



Biotech Daily

SPECIAL SUMMER CATCH UP EDITION

Sunday, January 20, 2013

The Summer Catch-Up Edition was compiled by Jane Sugden

- * **RESONANCE LIVER FIBROSIS TRIAL: NOT COMPETITIVE**
- * **CORRECTION: BLUECHIIP**
- * **ENDO RETURNS UROCIDIN RIGHTS TO BIONICHE**
- * **PRIMA DIRECTOR MARTIN ROGERS SELLS 10.5m SHARES**
- * **NEUREN TO BEGIN PHASE II TRIAL OF NNZ-2566 IN RETT SYNDROME**
- * **CONSEGNA RAISES \$357k; APPOINTS PHILLIP HAINS JOINT CO SEC**
- * **BRUCE GRAY SELLS \$7m SIRTEX SHARES**
- * **AGENIX SAYS FORTREND RENEGED ON FACILITY; FUND RAISING**
- * **MEDICAL DEVELOPMENTS SIGNS SPACER DEAL WITH GLAXOSMITHKLINE**
- * **PROGEN PG545 LICENCE WITH MEDIGEN**
- * **HEALTHLINX AGREEMENT WITH MANE EXPIRES**
- * **MALCOLM LUCAS-SMITH REPLACES HEALTHLINX DIRECTOR JOHN EVANS**
- * **INVION BEGINS PHASE II ASTHMA TRIAL**
- * **NUSEP RECEIVES \$227k SHARE PAYMENT**
- * **SIENNA APPOINTS DR DAVID EARP DIRECTOR**
- * **CLINICAL NETWORK SERVICES BUYS NZ PARTNER BELTAS**
- * **MARIA MAILELI REPLACES ELLEX CO SEC GUISEPPE CANALA**
- * **CONSEGNA TO ISSUE 48m PLACEMENT SHARES**
- * **PROXIMA TAKES 33% OF BONE**
- * **HEARTWARE 2012 Q4 REVENUE UP 40% TO \$32m**
- * **SUNSHINE HEART BEGINS PIVOTAL US C-PULSE TRIAL**
- * **NUSEP'S SINGAPORE FACILITY PRODUCES GMP-QUALITY ALBUMIN**

- * RAFF GROUP TAKES 7% OF GENERA
- * CITIGROUP TAKES 7% OF PATRYS
- * SIRTEX SIR-SPHERES 2102 Q4 SALES UP 25%
- * NEUREN APPOINTS DR NANCY JONES HEAD CLINICAL DEVELOPMENT
- * CLIFFORD EU TAKES 10% OF NUSEP
- * ALLIED'S ADAPT TISSUE SUPERIOR OR EQUAL TO SYNTHETIC IMPLANT
- * WEHI DISCOVERS HOW INSULIN ATTACHES TO RECEPTOR
- * GI DYNAMICS, GORE SETTLE PATENT LITIGATION
- * BONE COMPLETES PHASE II BN006 RHEUMATOID ARTHRITIS PHASE II TREATMENT
- * NUSEP COMPLETES SINGAPORE-BASED PRIME FACILITY LEASE
- * MESOBLAST PHASE II LUMBAR RESULTS TAKE LUMBAR SPINE FUSION TO PHASE III
- * SIRTEX FOUNDER DR BRUCE GRAY SELLS \$9.6m SHARES
- * PATRYS PHASE I/IIa MULTIPLE MYELOMA TRIAL DOSES SECOND GROUP
- * BLUECHIP SIGNS 1st NORTH AMERICA DISTRIBUTOR
- * OXFORD'S ISIS APPOINTS HELEN UJVARY AUSTRALIA REPRESENTATIVE
- * US REGISTERS 25 GENE STEM CELL LINES
- * PROGEN EXPECTS \$723k R&D TAX REFUND
- * VICTORIA \$300k FOR INFECTION, IMMUNITY ALLIANCE
- * BIONOMICS EXPECTS \$4.2m R&D TAX REFUND
- * CELL CARE TAKES 23% OF CRYOSITE
- * QRX'S MOXDUO EXPECTED TO LAUNCH IN Q3, 2103
- * ASPIRE \$US25m SUNSHINE HEART STOCK PURCHASE FACILITY
- * PHOSPHAGENICS BEGINS PHASE I OXYMORPHONE PATCH TRIAL
- * SPAIN APPROVES PSIVIDA, ALIMERA ILUVIEN
- * JAPAN PATENT FOR BPH, DIAGNOSTIC ARRAY RESPIRATORY PATHOGEN TEST

Detailed summaries continue on the following pages

The following articles appear in date order

Friday, December 21, 2012

RESONANCE LIVER FIBROSIS TRIAL: NOT COMPETITIVE

[RESONANCE HEALTH](#)

Resonance says the results of its magnetic resonance imaging diagnosis of liver fibrosis trial are not sufficiently accurate or sensitive to be competitive with other available products.

Monday, December 24, 2012

CORRECTION BLUECHIIP

[BLUECHIIP](#)

In the last edition of 2012, Biotech Daily reported correctly that Bluechiip raised \$586,500, in addition to the \$1.5 million raised in a private placement in November but the headline said the total was \$1.5 million not the correct figure of \$2.1 million. The former sub-editor was far too full of Christmas cheer.

PRIMA DIRECTOR MARTIN ROGERS SELLS 10.5m SHARES

[PRIMA BIOMED](#)

Prima director Martin Rogers says he sold 10,479,500 shares to meet tax bills and as the company's largest shareholder he has "full confidence in the Prima team and for the potential of CVac".

ENDO RETURNS UROCIDIN RIGHTS TO BIONICHE

[BIONICHE](#)

Bioniche says that Endo Pharmaceuticals has returned the global rights to Urocidin to Bioniche and will receive a royalty payment on future revenue.

FDA APPROVES NEUREN PHASE II NNZ-2566 RETT SYNDROME TRIAL

[NEUREN PHARMACEUTICALS](#)

Neuren says the US Food and Drug Administration has approved its phase II trial of NNZ-2566 in Rett syndrome in 60 adolescent and adult patients.

CONSEGNA RAISES \$357k; APPOINTS PHILLIP HAINS JOINT CO SEC

[CONSEGNA GROUP](#)

Consegna says it has raised \$307,200 through the placement of 76,800,000 shares at 0.4 cents a share for working capital and to fund the 2013 launch of Breatheassist, and 12,500,000 shares for fees payable.

Separately, the company said it had appointed Phillip Hains as joint company secretary with company secretary Justin Stedwell.

SIRTEX FOUNDER DR BRUCE GRAY SELLS \$7m SHARES

[SIRTEX MEDICAL](#)

Sirtex founder and former chief executive officer Dr Bruce Gray says he has reduced his holding from 9,665,047 shares (17.33%) to 8,956,510 shares (15.23%) selling 708,477 shares for \$7,007,631 or an average price of \$9.89 a share.

Thursday, December 27, 2012

AGENIX SAYS FORTREND RENEGGED ON FACILITY; FUND RAISING

[AGENIX](#)

Agenix says Fortrend Securities would default on its draw down equity facility agreement from April 2012, and not pay its monthly installment due on January 1, 2013. Agenix said that cash requirements would be met through unsecured loans from directors, senior management and some shareholders, along with a rights issue.

MEDICAL DEVELOPMENTS SIGNS DEAL WITH GSK

[MEDICAL DEVELOPMENTS INTERNATIONAL, GLAXOSMITHKLINE](#)

Medical Developments says it has an agreement with Glaxosmithkline to supply 130,000 asthma space chambers a year for two years.

The company said it had UK reimbursement approval for its Space Chamber Plus and Space Chamber Compact Asthma Device, and had appointed distributors in Belgium, Netherlands, Luxembourg and the UK.

Medical Devices International said it had received its first Canadian order for 50,000 Reusable Space Chambers and a five-year tender to supply 70 percent of Canadian hospitals with space chambers.

Friday, December 28, 2012

PROGEN SIGNS LICENCE WITH MEDIGEN

[PROGEN PHARMACEUTICALS](#)

Progen says it has signed a licence term sheet with Medigen to develop and commercialize PG545 for hepatocellular carcinoma.

Monday, December 31, 2012

HEALTHLINX HEADS OF AGREEMENT WITH MANE EXPIRES

[HEALTHLINX](#)

Healthlinx says the agreement with Mane Cancer Diagnostics has expired as sale conditions had not been met, but the two companies would continue negotiations.

Wednesday, January 2, 2013

MALCOLM LUCAS-SMITH REPLACES HEALTHLINX DIRECTOR JOHN EVANS

[HEALTHLINX](#)

Healthlinx says company secretary Malcolm Lucas-Smith has replaced John Evans as a director.

INVION BEGINS PHASE II ASTHMA TRIAL

[INVION](#)

Invion says it has begun a third phase II trial of INV102 (nadolol) for inflammatory lung diseases such as asthma and chronic bronchitis. The company said the trial would assess effect on airways responsiveness as well as safety, signs, symptoms and biomarkers. Invion said Nadolol was registered for use in high blood pressure.

NUSEP RECEIVES \$227k FINAL SHARE PLAN PAYMENT

[NUSEP](#)

Nusep says it has received the third and final payment of \$227,090 under its share plan.

Monday, January 7, 2013

SIENNA APPOINTS DR DAVID EARP DIRECTOR

[SIENNA CANCER DIAGNOSTICS](#)

Sienna says it has appointed Dr David Earp as a non-executive director of the company. Sienna said Dr Earp had previously negotiating licences with the company as senior vice-president of business development and chief patent counsel at Geron Corp, where he worked for more than 13 years.

CLINICAL NETWORK SERVICES BUYS NZ PARTNER BELTAS

[CLINICAL NETWORK SERVICES](#)

Brisbane-based clinical research organization Clinical Network Services has acquired the business assets of its former New Zealand partner Beltas. Clinical Network Services said the terms of the deal were not disclosed.

MARIA MAILELI REPLACES ELLEX CO SEC GUISEPPE CANALA

[ELLEX MEDICAL LASERS](#)

Ellex says financial controller Maria Maileli has been promoted to company secretary, replacing Guiseppe Canala, who continues as a director.

CONSEGNA TO ISSUE 48.2m PLACEMENT SHARES

[CONSEGNA GROUP](#)

Consegna says it will issue 48,200,000 shares at 0.4 cents each as the balance of its \$500,000 placement.

PROXIMA INCREASES TO 33% OF BONE

[BONE MEDICAL](#)

Proxima Concepts says it has increased its substantial shareholding in Bone from 84,978,580 shares (17.81%) to 221,607,280 shares (33.02%).

Tuesday, January 8, 2013

HEARTWARE 2012 Q4 REVENUE UP 40% TO \$32m

[HEARTWARE INTERNATIONAL](#)

Heartware says that revenue for the three months to December 31, 2012 was up 40 percent to \$US32 million, bringing expected revenue for 2012 to \$US110 million.

SUNSHINE HEART BEGINS US C-PULSE TRIAL

[SUNSHINE HEART](#)

Sunshine Heart says that seven of up to 40 proposed trial sites for its pivotal C-pulse heart assist system study are engaged in contract negotiations with the first patient expected to be enrolled by April 2013.

NUSEP'S SINGAPORE FACILITY PRODUCES GMP-QUALITY ALBUMIN

[NUSEP](#)

Nusep says its Prime Singapore facility has produced human albumin to regulatory standards

RAFF GROUP TAKES 7% OF GENERA

[GENERA BIOSYSTEMS](#)

The Raff Super Fund and JPS Distribution have increased their substantial holding in Genera to 5,962,370 shares (7.19%), with 2,175,581 shares bought for \$228,436 or 10.5 cents a share in a placement. Dr John Raff is the former chief executive officer of Starpharma and the former chairman of the Bio-Melbourne Network.

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%).

Wednesday, January 9, 2013

SIRTEX SIR-SPHERES SALES UP 25%

[SIRTEX MEDICAL](#)

Sirtex says that sales of its SIR-Spheres increased 25 percent for the three months to December 31, 2012, compared to the previous corresponding period.

NEUREN APPOINTS DR NANCY JONES HEAD OF CLINICAL DEVELOPMENT

[NEUREN PHARMACEUTICALS](#)

Neuren says it has appointed Dr Nancy Jones as senior director of clinical development and clinical affairs. The company said that Dr Jones previously worked for Autism Speaks.

CLIFFORD EU TAKES 10% OF NUSEP

[NUSEP](#)

Singapore's Clifford Eu has increased his substantial holding in Nusep from 12,000,000 shares (9.0%) to 13,695,453 shares (10.3%), with 1,695,453 shares acquired for \$118,682 or seven cents a share.

Thursday, January 10, 2013

ALLIED'S ADAPT TISSUE SUPERIOR OR EQUAL TO SYNTHETIC IMPLANT

[ALLIED HEALTHCARE GROUP](#)

Allied says a Belgium-based comparative study of its Adapt bovine tissue compared to a synthetic implant in abdominal hernia and pelvic floor reconstructions showed its product had no evidence of infections, erosions or resorption in hernia repairs, and reduced infections and erosions in pelvic floor reconstructions.

WEHI DISCOVERS HOW INSULIN ATTACHES TO RECEPTOR

[THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH](#)

the Walter and Eliza Hall Institute says a discovery of how insulin docks on cells could help in the development of improved insulin for treating both type 1 and type 2 diabetes. WEHI said its researchers had captured the method in which insulin uses the insulin receptor to bind to the surface of cells, necessary for the cells to take up sugar from the blood as energy.

GI DYNAMICS, GORE SETTLE PATENT LITIGATION

GI DYNAMICS

GI Dynamics says it has settled intellectual property litigation with supplier WL Gore & Associates.

GI Dynamics said Gore supplied a material used to manufacture its Endobarrier and Gore began proceedings in 2010, claiming that it was the co-owner of all of the patents and patent applications, as well as claiming that certain of its employees were co-inventors of the company's issued patents.

GI Dynamics counterclaimed that Gore was neither a co-owner nor a co-inventor of any of its patents or applications and alleging misuse and misappropriation by Gore of the company's trade secrets, breach of contract, misrepresentation, and unfair and deceptive. GI Dynamics said it retained exclusive ownership and control of its patent portfolio and both parties have dismissed all claims against each other, with Gore granted a non-exclusive, royalty-free licence to use GI Dynamics' patents, but only for blood vessels and not any applications in the gastrointestinal tract.

GI Dynamics said neither side would make any cash payments, nor pay royalties.

BONE COMPLETES PHASE II BN006 RHEUMATOID ARTHRITIS TREATMENT

BONE MEDICAL

Bone says its phase II trial of BN006 for rheumatoid arthritis is moving from treatment stage to analytical stage, with results expected "in the very near future".

NUSEP COMPLETES SINGAPORE-BASED PRIME FACILITY LEASE

NUSEP

Nusep says the lease of its Singapore-based subsidiary Prime's clinical good manufacturing practice premises has been completed.

Friday, January 11, 2013

MESOBLAST PHASE II RESULTS TAKE LUMBAR SPINE FUSION TO PHASE III

MESOBLAST

Mesoblast says the 24-patient phase II trial of its mesenchymal precursor cells for lumbar spinal fusion showed success rates comparable to the gold standard of bone autograft. Mesoblast said that the cells were well tolerated, there was no evidence of ectopic bone fusion and significant improvements in low back pain scores and total disability index.

SIRTEX FOUNDER DR BRUCE GRAY SELLS \$9.6m SHARES

SIRTEX MEDICAL

Sirtex founder and former chief executive officer Dr Bruce Gray says he has reduced his holding from 8,956,510 shares (15.23%) to 8,216,130 shares (14.93%), selling 740,440 shares for \$9,580,279 or an average price of \$12.94 a share.

Monday, January 14, 2013

PATRY'S PHASE I/IIa MULTIPLE MYELOMA TRIAL DOSES SECOND GROUP

PATRY'S

Patry's says the phase I/IIa trial of PAT-SM6 for multiple myeloma at the University Hospital of Würzburg in Germany has treated the first group of three patients, receiving 0.3mg/kg with no significant adverse events and will progress to the second patient group to be treated with 1.0 mg/kg.

BLUECHIIP SIGNS 1st NORTH AMERICA DISTRIBUTOR

[BLUECHIIP](#)

Bluechiip says it has signed a distribution agreement with Micronic America LLC for the US and Canada.

OXFORD'S ISIS APPOINTS HELEN UJVARY AUSTRALIA REPRESENTATIVE

[UNIVERSITY OF OXFORD ISIS INNOVATION](#)

The University of Oxford's technology transfer company Isis Innovation has appointed the Adelaide-based Helen Ujvary as its Australia representative.

Isis said it was expanding its activities in Australasia, assisting technology providers from universities and industry to commercialise a broad spectrum of technologies.

US REGISTERS 25 GENE STEM CELL LINES

[GENEA STEM CELLS](#)

Genea says that 25 of its disease specific embryonic pluripotent stem cell lines have been placed on the US National Institutes of Health human stem cell registry.

The Sydney-based Genea said the embryonic stem cell lines were available commercially for use in medical research.

PROGEN EXPECTS \$723k R&D TAX REFUND

[PROGEN PHARMACEUTICALS](#)

Progen says it expects to receive a refund of \$723,000 from the Australian Taxation Office under the Federal Government's R&D tax refund scheme.

Tuesday, January 15, 2013

VICTORIA \$300k FOR INFECTION, IMMUNITY ALLIANCE

[VICTORIA GOVERNMENT](#)

The Victoria government has provided \$300,000 to the Victorian Infection and Immunity Network as part of its Collaborative Networks Pilot Program, to encourage partnerships between academic and industry groups.

A Victoria Government media release said the Network was convened by Monash Institute of Medical Research's Prof Paul Hertzog and the University of Melbourne's Prof Elizabeth Hartland.

The media release said the Network represented more than 900 infection and immunity scientists from Victoria's major universities and research institutions.

BIONOMICS EXPECTS \$4.2m R&D TAX REFUND

[BIONOMICS](#)

Bionomics says it expects to receive a refund of \$4.2 million from the Australian Taxation Office under the Federal Government's R&D tax refund scheme.

CELL CARE TAKES 23% OF CRYOSITE

[CRYOSITE](#)

Cell Care Australia and related parties have increased their substantial shareholding in Cryosite from 10,240,498 shares (21.97%) to 10,709,334 shares (22.96%).

Cryosite and Cell Care are both involved at cord blood storage.

Wednesday, January 16, 2013

QRX'S MOXDUEO EXPECTED TO LAUNCH IN Q3, 2103

QRX PHARMA

QRX says it will resubmit its Moxduo new drug application to the US Food and Drug Administration by April 2013 with a review date expected by October 2013.

QRX said that although the FDA's combination rule did not require a demonstration of greater efficacy or safety, the data indicated a Moxduo safety advantage compared to either morphine or oxycodone alone and Study 022 showed that oxygen desaturation was less severe with Moxduo than with oxycodone or morphine.

The company said that the FDA recommended a more extensive analysis of Study 022 when the revised application was resubmitted and the FDA "also voiced for the first time that no precedent exists for their review of combination products where two drugs in the same category are combined (e.g. morphine and oxycodone as opioids)".

QRX said that despite the FDA previously confirming there were no safety issues in the original NDA, the resubmitted application results would likely undergo review by July 2013 and the committee would evaluate the approvability of Moxduo for acute pain.

ASPIRE \$US25m SUNSHINE HEART STOCK PURCHASE FACILITY

SUNSHINE HEART

Sunshine Heart says that Aspire Capital has agreed to purchase up to \$US25 million of its shares over the next two years.

PHOSPHAGENICS BEGINS PHASE I OXYMORPHONE PATCH TRIAL

PHOSPHAGENICS

Phosphagenics says it will begin a phase I trial for tocopheryl phosphate mixture or TPM technology oxymorphone patches at the Royal Adelaide Hospital, with results expected in March 2013.

Friday, January 18, 2013

SPAIN APPROVES PSIVIDA, ALIMERA ILUVIEN

PSIVIDA

Psivida says that Iluvien for chronic diabetic macular oedema has received marketing authorization in Spain. Psivida said that in 2012 Iluvien received approval in the UK, France, Portugal, Austria and Germany, with sales expected to begin in Germany and a resubmission to the US FDA expected by April 2013.

JAPAN PATENT FOR BPH, DIAGNOSTIC ARRAY RESPIRATORY PATHOGEN TEST

BPH ENERGY

BPH says that investee company Diagnostic Array Systems has been granted a Japanese patent for its Bactrac System, for the identification of multiple respiratory pathogens.

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

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053
email: editor@biotechdaily.com.au; web: www.biotechdaily.com.au; twitter: [biotech_daily.com](https://twitter.com/biotech_daily)