TAKES 5% OF LBT

LBT INNOVATIONS

LBT chief executive officer Lusia Guthrie has become substantial in her company with a holding of 5,063,334 shares or 5.1 percent.

The shares are held by Ms Guthrie, High Guthrie and the Podlaska Superannuation Fund, of which Ms Guthrie is a trustee and member.

January 13, 2011

VIRALYTICS: ARTICLE BACKS CAVATAK COMBINATION CANCER THERAPY

VIRALYTICS

Viralytics says pre-clinical data shows that Cavatak (Coxsackievirus A21) enhances the effect of chemotherapy on human breast cancers both in vitro and in vivo.

Viralytics said an article co-authored by the company's director and chief scientist Dr Darren Shafren, entitled 'Enhanced oncolysis mediated by Coxsackievirus A21 in combination with doxorubicin hydrochloride', was published in the journal 'Investigational New Drugs'.

An abstract is available at http://www.ncbi.nlm.nih.gov/pubmed/21170760.

The abstract said that the researchers "showed that a single intravenous injection of CVA21 [Cavatak] in combination with an intraperitoneal injection of doxorubicin hydrochloride resulted in significantly greater tumor reduction compared to either agent alone".

Viralytics said the combination studies were undertaken over a number of years by researchers in the School of Biomedical Sciences and Pharmacy at The University of Newcastle.

The company said the article described the enhanced anti-cancer activity of Cavatak in combination with doxorubicin hydrochloride (a chemotherapeutic agent) as a new therapeutic regimen for both laboratory cultures of human breast cancer cells and mouse tumors models of human breast cancer.

Viralytics said doxorubicin hydrochloride was approved by the US Food and Drug Administration for use in the treatment of a number of metastatic human cancers including as breast, gastric, small cell lung and ovarian cancers.

Viralytics said the findings showed the potential of Cavatak for use in combination with chemotherapy, forming new therapeutic regimes in the treatment of human breast cancer.

ACRUX, ELANCO ANIMAL PROIDUCT APPLICATION DELAY

ACRUX

Acrux says the US Food and Drug Administration's Center for Veterinary Medicine has determined that an application for an animal health product is incomplete.

Acrux said the marketing application for the first animal health product using its transdermal delivery technology was submitted by licencee Eli Lilley's Elanco, but the Center for Veterinary Medicine said in its review that "one technical section of the marketing application is incomplete".

Acrux said Elanco was currently in dialogue with the Center for Veterinary Medicine to agree the requirements for the completion of this section.

The company said the additional requirements might "result in a delay to the decision on approval of the application, although the extent of any such delay has not been determined" and was pending further discussions with the Center for Veterinary Medicine.

Acrux said the delay was not financially material.

PHYLOGICA COLLABORATES WITH GERMANY'S XL-PROTEIN

PHYLOGICA

Phylogica says it has an alliance with Germany's XL-protein GmbH to provide access to XL-protein's modification technology for its Phylomer drug discovery platform.

Phylogica said XL-protein specialized in extending the circulation half-life of biopharmaceuticals with technology developed at the Technical University of Munich.

The company said the technology used a genetic technique to fuse a polymer of natural amino acids onto the relevant peptide or protein-based therapeutic, which slowed the body's clearance of the drug and prolongs the therapeutic effect.

Phylogica said the two companies would collaborate on a pilot study to validate the technology in combination with one of Phylogica's Phylomer peptides targeting CD40 ligand from its in-house anti-inflammatory program.

Phylogica said long-acting Phylomers "would be ideal for treating chronic indications, such as rheumatoid arthritis, coronary artery disease and inflammatory bowel disease, in which CD40 ligand has been implicated as a potential target".

CIRCADIAN, CHUGAI DEAL ON VEGF-D

CIRCADIAN TECHNOLOGIES

Circadian says wholly-owned subsidiary Vegenics has been granted an exclusive, global licence by Chugai Pharmaceutical granting access to its VEGF-D intellectual property.

Circadian said that both it and the Japan-based Chugai held extensive vascular endothelial growth factor-D (VEGF-D) portfolios which overlapped throughout the world.

Circadian said the licence enabled Circadian to enhance its intellectual property portfolio and secure its position as the dominant player in respect of VEGF-D worldwide.

Circadian said it would pay an upfront licence fee to Chugai milestone payments and royalties on certain VEGF-D related products.

January 14, 2011

USCOM APPOINTS US, EASTERN EUROPE DISTRIBUTORS

USCOM

Uscom has appointed the Nashville-based Provider Enterprises to distribute its ultra-sonic cardiac output monitor, "thereby doubling its coverage of US hospital beds".

Uscom said Provider would increase coverage from 23 percent to 56 percent of all US hospital beds.

Uscom said Provider had about 33 percent of all hospital beds in the US, in addition to the appointment the California-based Medical Dynamics which covered about 23 percent of the US hospital market.

Uscom said it had appointed Vok Medical to service the Russian Federation.

The company said it had appointed Medtel to cover the Australian market and was working with its partner in Asia, Pacific Medical Systems to establish greater penetration across the Asian markets.

*** Biotech Daily editor, David Langsam, owns shares in Alchemia, Bionomics, Biota, Chemgenex, Impedimed, Neuren, Optiscan and Sunshine Heart, as well as non-biotechnology stocks. These holdings are liable to change at any time.**