Biotech Daily

SPECIAL SUMMER CATCH-UP EDITION

Sunday, January 22, 2017

*** MGC ISSUES 26m 'PERFORMANCE SHARES'**

*** PROTEOMICS PLAN RAISES $575k, TAKES TOTAL TO $2m**
- DR RICHARD LIPSCOMBE, WILLIAM PARKER, JOHN DUNLOP INCREASE, DILUTED

*** IBSEN, EZAHC, NARULA TAKE 11% OF OPTISCAN**

*** MACH7 APPROVES 10-TO-1 CONSOLIDATION**

*** REDHILL RAISES $53m**

*** PERPETUAL REDUCES TO 7% OF SIRTEX**

*** REGENEUS $23m ASAHI GLASS LICENCE OF PROGENZA IN JAPAN**

*** ROBERT PETERS TAKES 7% OF OPTISCAN**

*** DSMB APPROVES PRIMA IMP321 FOR MELANOMA DOSE INCREASE**

*** PHARMAUST RIGHTS SHORTFALL PLACEMENT RAISES $1.6m, TOTAL $2.7m**

*** INNATE PLEADS SCHULTZ TO ASX 48% QUERY**

*** OPTISCAN CFO MICHAEL CORRY RESIGNS AS JOINT CO SEC**

*** PRIMA DEVELOPS IMP761 FOR AUTOIMMUNE DISEASES**

*** US FDA APPROVES ACTINOGEN PHASE II XANAMEM ALZHEIMER'S TRIAL**

*** USCOM MANUFACTURES 1000th USCOM 1A MONITOR**

*** CHAIR PROF ROBERT PHILLIPS INCREASES TO 19% OF USCOM**

*** DR OERN STUGE REPLACES GI DYNAMICS CHAIRMAN JACK MEYER**

*** PRIMA, CYTLIMIC COLLABORATE ON IMP321, CANCER PEPTIDE COMBINATION**

*** BV HEALTH, NRF, SAGAMORE TAKE 10% OF MACH7**

*** FIL TAKES 9% OF MEDIBIO**

*** EUROPE APPROVES CSL'S AFSTYLA FOR HAEMOPHILIA A**

*** MALLINCKRODT PAYS MESOBLAST $30m FOR TWO DRUG OPTION**

*** SIRTEX UNAUDITED H1 DOSE SALES UP 5.6%**

*** ADALTA 'AD-114 REDUCES LUNG AND LIVER FIBROSIS IN MICE'**

*** EUROPE APPROVES 3 MGC CANNABINOID COSMETICS**

*** PRANA PLEADS SCHULTZ TO ASX 30% QUERY**

*** FORMER CHAIR MARTIN ROGERS BELOW 5% IN ACTINOGEN**

*** ORTHOCELL RECEIVES $1.95m FEDERAL R&D TAX INCENTIVE**

*** PERPETUAL BELOW 5% OF SIRTEX**

*** CRESO TO RELEASE 6.4m ESCROW SHARES**

*** ROD GIBSON, ROSHERVILLE TAKE 13% OF REPRODUCTIVE HEALTH**

*** CSL TO MARKET ZAMBON, NEWRON XADAGO FOR PARKINSON'S DISEASE**

*** TGA APPROVES WEHI VENETOCLAX FOR LEUKAEMIA**

*** RESAPP, MASSACHUSETTS GENERAL EXTEND COLLABORATION**

*** MEDADVISOR BUYS OZDOCSONLINE FOR $150k**

*** OVENTUS QUALITY MANAGEMENT WINS ISO 13485:20121**

*** ADHERIUM APPOINTS SCOTT FLEMING FOR EURO BUSINESS DEVELOPMENT**

*** REDHILL BEGINS 2nd PHASE III RHB-105 FOR HELICOBACTER PK STUDY**

*** USPTO ACCEPTS LIVING CELL NTCELL PATENT APPLICATION**

*** MAYNE US LAUNCH OF FABIOR FOR ACNE, SORILUX FOR PSORIASIS**

*** REDHILL RHB-104 WINS US QIDP FOR NON-TB MYCOBACTERIA INFECTIONS**

*** STARPHARMA VIVAGEL WINS US QIDP STATUS FOR BACTERIAL VAGINOSIS**

*** MTP CONNECT '$18b SECTOR VALUE INCREASE, 28k JOBS IN 10 YEARS'**

*** PRIMA DOSES 1st PATIENT IN 2nd IMP321, KEYTRUDA COHORT TRIAL**

*** ORTHOCELL, J&J WORK ON ORTHO-ATI FOR TENDONS, LIGAMENTS**

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*** US FCC APPROVES NUHEAR IQBUDS**

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*** UNIQUEST: 'J&J, ARTHRITIS QLD BACK DENDRIGHT DEN-181 FOR RA'**

*** EU ORPHAN STATUS FOR BENITEC BB-301 FOR OPMD**

*** AIRXPANDERS 1st US PAID AEROFORM BREAST EXPANSION PROCEDURE**

*** IMPEDIMED LOSES DIRECTOR ELIZABETH GAINES TO FORTESCUE AS CFO**

*** GI DYNAMICS PLAN RAISES $294k OF HOPED-FOR $988k, TOTAL $1.8m**

*** MACH7 COMPLETES 10-FOR-1 STOCK CONSOLIDATION**

*** THORNEY TAKES 5.6% OF ANATARA**

*** FIL TAKES 7% OF COGSTATE**

*** GREG HUNT TAKES HEALTH, ARTHUR SINODINOS INNOVATION**

*** PRIMA MEETS NASDAQ $US1 RULE**

*** CELLMID WINS FEDERAL $100k FOR MIDKINE KIDNEY TRIALS IN RODENTS**

*** YARRA FUNDS TAKES 6.6% OF SIRTEX**

*** REGAL FUNDS REDUCES TO 5% OF ADHERIUM**

*** DORSAVI 'VIMOVE BETTER THAN GUIDELINE CARE FOR BACK PAIN'**

*** US ORPHAN STATUS FOR AD-114 FOR IDIOPATHIC PULMONARY FIBROSIS**

*** CRESO CLAIMS 1st EU APPROVAL FOR CANNABINOID ANIMAL FEED ADDITIVE**

*** RECCE SAYS MOUSE TRIAL NEWS MAY HAVE LED TO ASX 131% QUERY**

*** OVENTUS WINS O2VENT T 1st US SALE**

*** HARVEST ONE TO RAISE $C15m FOR MMJ CANNABIS SUBSIDIARIES**

*** TELIX PARTNERS WITH THERAPEIA GMBH FOR ACD-101 FOR GLIOBLASTOMA**

*** CLARITY APPOINTS DR COLIN BIGGIN HEAD OF QUALITY**

*** ALLAN GRAY REDUCES TO 13% OF ACRUX**

*** CSL UPGRADES 2017 NPAT**

*** USCOM: 'BP+ PREDICTS ETHNICITY, SMOKING, DRINKING, OBESE HEART RISK'**

*** JUSTYN STEDWELL REPLACES ALLEGRA CO SEC RICHARD ULRICK**

*** CYNATA: '$60m PARTNERSHIP WITH FUJIFILM FOR CYP-001 FOR GVHD'**

*** AUSTRALIAN ETHICAL TAKES MORE PROFIT TO 5% OF INNATE**

*** IMMURON STUDIES TO BACK IMM-124E FOR NASH**

*** PRIMA DOSES 1st BREAST CANCER PATIENT IN PART 2 OF IMP321 TRIAL**

*** COGSTATE APPOINTS DR RICHARD MOHS DIRECTOR**

*** DORSAVI SHARE PLAN RAISES $1m**

*** REGAL FUNDS REDUCE BELOW 5% OF ADHERIUM**

*** PARADIGM TO RELEASE 9.7m ESCROW SHARES**

Detailed summaries continue on the following pages

The following articles appear in date order

Very Late on Friday December 23, 2016

MGC ISSUES 26m 'PERFORMANCE SHARES'

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

At 4.37pm on Friday December 23, after the ASX closed for Christmas Eve, MGC said it had issued 26,200,000 "performance rights".

MGC said the shares were subject to meeting employment milestones as per previously filed notices of meeting, but primarily required remaining with the company to February 25 and December 31, 2017 and December 31, 2018.

Wednesday December 28, 2016

PROTEOMICS PLAN RAISES $575k, TAKES TOTAL TO $2m

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its share plan at 24 cents a share was oversubscribed and raised $574,500, taking the total raised with its placement to $2,014,500.

In December Proteomics said the placement raised $1,440,000 (BD: Dec 2, 2016).

Proteomics chief executive officer Dr Richard Lipscombe, William Parker and family and John Dunlop all increased and were diluted in the capital raising.

IBSEN, EZAHC, NARULA TAKE 11% OF OPTISCAN

OPTISCAN

Ibsen Pty Ltd, Ezahc Pty Ltd and Narula Family Settlement No 3 have increased their holding in Optiscan from 17,668,445 shares (5.67%) to 41,668,445 shares (11.14%).

The substantial shareholder notice, signed by Canterbury, Victoria-based director Ian Mann, said the entities converted $600,000 in debt to 24,000,000 shares or 2.5 cents a share.

MACH7 APPROVES 10-TO-1 CONSOLIDATION
MACH7 TECHNOLOGIES
Mach7 has approved a 10-to-one consolidation effective from January 11, 2017.

Thursday December 29, 2016

REDHILL RAISES $53m
REDHILL BIOPHARMA
Redhill says it has raised $US38,062,504 ($A52,823,235) through the underwritten and direct offer 3,713,415 American depositary shares at $US10.25 per ADS.
Redhill said it had an underwritten public offer of 2,250,000 ADSs, each representing 10 shares and a concurrent registered direct offer of 1,463,415 ADSs, with one attaching warrant for every two ADSs purchased exercisable at $US13.33 each within three years.
The company said that the underwriters had 30-days to purchase up to an additional 337,500 ADSs.
Redhill said that EMC2 Fund Ltd participated in the registered direct offer and investors in the public offer included Sabby Management, LLC, Dafna Capital Management, Rosalind Advisors, Koramic Holding, Lincoln Park Capital and Nexthera Capital LP.

PERPETUAL REDUCES TO 7% OF SIRTEX
SIRTEX MEDICAL
Perpetual and its subsidiaries have reduced their substantial shareholding in Sirtex from 4,700,509 (8.15%) to 4,092,503 shares (7.09%).
Perpetual said that it traded shares from December 21 to 23, 2016 at prices ranging from $14.31 to $14.43.
In November, prior to Sirtex downgrading dose sales and chief executive officer Gilman Wong stepping aside for an investigation of his share sales, Perpetual acquired 581,373 shares at prices ranging from $26.95 to $33.77 (BD: Nov 15, 2016).

REGENEUS $23m ASAHI GLASS LICENCE OF PROGENZA IN JAPAN
REGENEUS
Regeneus says it has a $22.9 million collaboration and licencing agreement with AGC Asahi Glass for its Progenza off-the-shelf stem cell technology.
Regeneus said that the Tokyo, Japan-based AGC would pay $US16.5 million ($22.9 million) for exclusive rights to manufacture Progenza in Japan and a 50 percent interest in Regeneus Japan, which had exclusive rights for the clinical development and commercialisation of Progenza in Japan for all therapeutic applications.
The company said it would receive $US5.5million upfront the remaining $US11 million in development and approval milestone payments and would be entitled to a share of licence fees, milestone payments and royalties from sub-licencing.
Regeneus said that AGC would be responsible for the manufacture of Progenza for the proposed phase II trial for osteoarthritis in Japan.

Friday December 30, 2016

ROBERT PETERS TAKES 7% OF OPTISCAN
OPTISCAN
The Cottesloe, Western Australia-based Robert Peters and Peters Investments say they have become substantial in Optiscan with 25,031112 shares or 6.69 percent.
Mr Peters said that on September 8 and December 28, 2016, he acquired 22,000,000 shares for $800,000 or 3.6 cents share.

DSMB APPROVES PRIMA IMP321 FOR MELANOMA DOSE INCREASE
PRIMA BIOMED
Prima says the database safety monitoring board has approved the next dose of 6mg IMP321 in its phase I two active immunotherapeutics for melanoma (Tacti-mel) trial.
Prima said that the board confirmed that 1mg IMP321 was safe and well-tolerated, with no drug related adverse events, in combination with the PD-1 blocking antibody Keytruda in unresectable or metastatic melanoma patients.

PHARMAUST RIGHTS SHORTFALL PLACEMENT RAISES $1.6m, TOTAL $2.7m
PHARMAUST
Pharmaust says its rights issue shortfall placement has raised a further $1,563,069 taking the total raised to $2,709,563.

INNATE PLEADS SCHULTZ TO ASX 48% QUERY
INNATE IMMUNOTHERAPEUTICS
Innate 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 company's share price rose 47.8 percent from 78.5 cents on December 20 to $1.16 on December 30, 2016 and noted an increase in the trading volume.

OPTISCAN CFO MICHAEL CORRY RESIGNS AS JOINT CO SEC
OPTISCAN IMAGING LIMITED
Optiscan says that Michael Corry has resigned as joint company secretary, but continues as chief financial officer, effective from December 30, 2016.
In June, Optiscan appointed Mr Corry to replace long-standing chief financial officer and company secretary Bruce Andrew (BD: Jun 10, 2016).
Earlier in December, the company appointed Justin Mouchacca joint company secretary (BD: Dec 16, 2016).

Tuesday January 3, 2017

PRIMA DEVELOPS IMP761 FOR AUTOIMMUNE DISEASES
PRIMA BIOMED
Prima says it has developed IMP761, a new, early-stage, humanized immunoglobulin 4 (IgG4) monoclonal antibody for autoimmune diseases.
Prima said that IMP761 was developed at its laboratory in Châtenay-Malabry south of Paris and was believed to be the first agonist antibody of LAG-3.

US FDA APPROVES ACTINOGEN PHASE II XANAMEM ALZHEIRMER'S TRIAL
ACTINOGEN MEDICAL
Actinogen says the US Food and Drug Administration has approved its 174-patient, phase II trial of Xanamem for mild Alzheimer's disease.
Actinogen said that the US Food and Drug Administration approved the investigational new drug application (IND) trial entitled 'Xanadu: a phase II double-blind, 12-week, randomized, placebo-controlled study to assess the safety, tolerability and efficacy of Xanamem in subjects with mild dementia due to Alzheimer's disease".
Actinogen chief executive officer Dr Bill Ketelbey said the company was "delighted with the IND approval as it represents a major milestone".
The company said it expected approvals in Australia and the UK within the next two months and for the trial to recruit patients by July, 2017.

USCOM MANUFACTURES 1000th USCOM 1A MONITOR
USCOM
Uscom says it has manufactured "record numbers" of its Uscom 1A ultra-sonic cardiac output monitors in the six months to December 31, 2016, including the one thousandth unit.

Wednesday January 4, 2017

CHAIR PROF ROBERT PHILLIPS INCREASES TO 19% OF USCOM
USCOM
Uscom executive chairman Prof Robert Phillips has increased his holding in the company from 18,080,066 shares (16.59%) to 21,352,794 shares (19.02%).
Prof Phillips said the shares were acquired through Australian Cardiac Sonography Pty Ltd Phillips Superannuation account.

Thursday January 5, 2017

DR OERN STUGE REPLACES GI DYNAMICS CHAIRMAN JACK MEYER
GI DYNAMICS
GI Dynamics says it has appointed medical device executive Dr Oern Stuge as a director replacing former chairman Jack Meyer.

PRIMA, CYTLIMIC COLLABORATE ON IMP321, CANCER PEPTIDE COMBO
PRIMA BIOMED
Prima says it has a collaboration agreement with Japan's NEC Corp spin-out Cytlimic to test a cancer peptide vaccine in combination with IMP321.
Prima said that under a material transfer agreement it would provide IMP321 for a formulation development targeting a pre-clinical and clinical development study to be conducted and funded by Cytlimic and would generate revenue for Prima.

BV HEALTH, NRF, SAGAMORE TAKE 10% OF MACH7
MACH7 TECHNOLOGIES
BV Healthcare, NRF and Sagamore say they have increased their holding in Mach 7 from 83,849,912 shares (7.71%) to 113,728,985 shares (9.62%).

FIL TAKES 9% OF MEDIBIO
MEDIBIO
The Hong Kong-based FIL Limited says it has increased its substantial shareholding in Medibio from 11,608,958 shares (7.82%) to 13,241,254 shares (8.92%).

Friday January 6, 2017

NO ANNOUNCEMENTS

Monday January 9, 2017

EUROPE APPROVES CSL'S AFSTYLA FOR HAEMOPHILIA A
CSL
CSL says that the European Commission approved Afstyla recombinant human coagulation factor VIII, single chain for children and adults with haemophilia A.

MALLINCKRODT PAYS MESOBLAST $30m FOR TWO DRUG OPTION
MESOBLAST
Mesoblast says Mallinckrodt Pharmaceuticals has paid $29.6 million for 20.04 million shares and for a nine month option on MPC-06-ID for chronic low back pain and MSC-100-IV for acute graft versus host disease.

SIRTEX UNAUDITED H1 DOSE SALES UP 5.6%
SIRTEX MEDICAL
Sirtex says that unaudited global dose sales of SIR-Spheres for the six months to December 31, 2016 are up 5.6 percent over the prior corresponding period.
Sirtex said that the growth was at the upper end of the four to six percent guidance provided on December 9, compared to the double-digit growth forecast provided in August (BD: Aug 24, Dec 9, 2016).

ADALTA 'AD-114 REDUCES LUNG AND LIVER FIBROSIS IN MICE'
ADALTA
Adalta says AD-114 reduces fibrosis in mouse models of lung and liver fibrosis.
Adalta said that AD-114 reduced collagen deposition and collagen gene expression.

EUROPE APPROVES 3 MGC CANNABINOID COSMETICS
MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS
MGC says the European Cosmetics Products Notification Portal has approved three cannabinoid-based products for acne, psoriasis and seborrhoea, or oily, skin.

PRANA PLEADS SCHULTZ TO ASX 30% QUERY
PRANA BIOTECHNOLOGY
Prana 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 company's share price rose 1.4 cents or 29.8 percent from 4.7 cents on January 5, to 6.1 cents on January 6, 2017 and noted a significant increase in trading volume.

FORMER CHAIR MARTIN ROGERS BELOW 5% IN ACTINOGEN

ACTINOGEN MEDICAL

Former chairman Martin Rogers says he is below the five percent substantial mark in Actinogen with the cancellation of 5,000,000 shares and the sale of 3,091,472 shares.

In 2015, Mr Rogers said his 36,250,000 shareholding was diluted to 6.07 percent in a capital raising at 9.5 cents a share (BD: May 8, 2015).

Last year, Actinogen said that completing the phase I Xanamem for Alzheimer's disease triggered the issue of 5,000,000 employee shares to Mr Rogers.

In the ceasing substantial notice, Mr Rogers said he sold the 3,091,472 shares for $242,990 or 7.9 cents a share.

ORTHOCELL RECEIVES $1.95m FEDERAL R&D TAX INCENTIVE

ORTHOCELL

Orthocell says it has received $1,947,998 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Orthocell said that the funds were for expenditure in the year to June 30, 2016.

PERPETUAL BELOW 5% OF SIRTEX

SIRTEX MEDICAL

Perpetual and its subsidiaries have reduced their substantial shareholding in Sirtex from 4,092,503 shares (7.09%) to below the 5.0 percent substantial mark.

Perpetual said that it traded shares from December 28, 2016 to January 5, 2017 at prices ranging from $14.18 to $14.85.

In November, prior to Sirtex downgrading dose sales and chief executive officer Gilman Wong stepping aside for an investigation of his share sales, Perpetual acquired 581,373 shares at prices ranging from $26.95 to $33.77 (BD: Nov 15, 2016).

CRESO TO RELEASE 6.4m ESCROW SHARES

CRESO PHARMA

Creso says that 6,412,500 shares will be released from escrow on January 19, 2017.

ROD GIBSON, ROSHERVILLE TAKE 13% OF REPRODUCTIVE HEALTH

REPRODUCTIVE HEALTH SCIENCE

Rod Gibson and Rosherville Pty Ltd say they have increased their substantial holding in Reproductive Health from 9,000,000 shares (11.36%) to 10,000,000 shares (12.6%).

Tuesday January 10, 2017

CSL TO MARKET ZAMBON, NEWRON XADAGO FOR PARKINSON'S DISEASE

CSL

CSL says has partnered with Zambon SPA to commercialize Newron's Xadago or safinamide for Parkinson's disease, in Australia and New Zealand.

CSL said the agreement, through its Seqirus subsidiary, which holds the previously acquired Novartis influenza vaccine business, and the Milan, Italy-based Zambon and Newron, would see Zambon provide the product and Seqirus undertake registration and commercialization in Australia and New Zealand.

According to the Zambon website, Xadago was approved and launched in Europe in 2015 and was accepted for review by the US Food and Drug Administration in 2015.

TGA APPROVES WEHI VENETOCLAX FOR LEUKAEMIA
THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH
The Walter and Eliza Hall Institute says that venetoclax has been approved by the Australian Therapeutic Goods Administration for chronic lymphocytic leukaemia.
WEHI said that venetoclax, to be marketed as Venclexta, followed the Institute's 1988 identification of BCL-2 a protein enabling cancer cells to survive and was developed with Abbvie and Genentech.
The Institute said that venetoclax had US and European approvals.

RESAPP, MASSACHUSETTS GENERAL EXTEND COLLABORATION
RESAPP HEALTH
Resapp says it has extended its work with Boston's Massachusetts General Hospital for additional analyses of its current Smartcough-C trial data "to investigate the state of respiratory disease clinical practice … and evaluate the efficacy of [its] cough-based diagnostic test in additional respiratory disease indications".

MEDADVISOR BUYS OZDOCSONLINE FOR $150k
MEDADVISOR
Medadvisor says it has acquired the assets of, the online doctor-patient communication platform Ozdocsonline for $150,000.

OVENTUS QUALITY MANAGEMENT WINS ISO 13485:20121
OVENTUS MEDICAL
Oventus says its quality management system complies with ISO 13485:20121 for the design, development and manufacture of oral appliances.

ADHERIUM APPOINTS SCOTT FLEMING FOR EURO BUSINESS DEVELOPMENT
ADHERIUM
Adherium says that Scott Fleming will replace John Tarplee as head of European business development.

Wednesday January 11, 2017

REDHILL BEGINS 2nd PHASE III RHB-105 FOR HELICOBACTER PK STUDY
REDHILL BIOPHARMA'
Redhill says it has begun dosing 18 healthy volunteers in a pharmacokinetic study of RHB-105 for Helicobacter pylori infection as part of a confirmatory US phase III trial.
Redhill said that the three-way crossover study would evaluate the bioavailability of RHB-105 actives against the comparator in the planned phase III study, as well as a food-effect study.
The company said the confirmatory phase III study was expected to begin by April 2017, subject to regulatory approvals and completion of the pharmacokinetic program.
Redhill said that if successful, the confirmatory phase III study and pharmacokinetic program were expected to complete the package required for a US new drug application.
The company said that the first phase III study showed that RHB-105 had 89.4 percent efficiency in eradicating Helicobacter pylori infection.

USPTO ACCEPTS LIVING CELL NTCELL PATENT APPLICATION
LIVING CELL TECHNOLOGIES
Living Cell says the US Patent and Trademark Office has accepted an application relating to its NTCell encapsulated pig brain choroid cells for Parkinson's disease.
Living Cell said the patent application was entitled 'Treatment Of CNS Disease With Inducible Choroid Plexus Cells', the provisional application was filed on May 15, 2015, the application was filed on May 13, 2016 and the USPTO published the application on December 15, 2016.

MAYNE US LAUNCH OF FABIOR FOR ACNE, SORILUX FOR PSORIASIS
MAYNE PHARMA GROUP
Mayne Pharma says it has launched Fabior, or tazarotene, foam for acne and Sorilux, or calcipotriene, foam for psoriasis in the US.
Mayne said that both products were acquired from Glaxosmithkline in August 2016 and were complementary to its Doryx antibacterial.

Thursday January 12, 2017

REDHILL RHB-104 WINS US QIDP FOR NON-TB MYCOBACTERIA INFECTIONS
REDHILL BIOPHARMA
Redhill says that RHB-104 has been granted US Food and Drug Administration qualified infectious disease product (QIDP) designation for non-tuberculous mycobacteria infections.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
The company said QIDP designation was intended to encourage development of new antibiotic drugs for serious or life-threatening infections, allowing fast-track status and priority review, potentially leading to a shorter new drug application review time and an additional five years of US market exclusivity.

STARPHARMA VIVAGEL WINS US QIDP STATUS FOR BACTERIAL VAGINOSIS
STARPHARMA HOLDINGS
Starpharma says the US Food and Drug Administration has granted Vivagel BV qualified infectious disease product and fast track designation for bacterial vaginosis.

MTP CONNECT '$18b SECTOR VALUE INCREASE, 28k JOBS IN 10 YEARS'
MTP CONNECT
MTP Connect says its 10-year sector competitiveness plan will increase the sector's value by $3.2 billion a year value and increase jobs by 28,000 over 10 years.
MTP Connect, or the Medical Technologies and Pharmaceuticals Industry Growth Centre, said that with Federal Government funding of $40 million over four years it would achieve an additional $3.2 billion in industry gross value added a year, an increase of 75 percent compared to 2015, resulting in an additional cumulative gross value added of $18 billion over the 10-year period from 2015 to 2025 and an additional 28,000 jobs compared to 2015, of which 14,000 jobs would be in universities and medical research institutes, reflecting "the substantial increase in research funding being delivered by the Medical Research Future Fund".
The proposed $20 billion Medical Research Future Fund is yet to release any funds.
The plan is available at www.mtpconnect.org.au/SCP.

PRIMA DOSES 1st PATIENT IN 2nd IMP321, KEYTRUDA COHORT TRIAL
PRIMA BIOMED
Prima says the first patient of six patients with unresectable or metastatic melanoma in the second cohort of its IMP321 with Keytruda trial has been dosed.

ORTHOCELL, J&J WORK ON ORTHO-ATI FOR TENDONS, LIGAMENTS
ORTHOCELL
Orthocell says it has a research collaboration with Johnson & Johnson's DePuy Synthes Products for its Ortho-ATI stem cells for degenerate tendons and ligaments.
Orthocell said the multi-centre study was planned to begin by April 2017.

BERGEN BELOW 5% OF ANTEO
ANTEO DIAGNOSTICS
Bergen Global Opportunity Fund, Bergen Asset Management and Eugene Tablis have ceased their substantial shareholding in Anteo.
The New York-based Bergen said that it bought and sold shares between December 8, 2016 and January 10, 2017, reducing its holding from 69,604,355 shares (6.14%) to 34,760,721 shares (3.1%), with the single largest sale, 22,481,423 shares for $879,069 or 3.9 cents a share.

ADHERIUM: 'UK NICE BACKS SMARTINHALER FOR ASTHMA MEDICATION'
ADHERIUM
Adherium says the UK National Institute for Health and Care Excellence has published a briefing on its Smartinhaler "recognising the role that it can play in improving adherence to asthma medication".

US FCC APPROVES NUHEAR IQBUDS
NUHEARA
Nuheara says its Iqbuds have US Federal Communications Commission certification allowing sales in the US.

Friday January 13, 2017

ANALYTICA 'PERICOACH HELPS 70% OF SEVERE INCONTINENCE PATIENTS'
ANALYTICA
Analytica says Pericoach post-market surveillance program shows that 70 percent of respondents with severe incontinence improved to moderate or better.
Analytica said that with 307 user responses, the intra-vaginal pelvic floor system for urinary incontinence showed consistent use was key to improvements in quality of life and that patient severity at onset influenced exercise behavior and that clinician recommendation influenced purchase, with women prefering self-management of incontinence problems.
The company said that Pericoach user surveys were conducted every six months as part of its post-market surveillance program, required by all class II medical device manufacturers and was intended to actively solicit feedback from medical device stakeholders.

MAYNE US LAUNCH OF 100mg AMIODARONE FOR ARRHYTHMIA
MAYNE PHARMA GROUP
Mayne says it has launched 100mg amiodarone tablets for life-threatening recurrent ventricular arrhythmia in the US.
Mayne said that amiodarone was a generic alternative to Pacerone tablets and it already marketed a 400mg dose.

SIRTEX SACKS CEO GILMAN WONG OVER SHARE-DEALING
SIRTEX MEDICAL
After the market closed today, Sirtex said it had "terminated [chief executive officer Gilman] Wong's employment … with immediate effect.
Sirtex said the investigation into the trading of shares by Mr Wong in October 2016 had been conducted by its legal advisers Watson Mangioni and investigation had been completed, but the report was "privileged and confidential".
The company said it had appointed chief operating officer Nigel Lange as acting chief executive officer and Anthony Dixon as chief executive officer for Europe, the Middle East and Africa, with immediate effect.

Monday January 16, 2017

BIOTRON HAS LESS THAN TWO QUARTERS CASH
BIOTRON
Biotron says its net operating cash burn for the three months to December 31, 2016 was $852,000 with cash at the end of the quarter of $1,426,000.

MAYNE PROMOTES, APPOINTS EXECUTIVES
MAYNE PHARMA
Mayne says that US head Stefan Cross has been appointed group chief commercial officer with John Ross promoted to head of US operations, Craig Boyd appointed as head of specialty brands, Teva's Gadi Ben-Nissim appointed head of generic products and Kimberly McClintock head of Metrics contract services.

MEMPHASYS MANUKAN PREFERENCE B SHARES INJUNCTION DISCHARGED
MEMPHASYS
Memphasys says a temporary injunction against Manukan to transfer and register preference B shares has been discharged.
Memphasys said that the matter relates to a call option relating to its preference B shares in Malaysia's Prime Biologics Pte Ltd and was one of three interrelated legal disputes between Memphasys, Prime, and Prime's major investor Pulau Manukan Ventures Labuan.
The company said that the share certificates would be held in escrow and Manukan was legally restrained from dealing with the shares unless the call option was enforceable and it the call option was unenforceable, transfer of the preference B shares to Manukan would be rendered invalid and the shares would be returned and held by Memphasys.
Memphasys said its legal advice was that the net effect of the injunction decision on the overall legal dispute remained unchanged.
The company said that it was seeking a negotiated settlement of the dispute and would continue to vigorously defend its position.

DAVID FRANKS REPLACES PHILLIP HAINS AS NOXOPHARM CO SEC
NOXOPHARM
Noxopharm says it has appointed David Franks as company secretary replacing the Melbourne-based Phillip Hains and the CFO solution.
Noxopharm said Mr Franks held a Bachelor of Economics from Macquarie University.

Tuesday January 17, 2017

UNIQUEST: 'J&J, ARTHRITIS QLD BACK DENDRIGHT DEN-181 FOR RA'
UNIQUEST
Uniquest says Johnson & Johnson has extended funds to Dendright, which has partnered with Arthritis Queensland for its DEN-181 rheumatoid arthritis immunotherapy.
Uniquest said that Johnson & Johnson's US-based Janssen Biotech had agreed to provide additional funding to Uniquest's start-up Dendright Pty Ltd under a 2013 research and development collaboration and option to licence agreement for Dendright's tolerizing immunotherapy.
The commercialization arm of Queensland University said that Arthritis Queensland had agreed to contribute funding to the clinical program for a first-in-human safety and tolerability study to begin by the end of 2017.

EU ORPHAN STATUS FOR BENITEC BB-301 FOR OPMD
BENITEC BIOPHARMA
Benitec says the European Commission has granted orphan drug designation for its DNA-directed-RNA-interference BB-301 for ocular-pharyngeal muscular dystrophy (OPMD).

AIRXPANDERS 1st US PAID AEROFORM BREAST EXPANSION PROCEDURE
AIRXPANDERS
Airxpanders says the first commercial Aeroform breast tissue expansion procedure has been performed in the US, following Food and Drug Administration clearance.

IMPEDIMED LOSES DIRECTOR ELIZABETH GAINES TO FORTESCUE AS CFO
IMPEDIMED
Impedimed says Elizabeth Gaines will retire as a director on February 3, 2017, following her appointment as Fortescue Metals Group chief financial officer.
Impedimed said a search for a replacement would begin immediately.

GI DYNAMICS PLAN RAISES $294k OF HOPED-FOR $988k, TOTAL $1.8m
GI DYNAMICS
GI Dynamics says its share plan raised $294,017 of a hoped for $987,910, taking the total raised to $1,831,047.
In December, GI Dynamics said it had commitments to raise $1,537,030 in a placement at 2.2 cents per Chess depositary interests and hoped to raise $987,910 in a share plan (BD: Dec 14, 2016).

MACH7 COMPLETES 10-FOR-1 STOCK CONSOLIDATION
MACH7 TECHNOLOGIES
Mach7 says it has completed its 10-for-one stock consolidation.

THORNEY TAKES 5.6% OF ANATARA
ANATARA
The Melbourne-based Thorney Technologies says it has become a substantial shareholder in Anatara with 2,787,773 shares or 5.64 percent of the company.
In a substantial shareholder notice, Thorney said the shares were held by Thorney Technologies and Thorney Investment Group along with UBS Nominees as a registered owner and Tiga Trading entitled to be a registered holder.
Thorney failed to disclose the price paid for the shares as required under the Corporations Act 2001, saying that 280,000 shares were acquired at "market prices" with a further 204,650 shares acquired "as per [an] asset sale agreement".

FIL TAKES 7% OF COGSTATE
COGSTATE
FIL Limited says it has increased its substantial shareholding in Cogstate from 6,270,548 shares (5.55%) to 8,163,578 shares (7.21%).
The Hong Kong-based FIL said it bought the shares between November 24, 2016 and January 13, 2017 at prices ranging from $1.07 to $1.25.

Wednesday January 18, 2017

GREG HUNT TAKES HEALTH, ARTHUR SINODINOS INNOVATION
FEDERAL GOVERNMENT
The Federal Government says Greg Hunt has replaced Sussan Ley as Minister for Health and Sport, following her resignation over travel claims.
The Government said that New South Wales Senator Arthur Sinodinos would replace Mr Hunt as Minister for Industry, Innovation and Science.

PRIMA MEETS NASDAQ $US1 RULE
PRIMA BIOMED
Prima says its American depositary shares have maintained a closing bid price of more than $US1.00 for 10 consecutive business and it has regained Nasdaq compliance.

CELLMID WINS FEDERAL $100k FOR MIDKINE KIDNEY TRIALS IN RODENTS
CELLMID
Cellmid says it will receive two Federal Innovation Connections Grants totalling $100,000 to test the efficacy of midkine antibodies for chronic kidney disease and cardiovascular complications in rodent models.

YARRA FUNDS TAKES 6.6% OF SIRTEX
SIRTEX MEDICAL
The Melbourne-based Yarra Funds Management says it has become a substantial shareholder in Sirtex with 3,803,242 shares or 6.59 percent.
Yarra Funds said co-holders included AA Australian Finco Pty Ltd, TA SP Australia Topco Pty Ltd and TA Universal Investment Holdings, with registered holders RBC Dexia Investor Services, UBS AG Australia, BNP Paribas Australia, State Street Australia, National Australia Bank, National Asset Servicing, National Nominees, and JP Morgan Chase Bank and the group held the shares "through [the] acquisition of [an] investment management agreement to act as [the] investment manager for a range of client portfolios".

REGAL FUNDS REDUCES TO 5% OF ADHERIUM

ADHERIUM

Regal Funds Management says it has reduced its substantial holding in Adherium from 10,235,108 shares (6.12%) to 8,780,862 shares (5.10%).

DORSAVI 'VIMOVE BETTER THAN GUIDELINE CARE FOR BACK PAIN'

DORSAVI

Dorsavi says that treating back pain with Vimove and guideline care is both more clinically effective and economically efficient, than guideline care alone.

Dorsavi said that an 83-patient health economic evaluation found that productivity improvements were the greatest contributor to the relative economic efficiency of the wearable sensor Vimove treatment, saving an average $4,781 per patient over 12-months, more that 60 percent of patients treated with Vimove had a clinically meaningful reduction in pain and reported feeling very much or much better compared with 20 percent of patients treated with guideline-based care alone.

The company said that the paper, entitled 'Cost-effectiveness of using a motion-sensor biofeedback treatment approach for the management of sub-acute or chronic low back pain: economic evaluation alongside a randomised trial' was authored by Prof Terry Haines and Dr Kelly-Ann Bowles of Monash University and Monash Health, was published by Biomed Central Musculoskeletal Disorders and was available at bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/s12891-016-1371-6.

US ORPHAN STATUS FOR AD-114 FOR IDIOPATHIC PULMONARY FIBROSIS

ADALTA

Adalta says the US Food and Drug Administration has granted orphan drug designation for AD-114 for idiopathic pulmonary fibrosis.

CRESO CLAIMS 1st EU APPROVAL FOR CANNABINOID ANIMAL FEED ADDITIVE

CRESO PHARMA

Creso says it is the first company to receive EU registration for two cannabinoid-based animal feed additive products.

RECCE SAYS MOUSE TRIAL NEWS MAY HAVE LED TO ASX 131% QUERY

RECCE

Recce has told the ASX that data from a trial of Recce 327 for carbapenem-resistant gram-negative Escherichia coliits in mice might explain a 131.25 share price increase.

The ASX said the company's share price climbed from 16 cents on Friday, January 13 to 37 cents on Monday, January 16, 2017 and noted an increase in trading volumes.

Recce said that 30 minutes before the ASX price and volume query on January 16 it received the data which "had not been assessed whether or not it was appropriate to announce from its contents".

"For this reason, the company does think it feasible that the information could have been the reason for the query," Recce said.

The company said it relied on Listing Rule 3.1A as the basis for not immediately announcing that information, "as the information required interpretation and assessment before any release could be assessed or made and was therefore considered confidential".

Recce released the data at the same time as the response to the ASX query, which showed that Recce 327 outperformed tigecycline a last line antibiotic used to treat bacterial infections.

OVENTUS WINS O2VENT T 1st US SALE
OVENTUS MEDICAL
Oventus says its O2Vent T has been launched in the US and the first appliances have entered manufacturing.

HARVEST ONE TO RAISE $C15m FOR MMJ CANNABIS SUBSIDIARIES
MMJ PHYTOTECH
MMJ says that Canada's Harvest One Capital has launched a $C15 million placement to acquire subsidiaries United Greeneries Holdings and Satipharm AG.

Thursday January 19, 2017

TELIX PARTNERS WITH THERAPEIA GMBH FOR ACD-101 FOR GLIOBLASTOMA
TELIX PHARMACEUTICALS
The Melbourne based pubic unlisted Telix says it has partnership with the Dresden, Germany-based Therapeia GmbH & Co for ACD-101 for glioblastoma.
Telix said the partnership added to its "pipeline of advanced theranostic radiopharmaceutical products" but said the financial terms were not disclosed.
The company said that ACD-101 was a synthetic amino acid targetting the L-type amino acid transporter 1 (LAT1), which was over-expressed in aggressive malignancies, including glioblastoma, multiple myeloma, melanoma, gastric, breast, prostate and primary hepatocellular carcinoma.
Telix chief executive officer Dr Chris Behrenbruch said that patient experience with ACD-101 in Germany showed "promising therapeutic results" and the company would work with Therapeia to take the program to phase II trials and beyond.

CLARITY APPOINTS DR COLIN BIGGIN HEAD OF QUALITY
CLARITY PHARMACEUTICALS
Clarity says it has appointed Dr Colin Biggin as head of quality.
Clarity said that Dr Biggin had more than 15 years' experience in radiochemistry and radiopharmaceutical development and most recently was employed by the Oslo, Norway-based Algeta ASA from 2006 to its acquisition by Bayer in 2014, rising to radiation protection director.

ALLAN GRAY REDUCES TO 13% OF ACRUX
ACRUX
Allan Gray Australia has reduced its substantial holding in Acrux, again, from 22,300,676 shares (13.39%) to 20,250,284 shares (12.16%).
Allan Gray said that between November 3, 2016 and January 17, 2017 it sold 2,050,392 shares for $675,478 or 32.9 cents a share.

CSL UPGRADES 2017 NPAT
CSL
CSL says it expects net profit after tax for the year to June 30, 2017 to be 18 to 20 percent above the previous year's $1.6 billion, compared to the forecast 11 percent.
CSL said that the figures were "at constant currency … after adjusting for the one-off gains and costs associated with the acquisition of the Novartis influenza vaccines business".

USCOM: BP+ PREDICTS ETHNICITY, SMOKING, DRINKING, OBESE HEART RISK
USCOM
Uscom says a 4,798 subject study of its BP+ central blood pressure monitor predicts cardiovascular disease based on ethnicity, smokers, drinkers and obese patients.
Uscom said that the multi-centre study of its supra-systollic oscillometric BP+ central blood pressure monitor was published in the Journal of Human Hypertension and showed that changes in central arterial blood pressure waves measured by the BP+ predicted the differing prevalence of cardiovascular disease between European, Pacific, Maori and South Asian people as well as identifying "significantly altered … aortic pulse pressure waves in smokers, heavy drinkers and the obese …[and was] significantly more useful than that of conventional arm blood pressure measurements".

JUSTYN STEDWELL REPLACES ALLEGRA CO SEC RICHARD ULRICK
ALLEGRA ORTHOPAEDICS
Allegra says it has appointed Justyn Stedwell as company secretary replacing Richard Ulrick.

CYNATA '$60m PARTNERSHIP WITH FUJIFILM FOR CYP-001 FOR GVHD
CYNATA THERAPEUTICS
Cynata says it has a partnership agreement with Japan's Fujifilm to develop and commercialize CYP-001 for graft-versus-host disease.
Cynata said that Fujifilm would take a$3.97 million equity stake with potential future upfront and milestone payments of more than $60 million as well as double-digit royalties on CYP-001 product sales.

AUSTRALIAN ETHICAL TAKES MORE PROFIT TO 5% OF INNATE
INNATE IMMUNOTHERAPEUTICS
Australian Ethical Investment says it has reduced its substantial shareholding in Innate from14,074,092 shares (6.34%) to 11,726,848 shares (5.28%).
Australian Ethical said it sold shares between December 5, 2016 and January 18, 2017 with the most recent sale 395,101 shares for $554,014 or $1.40 a share.
In July, Australian Ethical bought and sold shares in Innate, with the largest acquisitions 4,503,867 shares for $1,125,967 or 25 cents a share (BD: Jul 21, 2016).
It was widely reported in January that people associated with US President Donald Trump had shares in the company, including major shareholder US Republican Representative Chris Collins, who has been a director of Innate since 2006.

IMMURON STUDIES TO BACK IMM-124E FOR NASH
IMMURON
Immuron says it has begun several studies designed to support the mechanism of action of IMM-124E in non-alcoholic steatohepatitis, in partnership with Sanyal Biotechnology and Duke University under Dr Arun Sanyal and Prof Anna-Mae Diehl.

Friday January 20, 2017

PRIMA DOSES 1st BREAST CANCER PATIENT IN PART 2 OF IMP321 TRIAL
PRIMA BIOMED
Prima says first patient has been dosed in the randomized part of its phase IIb trial of IMP321 for metastatic breast cancer.

COGSTATE APPOINTS DR RICHARD MOHS DIRECTOR

COGSTATE

Cogstate says it has appointed Dr Richard Mohs as a non-executive director.
Cogstate said that Dr Mohs retired from Eli Lilly in 2015, where he was the head of Neuroscience Early Clinical Development and Alzheimer's drug development.
The company said that Dr Mohs previously spent 23 years with New York's the Mount Sinai School of Medicine as professor of psychiatry and was currently the Global Alzheimer's Platform Foundation's chief scientific officer.

DORSAVI SHARE PLAN RAISES $1m

DORSAVI

Dorsavi says its $1,000,000 share purchase plan closed oversubscribed.

REGAL FUNDS REDUCE BELOW 5% OF ADHERIUM

ADHERIUM

Regal Funds says it has reduced its substantial holding in Adherium from 10,235,108 shares (6.12%) to below the five percent substantial level (BD: Jul 28, 2016).
In July, The Sydney based Regal Funds Management said that it bought 30,000 shares at 52 cents each on April 8, sold 128,675 shares at 50 cents each on July 20 and was diluted in the $8,023,049 placement at 50 cents each with Fidelity International (BD: Jul 20, 28, 2016).
Today, Regal said it sold 343,135 shares at prices between 22 cents and 23 cents.

PARADIGM TO RELEASE 9.7m ESCROW SHARES

PARADIGM BIOPHARMA

Paradigm says 9,747,620 shares will be released from the ASX and voluntary escrow on February 7, 2017.
Paradigm said that following the release, it would have 67,584,602 shares available for trading on the ASX.