Biotech Daily

SPECIAL SUMMER CATCH-UP EDITION

Sunday, January 22, 2023

The Summer Catch-Up Edition was compiled by James Costa

*** IMMUTEP: FDA OKAYS EFTI, CHEMO BREAST CANCER TRIAL**

*** MESOBLAST UPS OAKTREE FACILITY TO $US200m; RAISE UP-TO $US125m**

*** CANN SELLS SOUTHERN FACILITY, ASSETS FOR $5.5m TO SATIVITE**

*** NEUREN FILES NNZ-2591 PRADER-WILLI SYNDROME IND TO US FDA**

*** STARPHARMA RECEIVES $7.1m R&D TAX INCENTIVE**

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*** LIVING CELL: DAVID HAINSWORTH CHAIR, LOSES PROF BERNIE TUCH**

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*** CARDIEX $880k MITCHELL FACILITY; APPOINTS REID YEOMAN US CFO**

*** VOLPARA WINS 5 CONTRACTS WORTH $11.3m**

*** LBT, ASTRAZENECA $1m TO DEVELOP APAS PHARMA ANALYSIS MODULE**

*** CYNATA AUSTRALIA STEM CELL PATENT FOR LUNG DISEASE**

*** TELIX $76.8m Q3 ILLUCCIX SALES; FY $150m**

*** PHARMAXIS RECEIVES $5m R&D TAX INCENTIVE**

*** IMUGENE: ADELAIDE ETHICS APPROVAL FOR VAXINIA SOLID TUMOR TRIAL**

*** ALTERITY OPENS US ATH434 PHASE II MSA TRIAL SITE**

*** CARTHERICS WINS CAR TAG-72 CHINA PATENT**

*** RESPIRI PATIENTS ENROLLED IN WHEEZO RPM PROGRAM**

*** CRESO DRAWS DOWN OBSIDIAN $500k**

*** JAPAN PATENT FOR ADALTA AD-214**

*** CHIMERIC TO RELEASE 115m SHARES FROM ASX ESCROW**

*** SALTER BROTHERS TAKES 5.6% OF NUHEARA**

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*** ZELIRA: CRESO REPAYS $1.75m HEALTH HOUSE LOAN**

*** CANN GROUP APPOINTS PETER KOETSIER CEO ON $350k PA**

*** ENA: $6.4m US DEFENSE DEAL FOR INNA-051 DRY POWDER NASAL SPRAY**

*** AMPLIA APPROVED FOR NEXT AMP945 DOSE COHORT**

*** CRESO, MERNOVA TO SELL 7 MARIJUANA PRODUCTS IN CANADA**

*** RADIOPHARM APPOINTS DR RAMA ABU SHMEIS CMC HEAD**

*** AUSTRALIAN SUPER BELOW 5% OF NANOSONICS**

*** PLANET INNOVATION DILUTED TO 30.6% OF LUMOS**

*** MEDLAB INTERIM NANABIS DATA: 55% PAIN RELIEF IMPROVEMENT**

*** STARPHARMA PLEADS SCHULTZ TO ASX 23% PRICE QUERY**

*** US FDA OKAYS CHILDREN IN DIMERIX DMX-200 PHASE III FSGS TRIAL**

*** EMYRIA RECEIVES $2.1m FEDERAL R&D TAX INCENTIVE**

*** AVECHO TAKES TPM-VITAMIN K TO US FDA PRE-IND MEETING**

*** MAYNE DEFERS $113m SHAREHOLDER CAPITAL RETURN UNTIL MARCH**

*** ANATARA HAS 1.87 QUARTERS OF CASH**

*** MAYNE NUVARING GENERIC CONTRACEPTIVE US LAUNCH**

*** MONASH, ONO TO WORK ON AUTOIMMUNE, INFLAMMATORY DISEASES**

*** PACIFIC EDGE COMPLETES TE WHATU ORA SOUTHERN CXBLADDER DEAL**

*** ANTERIS 'DURAVR REMARKABLE HAEMODYNAMIC FUNCTION'**

*** CLINUVEL AFAMELANOTIDE 'REDUCES DNA PHOTO-DAMAGE'**

*** FEDERAL $6m AUSTRALIA-INDIA RESEARCH GRANTS**

*** KAZIA PLACEMENT RAISES $4.5m, SHARE PLAN FOR MORE**

*** CRONOS TO CLOSE CDA CLINICS FOR TELEHEALTH**

*** POLYNOVO UNAUDITED H1 REVENUE UP 62% TO RECORD $29.5m**

*** PHARMAXIS APPOINTS HASHAN DE SILVA DIRECTOR**

*** UNIVERSAL BIOSENSORS APPOINTS GRAHAM MCLEAN CHAIR**

*** POLYNOVO EGM 25% BLOCKS VIRTUAL MEETING VOTE**

*** IMMURON CLOSTRIDIOIDES DIFFICILE TREATMENT EU PATENT**

*** NOXOPHARM '1600mg VEYONDA SAFE, WELL-TOLERATED'**

*** LINDMARK TAKES 9.5% OF CRYOSITE**

*** FIRST SENTIER REDUCES TO 7.2% OF NANOSONICS**

*** TELIX: $150m US ILLUCCIX SALES; Q4 CASH-FLOW POSITIVE**

*** VOLPARA 'Q3 $10m REVENUE - 1st CASH FLOW POSITIVE QUARTER'**

*** MEDICAL DEVELOPMENTS HALTS CHINA PENTHROX TRIALS**

*** ATOMO, NG BIOTECH TO MANUFACTURE, DISTRIBUTE PREGNANCY TESTS**

*** ADHERIUM: $880k NHS GRANT FOR HAILIE SOFTWARE**

*** BIONOMICS 37m CEO, CHAIR OPTIONS EGM**

*** IMMURON ENROLS 157 TRAVELAN DIARRHOEA TRIAL PARTICIPANTS**

*** PERENNIAL TAKES 12.6% OF MEDADVISOR**

*** INCANNEX: 29 PATIENTS COMPLETE PSILOCYBIN TREATMENT**

*** FIREBRICK: 'NASODINE CHRONIC RHINOSINUSITIS POTENTIAL, IN-VITRO'**

*** NYRADA EXTENDS WALTER REED, NSW UNI BRAIN INJURY WORK**

*** DRAY ANDREA REPLACES CRYOSITE CO SEC KIM BRADLEY-WARE**

*** PLATINUM TAKES 12.5% OF KAZIA**

*** MITSUBISHI REDUCES TO 7.2% IN NANOSONICS**

*** NANOSONICS EXPECTS $82m H1 REVENUE, $11.4m PROFIT**

*** CHIMERIC DOSES 1st CHM0201, VACTOSERTIB CANCER PATIENT**

*** CONTROL BIONICS APPOINTS JEREMY STEELE CEO ON $325k A YEAR**

*** AROVELLA PLACEMENT RAISES $1.65m**

*** ACRUX: 'POSITIVE' FDA ASSESSMENT ON UNNAMED GENERIC**

*** CEPI $6.4m FOR VAXXAS NEEDLE-FREE VACCINE**

*** CANN GROUP 'SATIPHARM CBD NOT SUPERIOR TO PLACEBO FOR SLEEP'**

*** INVEX OPENS 1st US PRESENDIN IIH TRIAL SITE**

*** NEUROTECH: US FDA APPROVES PRE-IND MEETING**

*** RESPIRI TELLS ASX IT IS NOT 'RAMPING UP' SHARE PRICE**

*** REGAL FUNDS BELOW 5% IN MEDADVISOR**

*** PRO MEDICUS, WASHINGTON UNI $25m PACS DEAL**

*** FEDERAL $1.2m FOR ARGENICA BRAIN INJURY RESEARCH**

*** TGA APPROVES ADHERIUM HAILIE WITH PARAMETERS**

*** ADHERIUM STARTS GSK HAILIE-ELLIPTA INHALER PRODUCTION**

*** ISLAND: US FDA ISLA-101 IND 'CLINICAL HOLD'**

*** PHARMAUST TAKES MONEPANTEL FOR MND TO HIGHER DOSE**

*** FISHER & PAYKEL EXPECTS FY REVENUE FALL TO $1.44-1.5b**

*** SEAN EKINS REPLACES AVITA CFO MIKE HOLDER; KATHY MCGEE GOES**

The following articles appear in date order

Friday December 23, 2022

IMMUTEP: FDA OKAYS EFTI, CHEMO BREAST CANCER TRIAL
IMMUTEP
Immutep says the US Food and Drug Administration has agreed to an up-to 70-patient, phase II/III trial of eftilagimod alpha with chemotherapy for metastatic breast cancer.
Immutep said that subject to approvals, it expected the trial to begin by March, 2023, with the phase III portion to follow, pending results.

MESOBLAST UPS OAKTREE FACILITY TO $US200m; RAISE UP-TO $US125m
MESOBLAST
Mesoblast says Oaktree Capital Management has extended its $US90 million facility by up-to $US30 million, subject to milestones by September 30, 2023.
Separately, Mesoblast filed a registration statement with the US Securities and Exchange Commission to raise up to $US125 million on the Nasdaq.

CANN SELLS SOUTHERN FACILITY, ASSETS FOR $5.5m TO SATIVITE
CANN GROUP
Cann Group says Brisbane's Sativite Pty Ltd will buy its Melbourne 'Southern' growing and manufacturing facility and associated assets for a total $5,480,000.
Cann Group said the sale included the land and building, business assets and employment of operating personnel, and access rights to certain "genetic strains".

NEUREN FILES NNZ-2591 PRADER-WILLI SYNDROME IND TO US FDA
NEUREN PHARMACEUTICALS
Neuren says it has submitted an investigational new drug application to the US Food and Drug Administration for a phase II trial of NNZ-2591 for Prader-Willi syndrome.

STARPHARMA RECEIVES $7.1m R&D TAX INCENTIVE
STARPHARMA HOLDINGS
Starpharma says it has received $7.1 million from the Australia Tax Office under the Federal Government Research and Development Tax Incentive program.

IMMURON: US FDA APPROVES TRAVELAN INFECTIOUS DIARRHOEA IND
IMMURON
Immuron says it has received US Food and Drug Administration approval for its Travelan investigational new drug application for infectious diarrhoea from enterotoxigenic escherichia coli.

RESPIRI: ARKANSAS HOSPITAL ENROLS WHEEZO COPD PATIENTS
RESPIRI
Respiri says Arkansas Heart Hospital has enrolled patients in its Wheezo remote patient monitoring program for chronic obstructive pulmonary disease.
In November, Respiri said Arkansas Heart Hospital would use its Wheezo remote patient monitoring program to manage heart patients with chronic obstructive pulmonary disease (COPD) (BD: Nov 28, 2022).

DIMERIX LOSES CHAIR DR JAMES WILLIAMS
DIMERIX
Dimerix says Dr James Williams, who was appointed in July, 2015, has resigned as its non-executive chair, effective immediately.

NEUROTECH OPTIONS FOR OCTOBER PLACEMENT INVESTORS
NEUROTECH INTERNATIONAL
Neurotech says it will offer October placement participants free options exercisable at 13.5 cents each, and will issue 10 million options to lead managers.
In October, Neurotech said it raised $9 million in a placement at 10 cents a share.

*** DIRECTOR BILL PENG INCREASES, DILUTED TO 7.1% OF AUDEARA**
AUDEARA
Director Hsin-Chieh 'Bill' Peng says he has increased and been diluted in Audeara from 10,000,000 shares (8.89%) to 10,227,380 shares (7.14%).

FORTUNE PIONEER, SHIH-YAO LIN TAKE 19.5% OF AUDEARA
AUDEARA
Fortune Pioneer International Holdings and Shih-Yao Lin say they have become substantial in Audeara with 28,000,000 shares or 19.54 percent of the company.

HEXIMA LOSES ACTING CEO DR VAN DER WEERDEN, REMAINS DIRECTOR
HEXIMA
Hexima says acting chief executive officer Dr Nicole van der Weerden will resign, effective December 31, 2022, but will continue as a non-executive director.

PERENNIAL BELOW 5% IN 4D MEDICAL
4D MEDICAL
Sydney's Perennial Value Management says it has ceased its substantial holdings in 4D Medical.
In October, Perennial said that it held 15,995,156 shares (5.43%) (BD: Oct 13, 2022).

Monday December 26, Tuesday December 27, 2022

ASX closed for Christmas, Boxing Day.

Wednesday December 28, 2022

MEDLAB HOPES FOR UP-TO $11.6m NASDAQ IPO
MEDLAB CLINICAL
Medlab says it hopes to list on the Nasdaq under the code 'MDLB' and raise up to $US8.0 million ($A11.6 million) at $US4.45 a share with attaching options.
Medlab said that New York's EF Hutton would be the underwriter and hoped to issue 1,797,752 shares with attaching warrants exercisable at $US4.4999 each.

RESPIRI SHARE PLAN FOR UP-TO $1.5m
RESPIRI
Respiri says it hopes to raise "up to $1.5 million" through an underwritten share purchase plan at five cents a share.

IMEX WINS $US900k MEXICO SOFTWARE CONTRACT
IMEX HEALTH SERVICES
Imex says it has an up to $US900,000, three-year software contract with Mexico's Social Security Institute for its Aquila radiology, and Alula pathology, platforms.
Imex said that it expected the software to be implemented by March, 2023

PARADIGM PPS OSTEOARTHRITIS TRIAL PASSES SAFETY REVIEW
PARADIGM BIOPHARMACEUTICALS
Paradigm says it has passed safety reviews to continue its phase III trial of injectable pentosan polysulfate sodium, or Zilosul, for knee osteoarthritis pain, unmodified.

ISLAND SUBMITS ISLA-101 DENGUE FEVER TRIAL IND TO US FDA
ISLAND PHARMACEUTICALS
Island says it has submitted an investigation new drug application to the US Food and Drug Administration for a 46-patient, phase IIa trial of its ISLA-101 for dengue fever.

M-D DR JAMES FIELDING INCREASES, DILUTED TO 5.8% IN AUDEARA
AUDEARA
Managing-director Dr James Fielding says he has increased and been diluted in Audeara from 8,214,263 shares (7.82%) to 8,307,497 shares (5.80%).

JDB SERVICES DECREASES, DILUTED TO 6.8% in AUDEARA
AUDEARA
Brisbane's JDB Services Pty Ltd says it has decreased and been diluted in Audeara from 9,715,950 shares (8.43%) to 9,713,777 shares (6.78%).

Thursday December 29, 2022

MACH 7: DYAN O'HERNE INTERIM CFO REPLACING STEVE PARKES
MACH 7 TECHNOLOGIES
Mach 7 says seven-year employee Dyan O'Herne will replace chief financial officer Steve Parkes on an interim basis, effective January 1, 2023

ALTERITY NEURODEGENERATIVE DISEASES US PATENT ALLOWED
ALTERITY THERAPEUTICS
Alterity says the US Patent and Trademark Office has allowed a patent for iron chaperone compounds for treating neurodegenerative diseases.
Alterity said that when granted, the patent, titled 'Compounds for and methods of treating diseases,' would protect its intellectual property until 2041.

Friday December 30, 2022

RADIOPHARM: US FDA APPROVES RAD301 PANCREATIC CANCER IND
RADIOPHARM THERANOSTICS
Radiopharm says the US Food and Drug Administration has approved its alpha-V-beta-6 Integrin, or RAD301, investigational new drug application.
Radiopharm said the approval allowed it to begin a phase I imaging trial in ambulatory patients with pancreatic cancer, to begin by April 2023 and close by October 2023.

CRESO EGM 24.25% OPPOSE JAMES ELLINGFORD SHARES
CRESO PHARMA
Creso says its extraordinary general meeting faced 73,206,129 votes (24.25%) in opposition to the issue of 4,000,000 shares to former director James Ellingford.
Creso said all other resolutions passed easily (BD: Nov 28, 2022) (AVW: Dec 2, 2022).
According to its most recent filing, Creso had a total of 1,835,962,135 shares on issue, meaning the votes against Mr Ellingford's shares amounted to 4.0 percent of the company, not sufficient to requisition extraordinary meetings.

TOTAL BRAIN EGM TO DELIST FROM ASX, PAYOUT $6.35m
TOTAL BRAIN
Total Brain says its extraordinary meeting will vote to delist from the ASX and pay shareholders 4.75 cents a share, worth $6,351,754.
Last month, Total Brain said it had completed the sales of the company and its subsidiaries to Sondermind Inc for $US10 million (BD: Nov 1, 2022).
Total Brain said both resolutions required at least 75 percent of total votes cast, and that if approved, it would delist from the ASX "on or about March 1, 2023".

CHAIR DAVID TRIMBOLI INCREASES, DILUTED TO 11.1% IN AUDEARA
AUDEARA
Non-executive chair David Trimboli says that he has increased and been diluted in Audeara from 15,235,459 shares (14.51%) to 15,940,805 shares (11.12%).

DEPUTY CHAIR MAURIE STANG INCREASES, DILUTED TO 9.1% IN VECTUS
VECTUS BIOSYSTEMS
Deputy chair Maurie Stang says he has increased and been diluted in Vectus from 2,562,000 shares (10.963%) to 4,858,952 shares (9.135%).

Monday January 2, 2023

ASX closed for New Year's Day.

Tuesday January 3, 2023

MACH 7 WINS $16.7m PACS AKUMIN CONTRACT
MACH 7 TECHNOLOGIES
Mach 7 says it has a 10-year, $16.7 million contract with the Plantation, Florida-based Akumin Inc for its picture archive communication system (PACS).
Mach 7 said that it expected $7.5 million worth of revenue from the contract in 2022-'23, with annual fees weighted to the second half of the contract term.

PROTEOMICS: AMA APPROVES PROMARKERD REIMBURSEMENT CODE
PROTEOMICS INTERNATIONAL LABORATORIES
Proteomics says the American Medical Association has approved the reimbursement code for its Promarkerd test for diabetic kidney disease.
Proteomics did not disclose the amount that would be reimbursed by Medicare and private health insurers in the US, but said the code would be effective from April 1, 2023.

VOLPARA APPOINTS MARK BOUW DIRECTOR
VOLPARA HEALTH TECHNOLOGIES
Volpara says it has appointed Mark Bouw as a non-executive director, effective from January 1, 2023.

MAYNE COMPLETES THERAPEUTICS MD $222.5m LICENCE
MAYNE PHARMA
Mayne says it has completed the $US153.1 million licencing agreement with Therapeutics MD for women's health products and pre-natal vitamins.
In December, Mayne said it would pay the Boca Raton, Florida-based Therapeutics MD $US140 million for three women's health products and a portfolio of pre-natal vitamins, and $US13.1 million for working capital and inventory (BD: Dec 5, 2022).

LBT TO RELEASE 31m VOLUNTARY ESCROW SHARES
LBT INNOVATIONS
LBT says it will release 30,660,377 voluntary escrow shares on December 31, 2022.

AUSCANN LOSES DIRECTOR KRISTA BATES
AUSCANN GROUP
Auscann says Ms Krista Bates has resigned as non-executive director.

Wednesday January 4, 2023

IMMUTEP ENROLS 50% OF IMP321 PHASE IIb TACTI-003 HNSCC TRIAL
IMMUTEP
Immutep says it has enrolled 77 of 154 patients in its 'Tacti-003' phase IIb trial of IMP321 or eftilagimod alpha, in first-line head and neck squamous cell carcinoma.
In 2021, Immutep said the US Food and Drug Administration had approved the trial comparing IMP321 with pembrolizumab to pembrolizumab alone.

AROVELLA APPOINTS DR NICOLE VAN DER WEERDEN COO
AROVELLA THERAPEUTICS
Arovella says it has appointed former Hexima chief executive officer Dr Nicole van der Weerden as its chief operating officer, effective from January 4, 2023

BERGEN, TABLIS, HEALTHCARE 2023 REDUCE TO 7.9% IN NUHEARA
NUHEARA
Bergen Asset Management, Eugene Tablis and Healthcare 2023 say they have decreased and been diluted in Nuheara from 13,240,000 shares (9.65%) to 12,192,555 shares (7.92%).

Thursday January 5, 2023

PROTEOMICS EXTENDS SONIC HEALTHCARE PROMARKERD LICENCE
PROTEOMICS INTERNATIONAL LABORATORIES
Proteomics says it has extended its Promarkerd test licencing agreement with Sonic Healthcare USA until January 31, 2023.

LIVING CELL: DAVID HAINSWORTH CHAIR, LOSES PROF BERNIE TUCH
LIVING CELL TECHNOLOGIES
Living Cell says it has appointed David Hainsworth as executive chair, and that interim chief executive officer Prof Bernie Tuch has left the company.

Friday January 6, 2023

PHARMAUST COMPLETES 1st MONEPANTEL MND/ALS COHORT
PHARMAUST
Pharmaust says it has competed the first cohort of six patients in its phase I/II monepantel trial for motor neurone disease and amyotrophic lateral sclerosis.

ALTERITY 1-FOR-10 ADS CONSOLIDATION; 1 ADS FOR 600 SHARES
ALTERITY THERAPEUTICS
Alterity says a one-for-10 American depository shares (ADSs) consolidation will take its ratio to one ADS for 600 Australian shares.

NANOMAB INCREASES, DILUTED TO 8.6% IN RADIOPHARM
RADIOPHARM THERANOSTICS
The Hong Kong-based Nanomab Technology says it has increased and been diluted in Radiopharm from 26,999,909 shares (10.7%) to 28,295,131 shares (8.6%).

CARDIEX $880k MITCHELL ASSET LOAN FACILITY
CARDIEX
Cardiex says it has an up to $880,000 short-term working capital loan facility with the Melbourne-based Mitchell Asset Management, at a 16 percent interest rate per annum.

CARDIEX APPOINTS REID YEOMAN AS US CFO
CARDIEX
Cardiex says it has appointed Reid Yeoman as its US chief financial officer, effective from January 2023

Monday January 9, 2023

VOLPARA WINS 5 CONTRACTS WORTH $11.3m
VOLPARA HEALTH TECHNOLOGIES
Volpara says it has five, five-year contracts worth more than $US7.8 million ($A11.3 million) for its breast mammography assessment technology.

LBT, ASTRAZENECA $1m TO DEVELOP APAS PHARMA ANALYSIS MODULE
LBT INNOVATIONS
LBT says it has a $1 million partnership with Astrazeneca to develop an automated plate assessment system ‘pharma analysis module’ into its APAS instrument.
LBT said that Astrazeneca would provide funding to identify microbial growth on settle plates used in sterility monitoring during drug manufacturing.

CYNATA AUSTRALIA STEM CELL PATENT FOR LUNG DISEASE
CYNATA THERAPEUTICS
Cynata says it has a notice of acceptance from Intellectual Property (IP) Australia for its mesenchymal stem cell platform technology for lung disease.
Cynata said the patent, titled 'Method for Treating Allergic Airways Disease/Asthma,' would protect its intellectual property until August 31, 2038.

TELIX $76.8m Q3 ILLUCCIX SALES; FY $150m
TELIX PHARMACEUTICALS
Telix says sales of its Illuccix kit for prostate cancer for the three months to December 31, 2022 was $76.8 million, bringing the total sales for the year to $149.7 million.

PHARMAXIS RECEIVES $5m R&D TAX INCENTIVE
PHARMAXIS
Pharmaxis says it has received a $4,953,337 research and development tax incentive from the Australian Tax Office for the financial year ended June 30, 2022

IMUGENE: ADELAIDE ETHICS APPROVAL FOR VAXINIA SOLID TUMOR TRIAL
IMUGENE
Imugene says it has ethics approval for a phase I trial of its oncolytic virotherapy candidate, Vaxinia from Tasman Oncology Research in Adelaide.
In 2022, Imugene said it had dosed patients in its up-to 100 patient phase I trial of intra-tumoral and intra-venous CF33-hNIS, or Vaxinia, and pembrolizumab for metastatic or advanced solid tumors (BD: Dec 5, 2022).

ALTERITY OPENS US ATH434 PHASE II MSA TRIAL SITE
ALTERITY THERAPEUTICS
Alterity says its ATH434 phase II trial for multiple system atrophy has opened for enrolment at Vanderbilt University Medical Centre in Nashville, Tennessee.
Last year, Alterity said Melbourne's St Vincent's Hospital had approved its 60-patient, randomized, double-blind, placebo-controlled study in patients with early-stage multiple system atrophy to evaluate the efficacy of ATH434 on neuro-imaging and protein biomarkers (BD: Oct 31, 2022).

CARTHERICS WINS CAR TAG-72 CHINA PATENT
CARTHERICS PTY LTD
Cartherics says the China Patent Office has granted a patent, titled 'Genetically modified cells and uses thereof,' protecting the technology until November 2036.

RESPIRI PATIENTS ENROLLED IN WHEEZO RPM PROGRAM
RESPIRI
Respiri says an unnamed North Carolina 'client' has enrolled patients in its Wheezo remote patient monitoring program for chronic obstructive pulmonary disease.

CRESO DRAWS DOWN OBSIDIAN $500k
CRESO PHARMA
Creso says it has drawn an additional $500,000 from its Obsidian Global GP LLC convertible note facility, taking the total to $5.5 million (BD: Nov 1, 2022).

Tuesday January 10, 2023

JAPAN PATENT FOR ADALTA AD-214
ADALTA
Adalta says the Japan Patent Office has granted a patent for its AD-214, titled 'CXCR4 binding molecules,' protecting its intellectual property until January 8, 2036.

CHIMERIC TO RELEASE 115m SHARES FROM ASX ESCROW
CHIMERIC THERAPEUTICS
Chimeric says it will release 115,226,336 ASX escrow shares, on January 18, 2023. According to its most recent filing, Chimeric would have a total of 437,094,375 shares on issue after the release from escrow.

SALTER BROTHERS TAKES 5.6% OF NUHEARA
NUHEARA
The Melbourne-based Salter Brothers Emerging Companies says it has become substantial in Nuheara with 8,655,556 shares or 5.62 percent of the company.

AUSTRALIAN PATENT FOR RECCE R327
RECCE PHARMACEUTICALS
Recce says Intellectual Property (IP) Australia intends to grant its patent for R327, titled 'Anti-Virus Agent and Method for Treatment of Viral Infection'.
Recce said the patent would protect its intellectual property until November 2037.

ZELIRA: CRESO REPAYS $1.75m HEALTH HOUSE LOAN
CRESO PHARMA, ZELIRA THERAPEUTICS, HEALTH HOUSE INTERNATIONAL
Zelira says Creso has repaid a $1,750,000 loan which Creso absorbed after acquiring Health House for about $4,600,000 (BD: Nov 21, 2022).

CANN GROUP APPOINTS PETER KOETSIER CEO ON $350k PA
CANN GROUP
Cann Group says it has appointed former Ipsen and Astrazeneca executive Peter Koetsier as its chief executive officer, replacing Peter Crock, from January 16, 2023.
Cann said that Mr Koetsier would have a base salary of $350,000 a year, with short-term incentives of up-to 40 percent of his base salary and up to 4.5 million options exercisable at prices from 45 cents each to 75 cents each.

Wednesday January 11, 2023

ENA: $6.4m US DEFENSE DEAL FOR INNA-051 DRY POWDER NASAL SPRAY
ENA RESPIRATORY
ENA says it has a $US4.38 million ($A6.4million) agreement with the US Department of Defense to develop its intranasal antiviral INNA-051 for respiratory viral infections.
ENA said the 12-month agreement would lead to an investigational new drug submission to the US Food and Drug administration for the intranasal dry powder formulation of its first-in-class, broad-spectrum antiviral innate immunomodulator, INNA-051.

AMPLIA APPROVED FOR NEXT AMP945 DOSE COHORT
AMPLIA THERAPEUTICS
Amplia says it has approval to begin the next dose cohort in its phase Ib/IIa, 'Accent' trial of focal adhesion kinase inhibitor AMP945 for advanced pancreatic cancer.

CRESO, MERNOVA TO SELL 7 MARIJUANA PRODUCTS IN CANADA
CRESO PHARMA
Creso says its wholly-owned subsidiary Mernova Medicinal will sell seven new recreational marijuana products across Nova Scotia, Canada.

RADIOPHARM APPOINTS DR RAMA ABU SHMEIS CMC HEAD
RADIOPHARM THERANOSTICS
Radiopharm says it has appointed Dr Rama Abu Shmeis as head of chemistry, manufacturing and controls

AUSTRALIAN SUPER BELOW 5% OF NANOSONICS
NANOSONICS
Australian Super Pty Ltd says it has ceased its holding in Nanosonics after selling shares at prices ranging from $2.89 to $4.97 a share.

PLANET INNOVATION DILUTED TO 30.6% OF LUMOS
LUMOS DIAGNOSTICS
The Melbourne-based Planet Innovation Holdings says it has been diluted in Lumos from 68,021,060 shares (32.41%) to 68,021,060 shares (30.64%).

Thursday January 12, 2023

MEDLAB INTERIM NANABIS DATA: 55% PAIN RELIEF IMPROVEMENT
MEDLAB CLINICAL
Medlab says interim data from 1,172 patients in its Nanabis observational study shows a 55 percent improvement in pain relief and a 75 percent reduction in opioid use.
In 2021, Medlab said an interim analysis of 119-patients in an observational study showed a 55 percent reduction in pain with its marijuana-based Nanabis.
The company said that 55 percent ($p < 0.00001$) reported improvement in pain relief after six months, with 23 percent ($p < 0.0001$) showing an average pain reduction.

STARPHARMA PLEADS SCHULTZ TO ASX 23% PRICE QUERY
STARPHARMA
Starpharma 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 that on December 13, 2022, Starpharma's share price rose 22.8 percent to a high of 62 cents following news of interim Astrazeneca AZD0466 trial results.
Starpharma said that a poster by Astrazeneca was due to be presented at the American Society of Hematology (ASH) meeting and was published on ASH's website prior to the conference, containing further details regarding interim analysis of an AZD0466 trial using its dendrimer enhanced product technology.
The company said that it only had access to the poster after it had been released to a limited audience on the ASH website, and that it published an announcement to the ASX "as quickly as possible" after it confirmed the results.

US FDA OKAYS CHILDREN IN DIMERIX DMX-200 PHASE III FSGS TRIAL
DIMERIX
Dimerix says the US Food and Drug Administration will allow children aged 12 to 17 years old in its phase III, DMX-200 trial for focal segmental glomerulosclerosis.

EMYRIA RECEIVES $2.1m FEDERAL R&D TAX INCENTIVE
EMYRIA
Emyria says it has received a $2,094,701 research and development tax incentive from the Australian Tax Office for the financial year ended June 30, 2022

AVECHO TAKES TPM-VITAMIN K TO US FDA PRE-IND MEETING
AVECHO BIOTECHNOLOGY
Avecho says it has presented its tocopheryl phosphate mixture injectable vitamin K to the US Food and Drug Administration in a pre-investigational new drug meeting.

MAYNE DEFERS $113m SHAREHOLDER CAPITAL RETURN UNTIL MARCH
MAYNE PHARMA GROUP
Mayne says it will defer its $113 million capital return to shareholders until “at least” March, 2023 in order to maintain “funding flexibility” (BD: Oct 28, 2022).

Friday January 13, 2023

ANATARA HAS 1.87 QUARTERS OF CASH
ANATARA LIFE SCIENCES
Anatara says it has $1,347,000 or 1.87 quarters of funding available, but expected to place the $300,000 shortfall from its entitlement offer.
Anatara said it would continue to have the current level of net operating cash flows for “the time being”.

MAYNE NUVARING GENERIC CONTRACEPTIVE US LAUNCH
MAYNE PHARMA GROUP
Mayne says it has launched Haloette, a generic version of the Nuvaring intra-vaginal hormonal contraceptive ring, combining etonogestrel and ethinyl estradiol, in the US.
Mayne said it would pay a EUR1.6 million ($A2.5 million) milestone payment to the Liège, Belgium-based Mithra under its long-term agreement (BD: Aug 8, 2022).

MONASH, ONO TO WORK ON AUTOIMMUNE, INFLAMMATORY DISEASES
MONASH UNIVERSITY
Monash says it has a research collaboration with Ono Pharmaceutical Co to develop therapeutics for autoimmune and inflammatory diseases.
Monash said the collaboration was funded by the Osaka, Japan-based Ono Pharmaceutical and that it would lead the antibody discovery program to target two G-protein-coupled receptors which were traditionally hard to target.

PACIFIC EDGE COMPLETES TE WHATU ORA SOUTHERN CXBLADDER DEAL
PACIFIC EDGE
Pacific Edge says it has completed its commercial agreement with Te Whatu Ora Southern for the use of its non-invasive Cxbladder genomic tests (BD: Sep 23, 2022).

Monday January 16, 2023

ANTERIS 'DURAVR REMARKABLE HAEMODYNAMIC FUNCTION'

ANTERIS TECHNOLOGIES

Anteris says its treated cow tissue Duravr trans-catheter heart valve trial met all performance endpoints with "remarkable heamodynamic function … [at] 12 months".

Last year, Anteris said eight patients in the second cohort of its 10-patient first-in-human study conducted at Georgia's Tbilisi Heart and Vascular Clinic showed "clinically significant improvements" after 30 days (BD: Jul 11, 2022).

The company said the first five patients implanted with Duravr heart valve had average blood flow velocity through the valve increased, patients showed improvements in the six-minute walk test, and there were no mortalities or device-related complications.

CLINUVEL AFAMELANOTIDE 'REDUCES DNA PHOTO-DAMAGE IN 3 PATIENTS'

CLINUVEL PHARMACEUTICALS

Clinuvel says results from three patients with xeroderma pigmentosum in its phase II study showed afamelanotide reduces DNA photo-damage.

Clinuvel said in three patients, a reduction of cyclobutane pyrimidine dimers was found which are "characteristic for photo-damage" and in two patients, skin specimens showed "an increase in p53 expression," a protein which controled cell division and death, associated with suppressing tumor formation.

The company said that three patients showed reduced erythema and increased melanin density, suggesting the formation of skin pigmentation acting as a physical ultra-violet light barrier.

FEDERAL $6m AUSTRALIA-INDIA RESEARCH GRANTS

FEDERAL GOVERNMENT

The Federal Government says it has opened applications for $6 million Australia-India strategic grants for research collaborations.

The Minister for Industry and Science Ed Husic said the grants supported "research collaborations in science and technology … [for] challenges facing both countries".

KAZIA PLACEMENT RAISES $4.5m, SHARE PLAN FOR MORE

KAZIA THERAPEUTICS

Kazia says it has raised $4.5 million in a placement at 11 cents a share, in part subject to shareholder approval, and will offer an uncapped share plan at the same price.

Kazia said the share plan had a record date of January 13, opened on January 19, and would close on February 24, 2023.

CRONOS TO CLOSE CDA CLINICS FOR TELEHEALTH

CRONOS AUSTRALIA

Cronos says physical CDA clinics on the Gold Coast, Brisbane and Sunshine Coast will close by March 31, 2023 and transition to telehealth services.

Cronos said the closing of the CDA (Cannabis Doctors Australia) clinics, would deliver "significant overhead cost savings… and a highly scalable business model".

POLYNOVO UNAUDITED H1 REVENUE UP 62% TO RECORD $29.5m

POLYNOVO

Polynovo says unaudited revenue for the six months to December 31, 2022 was up 62.2 percent to a record $29.5 million compared to the prior corresponding period.

PHARMAXIS APPOINTS HASHAN DE SILVA DIRECTOR
PHARMAXIS
Pharmaxis says it has appointed Hashan De Silva as a non-executive director, effective from January 16, 2023.

UNIVERSAL BIOSENSORS APPOINTS GRAHAM MCLEAN CHAIR
UNIVERSAL BIOSENSORS
Universal Biosensors says director and former Stryker head Graham McLean will replace Craig Coleman as chair, who will remain as non-executive director.

Tuesday January 17, 2023

POLYNOVO EGM 25% BLOCKS VIRTUAL MEETING VOTE
POLYNOVO
Polynovo says its extraordinary meeting failed to pass a special amendment to its constitution to allow for virtual meetings, with 25.14 percent dissent.
Polynovo said that all other resolutions passed easily, but the meetings resolution required a 75 percent vote to pass, faced 68,735,382 opposition votes (25.14%) with 204,718,421 votes (74.86%) in favor.
According to its most recent filing, Polynovo had 677,477,518 shares on issue, meaning the votes against the amendment to the constitution amounted to 10.1 percent of the company, sufficient to requisition extraordinary meetings.

IMMURON CLOSTRIDIOIDES DIFFICILE TREATMENT EU PATENT
IMMURON
Immuron says the European Patent Office has granted it a patent for the compositions and methods to treat clostridioides difficile associated disease.
Immuron said the patent, titled 'Methods and Compositions for the treatment and/or prophylaxis of Clostridium difficile associated disease, would protect its intellectual property until April 17, 2034.

NOXOPHARM '1600mg VEYONDA SAFE, WELL-TOLERATED'
NOXOPHARM
Noxopharm says 1,600mg doses of Veyonda, in combination with external beam radiotherapy is safe and well-tolerated and will progress to part two of the trial.
Last year, Noxopharm said that patients treated with 1,200 milligrams of Veyonda in its 'Darrt-2' phase II, dose-expansion and escalation trial for metastatic cancers showed safety and tolerability (BD: Aug 2, 2022).

LINDMARK TAKES 9.5% OF CRYOSITE
CRYOSITE
Melbourne's Lindmark Investments Staff Superannuation Fund says it has increased its holding in Cryosite from 4,004,569 shares (8.20%) to 4,654,494 shares (9.54%).

FIRST SENTIER REDICES TO 7.2% OF NANOSONICS
NANOSONICS
The Sydney-based First Sentier says it has reduced its holding in Nanosonics from 25,066,644 shares (8.30%) to 21,675,187 shares (7.18%).

Wednesday January 18, 2023

TELIX: $150m US ILLUCCIX SALES; Q4 CASH-FLOW POSITIVE
TELIX PHARMACEUTICALS
Telix says it has $149.7 million in revenue from US Illuccix sales for the nine months to December 31, 2022, with the three months to December 31 cash-flow positive.

VOLPARA 'Q3 $10m REVENUE - 1st CASH FLOW POSITIVE QUARTER'
VOLPARA HEALTH
Volpara says it has recorded its first positive cash flow quarter on customer receipts of $NZ11.2 million ($A10.4 million) for the three months to December 31, 2022.

MEDICAL DEVELOPMENTS HALTS CHINA PENTHROX TRIALS
MEDICAL DEVELOPMENTS INTERNATIONAL
Medical Developments says it has discontinued Penthrox trials in China following delays due to "the challenging regulatory environment and Covid-19 restrictions".

ATOMO, NG BIOTECH TO MANUFACTURE, DISTRIBUTE PREGNANCY TESTS
ATOMO DIAGNOSTICS
Atomo says it has a five-year agreement with NG Biotech to manufacture and distribute rapid blood-based pregnancy tests for professional and at-home use.
Atomo said it would retain ownership of the intellectual property associated with the Pascal blood test device component which the Bretagne, France-based NG Biotech would combine with its test for the early detection of pregnancy.

ADHERIUM: $880k NHS GRANT FOR HAILIE SOFTWARE
ADHERIUM
Adherium says the UK National Health Service's Small Business Research Initiative Healthcare has awarded it GPB499,871 ($A880,000) for a "pathfinder service project".
Adherium said the project, titled 'Smart Digital inhaler enabled asthma management in high-risk children aged five to 16 years managed in primary care to prevent asthma attacks' would use Hailie inhalers to alert children and display use on a smartphone.

BIONOMICS 37m CEO, CHAIR OPTIONS EGM
BIONOMICS
Bionomics says an extraordinary general meeting will vote to issue 37,067,015 options to chief executive officer Dr Spyridon Papapetropoulos and chair Dr Errol De Souza.
Bionomics said the meeting would vote to issue 27,067,015 options to Dr Papapetropoulos, exercisable at the five-day volume weighted average price prior to the grant date, and 10,000,000 options to Dr De Souza, exercisable at 5.2 cents each.

IMMURON ENROLS 157 TRAVELAN DIARRHOEA TRIAL PARTICIPANTS
IMMURON
Immuron says 157 participants have been enrolled in the 1,336-patients clinical trial to evaluate IMM-124E, or Travelan, for travelers' diarrhoea.

PERENNIAL TAKES 12.6% OF MEDADVISOR
MEDADVISOR
The Sydney-based Perennial Value Management says it has increased its holding in Medadvisor from 62,846,538 shares (11.56%) to 68,657,589 shares (12.62%).

INCANNEX: 29 PATIENTS COMPLETE PSILOCYBIN TREATMENT
INCANNEX HEALTHCARE
Incannex says 29 of 72 participants have completed treatment in its phase IIa trial of psilocybin with psychotherapy for generalized anxiety disorder.

FIREBRICK: NASODINE CHRONIC RHINOSINUSITIS POTENTIAL, IN-VITRO
FIREBRICK PHARMA
Firebrick says a research paper has found that its Betadine-based anti-viral Nasodine nasal spray has potential to manage chronic rhinosinusitis, in-vitro.
Firebrick said the paper, titled 'In vitro Nasodine Can be an Effective Antibiofilm Agent for Biofilms that May Cause CRS' and published in The Laryngoscope, found that "Nasodine demonstrated time and concentration-dependent bacterial killing against intact biofilm," and that "statistically significant reductions in viable bacteria from intact biofilms were seen with exposures as brief as [five minutes]".

NYRADA EXTENDS WALTER REED, NSW UNI BRAIN INJURY COLLABORATION
NYRADA
Nyrada says it has a two-year extension to its collaboration with the Walter Reed Army Institute of Research and the University of New South Wales, to January 2025.

DRAY ANDREA REPLACES CRYOSITE CO SEC KIM BRADLEY-WARE
CRYOSITE
Cryosite says Dray Andrea will replace Kim Bradley-Ware as company secretary, effective from January 18, 2023.

PLATINUM TAKES 12.5% OF KAZIA
KAZIA THERAPEUTICS
Platinum Investment Management says it has increased its holding in Kazia from 6,789,967 shares (4.89%) to 23,714,646 shares (12.56%).
The Sydney-based Platinum said it bought 16,924,679 shares at 11 cents each.

MITSUBISHI REDUCES TO 7.2% IN NANOSONICS
NANOSONICS
The Tokyo-based Mitsubishi UFJ Financial Group says it has decreased its holding in Nanosonics from 25,066,644 shares (8.30%) to 21,675,187 shares (7.18%).

Thursday January 19, 2023

NANOSONICS EXPECTS $82m H1 REVENUE, $11.4m PROFIT
NANOSONICS
Nanosonics says it expects total revenue for the six months to December 31, 2022 to be up 35 percent to $81.6 million, with profit before tax of about $11.4 million.

CHIMERIC DOSES 1st CHM0201, VACTOSERTIB CANCER PATIENT
CHIMERIC THERAPEUTICS
Chimeric says it has dosed the first of 12-patients in its phase Ib trial of CHM0201 Core NK compound with Vactosertib, for advanced colorectal and blood cancers.
Chimeric said the trial was at the Cleveland, Ohio-based Case Western Reserve University School of Medicine.

CONTROL BIONICS APPOINTS JEREMY STEELE CEO ON $325k A YEAR
CONTROL BIONICS
Control says Jeremy Steele will replace founder and interim chief executive officer Peter Ford as chief executive officer and director, effective from January 19, 2023.
Control said it would pay Mr Steele $325,000 including superannuation, up to 50 percent of his total fixed remuneration in short-term bonuses, and 2,000,000 options vesting over four years, exercisable at the 20-day volume weighted average price on January 19, 2023.

AROVELLA PLACEMENT RAISES $1.65m
AROVELLA THERAPEUTICS
Arovella says it has "firm commitments" for $1.5 million in a placement at two cents a share, with a further $155,000 from directors and management, subject to approval.
Arovella said the price was a 9.3 percent discount to the 15-day volume weighted average price of shares ending January 16, 2023.

ACRUX: 'POSITIVE' FDA ASSESSMENT ON UNNAMED GENERIC
ACRUX
Acrux says the US Food and Drug Administration gave a "favorable" Remote Regulatory Assessment for an undisclosed generic drug currently under review.

CEPI $6.4m FOR VAXXAS NEEDLE-FREE VACCINE
VAXXAS
Vaxxas says it will receive $6.4 million from the Coalition for Epidemic Preparedness Innovations to assess mRNA thermostability on its needle-free vaccine technology.
Vaxxas said it would use the funding from the Oslo, Norway-based Coalition to assess the thermostability of mRNA vaccines when printed in a dried-formulation on its novel vaccine administration technology, the high-density microarray patch, which delivers a vaccine when pressed against the skin for 10 seconds.

CANN GROUP 'SATIPHARM CBD NOT SUPERIOR TO PLACEBO FOR SLEEP'
CANN GROUP
Cann Group says preliminary analysis of its Satipharm cannabidiol (CBD) capsules for sleep disturbances has "not shown a statistically superior response compared to placebo".
Last year, Cann Group said it had enrolled more than 212 patients in its randomized, double-blind, placebo-controlled phase III trial of marijuana-based low-dose Satipharm CBD capsules for short-term sleep disturbance.
The company said it expected the trial results to delay submission of its registration application to the Therapeutic Goods Administration for the indication.

INVEX OPENS 1st US PRESENDIN IIH TRIAL SITE
INVEX THERAPEUTICS
Invex says it has opened its first US site at the Bellaire, Texas Eye Wellness Center in its 240-patient phase III trial of Presendin for idiopathic intracranial hypertension.

NEUROTECH: US FDA APPROVES PRE-IND MEETING
NEUROTECH INTERNATIONAL
Neurotech says the US Food and Drug Administration has approved its request for a pre-investigational new drug application meeting on March 15, 2023.

RESPIRI TELLS ASX IT IS NOT 'RAMPING UP' SHARE PRICE
RESPIRI
Respiri has told the ASX it is not making market sensitive announcements with the view to ramping up the price of its securities.
An ASX query asked if the multiple announcements announcing the contracting of US healthcare companies and on-boarding of patients in the Wheezo remote patient monitoring program contained any new information, and if Respiri considered "any of the announcements listed … [contravened] guidance on 'ramping announcements'"?
Respiri said each announcement contained new information which was "factual based and [was] considered market sensitive given the significant achievements in initially contracting and then on-boarding patients in these US medical institutions/healthcare organizations".

REGAL FUNDS BELOW 5% IN MEDADVISOR
MEDADVISOR
The Sydney-based Regal funds Management says it has ceased its substantial holding in Medadvisor.

Friday January 20, 2023

PRO MEDICUS, WASHINGTON UNI $25m PACS DEAL
PRO MEDICUS
Pro Medicus says it has a $25 million contract with Seattle's University of Washington UW Medicine for its Visage picture archiving communication system.

FEDERAL $1.2m FOR ARGENICA BRAIN INJURY RESEARCH
ARGENICA THERAPEUTICS
Argenica says the Federal Government's Cooperative Research Centre Projects program has granted it $1.2 million for its traumatic brain injury research activities.
Argenica said the grant would contribute to a pre-clinical program with Perth's Curtin University, the University of Adelaide, Melbourne's Auspep and Perth's Connectivity Traumatic Brain Injury Australia, to assess the efficacy of ARG-007 in animal models of mild to moderate traumatic brain injury.

TGA APPROVES ADHERIUM HAILIE WITH PARAMETERS
ADHERIUM
Adherium says the Therapeutic Goods Administration has approved its Hailie sensors with physiological parameters for commercial distribution.

ADHERIUM STARTS GSK HAILIE-ELLIPTA INHALER PRODUCTION
ADHERIUM
Adherium says it has begun production and market release of its Hailie sensors for Glaxosmithkline Ellipta inhalers for asthma and chronic obstructive pulmonary disease.

ISLAND: US FDA ISLA-101 IND 'CLINICAL HOLD'
ISLAND PHARMACEUTICALS
Island says the US Food and Drug Administration has placed a "clinical hold" on its phase IIa, ISLA-101 trial investigation new drug application.
Island said the FDA specified amendments to the trial protocol may be required.

PHARMAUST TAKES MONEPANTEL FOR MND TO HIGHER DOSE
PHARMAUST
Pharmaust says it has approval to begin the next dosing level in its phase I/II trial of monepantel for motor neurone disease, after six patients reported no adverse events.

FISHER & PAYKEL EXPECTS FY REVENUE FALL TO $1.44-1.5b
FISHER & PAYKEL HEALTHCARE CORP
Fisher Paykel says it expects revenue for the 12 months to June 30, 2023 to be in the range of $NZ1.55 billion to $NZ1.60 billion ($A1.44 billion to $A1.49 billion).
In May 2022, Fisher & Paykel reported total operating revenue for the 12 months to March 31, 2022 down 15 percent to $NZ1,681.7 million with net profit after tax down 28 percent to $NZ376.9 million.

SEAN EKINS REPLACES AVITA CFO MIKE HOLDER; KATHY MCGEE GOES
AVITA MEDICAL
Avita says finance head Sean Ekins will replace chief financial officer Michael Holder on an interim basis and chief operating officer Kathy McGee will resign.