Biotech Daily

SPECIAL SUMMER CATCH UP EDITION

Sunday January 22, 2012

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*** US PHASE I TRIAL SHOWS BENITEC TECHNOLOGY SAFE, IMMUNE RESPONSE**

*** BALAM TAKES 13% OF CONSEGNA**

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*** CBIO APPOINTS GREGORY THOMAS BROWN ALTERNATE DIRECTOR**

*** US PATENT FOR ANTEO 'USE OF METAL COMPLEXES'**

*** JAPANESE PATENT FOR PRIMA CANCER ANTIGEN CRIPTO-1 ANTIBODY**

*** CBIO REVIEW CONSIDERS ALL XTOLL, ARTHRITIS OPTIONS**

*** VIRALYTICS: US TRIAL SUPERSEDES AUSTRALIAN TRIAL**

*** CITIGROUP TAKES 7% OF PATRYS**

The following articles appear in date order

Monday, December 19, 2011

MAYNE PHARMA EGM FOR 7.5m OPTIONS FOR M-D SCOTT RICHARDS
MAYNE PHARMA
Mayne Pharma will hold an extraordinary general meeting to issue 7,500,000 options to incoming managing director Scott Richards.

MACQUARIE UNI HOSPITAL TAKES 30% OF CYCLOPHARM IMAGING VENTURE
CYCLOPHARM
Cyclopharm says Macquarie University Hospital will take a 30 percent stake in Macquarie Medical Imaging with Cyclopharm retaining 20 percent and Alfred Health 'Solutions' - was a group of radiology and nuclear medicine specialists - holding 50 percent.

PATRYS PLANS PHASE II PAT-SM6 MULTIPLE MYELOMA TRIAL
PATRYS
Patrys says it expects to begin a phase I/IIa open-label multi dose escalation trial in relapsed and multi-resistant multiple myeloma patients in April 2012.
Patrys said that 10 to 12 patients in three or four dosing groups would be enrolled at Germany's University of Würzburg, in a 12 month trial with continual rolling data available.
Patrys said the primary objective was the safety and tolerability of escalating doses of PAT-SM6 in relapsed multiple myeloma patients, with efficacy a secondary objective.

CONSEGNA RAISES $613,000
CONSEGNA GROUP (FORMERLY HELICON GROUP)
Consegna says it has raised $613,000 through the placement of 24,520,000 shares and 24,520,000 attaching options at 2.5 cents a share to sophisticated investors
Consegna said the options were exercisable at 3.5 cents by December 31, 2013.

NEOCLONE TO DISTRIBUTE TYRIAN ANTIBODIES
TYRIAN DIAGNOSTICS
Tyrian says Neoclone LLC has an exclusive distribution agreement for the manufacture and distribution of antibodies it developed to detect tuberculosis proteins.
Tyrian said the deal with the Madison, Wisconsin-based Neoclone included antibodies to Tyrian's lead active tuberculosis protein biomarker and the company would receive 40 percent of gross income on products, with Neoclone paying all costs associated with the manufacture, marketing and distribution of the antibodies, to be sold for research only.
Tyrian said it retained the sole rights to grant licences to third parties to use the antibodies for development and sale of products for other commercial purposes.

STARPHARMA, ELI LILLY CONTINUE DRUG DELIVERY PROGRAM
STARPHARMA
Starpharma says its undisclosed dendrimer drug delivery program with Eli Lilly will continue to further animal studies and if successful human clinical trials.
Starpharma said it had "a number of projects underway with Lilly".

ANTHONY BARTON CEASES IN PHYLOGICA
PHYLOGICA
Anthony Barton and associates have ceased their substantial holding in Phylogica, selling 10,000,000 shares (2.47%) for $474,038 or an average price of 4.7 cents a share.

JOHN LEAVER TAKES 5% OF BIONOMICS
BIONOMICS
John Leaver has become a substantial shareholder in Bionomics acquiring 17,875,590 shares (5.18%), acquiring the shares through Balzac Investments, Wenola Pty Ltd and Leagou Funds Management of which he was a director.
Mr Leaver said the most recent purchases were of 7,796,969 shares for $3,575,831 or an average price of 45.86 cents a share.

AUSTRALIAN ETHICAL INCREASES TO 15% IN AVITA
AVITA MEDICAL
Australian Ethical Smaller Companies Trust has increased its share-holding in Avita from 32,662,336 shares (13.71%) to 36,088,191 shares (15.15%).

SELECT VACCINES GOES URANIUM, COAL MINING IN TANZANIA
SELECT VACCINES
Select says it has an agreement with Mauritian explorer Indigo Metals to acquire two Mauritian entities and their subsidiaries, which own coal and uranium projects in Tanzania.

CBIO CEO HELEN CAMERON SELLS SHARES
CBIO
CBio interim chief executive officer Helen Cameron sold 238,421 shares in her company for $38,598 on December 12 and 13, 2011.
In her Appendix 3Y director's interest statement, Ms Cameron said she held 448,000 shares prior to the sale, reducing her holding by 53.2 percent.
On December 16, 2011, CBio said Novo Nordisk did not take up its option to continue development of XToll for rheumatoid arthritis, which followed the phase IIa trial failing to meet its primary endpoint (BD: Aug 1, Dec 16, 2011).
Biotech Daily contacted Ms Cameron but she declined to comment.

Tuesday, December 20, 2011

COCHLEAR: 'BRAZING' THE ROOT CAUSE OF IMPLANT FAILURE
COCHLEAR
Cochlear says the root cause of the failure of its Nucleus CI500 series implant is a loss of hermeticity from unexpected variations in the brazing process during manufacturing.
Cochlear chief executive officer Dr Chris Roberts wrote to clinicians explaining the problem saying that understanding the root cause "now forms the basis of the plan for the return of the Nucleus CI500 series implant to market".
"The overall proportion of CI500 … devices that has failed is approximately 1.9 percent of registered implants globally with similar percentages in all three regions," he said.
Dr Roberts said that brazing was the process joining the feed-through to the titanium chassis and variations in brazing resulted in a limited number of implants being more susceptible to developing micro-cracks in the braze joint during manufacturing steps.
Dr Roberts said the micro-cracks allowed water molecules to enter the implant resulting in the malfunction of specific electronic components, typically one of four diodes.
Dr Roberts said the older model Nucleus CI24RE and Nucleus CI422 series implants were not affected by this failure mechanism and the manufacturing process, including brazing, was different between the Nucleus CI500 series and Nucleus CI24RE and CI422 series.
Dr Roberts said there were more than 62,000 registered Nucleus CI24RE devices globally and this failure mechanism had never been reported.

CLINUVEL: PHASE III SCENESSE SIGNIFICANT PROPHYLAXIS FOR EPP

CLINUVEL PHARMACEUTICALS

Clinuvel says that final analyses of its phase III European study of afamelanotide (Scenesse) for erythropoietic protoporphyria has shown a positive prophylactic effect.

Clinuvel said that 74 patients started the study and 68 completed Scenesse or afamelanotide 16mg controlled-release medication and all clinical visits with a total of 17,377 patient-days evaluated.

The company said that Scenesse was well tolerated, allowed patients to expose their skin to sunlight during the middle of the day without pain or with reduced pain.

Clinuvel said the study demonstrated a strong clinical benefit to patients, despite their deeply learned behavior to avoid reactions caused by sun exposure.

The company said afamelanotide recipients experienced half as many phototoxic reactions as placebo recipients ($p = 0.044$) and had a lower total median pain score (6.0 compared to 17.5; $p = 0.035$) and total lower maximum pain score per phototoxic episode in comparison to placebo patients (4.0 compared to 6.0; $p = 0.018$).

Clinuvel said that reduction of the intolerable pain in patients was meaningful since no therapies, including analgesics, were effective in these patients.

Clinuvel said that afamelanotide recipients were able to spend more time in direct sunlight between 10am and 8pm ($p = 0.005$) and for the majority of study days, patients in the afamelanotide group were able to spend up to seven times longer in direct sunlight without experiencing pain and patients treated with afamelanotide reported greater improvement in their quality of life than placebo recipients and the difference was significant on Days 120 ($p = 0.005$) and 270 ($p = 0.011$).

Clinuvel said the most common adverse events were pain or bruising following injection, transient nausea, headache and the common cold.

The company said the safety data, the independent data safety monitoring board deemed afamelanotide suitable for further use in man.

Clinuvel said that all European study centres requested the drug on behalf of their patients for compassionate use.

VIRALYTICS SHARE PLAN RAISES $4.7m

VIRALYTICS

Viralytics says its share plan raised $4.7 million at 30.84 cents a share and it would have $8 million in cash at December 31, 2011.

ISONEA RAISES UNDERWRITTEN $3.7m OF HOPED-FOR $4.3m

ISONEA (FORMERLY KARMELSONIX)

Isonea received applications for $1,952,307 of shares at half a cent each in partly-underwritten, three-for-four share rights issue.

Isonea said in November it hoped to raise up to $4.3 million and Patersons Securities had underwritten the offer to $3.7 million (BD: Nov 18, 2011).

Isonea said Patersons would place the 349,538,553 shortfall shares and 87,384,638 attaching options.

PHARMAXIS 'MINOR RESUBMISSION' TO REBATE COMMITTEE

PHARMAXIS

Pharmaxis says it has filed " minor resubmission" with the Australian Pharmaceutical Benefits Advisory Committee for Bronchitol to be listed with the Australian Pharmaceutical Benefits Scheme for the treatment of cystic fibrosis.

Pharmaxis said the submission would be considered at a meeting scheduled for March 2012 following two refusals last year (BD: Apr 21, Nov 9, 2011).

AUSBIL DEXIA TAKES 7% OF BIONOMICS

BIONOMICS

Ausbil Dexia has increased its substantial shareholder in Bionomics from 20,000,000 shares (5.81%) to 24,000,000 shares (6.96%).

The substantial shareholder notice said that Ausbil Dexia was an investment manager for institutional investors which were generally superannuation funds. Ausbil Dexia's website said the company was an equities specialist with about $14 billion under management.

'BALAM GLOBAL' TAKES 6% OF CONSEGNA

CONSEGNA GROUP (FORMERLY HELICON)

Balam Global of the British Virgin Islands and Leon Semenenko have become substantial shareholders in Consegna with the acquisition of 38,388,990 shares (6.23%).

The initial substantial shareholder notice said that Balam was based in the British Virgin Islands and Mr Semenenko was based in Geneva Switzerland but did not explain the relationship between the two entities.

The notice was issued through Perth Western Australia lawyers Clifford Chance.

BROOKSIDE CAPITAL TAKES 8.5% OF REVA

REVA MEDICAL

The Delaware-based Brookside Capital Partners Fund has become a substantial shareholder in Reva with the acquisition of 27,832,040 shares or 8.49 percent.

The company did not file an Australian initial substantial shareholder notice but reported the acquisition to the US Securities and Exchange Commission.

IMMUSANT RAISES $20m FOR WEHI COELIAC VACCINE

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that more than $US20 million has been raised by the US-based Immusant Inc to develop a therapeutic vaccine for coeliac disease.

Describing the project as "a world first" the Institute said that Nexvax2 was among "the first of a new class of vaccines that are predicted to specifically suppress damaging immune reactions" and Nexvax2 targeted the immune response to gluten which was responsible for coeliac disease.

CATHOLIC UNI, O'BRIEN REGENERATIVE WOUND CENTRE

AUSTRALIAN CATHOLIC UNIVERSITY, O'BRIEN INSTITUTE

The Australian Catholic University and the Bernard O'Brien Institute say they will establish a Centre for Regenerative Wound Healing at Melbourne's St Vincent's Hospital.

Most recently the Institute faced controversy over the closure of the Australian Tissue Engineering Centre and the dismissal of staff at Neopec (BD: Mar 3, 4; Jul 20 2011).

The Institute said it had performed "Australia's first hand transplant, the reattachment of a woman's face and the growing of a new ear" and the new Centre would focus on research, new technologies and health care initiatives in wound healing and tissue engineering.

ELASTAGEN APPOINTS XAVIER YON DIRECTOR

ELASTAGEN

Elastagen says it has appointed Xavier Yon as a non-executive director.

Elastagen said it was "a clinical stage medical device company that is pioneering Elastatherapy using the human protein elastin to naturally repair and augment the skin".

The company said that Mr Yon was previously an executive with Pfizer, Solvay, Alcon and was chief executive officer of Galderma for 17 years.

Wednesday, December 21, 2011

ACTAVIS PAYS $6m UPFRONT FOR QRX'S MOXDUO IN US

QRX PHARMA

Actavis Inc has paid QRX a $US6 million upfront fee for a US licence for Moxduo Immediate Release (IR) with a potential 50 percent royalty on $US150 million in sales.

In a teleconference, QRX chief executive officer Dr John Holaday told Biotech Daily that for the first three to six months there would be a tiered royalty rate from 10 percent to 30 percent rising to 50 percent for the next $US150 million in sales.

Following the teleconference Dr Holaday told Biotech Daily that the 10 to 30 percent royalty was for the first few months to allow the Iceland-founded and Switzerland-based Actavis to recover launch and marketing costs.

The teleconference was told that Actavis was "the fourth largest generic pharmaceutical company in the world" and the US launch was expected by October 2012.

Moxduo IR is a dual opiate combining morphine and oxycodone in a three-to-two fixed ratio, intended to provide greater pain relief with fewer and less intense opiate side effects.

Actavis chief executive officer Doug Boothe told the teleconference that his company's lead drug Kadian had been challenged by generic competition and Moxduo IR would become the flagship for the Actavis branded division. He said the US had a $US2.5 billion acute pain market and $6 billion market for chronic pain.

Dr Holaday avoided giving a precise value to the deal or percentage of market share he expected, but said 10 percent of the $2.5 billion would be "aggressive" while a five percent share of the annual 220 million prescriptions would be highly profitable.

Dr Holaday said that pending sales milestones, Actavis would work with QRX to licence the Moxduo controlled release product and had an option to licence the intravenous version by January 31, 2013.

Dr Holaday told the teleconference that Actavis would be responsible for the costs of the launch and marketing, but QRX retained the right to establish its own sales force to provide up to 25 percent of US sales and retained all rights outside the US.

QRX said the US Food and Drug Administration Prescription Drug User Fee Act (PDUFA) date for consideration of Moxduo IR was set for June 25, 2012.

A notional five percent of the $US2.5 billion market equates to $US125 million, implying the $US75 million royalty on the $US150 million in sales could not be achieved in 12 months following the launch, possibly explaining the less-than-expected lift in the company's share price following the announcement by 23 cents or 19.3 percent to $1.42.

But Dr Holaday told Biotech Daily he was referring to the 220 million US prescriptions and there would be a different price for a branded product compared to a generic. He said the premium as a branded product could return revenues "several hundred million dollars".

PROGEN MOVES ANTI-CANCER PG545 FROM SUB-CUTANEOUS TO IV

PROGEN

Progen says it has changed route of administration of PG545 for cancer from subcutaneous to intravenous (IV).

In September, Progen put its phase Ia PG545 trial in advanced cancer patients "on hold due to unexpected local injection site reactions seen in patients" (BD: Sep 20, 2011).

Progen said that independent experts reviewed a change in administration route from subcutaneous to intravenous, from preclinical, clinical and commercial perspectives.

The company said that "neither the management nor the independent experts found any reason that would halt the development of PG545 based on an IV route of administration" and it would begin licencing discussions with potential partners for development of PG545.

CBIO DETAILS XTOLL TIMING, CEO SHARE TRADING

CBIO

CBio has told the ASX that it first received notification from Novo Nordisk that it would not take up the option to further develop XToll at about 10.35am on December 15, 2011.

The company made its announcement that XToll for rheumatoid arthritis had been rejected by partner Novo Nordisk at 11.18am on December 16, 2011, and told the ASX that the announcement followed board discussions requiring input from two overseas directors whose input "was critical as they are the scientific experts on the board".

The ASX asked CBio a series of questions relating to the timing of the receipt of the information and the announcement to the market.

CBio responded fully to each question concluding that it was in compliance with ASX Listing Rule 3.1 on disclosure of material information.

In a separate series of announcements, CBio said that acting managing director Helen Cameron sold more than half her holding in CBio on December 13 and 14, 2011 (see above) and on December 16, 2011 Ms Cameron sold a further 5,900 CBio shares for $944 or 16 cents a share. Ms Cameron declined to comment on the sale of CBio shares.

US PATENT FOR NOVOGEN, MARSHAL EDWARDS CANCER DRUGS

NOVOGEN

Novogen's Marshall Edwards says the US Patent and Trademark Office has issued a new patent covering isoflavone-based compounds, including lead oncology drug candidates ME-143 and ME-344 and their pharmaceutical compositions.

Novogen said the patent provided protection until March 2027.

START UP REDUCES BELOW 5% IN BIONOMICS

BIONOMICS

Dr George Jessup's Start-up Australia has ceased its substantial holding in Bionomics selling 15,000,000 shares for $7,800,000 or 52 cents a share.

In May, Start-up sold 60,000,000 shares leaving it with 28,364,866 shares or 8.24 percent of the company (BD: May 12, 2011).

LANDON CLAY, EAST HILL TAKE 10% OF BIOTA

BIOTA HOLDINGS

Landon Clay, East Hill Holding Co and associates have increased their substantial shareholding in Biota from 18,625,357 shares (10.25%) to 20,577,735 shares (11.33%).

Thursday, December 22, 2011

FDA APPROVES NEUREN NZ2566 HUMAN TRIALS

NEUREN

Neuren says the US Food and Drug Administration has approved human clinical trials under an investigational new drug application for the oral formulation of NNZ-2566, allowing it to proceed with a phase I trial in healthy volunteers in preparation for phase II clinical trials in patients with concussion and Rett syndrome.

The company said the phase I study was expected to start in January 2012 with the other studies beginning by October 2012, depending on reviews of protocols by the FDA and institutional review boards.

Neuren said that selection of an aqueous oral formulation of NNZ2566 enabled the completion of pre-clinical requirements for the application ahead of schedule and at lower cost than was originally anticipated.

REVA BEGINS BIORESORBABLE STENT TRIAL

REVA MEDICAL

Reva says it has initiated enrollment in a 50-patient pilot clinical study to evaluate its Rezolve bioresorbable stent in Brazil and Europe

Reva said the Rezolve sirolimus-eluting coronary scaffold was a fully bioresorbable polymer scaffold designed to provide the benefits of a metal drug-eluting stent, with the advantage of dissolving from the body after it was no longer needed, leaving the patient free of a permanent implant.

The company said the first patient implant was performed by the Instituto Dante Pazzanese de Cardiologia's chief of coronary interventions and the study's principal investigator, Dr Alexandre Abizaid, in Sao Paulo, Brazil.

"The procedure went very smoothly in a 90 percent occluded coronary artery utilizing standard practices that are used to implant conventional metallic stents around the world today," Dr Abizaid said.

"The Reva …. scaffold deployed and became well-apposed against the artery wall and we were able to visualize the entire scaffold under standard x-ray imaging, which was very helpful," Dr Abizaid said.

Reva said data from the trial would become available throughout 2012 and if the results were acceptable the company would initiate a larger trial to provide the data needed to apply for Conformité Européenne (CE) mark approval in Europe.

CALZADA, POLYNOVO READY FOR 2 NOVOSORB SKIN TRIALS

CALZADA

Calzada says wholly-owned subsidiary Polynovo Biomaterials has "outstanding interim reports" for Novosorb's biodegradable temporising matrix (BTM) safety studies.

Calzada said the Novosorb product was intended to treat full thickness burns and wounds.

The company said the studies included completion of the final two in vivo studies of 180-day long term implantation and genetic toxicity.

Calzada said it had approved two pilot clinical trials of Novosorb for the reconstruction of "free-flap donor sites" and in comparison with Granufoam bridge dressing with vacuum-assisted closure in the management of pressure sores. The company said that vacuum-assisted closure promoted wound healing by delivering negative pressure at the wound site and the free flap trial would study full thickness skin replacement.

Calzada said the trials would be conducted by Prof John Greenwood, a partner with Polynovo in the Novoskin project at the Royal Adelaide Hospital (BD: Jun, 17, 2010).

Calzada said that treatment was expected to commence on the vacuum-asisted closure trial by early February 2012 and on the open flap trial in March 2012, with preliminary results due in May and June 2012, respectively.

The company said patents had been accepted for registration including a Japanese patent for biodegradable, injectable, in-situ curable materials designed primarily for use in orthopaedic applications with the scope not limited to this field.

Calzada said Chinese and Malaysian patents were directed to biocompatible compositions which could be cured from a liquid pre-polymer to a solid polymer upon demand, in particular when exposed to visible light.

ACORN TAKES 6% OF PHARMAXIS

PHARMAXIS

Acorn Capital has become a substantial shareholder in Pharmaxis with the acquisition of 17,532,666 shares or 5.73 percent at an average price of $1.196 a share.

CONSEGNA CLOSES ASPEN MEDISYS DEAL
CONSEGNA GROUP (FORMERLY HELICON)
Consegna says it has closed of the purchase of Aspen Medisys acquiring its nanoparticle magnetic thermotherapy technology platform for solid tumors and other pathologies.
Consegna said the transaction included a nominal up-front payment to the vendors followed by performance and time-dependant milestone payments to be made in the form of Consegna shares, with the first payment, $1,410,000 in scrip to be made at Consegna's discretion on or before July 1, 2012, with further payments in scrip to the value of $940,000, $470,000 and $470,000.

Wednesday, December 28, 2011

CBIO LOSES DIRECTORS DR TERJE KALLAND, DR THOMAS LONNGREN
CBIO
CBio says directors Dr Terje Kalland and Dr Thomas Lonngren have resigned.

BARINGS ACCEPTANCE TAKES 14% OF CYCLOPHARM
CYCLOPHARM
Barings Acceptance has increased its substantial shareholding in Cyclopharm from 17,052,895 shares (9.97%) to 31,846,991 shares (14.24%).
The substantial shareholder notice said Barings was based at Russell Bedford House, 250 City Road, London.

'BALAM GLOBAL' TAKES 9% OF CONSEGNA
CONSEGNA GROUP (FORMERLY HELICON)
Balam Global and Leon Semenenko have become increased their substantial shareholding in Consegna from 38,388,990 shares (6.23%) to 56,267,140 shares (9.14%).
The substantial shareholder notice said that Balam was based in the British Virgin Islands and Mr Semenenko was based in Geneva Switzerland but did not explain the relationship.
The notice was issued by Balam director Brett Sinclair Armitage.

LIVING CELL APPOINTS DR ANDREA GRANT CEO
LIVING CELL TECHNOLOGIES
Living Cell has appointed Roche Products New Zealand public policy and communications manager Dr Andrea Grant as chief executive officer effective from January 15, 2012.
Living Cell said that at Roche Dr Grant was responsible for government and corporate relations and prior to emigrating to New Zealand from the UK, Dr Grant was the business development director and then managing director at Galapagos NV and held a PhD in molecular neurobiology from the University of Cambridge.

PRIMA DEVELOPING ORAL CANCER VACCINE
PRIMA BIOMED
Prima says research for an oral delivery system for cervical cancer vaccines is testing formulations of a nanoparticle delivery system in a mouse model.
Prima said that in 2009 it engaged University of New South Wales and University of Queensland to develop an oral delivery system for vaccines for cervical cancer and had shown that a coated nanoparticle protein delivery system was feasible.
Prima said that work to be performed in 2012 by Prof Neil Foster and Prof Ian Frazer's laboratories would determine which oral formulation best delivered an immunogenic dose of protein to the lower gastrointestinal tract.

JCP CEASES IN RESMED
RESMED
Melbourne's JCP Investment Partners has ceased its substantial shareholding in Resmed.

WESTPAC, BT INCREASE DILUTED IN QRX
QRX PHARMA
Westpac Banking Corp and BT Investment Management have increased their substantial shareholding and were diluted in QRX from 7,584,436 shares (7.44%) to 7,869,990 shares (5.45%).

Thursday, December 29, 2011,

ISONEA RAISES $4.6m
ISONEA (FORMERLY KARMELSONIX)
Isonea says that further to its share rights issue raising $1,952,307 through applications for shares, underwriters, Patersons Securities had assisted in raising a total of $4.6 million of the hoped for $4.3 million (BD: Nov 18, 2011).

Friday, December 30, 2011

NOVOGEN $2m FOR MARSHALL EDWARDS; CHANGES ADR RATIO
NOVOGEN
Novogen has invested $2 million in subsidiary Marshall Edwards and modified its American depository receipt (ADR) program to comply with Nasdaq requirements.
Novogen said the previous conversion ratio of five shares for each ADR share would be changed to 25 Novogen shares for each ADR share, effective from January 3, 2012, but the change would have no effect on the number of outstanding common shares on issue or the listing of its common shares on the ASX.
Novogen chairman William Rueckert said "the ratio change and resulting increase in the market price for our ADR shares, as listed on Nasdaq, will bring our ADR shares back into compliance with Nasdaq's $US1.00 minimum bid price requirement".
Novogen separately announced it had invested $US2 million in its US subsidiary Marshall Edwards, purchasing 1,941,747 shares to support the continued development of Marshall Edwards' drug development programs and held 58.1 percent of Marshall Edwards.

Tuesday, January 3, 2012

PHYLOGICA, JANSSEN COLLABORATION
PHYLOGICA
Phylogica says it will collaborate with Johnson & Johnson's Janssen Biotech to discover new classes of drugs derived from its Phylomer peptide platform.
Phylogica said it would identify cell-penetrating Phylomer peptides and Janssen could develop Phylomer-based drug candidates, with the option to expand the collaboration to include additional cell-specific Phylomers to develop a further 10 drug candidates.
Phylogica said it would receive an initial technology access fee as well as research funding over the first 18 months of the collaboration and that pending discussions it could receive further research funding, licence fees, milestone payments and royalties on worldwide sales. Phylogica did not provide any further details.

ISONEA BEGINS TRADING ON US OTCQX
ISONEA (FORMERLY KARMELSONIX)
Isonea says its American depositary receipts have begun trading on the US over the counter quality exchange (OTCQX) under the symbol ISOAY.

Wednesday, January 4, 2012

ALCHEMIA TREATS 1st PHASE III HYACT CANCER PATIENT
ALCHEMIA
Alchemia says the first of 390 cancer patients in its phase III trial of hyaluronic acid (HA) irinotecan has received their first cycle of treatment.
Alchemia said its Hyact technology targeted the widely used chemotherapy drug irinotecan directly to cancer cells.
The company said the phase III study would compare the safety and effectiveness of HA-irinotecan with irinotecan in a double blind trial in second and third line metastatic colorectal cancer patients when administered as part of a standard of care regimen.
Alchemia said the trial would take about 12 months to recruit the 390 patients with the primary endpoint reached when 350 patients experienced disease progression; expected by October 2013.

FDA APPROVES PHASE II PRANA PBT2 HUNTINGDON'S TRIAL
PRANA BIOTECHNOLOGY
Prana says the US Food and Drug Administration has approved recruitment of 100 patients for its phase II clinical trial of PBT2 in patients with Huntington's disease.

US PATENT FOR NOVOGEN MARSHALL EDWARDS COMPOUNDS
NOVOGEN
Novogen says the US Patent and Trademark Office has issued a method of use patent to 58.1 percent subsidiary Marshall Edwards covering mitochondrial inhibitor compounds, including lead drug candidate ME-344, for the treatment of cancer or a tumor mass.
Novogen said the patent provided protection until September 2025.

UNNAMED US COMPANY PAYS CALZADA, POLYNOVO $100k
CALZADA
Calzada says wholly-owned subsidiary Polynovo has received the final of four $US100,000 payments from an unnamed US medical device company.
Calzada said it had been working with the company since 2009, which was "an industry leader with a dominant market share in the field under review".
The company said that in January 2011 the feasibility study was extended for 12 months to progress animal trials aimed at testing product safety and efficacy.
Calzada said discussions with the US medical device company were continuing.

GI ENDOBARRIER COMMERCIALLY AVAILABLE IN NETHERLANDS
GI DYNAMICS
GI Dynamics says its Endobarrier gastro-intestinal liner for obesity and type 2 diabetes is commercially available in the Netherlands.
GI Dynamics said the device had been trialed at the Rijnstate Hospital in Arnhem and had been approved for commercial sales.

Thursday, January 5, 2012

IRONWOOD, BIONOMICS BNC210 DEAL STARTS WITH $2.9m

BIONOMICS

The Cambridge Massachusetts-based Ironwood Pharmaceuticals will pay Bionomics a $US3 million ($A2.9 million) upfront fee for a licence for anti-anxiety compound BNC210.
Bionomics said the collaboration, research and licencing agreement extended to other related compounds and was potentially worth up to $US345 million in upfront and milestone payments and research funding, as well as royalties on sales of products incorporating BNC210 and other related compounds.
The company said that following the initial $US3 million payments it could receive up to a further $US10 million over 24 months in research funding and milestone payments.
Bionomics said the collaboration would evaluate BNC210's potential as an anti-anxiety treatment, with Ironwood responsible for development and commercialization of all products incorporating BNC210 or other licenced compounds, including clinical trials.

Friday, January 6, 2012

BIOTRON OPTIONS RAISE $8m

BIOTRON

Biotron says the exercise of 79,865,226 options at 10 cents each has raised $7,986,523.
Biotron said the options were due to expire on December 30, 2011, when the company's shares were trading at 11.5 cents.

Monday, January 9, 2012

BENITEC: PFIZER, TACERE, POSITIVE HEP C PRECLINICAL RESULTS

BENITEC BIOPHARMA

Benitec says Pfizer and Tacere Therapeutics researchers have published Pfizer's "extremely positive" pre-clinical results on the use of its technology to develop a novel therapeutic for hepatitis C. Benitec chief executive officer Dr Peter French told Biotech Daily that preclinical results for the ddRNAi molecule PF-05095808, came from gene silencing technology licenced from Benitec.
The company said the paper entitled 'In vitro characterization of the activity of PF-05095808 a novel biological agent for Hepatitis C Virus therapy' was published on line in Antimicrobial Agents and Chemotherapy, a journal published by the American Society of Microbiology.
The abstract is at: http://aac.asm.org/content/early/2011/12/20/AAC.05357-11.abstract.
Benitec said PF-05095808 was specifically designed to achieve complete transduction of all liver cells in the liver without causing cell damage.
The company said there was no evidence of cytotoxicity nor of induction of the interferon response associated with the administration of PF-05095808.
Benitec said PF-05095808 was highly effective at inhibiting the commonly circulating clinical isolates of hepatitis C virus, with the ability to eliminate resistance to the molecule through the use of three short-hairpin RNA (shRNA) sequences.
The authors concluded that "PF-05095808 represents the prototype of a new approach to HCV therapy, a single dose treatment that can be administered alone or in combination with other anti-HCV agents", Benitec said.

CIRCADIAN BEGINS PHASE I VGX-100 SOLID TUMOR TRIAL
CIRCADIAN TECHNOLOGIES
Circadian says it has begun its first phase I clinical trial of its VGX-100 human monoclonal antibody against VEGF-C, at a US-based cancer treatment centre.
Circadian said the phase I study would examine the safety and tolerability of escalating doses of VGX-100 in patients with advanced solid tumors who had no other standard treatment options, both as a monotherapy and also when used in combination with other anti-angiogenic agents, with results expected by January 2013.

Tuesday, January 10, 2012

HEARTWARE DUALIS COLLABORATE ON WIRELESS HEART PUMP
HEARTWARE
Heartware will work with Dualis Medtech GmbH to develop ventricular assist devices with wireless, transcutaneous energy transfer system technology.
Heartware said that with Avra Surgical subsidiary Dualis engineers it had demonstrated the feasibility of integrating Dualis' proprietary wireless energy transfer technology with the Heartware left ventricular assist device and miniature ventricular assist device systems.
Heartware said it would fund a transcutaneous energy transfer system development program for left ventricular assist devices, as well as receive an option to fund programs to explore developments in bi-ventricular support and first rights to future developments outside the field of transcutaneous energy transfer system and ventricular assist devices.

J&J'S LIFESCAN LAUNCHES UNIVERSAL BIOSENSORS ONETOUCH IN US
UNIVERSAL BIOSENSORS
Universal Biosensors says that Johnson & Johnson's Lifescan has launched the Onetouch Verio blood glucose test in the US, "a major milestone" in the roll-out of the technology.
The company said that the Onetouch Verio was available in all major self-monitoring blood glucose (SMBG) markets including the US, Canada, Europe and Australia.
Universal Biosensors said the roll-out showed Lifescan's commitment to the technology and the SMBG market in the US in 2010 was about $US3.84 billion which was 40 percent of the global market and expected to grow to $US5.59 billion by 2015, with Lifescan the market leader in North America.
Universal Biosensors manufactures test strips for the Onetouch Verio system in its Rowville facility in Melbourne.

FDA APPROVES IMMURON PHASE IIb FATTY LIVER TRIAL
IMMURON
Immuron says the US Food and Drug Administration has approved its phase IIb clinical trial of (IMM-124E) for the treatment of non-alcoholic steatohepatitis and fatty liver.
Immuron said that the trial of the bovine colostrum-derived therapeutic was a double-blind, placebo-controlled, dose-ranging trial with sites in the US, Australia and Israel.
The company said the principal aims were to determine the safety and efficacy of oral IMM-124E in patients with biopsy-confirmed non-alcoholic steatohepatitis.
Immuron chief executive officer Joe Baini said the approval was "a major milestone for Immuron with global significance for an unmet and rapidly growing disease".

DUTCHESS $5m FUNDING FOR VIRAX
VIRAX HOLDINGS
Virax says it has secured a $5 million funding facility with Dutchess Capital.

US PHASE I TRIAL SHOWS BENITEC TECHNOLOGY SAFE, IMMUNE RESPONSE
BENITEC BIOPHARMA
Benitec says a phase I cancer vaccine trial using its gene-silencing technology showed the vaccine was safe and elicited an immune response correlated with prolonged survival.
Benitec said the US-based Gradalis used DNA-directed RNA interference technology and the trial evaluated the vaccine in patients with advanced or metastatic non-curable solid tumors, including melanoma, colon, breast, liver, bile duct and colon cancers.
The company said the patients received up to 12 monthly intradermal injections of the vaccine and concluded that phase II assessment was justified.

BALAM TAKES 13% OF CONSEGNA
CONSEGNA GROUP
Balam Global has increased its substantial shareholding in Consegna from 56,267,140 shares (8.14%) to 71,986,927 shares (11.69%).

Wednesday, January 11, 2012

HEARTWARE 2011 REVENUE UP 50% TO $82m
HEARTWARE
Heartware says it expects revenue for the year to December 31, 2011 to be about 50 percent greater than the previous year at $US82 million.
The revenue figure was contained in a presentation and did not include further financial information other than the revenue for the three months to December 31, 2011 was its "highest quarter to date" at $US22 million.

FDA SIGNS-OFF ON STARPHARMA PHASE III VIVAGEL VAGINOSIS TRIAL
STARPHARMA
Starpharma says it has US Food and Drug Administration approval on its phase III studies of Vivagel for bacterial vaginosis under a special protocol assessment scheme.
Starpharma said the scheme was "a binding declaration from the FDA that the phase III clinical study design, endpoints, statistical analyses and other aspects of the planned studies are acceptable to support regulatory approval of the product".

PRANA APPOINTS PROF RUDY TANZI CSO
PRANA BIOTECHNOLOGY
Prana says that Prof Rudy Tanzi has been appointed as chief scientific advisor.
Prana said Prof Tanzi was a professor of neurology at Harvard University and the director of the genetics and aging research unit at Massachusetts General Hospital.

BERGEN TAKES 7% OF ISONEA
ISONEA (FORMERLY KARMELSONIX)
The New York- based Bergen Asset Management has become a substantial shareholder in Isonea with the acquisition of 152,327,365 shares or 6.75 percent of the company.

XENOME APPOINTS DR JULIE CHERRINGTON CHAIR
XENOME
Xenome says that Dr Julie Cherrington has been appointed the chair of its board of directors.
Xenome said Dr Cherrington was the president and chief executive officer of Pathway Therapeutics and was previously a director of Progen and Chemgenex.

Thursday, January 12, 2012

BIO-MELBOURNE BREAKFASTS ON 3-D TISSUE-PRINTING
BIO-MELBOURNE NETWORK
The Bio-Melbourne Network says Invetech's Peter Riddell and Chris Leigh-Lancaster will discuss the commercialization of the 3D bio-printer at its February 7, 2012 Bio-Breakfast, which would cover research and clinical applications, as well as technical challenges in developing a platform to create tissues and manufacture complex organs.
The Network said that Organovo partnered with Invetech to develop the first commercially viable 3D bio-printer to print human tissues and won the National Engineering Innovation Award for the 3D bio-printer (BD: Nov 24, 2011) which took patient's cells and made three dimensional organs, potentially addressing low organ donor rates and transplant rejection.

MARIPOSA TO LIST THROUGH GENESIS
GENESIS RESEARCH AND DEVELOPMENT CORPORATION
New Zealand's Genesis Research and Development Corp says it has signed a memorandum of understanding to merge with Sydney's Mariposa Health.
Genesis said that Mariposa had several projects, including lead product TA-270 an oral treatment of chronic obstructive lung disease and neutrophilic asthma and the rights to an immune modulator to staphylococcus aureus.

Friday, January 13, 2012

CLINUVEL PLEADS SCHULTZ, GOOD NEWS TO ASX 22% QUERY
CLINUVEL PHARMACEUTICALS
Clinuvel has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities, but had previously published US phase II and European phase III results (BD: Nov 4, 2011; see above).
The ASX said the company's share price rose from $1.58 on January 6, 2012 to $1.92 on January 12, 2012, a 21.5 percent increase and noted an increase in trading volume.

ACORN INCREASES, DILUTED TO 13% OF STARPHARMA
STARPHARMA
Melbourne's Acorn Capital has increased its substantial holding in Starpharma but has been diluted through a placement. Acorn said it increased and was diluted from 29,920,807 shares (14.44%) to 36,614,463 shares (13.05%).

CITIGROUP INCREASE TO 11% IN PHYLOGICA
PHYLOGICA
Citigroup Global Markets Australia has increased its holding in Phylogica from 40,887,374 shares (10.091%) to 49,676,929 shares (11.141%).

Monday, January 16, 2012

BIOTRON PLEADS SCHULTZ TO ASX 36% QUERY
BIOTRON
Biotron has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the share price rose from 12.5 cents on January 9, 2012 to 17 cents on January 13, 2012, a 36 percent increase and noted an increase in trading volume.

BONE PLEADS SCHULTZ, CAPITAL RAISINGS TO ASX 175% QUERY
BONE MEDICAL
Bone has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the share price rose from 0.4 cents on January 12, 2012 to 1.1 cents on January 13, 2012, a 175 percent increase and noted an increase in trading volume.
Bone said it had a facility with La Jolla Cove and shareholder approval to raise $1 million.

PALADIN, IMMURON COMPLETE DRAW DOWN FACILITY AGREEMENT
IMMURON
Immuron says it has a debenture agreement with Canada's Paladin Labs facilitating up to $C1.5 million, following a Travelan for diarrhoea licence agreement (BD: Nov 29, 2011).
The company said the initial drawdown would be $C100,000 and included a coupon rate of 10 percent not due for repayment for three years and Paladin had the right to convert all or part of the funds into shares of at an agreed conversion price of 4.73 cents a share.

SIENNA GERON LICENCE, $260k GRANTS, APPOINTS CARL STUBBINGS
SIENNA DIAGNOSTICS
Sienna says it has a licence from investor Geron Corp to further develop and commercialize a diagnostic method to directly detect the telomerase protein in cancer cells. Geron would be entitled to payments for regulatory and commercial milestones, as well as royalty and revenue share payments based on commercial sales.
Sienna said it had a second Commercialisation Australia proof-of-concept follow-on grant of $250,000 to support a clinical trial in 2012 and a Victorian Small Technologies $10,00 grant to assist with mechanical aspects of its slide-based diagnostic test.
Sienna said that the California-based Carl Stubbings had been appointed as a director to assist with partnering activities. Mr Stubbings was the head of sales and marketing at Quest's Focus Diagnostics and was previously vice-president of Brisbane's Panbio.

Tuesday, January 17, 2012

DR GREGORGY WINTER BIOSCEPTRE INVESTOR BREIFING, TO RAISE $15m
BIOSCEPTRE INTERNATIONAL
Biosceptre says that scientific advisory board chairman and Cambridge Antibody Technology founder Dr Gregory Winter will meet investors in Sydney on January 24.
The company said its core technology was based on a cancer biomarker known as non-functional P2X7 (nf-P2X7) which had been identified in more than 20 cancer indications.
Biosceptre said it had appointed investment bank Moss Capital as its advisor and hoped to raise $15 million in 2012.

UNIQUEST, JANSSEN-CILAG TO DEVELOP RHEUMATOID ARTHRITIS TREATMENT
UNIQUEST, JANSSEN-CILAG
University of Queensland commercialization company Uniquest says it has facilitated a strategic collaboration with Janssen-Cilag to develop a treatment for rheumatoid arthritis.
Uniquest said that its subsidiary Dendright Pty Ltd would receive a seed grant to fund pre-clinical development of its treatment for rheumatoid arthritis to help Prof Ranjeny Thomas and her team at the University of Queensland Diamantina Institute develop the treatment, which could also apply to other autoimmune diseases such as type 1 diabetes and multiple sclerosis.

WEHI SHOWS AML MAY BE SUSCEPTIBLE TO DRUGS TARGETING MCL-1
THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH
The Walter and Eliza Hall Institute says its researchers have discovered that acute myeloid leukaemia may be susceptible to drugs targeting the Mcl-1 protein.
The Institute said a research team led by Dr Stefan Glaser and Prof Andreas Strasser was working with the Australian Centre for Blood Diseases and St Vincent's Institute of Medical Research in Melbourne, as well as Austrian and American researchers.
WEHI said that acute myeloid leukaemia was the most common type of acute leukaemia in Australia and patients were normally treated with chemotherapy, but even in the least severe forms, the disease returned after chemotherapy in about one third of cases and in the most severe forms, fewer than one in six would survive for five years after diagnosis.
The Institute said the research team determined that treatments that remove the protein Mcl-1 from acute myeloid leukaemia cells could rapidly kill the aggressive cancer cells.

CBIO APPOINTS GREGORY THOMAS BROWN ALTERNATE DIRECTOR
CBIO
CBio says it has appointed Gregory Thomas Brown as an alternate director to Warren Brown. CBio's Gregory Thomas Brown is not Impedimed's Gregory Wayne Brown.

US PATENT FOR ANTEO USE OF METAL COMPLEXES
ANTEO DIAGNOSTICS
Anteo says the US Patent and Trademark Office has issued a notice of allowance for the 'Use of Metal Complexes' patent for its Mix&Go bio-glue.

JAPANESE PATENT FOR PRIMA CANCER ANTIGEN CRIPTO-1 ANTIBODY
PRIMA BIOMED
Prima says the Japanese Patent Office has grant a patent for its antibody to cancer antigen Cripto-1 entitled 'Antibodies against Cancer' and expiring in March 2022.
Prima said the patent had been granted in Australia, New Zealand, China, South Korea and the US.

Wednesday, January 18, 2012

CBIO REVIEW CONSIDERS ALL XTOLL, ARTHRITIS OPTIONS
CBIO
CBio says it has conducted strategic planning and review sessions to determine the future of the company and lead drug candidate, XToll for rheumatoid arthritis.
Last year, XToll failed to meet its phase II trial primary endpoint, the board was rolled by a shareholder group and CBio lost partner Novo Nordisk (BD: Aug 1, Nov 4, Dec 16, 2011).
CBio said it had a strong patent portfolio around XToll and its derivatives and completed preclinical and clinical studies in autoimmune diseases and it would further strengthen XToll's science and intellectual property position with the statistical analysis of data from the long-term follow up rheumatoid arthritis study; recommence mode of action studies which lapsed in 2008; generate and characterize specific XToll monoclonal antibodies required for pharmacokinetic assay development in the target patient population; conduct host cell protein (HCP) assay development and validation; review potential new molecules synergistic with the targeted therapeutic indications for the purposes of identifying potential new projects for CBio's drug pipeline; and identify potential partners.
CBio acting managing director Helen Cameron said that when the review was completed, "further decisions will be made regarding a way forward for XToll and CBio, including a targeted therapeutic indication and funding requirements."

Thursday, January 19, 2011

VIRALYTICS: US TRIAL SUPERSEDES AUSTRALIAN TRIAL

VIRALYTICS

Viralytics says it has closed its nine-patient Australian phase I intra-tumoral late stage head and neck cancer trial as it has been "superseded" by its US phase II trial.

Viralytics said the phase I trial was designed to be a multi-dose, multi-injection safety study and three patients had been treated with Cavatak and the US 54-patient phase II intra-tumoral late stage melanoma trial had begun patient treatment at two sites, with further sites expected to commence treatment shortly.

Viralytics said trial details were at http://clinicaltrials.gov/ct2/show/NCT01227551.

The company said that eight of nine patients in its Australian phase I intravenous late stage melanoma, prostate, breast and colorectal cancer trial had been infused with Cavatak and had completed the trial, with the last patient expected to enter the trial in early February.

Friday, January 20, 2012

CITIGROUP TAKES 7% OF PATRYS

PATRYS

Citigroup Global Markets Australia has increased its substantial shareholding in Patrys from 15,348,195 shares (6.159%) to 26,353,542 shares (7.243%).

*** Biotech Daily editor, David Langsam, owns shares in Alchemia, Allied Health, Biota, Neuren, Optiscan and Pharmaxis, as well as non-biotechnology stocks. These holdings are liable to change at any time.**

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