Biotech Daily

SPECIAL SUMMER CATCH UP EDITION

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The Summer Catch-Up Edition was compiled by Jane Sugden

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*** JAPAN APPROVES BIOTA, DAIICHI SANKYO INAVIR FOR 'FLU PREVENTION**

*** ANTISENSE: 'HIGHER DOSE ATL1103 REDUCES ACROMEGALY MARKER'**

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*** PRIMA AMENDED PHASE II APPROVED IN BELGIUM**

*** AUSTRALIAN LEADERS BELOW 5% IN ATCOR**

The following articles appear in date order

Friday December 20, 2013

MESOBLAST PAYS OSIRIS $15m MILESTONE FOR PROCHYMAL
MESOBLAST
Osiris says it has received a $US15 million milestone payment from Mesoblast for the successful completion of the transfer of its Prochymal assets.

JAPAN APPROVES BIOTA, DAIICHI SANKYO LANINAMIVIR FOR 'FLU PREVENTION
BIOTA PHARMACEUTICALS
Biota says Daiichi Sankyo has been granted regulatory approval in Japan to manufacture and market Inavir Dry Powder Inhaler 20mg for the prevention of influenza A and B.
Biota said it was is developing laninamivir outside Japan for the treatment of influenza, and was conducting a large, multi-national phase II trial of laninamivir octanoate in adults with influenza.

Monday December 23, 2013

ANTISENSE: 'HIGHER DOSE ATL1103 REDUCES ACROMEGALY MARKER'
ANTISENSE THERAPEUTICS
Antisense says its two-arm, eight-patient phase II trial of ATL1103 for acromegaly has shown the stronger 400mg a week dose reduces insulin-like growth factor-I.
Antisense said the three-month interim analysis of four patients receiving 200mg of ATL1103 once per week and four receiving 200mg twice per week (400 mg) showed that the higher dose reduced insulin-like growth factor-I levels by an average 30 percent at week 14, one week after the last dose and the primary efficacy time point for the trial.
The company said the reduction in insulin-like growth factor-I levels appeared weight-to-dose related and at the 200mg per week dose, no consistent reduction in mean insulin-like growth factor-I levels was observed at week 14, although some reduction was noted in individual patients.
Antisense said that acromegaly patients had elevated insulin-like growth factor-I levels compared to the normal population and reduction to within the normal range in a significant proportion of patients was the goal in phase III registration trials for acromegaly.
The company said that no patients dosed with ATL1103 had withdrawn from the study and no serious treatment-related adverse events had been reported and with both doses appearing to be well tolerated the safety profile suggested the drug might be tolerated at higher levels than 400mg per week and a small add-on study to support the use of a higher dose in phase III trials was being considered.

CALZADA, POLYNOVO BEGIN NOVOSORB SERIOUS BURNS TRIAL
CALZADA
Calzada says wholly-owned subsidiary Polynovo will begin a five-patient trial of Novosorb Biodegradable Temporising Matrix in significantly injured burn patients in 2013.
Calzada said that ethics approval had been received for the trial at the Royal Adelaide Hospital to assess Novosorb when implanted in adult patients with deep dermal and full-thickness burns to between 20 percent and 50 percent of their body surface area.

COGSTATE AWARDED PHASE II/III ALZHEIMER'S TRIAL TENDER, RAISES $8m
COGSTATE
Cogstate says it has been awarded a tender for a phase II/III trial in Alzheimer's disease, expected to generate less than $500,000 and has completed its $8 million capital raising.

CRYOSITE EXPECTS LOWER PROFIT FOR 2013-'14
CRYOSITE
Cryosite says its profit for the year to June 30, 2014 is expected to be in line with expectations but below $1.0 million compared to the previous year's $1.18 million.

AVEXA RAISES $1m OF HOPED-FOR $3.3m
AVEXA
Avexa says its share purchase plan to raise up to $3,305,986 through the issue of shares at 1.3 cents a share has raised $1,033,500.

BIOXYNE EGM CLOSES FAILED VITALITY DEAL
BIOXYNE
Bioxyne says its extraordinary general meeting passed all resolutions relating to the transaction funding for the failed acquisition of Vitality Devices (BD: Nov 25, 2013).

LEAF JOINS ACTINOGEN FOR BIO-ETHANOL EFFICIENCY, FUNDS TRIALS
LEAF ENERGY, ACTINOGEN
Leaf says it will spend up to $100,000 in a collaboration with Actinogen to improve the efficiency of the glycerol to ethanol breakdown process at Murdoch University.

Tuesday December 24, 2013

ADMEDUS EXPECTS $690k R&D TAX CREDIT
ADMEDUS (FORMERLY ALLIED HEALTHCARE GROUP)
Admedus says it expects to receive a Federal Government R&D Tax Incentive of $690,072.

MALAYSIA'S XERAYA INVESTS $14m IN NUSEP'S PRIME
NUSEP
Nusep says its Prime subsidiary has received conditional approval for the Malaysian-based Xeraya Capital Labuan to invest $S15 million ($A13.4 million).

Monday December 30, 2013

PROGEN COMPLETES PHASE III LIVER CANCER ENROLMENT
PROGEN PHARMACEUTICALS
Progen says that licencee Medigen's phase III liver cancer trial has completed recruitment of 500 patients and a new drug application is expected to be lodged with Taiwan Food and Drug Administration during 2014.

Thursday January 2, 2014

*** OSPREY: '40% DYE REDUCTION' IN AVERT PILOT TRIAL**
OSPREY MEDICAL
Osprey says that a 2012 pilot trial of its Avert cardiac dye reduction system reduced the amount of imaging material required by 40 percent with results of trial at Melbourne's Alfred Hospital published in 'Catheterization and Cardiovascular Interventions'

Friday January 3, 2014

ADMEDUS ACQUIRES WA MANUFACTURING FACILITY
ADMEDUS
Admedus says it has completed the acquisition of a former Genzyme manufacturing facility in Malaga, Western Australia to scale up the manufacture of Cardiocell tissue.

PSIVIDA TO RAISE $US19m
PSIVIDA
Psivida has sought permission from the US Securities and Exchange Commission to raise up to $US19,166,895.

PHYLOGICA RAISES $5.2m
PHYLOGICA
Phylogica's rights issue raised $5.2 million with an underwritten shortfall of $779,943.

Monday January 6, 2014

BENITIC'S TT-034 FDA APPLICATION DELAYED ONE WEEK
BENITEC BIOPHARMA
Benitec says its investigational new drug application to the US Food and Drug Administration for the pivotal trial of TT-034 for hepatitis-C has been delayed by one week.

ELLEX BUYS ISCIENCE FOR CANALOPLASTY
ELLEX MEDICAL LASERS
Ellex says it has completed the acquisition of Iscience Interventional, a canaloplasty business which manufactures a catheter and suture device.

ROSS HAGHIGHAT REPLACES ISONEA'S STEWART WASHER, TIM OLDHAM CEO
ISONEA
Isonea says chairman Dr Stewart Washer has resigned, director Ross Haghighat has been appointed chairman with Dr Tim Oldham appointed a director and Jerry Korten CEO.

ONCOSIL RE-APPROVES DR NEIL FRAZER, MARTIN ROGERS LOAN SHARES
ONCOSIL MEDICAL
Oncosil says its extraordinary general meeting overwhelmingly re-approved the issue of 20,000,000 loan shares to chief executive officer Dr Neil Frazer and 5,000,000 loan shares to chairman Martin Rogers.

Tuesday January 7, 2014

OSPREY ENROLS FIRST PATIENT IN AVERT DEVICE TRIAL
OSPREY MEDICAL
Osprey says the first of 700 patients has been enrolled in the Avert cardiac dye trial to be conducted at 45 centres in the US, Canada, Europe, Australia and New Zealand.

BIONICHE APPOINTS DONALD OLDS COO
BIONICHE LIFE SCIENCES
Bioniche says it has appointed Donald Olds as chief operating officer.

GENETIC TECHNOLOGIES CEO ALISON MEW EXTENDS LEAVE
GENETIC TECHNOLOGIES
Genetic Technologies says chief executive officer Alison Mew has extended her leave until the end of March 2014 and Tom Howitt continued as acting chief executive officer.

ISONEA LAUNCHES ASTHMASENSE PRIME
ISONEA
Isonea says it will unveil its Asthmasense Prime asthma monitor at the Consumer Electronics Show in Las Vegas, this week

Wednesday January 8, 2014

RESMED DETAILS PETER FARRELL'S MOVE TO NON-EXECUTIVE
RESMED
Resmed says former executive chairman Peter Farrell has become a non-executive chairman and will receive a retainer of $US65,000, an annual equity grant of $US250,000, an annual salary of $US300,000 along with benefits and other perquisites.

CAPITAL GROUP TAKES 5.6% OF MESOBLAST
MESOBLAST
The Los Angeles, California-based Capital Group Companies has become substantial in Mesoblast with 18,116,901 shares or 5.64 percent.

SIRTEX SIR-SPHERES DECEMBER QUARTER SALES UP 19%
SIRTEX MEDICAL
Sirtex says that SIR-Spheres dose sales were up18.7 percent for the three months to December 31, 2013 compared to the previous corresponding period.

GENETIC TECHNOLOGIES CLAIMS 23% INCREASE IN BREVAGEN TESTS
GENETIC TECHNOLOGIES
Genetic Technologies says it received 1,125 Brevagen breast cancer tests in the three months to December 31, 2013 up 23 percent on the 914 samples received in the three months to September 30, 2013.

VIRALYTICS COMPLETES PHASE II MELANOMA TREATMENT
VIRALYTICS
Viralytics says it has treated 54 patients in its US phase II trial for late stage melanoma with 14 (35%) of 40 evaluable patients reaching the six month progression-free survival rate and a one-year survival rate of 60 percent for the first 20 patients.

Thursday January 9, 2014

ATCOR H1 SALES DOWN 50%, $1m LOSS
ATCOR MEDICAL
Atcor says sales for the six months to December 31, 2013 are expected to be 50 percent lower than the previous corresponding period, resulting in an expected loss of $1 million.

EUROPEAN PATENT FOR BONE'S LEXCICON
BONE MEDICAL
Bone says it has been allowed a European patent for its Lexcicon platform technology, that with its Mozaic platform, was the basis of its rheumatoid arthritis compound BN006.

Monday January 13, 2014

PSIVIDA SHIPS FIRST ORDERS OF ILUVEN TO NHS HOSPITALS
PSIVIDA
Psivida says that licensee Alimera Sciences' first order for Iluven has been shipped to British National Health Service hospitals for treatment of chronic diabetic macular oedema.

ANALYTICA APPOINTS CARL STUBBINGS DIRECTOR
ANALYTICA
Analytica says that Benitec's chief business officer Carl Stubbings has been appointed as a non-executive director. Analytica said that Mr Stubbings continued at Benitec and as a director of Sienna Diagnostics.

Tuesday January 14, 2014

OVER-SUBSCRIBED BIOTA OFFER RAISES $31m
BIOTA PHARMACEUTICALS
Biota says its over-subscribed placement has raised $US26.9 million ($A30.6 million) at $US4.30 a share, equivalent to 61.25 cents per Australian share, prior to leaving the ASX.

HEARTWARE 2013 REVENUE UP 87% TO $237m
HEARTWARE INTERNATIONAL
Heartware says that its preliminary revenue for the 12 months to December 31, 2013 was up 87 percent to $US208 million ($A236.9 million) compared to 2012.

FDA APPROVES BENITEC HEPATITIS C TRIAL
BENITEC BIOPHARMA
Benitec says the US FDA has approved its trial of TT-034 for hepatitis C.

REVA COMPLETES CE APPROVAL STUDY ENROLMENT
REVA MEDICAL
Reva says 112 patients have been enrolled in its Rezolve2 trial enabling it to file for Conformité Européenne (CE) mark approval, which it expect to do this year.

STARPHARMA EXPECTS $4.7m R&D TAX INCENTIVE
STARPHARMA HOLDINGS
Starpharma says it expects to receive a Federal Government R&D Tax Incentive payment of $4.7 million for the year to June 30, 2013.

ATCOR'S SPHYGMOCOR APPROVED IN CHINA
ATCOR
Atcor says its Sphygmocor XCel non-invasive measure of central blood pressure and arterial stiffness has been approved for sale in China

CIRCADIAN, OPTHEA LICENCE OPT-302 (VEX-300) TO SELEXIS
CIRCADIAN TECHNOLOGIES
Circadian says subsidiary Opthea has licenced OPT-302 (formerly VEX-300) a soluble form of vascular endothelial growth factor-3 (VEGFR-3) to the Geneva, Switzerland-based Selexis SA for wet age-related macular degeneration.

PATRYS RAISES A FURTHER $1.3m
PATRYS
Patrys says it has raised $1,275,000 through the placement of 25,500,000 shares at five cents a share to BBY and Azure Capital (BD: Dec 16, 2013).

Wednesday January 15, 2014

STIRLING (DOCA) TO RE-LIST
STIRLING PRODUCTS
William Buck as deed of company arrangement administrator says that Stirling hopes to recapitalize and relist on the ASX to develop a virus detection technology known as "rapid enhanced viral amplification culture".
In 2009, with former Victoria Police officer Peter Boonen as managing director Stirling attempted to commercialize the Kiev, Ukraine-developed herbal remedy Immunoxel which it claimed was effective against tuberculosis, influenza and kidney disease. Stirling also attempted to acquire a number of companies and eventually, with 1,347,653,601 shares on offer, asked shareholders to approve the issue of a further 1,616,657,716 shares to cover placements acquisitions, convertible notes and working capital (BD: Nov 2, 2010).
Having failed to list on London's Alternative Investment Market, Stirling moved into a voluntary suspension (BD: Jul 26, 2011).

SUDA'S HEMOSTYP LAUNCHED IN AUSTRALIA
SUDA
Suda says that subsidiary Westcoast Surgical and Medical Supplies has launched its wound healing gauze Hemostyp following Australian Therapeutic Goods Administration approval.

Thursday January 16, 2014

AGENIX GRANTED CANADA THROMBOVIEW PATENT
AGENIX
Agenix says it has been granted a patent in Canada for 'Humanised antibodies derived from DD-3B6/22, specific for the D-Dimer fragment of Fibrin' the basis of lead diagnostic product Thromboview for pulmonary embolism.

CYNATA APPOINTS DR KILIAN KELLY PRODUCT DEVELOPMENT V-P
CYNATA
Cynata says that Dr Kilian Kelly has been appointed product development vice-president to lead regulatory, pre-clinical and clinical development of the mesenchymal stem sell pipeline.
The company said that Dr Kelly was previously senior director for drug development at Biota and vice-president of regulation and clinical development at Mesoblast.

Friday January 17, 2014

PRIMA AMENDED PHASE II TRIAL APPROVED IN BELGIUM.
PRIMA BIOMED
Prima says its amended CAN-004 phase II trial of CVac for the maintenance treatment of epithelial ovarian cancer in remission has been approved in Belgium.
The company said that trial would enrol a new cohort of 210 patients in addition to the 71 already enrolled.

AUSTRALIAN LEADERS BELOW 5% IN ATCOR
ATCOR MEDICAL
The Sydney-based Australian Leaders Fund says it has reduced its substantial shareholding in Atcor from 12,269,428 shares (7.84%) to less than five percent.

*** Biotech Daily editor, David Langsam, owns shares in Acrux, Alchemia, Admedus, Benitec, Biota, Mesoblast, Nanosonics and Neuren, as well as non-biotechnology stocks. These holdings are liable to change at any time.**