# Biotech Daily

SPECIAL SUMMER CATCH UP EDITION

**Sunday January 17, 2010**

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**December 18, 2009**

## PHYLOGICA SIGNS EVALUATION DEAL WITH ROCHE

PHYLOGICA, ROCHE

Phylogica signed an agreement with Roche to evaluate its Phylomer technology in transporting large molecules to attack disease targets within cells.

Phylogica chief scientific officer Prof Paul Watt said the challenge of targeting macromolecules to the intracellular matrix was "an exciting new frontier in drug development".

Phylogica said Roche would evaluate the Phylomer technology for transporting large molecules to attack disease targets within cells.

## FEDERAL R&D TAX CREDIT SUBMISSIONS BY FEB 5

FEDERAL GOVERNMENT R&D TAX CREDIT

The Federal Government has released draft legislation for its Research and Development Tax Credit calling it "the biggest reform to business innovation policy in over a decade".

A Federal Government media release said the draft legislation "follows through on the Government's commitment to deliver a more generous, more predictable and less complex tax incentive by replacing the outdated and complicated R&D Tax Concession".

The Federal Government said the proposed legislation would "cut red tape and provide better incentives to help boost the competitiveness of the Australian economy".

The media release said the Tax Credit was a central element of the Government's long-term agenda to lift Australia's innovation capacity and performance.

Under the R&D Tax Credit, companies can invest, knowing they can claim a tax offset of at least 40 percent of their expenditure on R&D activities, rising to 45 percent for companies with a turnover of less than $20 million a year, the media release said.

The Government said the R&D Tax Credit would "allow small innovative firms to get an immediate contribution towards their R&D spend even if they are not yet turning a profit".

For example, a company in tax loss turning over $10 million and spending $1 million on eligible R&D activities would receive a refund of $450,000 rather than adding $375,000 to its tax loss, the Federal Government said.

"This will provide innovative start-ups with the certainty they need to invest in growing their business," the Government said.

The exposure draft legislation follows the consultation paper released in September 2009.

The legislation is expected to be introduced into Parliament in early 2010 to ensure that taxpayers have certainty well ahead of the proposed July 1, 2010 start date for the new scheme.

The media release said submissions were requested by February 5, 2010.

The exposure draft legislation and explanatory materials are at www.treasury.gov.au.

## PRIMA READY FOR US PHASE IIb TRIAL

PRIMA

Prima says it has FDA and local ethics approval for a 60-patient phase IIb trial in the US and Australia to be run from the Fred Hutchinson Cancer Centre in Seattle, Washington.

Prima said the trial objective was "to further confirm the ability of CVac to reduce the instance of relapse in ovarian cancer patients, control the metastases of the cancer and increase the life expectancy of patients".

The company said it would seek to add to the positive efficacy results from CVac's 2007 28 patient phase IIa trial on a larger patient population.

**HELICON PLAN RAISES $113K, ABANDONS MINING PROJECT**

HELICON GROUP

Helicon won't exercise its option to acquire all of the issued capital of Arequipa Resources Pty Ltd for a 50 percent interest in Peru's El Serrano copper gold project.

Helicon said that "sustained selling from two holders of a substantial quantity of founder shares has seen the company's share price soften recently".

The company said that "whether as a consequence or not, the share purchase plan was not well supported, raising $113,000" taking the present cash position to about $500,000.

Helicon said it could not meet the capital requirements of the El Serrano project.

Helicon said it would continue to seek opportunities to allow it to raise capital and pursue a new business as well as continuing to develop the China pharmaceutical business.

**December 21, 2009**

**OMI LOSES US RITRACT CASE; VOLUNTARY ADMINISTRATION**

OCCUPATIONAL & MEDICAL INNOVATIONS

Occupational & Medical says the jury in its US Court action brought by Ritract (BD: Dec 14, 2009) has found in favor of Ritract.

On December 31, 2009 the company said it was in voluntary administration (see below).

Occupational & Medical (OMI) said the jury verdict was delivered to the Court on December 18, 2009 that: Ritract (RTI) was not statute barred from claiming misappropriation of trade secrets; that OMI had misappropriated certain trade secret information from RTI; that OMI should pay damages to RTI in the sum of $US2,240,640 on account of that misappropriation; that RTI's '584 patent was valid and enforceable; that OMI's current Auto-Retractable Safety Syringe product infringed all the asserted claims under RTI's '584 patent; and that OMI should pay damages to RTI in the sum of $US1,571,103 on account of that infringement.

Occupational & Medical said it was "extremely disappointed" with the decision but "for formal purposes this decision is not legally final or binding until such time as the Court gives its judgment in the matter".

The company said that under US District Court processes, there were several steps likely to take place prior to a judgment and, as the Court was not obliged to follow the jury verdict (although that is usually the case) the final judgment would not be known until early to mid February 2010.

**SUNSHINE HEART IMPLANTS 5th PATIENT; EXPANDS SITES, TEAM**

SUNSHINE HEART

Sunshine Heart has implanted its fifth C-Pulse aorta cuff pump – the first patient to be implanted at the University of Alabama Medical Centre in Birmingham.

Sunshine Heart chief executive officer Dave Rosa said the company would expand the number of sites implanting the C-Pulse and plans to include centres in Australia.

Mr Rosa said he was "encouraged by the feedback … from our current sites and are keen to support some additional centres that have expressed an interest in participating".

Mr Rosa also announced the hiring of Debra Kridner to take charge of clinical research and regulatory affairs.

Ms Kridner was previously a vice-president at St Jude Medical Cardiovascular Division and has held similar positions at Medtronic and Edwards Lifesciences.

Mr Rosa also announced the promotion of Rowena Hubble to chief financial officer, effective immediately.

## J&J'S CENTOCOR EXTENDS LIVING CELL ENCAPSULATION OPTION

LIVING CELL TECHNOLOGIES

Living Cell has extended the research collaboration with Centocor Research & Development Inc and granted an option for a licence to its encapsulation technology.

Living Cell said the exclusive two-year option with the Pennsylvania-based Johnson & Johnson subsidiary was for a global licence for human cell lines for a specific, but undisclosed, field of use.

Living Cell's chief executive officer Dr Paul Tan said that significant progress in the collaboration showed that the proprietary encapsulation technology for lead product Diabecell was applicable to other cells.

The agreement includes a Centocor-funded research program for two years.

Living Cell said the option to licence is for two years with a fee payable each year.

On exercise of the option, the parties would enter into a licencing agreement including upfront, annual, milestone and royalty payments but, for commercial reasons, Living Cell said it could not disclose details.

## CLINUVEL PHASE III EPP TRIAL 'PROMISING'

CLINUVEL PHARMACEUTICALS

Clinuvel says it has "promising four-months results" form its phase III trial of afamelanotide for erythropoietic protoporphyria.

On December 18, 2009 Clinuvel said a 36 patient trial of afamelanotide for polymorphic light eruption produced non significant results.

Today, the company said erythropoietic protoporphyria (EPP) patients were "known to be absolutely intolerant to visible and [ultra-violet] light".

Clinuvel said the genetic disorder led to an accumulation of protoporphyrin IX in the skin and an increased risk of incapacitating phototoxic reactions manifesting as pain and severe ulceration of the skin.

The company said the quality of life of EPP patients was much reduced by the significant restriction of activities that involve exposure to sunlight such as outdoor activities.

Clinuvel said an interim analysis of data from the first four months of the 12-month which was undertaken.

The study employed a crossover comparison of afamelanotide (three doses) and placebo (three doses) in 100 patients.

Clinuvel said that at dose intervals of two months, each patient received a single dose of either treatment.

Analysis of two treatment arms showed an overall reduction in the average number of phototoxic reactions.

Clinuvel said 35 patients with severe and/or moderate pain reported the greatest reduction in mean number of reactions ($p=0.03$, 95% confidence interval).

The company said that analysis of pain severity was positively correlated with treatment, indicating that patient pain scores differed significantly between treatment groups ($p=0.006$, 95% CI).

Although the analysis of quality of life data is not yet complete, all eight physicians involved in the trial reported a dramatic improvement in the patients' ability to engage in outdoors activities.

Safety reports from all academic centres are excellent to date, Clinuvel said.

The company said the study would be completed by the end of December 2009, after which a full analysis of data would follow.

**COMMERCIALISATION AUSTRALIA 'READY FOR BUSINESS'**

FEDERAL GOVERNMENT COMMERCIALISATION AUSTRALIA

In a pun on car-racing, the Federal Government has called for application for "assistance" from Commercialisation Australia.

In a media release entitled 'Start your applications' Innovation Minister Senator Kim Carr again described Commercialisation Australia "the Government's radical new approach" to commercializing research (BD: Oct 21, 2009).

"Commercialisation Australia has launched a range of new online and telephone resources as it gears up to receive applications from early January," Senator Carr said.

"From today, potential applicants can access detailed information about how Commercialisation Australia can help them realize their innovation potential, including a useful pre-application checklist," Senator Carr said.

"Innovators can access the checklist and other resources on the new website, www.commercialisationaustralia.gov.au," Senator Carr said.

The Government media release said Commercialisation Australia would "take a hands-on approach to help bring ideas to market offering a range of tailored assistance measures". Measures include specialist advice and services, financial support to engage experienced executives and grants for proof-of-concept and early stage commercialization activities. Applications will be assessed through a competitive, merit-based, selection process.

A Commercialisation Australia Hotline (13 22 56) has been established to provide potential applicants with program information and advice.

**AUSBIOTECH CAUTIOUS WELCOME TO R&D TAX CREDIT PAPER**

AUSBIOTECH

Ausbiotech chief executive officer Dr Anna Lavelle said her industry organization had "begun a detailed review of the exposure draft legislation, including discussions with other industry associations and accounting firms, in preparation for a discussion paper for members' information in January".

"Ausbiotech was heartened by and applauds comments made by the Minister for Innovation Senator Kim Carr that the proposed tax credit 'cuts red tape and provides a better incentive for business to invest in research and innovation'," Dr Lavelle said.

Dr Lavelle said smaller companies were "keen to see the tax credit deliver a simpler system that encourages investment in research and development" and delivers the benefits that Senator Carr claims. "However, there are items of note in the legislation, which Ausbiotech will investigate before making further comments," Dr Lavelle said.

**December 22, 2009**

**SIRTEX APPOINTS MICHAEL MANGANO US SALES PRESIDENT**

SIRTEX MEDICAL

Sirtex has appointed Michael Mangano as president of the US-based Sirtex Medical Inc. Mr Mangano was previously a senior executive with medical device company Boston Scientific Corporation.

From January 5, 2010 Mr Mangano will be responsible for increasing the sales of Sirtex's SIR-Spheres microspheres for liver cancer in the US.

Mr Mangano spent more than 15 years with Boston Scientific in sales and marketing, international business, mergers and acquisitions, project management and new business development. He will be based in Wilmington, Massachusetts and replaces Dr John Reddington who leaves the company on December 31, 2009.

## LEO (PEPLIN) PHASE III TRIAL CLEARS FACE, SCALP LESIONS

PEPLIN LEO PHARMA

Leo Pharma says two phase III trials of Peplin's PEP005 achieved their primary and secondary endpoints with statistically significant clearance of actinic keratosis lesions.

Leo Pharma said the two phase III actinic (solar) keratosis clinical trials using PEP005 (ingenol mebutate) gel for the treatment of lesions on head treatment areas, which include the face and scalp was begun by Peplin, which Leo acquired late last year (BD: Nov 12, 2009).

Leo said actinic keratosis was a common pre-cancerous skin condition caused by sun exposure, which can develop into skin cancers if left untreated.

Leo's executive vice president for research and development Lars Olsen said that the "strong results from the trials are an important step towards a unique and novel treatment model for AK".

"The results are also an important step in Leo Pharma's growth strategy," Mr Olsen said.

"The trials confirm the results of prior trials and we are closer to being able to provide the patients a three-day course of therapy than ever," he said.

The company said trials were initiated and run by US and Australia-based Peplin.

The two phase III trials each achieved their primary and secondary efficacy endpoints with statistically significant clearance of actinic keratosis lesions compared to vehicle.

The two completed phase III clinical trials, known as Region-IIa and Region-IIb, enrolled about 250 patients each and evaluated the use of a 0.015% concentration of PEP005 Gel applied daily for three consecutive days to actinic keratosis lesions on the face and scalp.

"The Peplin team has done an excellent job of executing the development program and completing the phase III trials within the expected timeframe," Mr Olsen said.

"We are happy to have confirmed the basis for a novel, competitive product, even if we still have some way to go," Mr Olsen said.

Leo said it had one additional phase III clinical trial ongoing with PEP005 Gel for actinic keratosis lesions.

The company said that trial known as Region-Ib was for lesions on non-head locations, which includes the trunk and extremities and was designed to replicate the previously completed, successful Region-I trial and confirm its results.

Region-Ib completed enrolment of about 250 patients earlier this year and the company said the data was expected by April 2010.

Leo said it expected to market the actinic keratosis treatment in 2012.

## CASH-STRAPPED NEURODISCOVERY DILUTED IN PAIN TRIAL

NEURODISCOVERY

Neurodiscovery will not commit to a NSL-043 phase II trial and its stake in the collaboration agreement with Japan's Sosei Corp will fall to about 32 percent.

Neurodiscovery said that in order to preserve its cash reserves it advised Sosei that it would not contribute to its share of the outstanding costs of development of NSL-043 for the period January to December 2008.

NSL-043 is being developed as an oral treatment for neuropathic pain.

## NARHEX BOARD CHANGES

NARHEX LIFE SCIENCES

Narhex says that following the sudden death of executive chairman Dr Michael Cohen, David Mandel had been appointed chairman and acting managing director.

Peter Nash continues as executive director for China operations.

**ACUVAX SAYS 'BUST' HAWAIIAN STEP-SISTER HAS RAISED $1.65m**

ACUVAX

Acuvax says that its US affiliate Hawaii Biotech has received an initial $US500,000 cash injection with an additional $US1 million ($A1.1 million) for near-term financing needs.

Acuvax has previously said that the chief executive officer of 28 percent sister company Hawaii Biotech Dr Elliot Parks was taking steps to file a petition with the US Bankruptcy Court in Honolulu (BD: Dec 14, 2009).

"This is an unprecedented step as Hawaii Biotech Inc has been offered a number of financing alternatives" Acuvax chairman Patrick Elliott said at the time.

In November, Acuvax requisitioned an extraordinary meeting of Hawaii Biotech shareholders to replace two directors including Dr Parks (BD: Nov 9, 2009).

Acuvax said the funding was a convertible note led by a Hawaii-based individual with biotechnology experience and its Hawaii Biotech stake would be reduced to 26 percent.

Acuvax chief executive officer Dr William Ardrey said: "I have never seen a bankruptcy proceeding with so much capital available to a company."

**December 23, 2009**

**XCEED'S 22% GIVES CALZADA 88%OF POLYNOVO**

CALZADA

Calzada (formerly Metabolic) will buy all of Xceed Capital's 8,833,333 shares in Polynovo Biomaterials for 28,840,832 Calzada shares.

Xceed will hold 8.7 percent of Calzada, making it the second largest shareholder.

Calzada's holding in Polynovo will increase from 65.85 percent to 87.65 percent.

In 2008, Metabolic invested $3.5 million for 60 percent of Polynovo from Xceed and the Commonwealth Scientific and Industrial Research Organisation (BD: Dec 18, 2008).

In November 2008, an agreed acquisition of Polynovo by Metabolic collapsed at the Metabolic annual general meeting when major shareholders unexpectedly voted against merger resolutions (BD: Nov 27, 2008).

Metabolic said it would exchange $3.5 million for 20,750,000 Polynovo series A from Polynovo's shareholders, Xceed and the CSIRO.

The company said the conversion of its $1.25 million loan to Polynovo (with interest) was included in the $3.5 million.

Following the Metabolic investment, Xceed and CSIRO, held 25.5 per cent and 14.5 percent of Polynovo, respectively.

Following a raft of problems, on April 2009, Entrust took a 19.8 percent stake in Metabolic, (BD: Apr 7, 2009).

On November 17, 2009, Metabolic increased to 66 percent of Polynovo.

The agreement is subject to conditions with completion expected early in 2010.

Calzada said it had offered a separate scrip based offer to CSIRO to acquire its 12.35 percent Polynovo shareholding, giving Calzada 100 percent of Polynovo.

Calzada said the offer was under consideration with a decision expected early in 2010.

The company said neither deal was conditional on the other.

**HEALTHLINX COMPLETES HALF OF $1.1m PLACEMENT**

HEALTHLINX

Healthlinx has completed the first tranche of a $1.1 million placement at eight cents a share, raising $550,000 (BD: Nov 30, 2009).

## CSL CONTINUES AUSTRALIAN PLASMA PRODUCT SUPPLY

CSL

CSL will supply Australia's National Blood Authority, on behalf of Federal and State Governments, "safe, secure and affordable plasma therapeutic products".

CSL said the National Blood Authority supported the long standing collaboration with the Australian Red Cross Blood Service, for the fractionation of plasma supplied through the efforts of volunteer donors.

The company said the new agreement would commence on January 1, 2010 and run for eight years until December 31, 2017, subject to review.

## NEUREN RAISES $1.5m EQUITY DRAW DOWN PREREQUISITE

NEUREN PHARMACEUTICALS

Neuren says that following approval of all resolutions at the special shareholders' meeting, it has completed a placement of shares and options for a further $1.5 million.

The company said the funding met a prerequisite of the convertible loan agreement with Springtree Special Opportunities Fund to raise a further $US1 million.

## STIRLING'S INDIA DEAL; OTC, GENERIC LAUNCH

STIRLING PRODUCTS

Stirling says it has a working relationship with Indian drug manufacturer Cipla and would launch a range of over-the-counter and generic prescription drugs in Australia.

Stirling said the drugs would be launched under the Stirling Pharma brand, in March 2010.

**December 24, 2009**

## MERCK RENEGS ON BIODIEM'S JAPAN LICENCE

BIODIEM

Biodiem says the US Merck & Co takeover of Schering-Plough has led to a non-renewal of a licence for its live attenuated influenza vaccine technology for Japan.

Biodiem said it previously held the co-marketing rights for its live attenuated influenza vaccine (LAIV) technology in conjunction with Nobilon, whose parent company Schering-Plough merged with Merck, and has claimed full rights to the Japan market.

Biodiem said the reversion of the rights meant that Merck would not have to pay the final milestone of $US1 million in accordance with the licence agreement signed in 2004.

Biodiem's chief executive officer Julie Phillips told Biotech Daily that Nobilon had a licence to its LAIV for the whole world except Russia and Japan and did not have marketing rights for North America.

Ms Phillips said Merck could take up licences for Japan and North American marketing in the future and all other LAIV agreements with Nobilon and other entities would continue.

Biodiem said in its media release that it had begun discussions on the manufacturing and marketing rights of its live attenuated influenza vaccine technology for the Japanese market.

**PSIVIDA PHASE III ILUVIEN DIABETIC MACULAR EDEMA 'SUCCESS'**

PSIVIDA

Psivida says that significantly more patients receiving Iluvien showed improvement in best corrected visual acuity of 15 or more letters at two years compared to placebo.

Psivida said licencee Alimera Sciences planned to file a new drug application with the US Food and Drug Administration by July 2010.

The company said that top-line 24 month results from the 956-patient phase III study of Iluvien for the treatment of diabetic macular oedema (DME) conducted by Alimera met the primary efficacy endpoint of the difference in the percentage of patients whose best corrected visual acuity improved by 15 or more letters from baseline.

The patients were randomized to receive either 0.45 micrograms/day Iluvien, 0.23 micrograms/day or placebo.

Based on Alimera's analysis the primary efficacy endpoint was met with statistical significance for both doses and both the low and high dose Iluvien showed greater numerical efficacy at month 24 than at month 18, a requirement for approval.

Intraocular pressure increases to 30 millimeters of mercury (mmHg) or greater at any time point, a key adverse event studied in the trial, were seen in 21.6 percent of the high dose patients and 16.3 percent of the low dose patients. Over the 24 month period 5.1 percent of high dose patients and 2.1 percent of low dose patients received a trabeculectomy (filter surgery) to reduce eye pressure.

Psivida said that Alimera planned to file for approval of the low dose of Iluvien for diabetic macular oedema by July 2010, followed by filings in European countries and Canada.

Psivida chief executive officer Dr Paul Ashton said the company was "very encouraged by these data and look forward to our collaborative partner Alimera filing the NDA for potentially the first ophthalmic drug therapy approved for DME".

**ALCHEMIA RIGHTS ISSUE RAISES $15.5m**

ALCHEMIA

Alchemia says its two-for-11 renounceable rights issue at 53 cents a share has raised the maximum $15.5 million.

The rights issue was oversubscribed with demand being significantly greater than the 29,269,081 shares available under the rights issue.

**'OVERSUBSCRIBED' AVEXA PLAN RAISES $15m**

AVEXA

Avexa says its 14 cents a share purchase plan was heavily oversubscribed and raised about $15 million.

Avexa said it would scale back applications "to ensure that all shareholders were allowed to participate" and all eligible shareholders would receive 80 percent of their application.

**NORWOOD ABBEY EXTENDS CONVERTIBLE NOTE, RAISES $250k**

NORWOOD ABBEY

Norwood Abbey has negotiated an extension of the convertible loan from Lettered Management Pty Ltd to December 31, 2010. The loan will be interest free and will convert automatically upon a completion of the proposed Sino-Excel deal.

Norwood Abbey said it would issue 9.5 million shares as consideration for the interest-free extension. A further 10 million shares and 5 million options will be issued in consideration of the facilitation of previous extensions and variations to the loan agreement.

**December 29, 2009**

## FDA KNOCKS BACK PHARMAXIS ARIDOL NDA

PHARMAXIS

Pharmaxis says the US Food and Drug Administration has determined that the new drug application for Aridol for asthma management "cannot be approved in its present form".

Pharmaxis said the FDA complete response letter listed deficiencies observed at three subcontract manufacturing and testing facilities; submission of revised labeling; and agreement to post-marketing requirements.

Pharmaxis' chief executive officer Dr Alan Robertson said the complete response letter "provides us with a clear outline of the FDA's requirements".

"Importantly, we have not been requested to undertake any additional clinical studies prior to product approval," Dr Robertson said.

Pharmaxis said it filed the application for Aridol in February 2009 and following a meeting on November 20, 2009 the FDA's pulmonary-allergy drugs advisory committee recommended the approval of Aridol.

## BIOPHARMICA CHANGES NAME, ISSUES DIRECTOR STOCK

BIOPHARMICA

Biopharmica says all annual general meeting resolutions passed easily, with up to 12.3 percent of proxy votes opposing the issue of stock to directors.

The meeting overwhelmingly approved resolutions on the name to change to BPH, share and option placements and the acquisition of $14 million of shares in Advent Energy but there was dissent on the issue of shares and options to directors David Breeze and Deborah Ambrosini.

The most significant dissent was on the issue of 2,000,000 MDSystems options to Mr Breeze with 8,153,778 proxy votes (87.7%) in favor and 1,146,317 votes (12.3%)against.

**December 30, 2009**

## STIRLING APPOINTS BOB PRITCHARD MARKETING CONSULTANT

STIRLING PRODUCTS

Stirling has appointed Bob Pritchard as a product, brand and marketing consultant for 18 months commencing January 1, 2010.

Mr Pritchard will be involved in all aspects of the positioning and promotion of the company's products and commercialization.

Stirling said Mr Pritchard's "proven skills as a speaker and motivator will be of particular ongoing benefit to the company following the launch of the Company's 'i-naturals' botanical multi-level marketing business as well as the Stirling Pharma launch".

## OCCUPATIONAL & MEDICAL INNOVATIONS IN VOLUNTARY ADMINISTRATION

OCCUPATIONAL & MEDICAL INNOVATIONS

Occupational & Medical Innovations says that David Stimpson and Terrence Rose of SV Partners were appointed as joint and several voluntary administrators (see above, Dec 21, 2009).

**January 4, 2010**

## BENITEC BUYS OUT CSIRO WITH 10% HOLDING

BENITEC, CSIRO

Benitec says its long-standing and problematic contract with Commonwealth Scientific and Industrial Research Organisation has been terminated for a 10 percent equity stake.

Benitec chief executive officer Sue MacLeman said the “renegotiated agreements further strengthen the Benitec and CSIRO relationship and allows the company to be a more attractive investment option”.

The company said that in 2007 the CSIRO Benitec capital growth agreement and onerous terms of the commercial agreement “were negatively impacting investment, collaboration and potential merger/acquisition options”.

Benitec said it approached CSIRO with an equity offer in exchange for removal of the capital growth agreement and commercial agreement. The other objective was to provide clarity and simplification for both parties so they could maximize value from this portfolio.

Benitec said that there would be one substantive licence agreement which with transition arrangements would be effective from January 4, 2010.

Benitec retains its exclusive worldwide licence to the human field while CSIRO has animal, plant and other rights.

Benitec said it retained worldwide non-revocable human field rights to the Graham patent, the basis of its RNA interference technology.

The company said no royalties would be payable to CSIRO in the future and Sigma-Aldrich and sub-licencee revenues for research use and reagents will revert to Benitec from March 31, 2010, improve the company’s revenue and cash flow.

Benitec said there would be “better aligned interests for patent prosecution and maintenance with the establishment of a patent management committee”.

Patent costs will be paid by Benitec based upon a jointly agreed budget.

CSIRO will have rights to research tools and research services, subject to the exclusive rights in the Sigma-Aldrich licence, but would pay Benitec 50 percent net revenues from any related commercialization.

## HEARTWARE REPAYS THORATEC LOAN

HEARTWARE

Heartware says it has repaid its $US20 million loan from Thoratec in full and any right of Thoratec to convert the loans to Heartware shares has been extinguished.

## USCOM LOSES CEO, DIRECTOR PAUL BUTLER

USCOM

Uscom says chief executive officer and director Paul Butler will resign due to ongoing international travel requirements.

Uscom said executive chairman Rob Phillips would be acting chief executive officer while a new CEO was recruited along with a global sales manager.

Nick Schicht will continue as general manager.

Mr Butler joined Uscom in 2002 and was appointed as chief executive officer in January 2007. From February 1, 2010 he will continue on a consultative basis working on business development projects.

**CATHRX APPLIES FOR CE MARK FOR IRRIGATED ABLATION CATHETER**
CATHRX
Cathrx has submitted an application for Conformitée Européenne (CE) marking of its irrigated ablation catheter coupled with the company's variable deflectable stylet.
Cathrx said the irrigated ablation catheter was the first in its therapeutic catheter range designed for use in the treatment of cardiac arrhythmias.
Cathrx chief executive officer Neil Anderson said with irrigated ablation catheter CE mark approval, "we'll have a complete modular catheter offering for the diagnosis and treatment of atrial flutter and atrial fibrillation".

**AGENIX LOSES CEO DR STEPHEN PHUA; APPOINTS NICHOLAS WESTON**
AGENIX
Agenix says chairman Nicholas Weston has been appointed as executive chairman, effective immediately.
Agenix said Mr Weston would replace Singapore-based chief executive officer, Dr Stephen Phua, whose resignation was announced on August 19, 2009 but Dr Phua would "complete his employment and role as a director with effect from today instead of fully serving the entire notice period".

**January 6, 2010**

**GENETIC TECHNOLOGIES DISTRIBUTES RESPONSE GENETICS TEST**
GENETIC TECHNOLOGIES
Genetic Technologies will distribute Response Genetics's tests in Australia and South East Asia.
Genetic Technologies said it would have be the exclusive distribution in Australia, Indonesia, Malaysia, the Philippines, Singapore and Thailand for Response Genetics' colon, lung and gastric genetic test panels, proprietary polymerase chain reaction (PCR) based molecular diagnostic tests for cancer.

**CASHED-UP BPH CORP INVESTS IN ADVENT ENERGY**
BPH CORPORATE, (BIOPHARMICA)
BPH Corporate (formerly Biopharmica) says that having raised $11.3 million in a placement, it will acquire up to 19.4 percent of Advent Energy's capital at 50 cents a share.

**TYRIAN REPLACES CFO JAIME PINTO WITH MICHAEL VAMOS**
TYRIAN DIAGNOSTICS
Tyrian says Jaime Pinto has resigned as chief financial officer and assistant company secretary from January 15, 2010.
Tyrian said Michael Vamos would be appointed as chief financial officer and assistant company secretary from February 2, 2010.
The company said Mr Vamos was a chartered accountant with more than 15 years experience in finance operations and general management, most recently as group commercial manager for Mini-Tankers Australia.

**January 7, 2010**

## AUSTRALIAN PATENT FOR VIRALYTICS' ECHOVIRUSES FOR CANCER

VIRALYTICS

Viralytics says it has been granted an Australian patent for the use of echoviruses for the treatment of all cancers bearing expression of the integrin alpha-2-beta-1 (α2β1).

Viralytics chief scientist officer and inventor of the technology Prof Darren Shafren said that may cancers, in particular ovarian and gastric cancers, had elevated surface levels of integrin α2β1.

"The presence of integrin α2β1 allows our family of echoviruses to lock onto the surface of cancer cells, leading to rapid infection and cellular destruction," Prof Shafren said.

"This is a similar process to the company's lead candidate Cavatak which uses an ICAM-1 receptor instead of the integrin α2β1 to lock onto the surface of cancer cells," Prof Shafren said.

Viralytics said the patent also covered the right to use Evatak (the name of Viralytics' proprietary formulation of the echovirus type 1) in conjunction with other oncolytic viruses such as the company's lead product Cavatak.

The company said it had granted patents for this family of viruses from the US, India, South Africa and Singapore.

## TISSUE THERAPIES TO CONDUCT CARDIFF VITROGRO TRIAL

TISSUE THERAPIES

Tissue Therapies says Cardiff University's Prof Keith Harding will conduct a trial of Vitrogro for skin wound repair expected to be completed by the end of 2010.

Tissue Therapies said the trial would assist in producing the final data necessary for approval of Vitrogro for sale, initially in Europe, Canada, Australia and New Zealand.

Tissue Therapies chief executive officer Dr Steven Mercer said Prof Harding was "widely recognized as one of the most eminent wound healing physicians and researchers in the world today".

**January 11, 2010**

## ACUVAX'S HAWAII COMPLETES PHASE I DENGUE VACCINE DOSING

ACUVAX, HAWAII BIOTECH

Acuvax 26 percent affliate Hawaii Biotech has completed recruitment and dosing for a multiple-dose phase I clinical study of its dengue virus monovalent vaccine.

Acuvax said the dengue fever vaccine was a double-blind, placebo controlled, dose escalation safety study in healthy subjects conducted at the Saint Louis University Center for Vaccine Development.

The company said vaccine recipients were being monitored for safety and the development of virus neutralizing antibodies and said Hawaii Biotech expected preliminary safety results and immunologic data by April 2010 with complete results by the end of the year.

## UNILIFE INVESTORS VOTE FOR US MOVE

UNILIFE MEDICAL SOLUTIONS

Unilife says the resolutions on the move to the US put to shareholders and option holders at its scheme meetings on January 8, 2010 have been passed.

## MARSHALL HEINBERG REPLACES UNIVERSAL BIO'S CHARLES KIEFEL

UNIVERSAL BIOSENSORS

Universal Biosensors has appointed Marshall Heinberg to replace Charles Kiefel as a director.

Universal Biosensors said Mr Heinberg was "a well known and respected senior US financial industry executive" and was senior managing director and head of investment and corporate banking at the US-based Oppenheimer & Co investment bank.

## IMMUNOXEL INVENTOR SAYS FURTHER STUDY WARRANTED

STIRLING PRODUCTS

A journal article on a small trial of Stirling's botanical immunomodulator Immunoxel (Dzherelo) in TB/HIV patients has shown that further study is warranted.

The article 'Impact of Adjunct Immunotherapy with Multi-herbal Supplement Dzherelo (Immunoxel) on Treatment Outcomes in End-stage TB/HIV Patients' by Dr Galyna A Kutsyna of the Ukraine's Luhansk State Medical University is in the Journal of Antivirals & Antiretrovirals at: http://omicsonline.org/ArchiveJAA/2009/December/03/JAA1.86.php.

Stirling said that in the two-month study Immunoxel was administered to 20 of 40 late-stage terminal TB/HIV patients.

Six patients in the Immunoxel group died compared to 12 in the group on conventional TB therapy, the company said.

Stirling said the remaining 14 patients in the Immunoxel group experienced "marked clinical improvements and one patient was discharged due to full recovery".

Among the 20 matched subjects on conventional TB regimen, 12 died and only one was slightly better-off.

The company said the results indicated that Immunoxel might reduce mortality and improve significantly the quality of patient life.

Stirling said that improvement in quality of life was supported by the substantial weight gain (mean/median 3.3/4 kg) observed in the much higher proportion of patients in the Immunoxel group than among those who received TB drugs alone in a ration fo 16 to one.

At the end of two months 13 patients (65%) patients in the Immunoxel group became TB sputum smear negative compared to only one individual (5%) in the group on conventional TB treatment.

These results suggest that adjuvant immunotherapy with Immunoxel may significantly improve TB/HIV outcome in terminally ill patients and reduce mortality.

Stirling is the distributor of Immunoxel which was developed by Dr Galyna A Kutsyna in Kiev

## MESOBLAST PLEADS SCHULTZ TO ASX 32% PRICE QUERY

MESOBLAST

Mesoblast has told the ASX 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 $1.36 on December 31, 2009 to $1.79, a 31.6 percent increase, on January 8, 2010.

Biotech Daily reported "algorithm" trading of one or two shares at a time when Mesoblast appeared to have a floor of $1.02 in mid-October.

Mesoblast closed up 18 cents or nine percent to $2.18 on January 15, 2010.

**January 12, 2010**

## PHARMAXIS BUYS CANADA'S TOPIGEN FOR $9-24m

PHARMAXIS

Pharmaxis will acquire Canadian-based private biopharmaceutical company Topigen for about $8.6 million in shares and up to $22.1 million in shares.

Pharmaxis said the transaction would enhance its respiratory drug development portfolio and complement the existing products and drugs under development.

On closing of the transaction, Pharmaxis said it would issue 3,200,000 shares with an additional 5,000,000 shares to be issued subject to the achievement of certain preclinical and clinical milestones specified in the purchase agreement.

Biotech Daily's calculations were based on the $2.70 close on January 11, 2010, but on January 15, Pharmaxis closed at $2.95 a share increasing the value of the acquisition to $9.44 million to $24.2 million. The final value depends of Pharmaxis's share price.

Pharmaxis said Topigen had a number of innovative therapeutic candidates for respiratory disorders based on its multi-targeted oligonucleotide technology.

The lead candidate TPI ASM8 is in phase II development for moderate to severe asthma with TPI 1100 in preclinical development for chronic obstructive pulmonary disease.

Pharmaxis chief executive officer Dr Alan Robertson said the potential new medicines were "an ideal fit for Pharmaxis".

"With Bronchitol moving into its commercialization cycle and PXS25 well-positioned in phase I trials, we have sought to expand our product pipeline and utilize our existing clinical development capacity with an additional phase II product," Dr Robertson said.

He said Topigen was due to report ASM8 phase II dosing trial results by July 2010.

"On closing, Topigen will bring to the combined company sufficient cash resources to complete the current phase IIa study and the next clinical milestone. We expect to close the acquisition within the next 60 days," Dr Robertson said.

## CYTOPIA MEETING APPROVES YM BIOSCIENCES TAKEOVER

CYTOPIA

Cytopia says the resolution to be taken over by the Toronto-based YM Biosciences was approved overwhelmingly with 50,528,494 votes in favor and 165,558 votes against.

## ARC LINKAGE GRANTS REVIEW COMMENTS OPEN

AUSTRALIAN RESEARCH COUNCIL

Australian Research Council chief executive officer Prof Margaret Sheil has called for comment on a proposed new application process for the Linkage Projects scheme.

"Linkage Projects is the main ARC funding scheme to advance research collaborations with end users," Prof Sheil said.

Prof Sheil said the scheme promoted partnerships between higher education organizations and other organizations, including industry and encouraged investment.

"As part of this review, the ARC is proposing to adjust the type of proposals invited in each Linkage Projects funding round by having round one cater [for] more flexible student awards and round two cater to all other Linkage Projects proposals," Prof Sheil said.

Prof Sheil said the consultation paper proposed changes to the timing of the scheme, with the aim of offsetting the main Linkage Projects round from the Discovery Projects round.".

The consultation period closes on February 8, 2010, with the consultation paper and response templates available at http://www.arc.gov.au/ncgp/lp/lp_consultation.htm.

**BIOPHARMICA BECOMES BPH CORPORATE.**

BIOPHARMICA, BPH CORPORATE.

Biopharmica has formally changed its name to BPH Corporate. The ASX code of BPH remains the same.

**January 13, 2010**

**ANTEO UP 171% ON 1st US LICENCE**

ANTEO

Anteo jumped 171 percent on signing its first commercial agreement for the global rights to its Mix & Go technology with the Indiana-based Bangs Laboratories Inc.

Anteo said Bangs was "one of the world's leading suppliers of beads" to the in vitro diagnostic and research markets.

The company said the details were confidential but included "a modest upfront payment, revenues from the supply of Mix & Go reagent, research and collaboration payments and double digit royalty payments on Bang's products sold that have been coated with the Mix & Go product, with the first revenues expected by April 2010.

Bangs Laboratories president Chad Owen said: "I have been in this business for more than 13 years now and regularly encounter interesting new technologies. The Anteo Mix & Go technology is one of the most exciting innovations I have seen in all of that time."

Anteo said the agreement was a global non-exclusive licence to use Mix & Go on Bang's beads.

The company said that such products were at the core of many of the tests undertaken in the multi-billion dollar global in vitro diagnostic market and were widely used by research institutions in the development of new diagnostic tests.

Anteo chairman James Henderson said the agreement was "a major step forward".

"It has significant ramifications for the commercialization of the technology and demonstrates that our strategy of engaging both the major IVD suppliers and bead manufacturers is bearing fruit," Mr Henderson said.

Anteo said Mix & Go was "a novel patented process that allows proteins (or biomarkers) to be detected at lower concentrations, with improved stability and across a broader concentration range" providing the potential for earlier disease detection and improved treatment monitoring.

Anteo was up 1.2 cents or 171.43 percent to 1.9 cents with 89.1 million shares traded.

**CHINA PAYMENTS CONTINUE TO DRIBBLE IN TO AGENIX**

AGENIX

Agenix says that ongoing efforts to recover payments from its Chinese bio-pharmaceutical partners "continue to produce results".

Agenix began a process to acquire two Shanghai pharmaceutical in February 2007 but was brought unstuck when a four percent Chinese landlord failed to provide a waiver for the completion of the share transaction (BD: Feb 14, Jun 6, 2007; Jul 24, 2008).

Agenix said that in December 2009, the Agenix Wholly Foreign Owned Enterprise collected RMB1,500,000 (about $A237,000) in relation to the failed transaction in addition to the RMB1,500,000 collected in November 2009.

**January 14, 2010**

## PROBIOTEC ACQUIRES PLANT FOR IMMUNE SYSTEM RESEARCH

PROBIOTEC

Probiotec says it has acquired all the shares in the Australian Dairy Proteins joint venture with Dairy Farmers Ltd (now National Foods).

Probiotec said the venture was established in May 2002 for the development and construction of a fractionation plant to extract high purity dairy proteins from whey, a by-product of cheese manufacture.

Probiotec held 50.001 percent and Dairy Farmers held 49.999 percent of Australian Dairy Proteins (ADP), which Probiotec has acquired for an undisclosed price. Its operations are adjacent to the Dairy Farmers processing plant in Malanda, Queensland.

Probiotec managing director Wayne Stringer said the acquisition provided “the opportunity to capitalize on both the potential markets for ADP’s products as well as the substantial intellectual property developed by the joint venture”.

ADP produces the dairy protein fractions lactoferrin and the only dairy-based high purity immunoglobulins.

Probiotec said that immunoglobulins and lactoferrin together would result in a range of new pharmaceutical products and it was undertaking human clinical trials.

The company said the level of whey available to the Malanda plant was below optimum and it was negotiating with five dairy groups to secure access to a large whey stream.

## STIRLING WINS UNDISCLOSED US GRANT FOR OTC IMMUNOMODULATOR

STIRLING PRODUCTS

Stirling says it has am undisclosed grant from the US Civilian Research & Development Foundation for a clinical trial of its botanical immunomodulator Immunoxel.

Stirling said Immunoxel was its “flagship product” for tuberculosis and AIDS.

Stirling said that no double-blind, placebo-controlled clinical trials had been conducted and the grant would allow trial investigators to conduct a trial.

## PRANA APPOINTS PAUL MARKS DIRECTOR

PRANA BIOTECHNOLOGY

Prana has appointed Paul Marks as a director.

Prana said Mr Marks had experience in healthcare and mining investment, foreign exchange and commodities trading and was formerly vice-president of foreign exchange with Prudential-Bache Securities and a senior foreign exchange strategist with National Australia Bank. The company said Mr Marks was a large shareholder in Prana.

Prana said that Mr Marks was a chemical engineer and mathematician by training and held a Bachelor of Chemical Engineering and a Masters in Applied Finance.

Mr Marks is a director of Conquest Mining and on the board of unlisted private companies.

## COURT APPROVES UNILIFE RELOCATION TO THE US

UNILIFE MEDICAL SOLUTIONS

Unilife says the Federal Court of Australia has approved the schemes of arrangement with shareholders and option holders.

Unilife said the Court decision was the final approval step for the group's move to the US.

Implementation is expected on January 27, 2010 and no further action is required by shareholders and option holders of the Company.

**OPTUMHEALTH PAYS BRAIN RESOURCE $3.2m TO RENEW LICENCE**

BRAIN RESOURCE

Brain Resource says Optumhealth Behavioral Solutions has paid $US3 million ($A3.2 million) fee for its third year use of Brain Resource's web-based Webneuro product.

Brain Resource said Webneuro was a clinical decision support product and the renewal "demonstrates their confidence in the use of this product in the US healthcare sector".

**TYRIAN PLEADS SCHULTZ TO ASX 50% PRICE QUERY**

TYRIAN DIAGNOSTICS

Tyrian has told the ASX 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 1.6 cents on January 14, 2010 to 2.4 cents, a 50 percent increase, on the same day and noted an increase in trading volume.

Tyrian closed up 0.4 cents or 25 percent at two cents with 50.9 million shares traded.

**January 15, 2010**

**CELLMID PLEADS SCHULTZ TO ASX 31% PRICE QUERY**

CELLMID

Cellmid has told the ASX 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 3.2 cents on January 14, 2010 to 4.2 cents, a 31.25 percent increase, on January 15, 2010 with an increase in trading volume.

Cellmid closed up 0.4 cents or 12.5 percent at 3.6 cents with 36.5 million shares traded.

**SUPREME COURT APPROVES CYTOPIA MERGER MEETINGS**

CYTOPIA

Cytopia says the Supreme Court of Victoria has approved the scheme of arrangement to be taken over by Toronto's YM Biosciences.

The company said the scheme would become effective on January 18, 2010 when shares on the ASX would be suspended.

Cytopia said the implementation date was January 28, 2010 with scheme consideration on February 1, 2010 when shareholders will begin to receive their YM share certificates.

**BIOTRON RAISES $2.3m**

BIOTRON

Biotron says its one option-for-one share entitlement issue has raised $2,290,746 and was 23 percent oversubscribed with applications for 141,307,254 options (BD: Dec 10 2009).

Biotron said 114,537,315 options would be issued at two cents each.

*** Biotech Daily editor, David Langsam, owns shares in Alchemia, Avexa, Chemgenex, Impedimed, Neuren and Optiscan, as well as non-biotechnology stocks and has an indirect interest through Australian Ethical trusts in Cochlear, Genera, Pharmaxis, QRX, Resmed and Tissue Therapies. These holdings are liable to change at any time.**

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