

Biotech Daily

SPECIAL SUMMER CATCH UP EDITION

Monday, January 25, 2016

The Summer Catch-Up Edition was compiled by Olga Galacho

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- * ONCOSIL APPOINTS COCHLEAR'S DR CHRIS ROBERTS DIRECTOR
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- * ELLEX TO EXPAND PRODUCTION FACILITIES
- * RESMED Q2 SALES INCREASE 7% TO \$454.5 MILLION
- * BERNARD STANG REDUCES TO 7% OF NANOSONICS
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Detailed summaries continue on the following pages

The following articles appear in date order

Monday December 21, 2015

3D MEDICAL LOSES CEO MAX GHOBRIAL, ALBERT LIONG MD MACH7 3D MEDICAL

3D Medical says chief executive officer Max Ghobrial has retired and when the merger with Mach7 has been completed Albert Liong will be appointed as managing director with 3D chairman Dr Nigel Finch assuming an executive-chairman role.

UBS AG REDUCES TO 7% of GI DYNAMICS

GI DYNAMICS

UBS AG says it has reduced its substantial shareholding in GI Dynamics from 38,752,716 shares (8.15%) to 33,870,658 (7.13%).

JOHN LEAVER BELOW 5% IN BIONOMICS

BIONOMICS

John Leaver and associated companies say they have reduced their holding in Bionomics to below the five percent substantial shareholder level.

Mr Leaver previously held 24,241,071 Bionomics shares or 5.89 percent of the company (BD: Sep 5, 2013).

GENETIC TECHNOLOGIES: 'RESULTS SUPPORT BREVAGENPLUS' GENETIC TECHNOLOGIES

Genetic Technologies says data from 1150 women aged between 35 and 50 years support its Brevagenplus breast cancer-risk test for Caucasian women.

CSL SIGNS \$1.8b DEBT DEAL

CSL

CSL says it has renegotiated debt facilities of \$US1.25 billion (\$A1.79 billion) over five years.

POLYNOVO PLAN RAISES \$4.4m, TOTAL \$12.9m

POLYNOVO

Polynovo says its share purchase plan raised \$4.4 million taking the total raised to \$12.9 million, following the November \$8.5 million placement (BD: Nov 25, 2015).

Tuesday, December 22, 2015

PSIVIDA'S MEDIDUR MEETS PRIMARY PHASE III ENDPOINT PSIVIDA

Psivida says it has achieved positive top-line results from its 129-patient phase III trial of Medidur for chronic non-infectious uveitis.

Psivida said that a six-month follow-up of the multi-centre trial found that 18.4 percent of Medidur-treated eyes compared to 78.6 percent of control eyes experienced recurrence of the uveitis (a statistically significant p < 0.00000001) and 23 percent of treated eyes compared to 4.9 percent of control eyes showed improved visual acuity.

COGSTATE SIGNS \$4.6m ALZHEIMER'S TRIAL DEAL

COGSTATE

Cogstate says it has signed a \$US3.2 million (\$A4.6 million) two-year contract with an unnamed pharmaceutical company for cognitive assessments in an Alzheimer's disease clinical trial.

IMMURON CLAIMS 80% C-DIFFICILE PRE-CLINICAL EFFICACY IMMURON

Immuron says a pre-clinical, proof-of-concept program in Clostridium difficile showed 80 percent efficacy in both the treatment and prevention of infections without using antibiotics.

RHINOMED RECEIVES \$436k FEDERAL R&D TAX INCENTIVE RHINOMED

Rhinomed says it has received \$435,774 Federal Government Research and Development Tax Incentive for research and development on its sleep and respiratory technology platform for the 2014-'15.

PRIMA BEGINS PHASE IIb IMP321 METASTATIC BREAST CANCER TRIAL PRIMA BIOMED

Prima says the first seven trial sites have been approved for its phase IIb study of IMP321 immunotherapy with paclitaxel for metastatic breast cancer.

The company said four Belgian sites and three Netherlands sites would begin enrolments, with initial dosing expected early in 2016.

ORTHOCELL EGM

ORTHOCELL

Orthocell says it will hold an extraordinary general meeting on January 27, 2016 at Murdoch University in Western Australia to discuss the issues of new shares and directors' participation in the placements.

SIMAVITA LOSES CFO, CO SEC TOM HOWITT

SIMAVITA HEALTH CARE

Simavita says company secretary and chief financial officer Tom Howitt has will resign effective from January 15, 2016.

Simavita said that chief commercial officer Peta Jurd would take over Mr Howitt's roles until a replacement was found.

AUSTRALIAN ETHICAL REDUCES TO 6% OF AVITA

AVITA MEDICAL

Australian Ethical Share Fund says it has reduced its substantial holding in Avita from 37,071,942 shares (6.96%) to 31,662,304 shares (5.94%).

ADMEDUS RAISES \$7m

ADMEDUS

Admedus says it has raised \$US5 million (\$A7.2 million) in a private placement to a US healthcare institutional investor at 66 cents a share.

MEDIBIO SIGNS NON-BINDING DEAL WITH MEDTRONIC

MEDIBIO

Medibio says it has signed a non-binding memorandum of understanding with the Dublin-based Medtronic for its heart rate test for mental health disorders.

Wednesday December 23, 2015

MEDIBIO SAUDI ARABIA STRESS DEAL

MEDIBIO

Medibio says it has a memorandum of understanding with Wellnovation for its corporate stress product for Saudi Arabia and the Arabian Gulf region.

ANTEO RAISES \$5m OF \$12m FOR DIASOURCE ACQUISITION

ANTEO DIAGNOSTICS

Anteo says its shareholder entitlement issue raised \$5,235,210 with a shortfall of \$6,765,217 and it is finalizing the underwriting placements.

QUEST, BVF INCREASE IN VIRALYTICS

VIRALYTICS

BVF Partners says it has increased its holding in Viralytics form 24,931,933 shares (13.55%) to 35,964,778 shares (15.58%).

Quest Asset Partners said it had increased its holding in Viralytics from 9,230,296 shares (5.02%) to 14,846,675 shares (6.43%).

Thursday December 24, 2015

MEDICAL DEVELOPMENTS TAKES AVITA RESPIRATORY BUSINESS FOR \$2.6m MEDICAL DEVELOPMENTS, AVITA MEDICAL

Avita says it has agreed to sell its respiratory business to Medical Developments for \$2.64 million, of which \$2.2 million would be in cash.

The company said the respiratory unit had two asthma spacer products, the Breath-a-Tech and Funhaler, designed to optimise the use of medicinal puffers.

SABBY TAKES 5% OF ADMEDUS

ADMEDUS

Sabby Management says it has become a substantial shareholder in Admedus with 10,500,000 shares or 5.35 percent of the company.

Tuesday December 29, 2015

PSIVIDA TO FILE FOR EU APPROVAL FOR EYE THERAPY

PSIVIDA CORP

Psivida says it will file for European Union marketing approval of Medidur for chronic, non-infectious, posterior uveitis, based on data from a single, pivotal study, its first phase III clinical trial, that indicated statistically significant results for the condition, which affects the back of the eye.

BRAIN RESOURCE SHARE PLAN RAISES \$109.5k

BRAIN RESOURCE

Brain Resource says it has raised \$109,500 from 15 shareholders under a share purchase plan following its November 2015 \$3 million placement (BD: Nov 19, 2015).

Thursday December 31, 2015

BRAIN RESOURCE CHAIR EVIAN GORDON DILUTED TO 8%

BRAIN RESOURCE

Brain Resource executive chairman Evian Gordon says he has reduced his holding from 18.47 percent to 8.17 percent following the \$3.1 million capital raising.

CYCLOPHARM COLLECTS \$2m INSURANCE PAY-OUT

CYCLOPHARM

Cyclopharm says it has received a \$2.1 million settlement resulting from a claim against water damage at Macquarie University Hospital, which damaged its cyclotron facility.

Monday January 4, 2016

NEUREN READY FOR TROFINETIDE PHASE II RETT TRIAL

NEUREN PHARMACEUTICALS

Neuren says it expects to start a phase II clinical trial of trofinetide in girls aged between five and 15 years with Rett syndrome by April 2016 and conclude the trial by the end of 2016.

UNILIFE SIGNS \$21m EXCLUSIVITY DEAL WITH AMGEN

UNILIFE CORP

Unilife says Amgen has paid a non-refundable \$US15 million (\$A21.4 million) to negotiate until the end of January 2016 for wearable injector devices for Amgen drugs.

Tuesday January 5, 2016

SUNSHINE HEART APPOINTS ERIC LOVETT FOR PIVOTAL STUDY SUNSHINE HEART

Sunshine Heart says it has appointed Eric Lovett as vice-president of clinical affairs to manage the US pivotal study of its C-Pulse heart assist system.

US PATENT FOR ORTHOCELL TISSUE REPAIR TECHNOLOGY ORTHOCELL

Orthocell says it has been granted a US patent for cell factory-derived bioactive molecules for the generation of tissue specific growth factors to help tissue regeneration.

The company said the patent would expires in 2027 and covered the "method of producing components such as growth factors or extracellular matrix proteins, through cell culture of tissue samples for tissue repair".

ASX QUERIES PHOSPHAGENICS 33% JUMP

PHOSPHAGENICS

Phosphagenics says it is not aware of any undisclosed information that led to a 33.3 percent increase in its share price from 1.2 cents on December 31, 2015 to 1.6 cents on January 4, 2016.

UBS GROUP TAKES 6% OF IDT

IDT AUSTRALIA

UBS Group and associated entities say they have become substantial shareholders in IDT with 14,279,024 shares (6.51%)

Wednesday January 6, 2016

ANTEO, DIASOURCE AGREE NEW TERMS

ANTEO DIAGNOSTICS

Anteo says the purchase price for Belgium's Diasource Immunoassays is unchanged at \$23.7 million, but it will pay half in cash and the balance via a deferred plan.

PHOSPHAGENICS SUES MYLAN LABORATORIES

PHOSPHAGENICS

Phosphagenics says it has launched legal action at the Singapore International Arbitration Centre against Mylan Laboratories for breaches of agreements it had with Agila Specialties for the use of its tocopheryl phosphate mixture.

ALLAN GRAY REDUCES TO 7.5% OF PHOSPHAGENICS

PHOSPHAGENICS

Allan Gray Australia says it has reduced its holding in Phosphagenics from 114,497,043 shares (9.07%) to 94,853,127 shares (7.52%).

COGSTATE LOSES DIRECTOR DR ALAN FINKEL

COGSTATE

Cogstate says Alan Finkel ceased to be a director on December 31, 2015, having been appointed in May, but in October, was appointed Australia's chief scientist.

ASIA UNION BELOW 5% IN COGSTATE

COGSTATE

Asia Union Investments says it has ceased its substantial holding in Cogstate, reducing from 6,600,000 shares (6.12%) to 5,230,500 shares (4.76%).

Friday January 8, 2016

PRIMA TELLS ASX 'REPORTS MAY HAVE PUSHED PRICE 13.5%'

PRIMA BIOMED

Prima has told the ASX that it had been the subject of favourable research reports from Roth Capital Partners and Edison.

The ASX said Prima's shares rose 0.7 cents or 13.5 percent from 5.2 cents on January 6 to 5.9 cents on January 7, 2016.

PSIVIDA HOPES TO RAISE \$23m

PSIVIDA CORP

Psivida says it hopes to raise \$US16 million (\$A22.8 million) through the issue of four million shares at \$US4.00 each, with underwriters Ladenburg Thalmann & Co and Northland Securities having a 30-day option buy up to an additional 440,000 shares.

Monday January 11, 2016

AUSTRALIAN ETHICAL REDUCES TO 11% OF ELLEX

ELLEX MEDICAL LASERS

Australian Ethical Smaller Companies Trust says it has reduced its holding in Ellex from 13,151,270 shares (12.21%) to 12,005,022 shares (11.15%).

MESOBLAST PHASE 3 HEART FAILURE TRIAL SCALED BACK MESOBLAST

Mesoblast says its phase III chronic heart failure trial of its MPC-150 stem cells with Israel's Teva Pharmaceuticals may be reduced, shortening the time to completion. Mesoblast said that following talks with Teva and the US Food and Drug Administration, the FDA had agreed to scale back the trial from 1,165 patients to 600 patients because of a revision to the primary endpoint.

The company said the revised primary endpoint would be a comparison of recurrent heart failure-related major adverse cardiovascular events between patients treated with MPC-150 and controls.

AVITA COMPLETES 30-PATIENT ACUTE BURNS TRIAL RECRUITMENTAVITA MEDICAL

Avita says patient recruitment has been completed for its US Food and Drug Administration study evaluating Recell with meshed auto-grafting for acute burns. The company said the recruitment of the 30 patients would put it on track for a "readout on primary effectiveness data" by the end of March 2016.

HEARTWARE APPOINTED STEPHEN OESTERLE DIRECTOR HEARTWARE INTERNATIONAL

Heartware says it has appointed Stephen Oesterle as a director, effective from January 18, 2016.

IMPEDIMED CREATES CHRONIC HEART FAILURE ADVISORY BOARD IMPEDIMED

Impedimed says it has established a medical advisory board for the design of trials for the use of bio-impedance spectroscopy in fluid detection for chronic heart failure.

Tuesday January 12, 2016

ANTEO COMPLETES DIASOURCE BUY-OUT

ANTEO DIAGNOSTICS

Anteo says it has completed the \$23.7 million purchase of Diasource Immunoassays. Anteo chief executive officer Dr Geoff Cumming said Diasource would expand its Mix & Go capabilities and become a cornerstone of its diagnostics division.

SIMAVITA PLANS \$5m PLACEMENT

SIMAVITA

Simavita says it hopes to raise \$5.06 million through the issue of up to 33.7 million common shares and Chess depository instruments (CDIs) at 15 cents a share or CDI.

REGENEUS SAYS PROGENZA STEM CELLS 'SAFE'

REGENEUS

Regeneus says a review of the first cohort of 10 patients in its trial of Progenza has been completed with no safety concerns identified.

The company said enrolment had opened for the second and final cohort of 10 patients for the allogeneic stem cell therapy for knee osteoarthritis.

Wednesday January 13, 2016

AVITA REPLACES PROF FIONA WOOD, DIRECTORS

AVITA MEDICAL

Avita says that founder and co-inventor of the Recell burns treatment, Prof Fiona Wood, has stepped down from the board to join the clinical advisory board. Avita said that directors Matt McNamara and Ian Macpherson had also resigned and would be replaced by Prof Suzanne Crowe, Louis Drapeau and Damien McDonald. The company said that Jeremy Curnock Cook and Lou Panaccio continued as directors.

3D: 'US PATENT FOR MERGER PARTNER MACH7' 3D MEDICAL

3D Medical says that Mach7 Technologies, with whom it will merge in February, has been awarded a US patent for any mobile device image and video capture function that can be uploaded into a patient's electronic medical record.

Thursday January 14, 2016

CANADA TO INSPECT MMJ CANNABIS CULTIVATION

MMJ PHYTOTEC

MMJ Phytotec says Health Canada will inspect subsidiary United Greeneries' Duncan, British Columbia facility on February 1, 2016.

The company said an inspection was the final step to receiving a cultivation licence under Marihuana for Medical Purposes Regulations.

AVITA SIGNS JAPAN, SOUTH KOREA RECELL DISTRIBUTION

AVITA MEDICAL

Avita says it has Recell wound treatment distribution agreements with Indee Medical for Japan and TRM Korea for South Korea.

PSIVIDA RAISES \$25m

PSIVIDA

Psivida says it closed the underwritten public offering of 4,440,000 shares at \$US4 each, raising \$US17.8 million (\$A25.4 million).

MEDIBIO RECEIVES \$1m R&D TAX INCENTIVE

MEDIBIO

Medibio says it has received \$1,216,128 in Federal funds under the Research and Development Tax Incentive Program related to expenses during the 2014-'15 financial year and it expected to receive a further rebate of \$600,000 in the current quarter related to activities conducted in the same period.

Friday January 15, 2016

SIMAVITA RECEIVES \$1m R&D TAX INCENTIVE

SIMAVITA

Simavita says it has received \$1,266,862 under the Federal Government's Research and Development Tax Incentive Scheme.

The company said the funds cover a claim for the year ended June 30, 2015 and that it may also be entitled to receive a further \$75,000 for eligible overseas expenditure.

Monday January 18, 2016

USCOM STUDY VALIDATES CLINICAL USE

USCOM

Uscom says an independent Great Ormond Street Hospital for Children study shows equivalence of its BP+ to catheter-based measures of central blood pressure.

The company said the study involving children aged one year to 18 years, found there was no significant difference in measures of central blood pressure directly from aortic catheters and those from the Uscom BP+.

DEUTSCHE BANK TAKES 6% OF GENETIC TECHNOLOGIES

GENETIC TECHNOLOGIES

Deutsche Bank AG and associated entities say they have increased their substantial holding in Genetic Technologies says from 86,880,000 shares (5.07%) to 107,477,250 shares (6.27%).

SOMNOMED CLAIMS 30% H1 SALES JUMP

SOMNOMED

Somnomed says sales revenue for its Somnodent sleep apnoea devices for the six months to December 31, 2015 increased 30.3 percent to \$18.05 million compared to the previous year.

IMUGENE DIRECTOR STEPS DOWN

IMUGENE

Imugene says Otto Buttula ceased being a director on January 15, 2016.

3DM RECORDS FIRST SALE THROUGH E-UNITY DEAL

3D MEDICAL

3D Medical says it has its first sale agreement under the Eunity medical image viewing and collaboration platform.

Tuesday January 19, 2016

MEDADVISOR APPOINTS SANDRA HOOK DIRECTOR

MEDADVISOR

Medadvisor says it has appointed Sandra Hook as a non-executive director.

Wednesday January 20, 2016

REVA HIRES RICHARD KIMES TO LEAD OPERATIONS

REVA MEDICAL

Reva says it has appointed Richard Kimes as head of operations responsible for manufacturing activities to support the launch of the Fantom coronary scaffold.

STARPHARMA RAISES \$1.9m

STARPHARMA

Starphama says it has raised \$1.9 million under a share purchase plan and that all eligible Australian directors took up the full \$15,000 allocation under the scheme.

IMUGENE EXTENDS VIENNA IMMUNOTHERAPY RESEARCH

IMUGENE

Imugene says it has extended its partnership with the Medical University of Vienna to discover and develop new mimotope-based immunotherapies for cancer.

PHOSPHAGENICS REPORTS POSITIVE PIG RESULTS

PHOSPHAGENICS

Phosphagenics says a study of its tocopheryl phosphate mixture (TPM) in 1,500 weaner pigs has shown positive results for the conversion of feed to weight gain.

Thursday January 21, 2016

ONCOSIL APPOINTS COCHLEAR'S DR CHRIS ROBERTS DIRECTOR ONCOSIL MEDICAL

Oncosil says that former Cochlear chief executive officer Dr Chris Roberts has been appointed as an independent, non-executive director.

Friday January 22, 2016

MEDADVISOR CLAIMS 1m TAP-TO-REFILL PRESCRIPTIONS

MEDADVISOR

Medadvisor says one million prescriptions have been filled via its Tap-to-Refill application function, accounting for about \$40 million in pharmacy sales.

RESAPP OPTIONS RAISE \$470k

RESAPP HEALTH

Resapp says it has issued 18,093,750 shares on the conversion of 18,093,750 unlisted options at 26 cents each raising \$470,438.

ELLEX TO EXPAND PRODUCTION FACILITIES

ELLEX MEDICAL LASERS

Ellex says it plans to buy a building in the northern suburbs of Adelaide to provide additional production capacity for its ophthalmic laser and ultrasound products.

RESMED Q2 SALES INCREASE 7% TO \$454.5 MILLION

RESMED

Resmed says that sales revenue for the three months to December 31, 2015 was up seven percent to \$454.5 million, compared to the previous corresponding quarter.

BERNARD STANG REDUCES TO 7% OF NANOSONICS

NANOSONICS

Bernard Stang says he has reduced his substantial holding in Nanosonics from 25,684,056 shares (9.72%) to 20,684,056 shares (7.3%).

SABBY TAKES 9% OF BENITEC

BENITEC BIOPHARMA

Sabby Management and associated parties say they have increased their holdings from 11,000,000 shares (7.54%) to 12,697,331 shares (8.70%).

SIMAVITA LAUNCHES PURCHASE PLAN

SIMAVITA

Simavita says it has opened a security purchase plan allowing investors to subscribe for up to \$15,000 worth of Chess depositary interests at 15 cents each.

Monday January 25, 2016

CLINUVEL INVESTOR RAISES HOLDING TO 8%

CLINUVEL

Lagoda Investment Management and associated entities say they have increased their holding in Clinuvel from 3,122,221 shares (7.01%) to 3,578,975 shares (8.04%).

VIRALYTICS COMPLETES OVERSUBSCRIBED \$4 MILLION SHARE PLAN VIRALYTICS

Viralytics says its share plan raised \$4 million with 6.5 million shares to be issued to retail investors at 61.5 cents each and more than \$10 million in applications.

PRESCIENT RECEIVES \$464k GRANTS

PRESCIENT THERAPEUTICS

Prescient says it has received a 2014-'2015 Research and Development Tax Incentive and an Overseas Funding Grant amounting to \$463,538.

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