



# Biotech Daily

SPECIAL SUMMER CATCH-UP EDITION

Sunday, January 20, 2019

*The Summer Catch-Up Edition was compiled by  
Rebekah Andrews and Alexander Campbell*

- \* BENITEC LATE BB-401 HEAD, NECK CANCER TRIAL CLOSURE
- \* RHINOMED SHARE PLAN RAISES \$95k OF HOPED-FOR \$1m
- \* PHOSPHAGENICS: ANNA LEGG OUT; MELANIE LEYDIN, MICHAEL SAPOUNTZIS IN
- \* PHYLOGICA LOSES CSO DR ROBERT HAYES
- \* ASX 'VERBAL CONFIRMATION' QUEENSLAND BAUXITE RELISTING
- \* RACE CEO PETER MOLLOY INCREASES, DILUTED TO 5%
- \* FIL BELOW 5% IN STARPHARMA, AGAIN
- \* TELIX COMPLETES \$8.3m AMNI SA ACQUISITION
- \* MGC EXPORTS CANNEPIL FROM SLOVENIA
- \* MICRO X RAISES \$2m
- \* ALTIUM TAKES 7.5% OF IMMUTEP
- \* MEDIBIO LOSES CHRISTOPHER INDERMAUR, APPOINTS CLAUDE SOLITARIO
- \* CANN GIVES PAYS CSIRO 91k SHARES
- \* DORSAVI CEO DR ANDREW RONCHI DILUTED BELOW 5%
- \* PRUDENTIAL (M&G) TAKES 5% OF MEDICAL DEVELOPMENTS
- \* ELIXINOL RELEASES 52k ASX ESCROW SHARES
- \* MMJ MEDIPHARM RECEIVES CANADA APPROVAL MARIJUANA PRODUCTION
- \* RACE CHAIR DR BILL GARNER TAKES 17.5%
- \* RACE CEO PETER MOLLOY INCREASES, DILUTED TO 5.2%
- \* FDA REQUESTS 'CLINICAL DATA' TO APPROVE STARPHARMA VIVAGEL BV

- \* PRANA RAISES \$44.6m FROM LIFE BIOSCIENCES, INVESTORS
- \* LANSTEAD REDUCES BELOW 5% IN NEUREN
- \* GI DYNAMICS EXTENDS \$6.6m CRYSTAL AMBER LOAN
- \* RESAPP SUBMITS CE MARK TECH FILE FOR SMARTPHONE DIAGNOSTIC
- \* JAPAN APPROVES STARPHARMA VIVAGEL CONDOM
- \* TOTAL BRAIN RELEASES 474k SHARES FROM ESCROW
- \* CRESO 'TAKES ADVANTAGE' OF ISRAELI MARIJUANA EXPORT RULES
- \* IMMURON RECEIVES \$1.19m FEDERAL R&D TAX INCENTIVE
- \* RESONANCE LICENCES WISCONSIN FAT-DISEASES PATENTS
- \* BIONOMICS PHASE II BNC105 COMBINATION CANCER TRIAL UNDERWAY
- \* LEIGH ELKOLLI REPLACES REVA CFO, CO SEC BRANDI ROBERTS
- \* GI DYNAMICS APPOINTS STEPHEN LINHARES CLINICAL, REGULATORY HEAD
- \* AUSTRALIA ACCEPTS CYNATA STEM CELL PATENT APPLICATION
- \* MESOBLAST PHASE III TRIAL COMPLETES RECRUITMENT
- \* STARPHARMA TELLS ASX: FDA DATA MATERIAL, JAPAN APPROVAL NOT
- \* NUHEARA LAUNCHES IQBUDS MAX
- \* IMUGENE APPOINTS PROF MICHAEL CALIGIURI SCIENTIFIC ADVISOR
- \* IMMUTEP \$6m COLLABORATION WITH CYTLIMIC
- \* REVA EXPANDS INTO SEVEN EUROPEAN COUNTRIES
- \* CRESO TO DISTRIBUTE MEDICAL MARIJUANA IN SRI LANKA
- \* FIL REDUCES TO 6.5% IN IMPEDIMED
- \* POLYNOVO: H1 NOVOSORB BTM SALES UP 320%
- \* PATRYS RECEIVES \$556k R&D TAX INCENTIVE
- \* TELIX: HUI591 DATA SUPPORTS PHASE III PROSTATE CANCER TRIAL
- \* AVITA US LAUNCH OF RECELL SYSTEM
- \* ELIXINOL CFO RON DUFFICY TO US, KIM BRADLEY-WARE CO SEC

- \* OVENTUS LAUNCHES NYLON O2VENT OPTIMA FOR SLEEP APNOEA
- \* ITL HEALTH VOTES TO QUIT ASX
- \* MMJ APPOINTS MICHAEL CURTIS DIRECTOR
- \* ZELDA PLEADS SCHULTZ TO ASX 20% QUERY
- \* MEDLAB: 'NANOSTAT IMPROVES ATORVASTATIN'
- \* NUHEARA LAUNCHES HEARING SERVICES APP, IQSTORE
- \* JENCAY CAPITAL TAKES 8% OF UNIVERSAL BIOSENSORS
- \* CRESO, MEDLEAF PARTNER FOR NZ MEDICAL MARIJUANA
- \* CANCER TRIALS JOINS SHAREROOT'S MEDIA CONSENT
- \* FDA: JULY 8 PDUFA DATE FOR CLINUVEL'S SCENESSE FOR EPP
- \* NIV DAGAN, FREEDOM TRADER TAKE 5.5% OF LIFESPOT
- \* INVITROCUE APPOINTS DR STEVEN FANG CHAIRMAN
- \* NUHEARA LAUNCHES IQCONNECT
- \* INVITROCUE APPOINTS PROF MASAKAZU TOI CLINICAL ADVISOR
- \* MEMPHASYS: UNI OF FLORENCE, ISFAHAN CLINIC TEST FELIX
- \* FEDERAL \$25m FOR WEHI DRUG DISCOVERY CENTRE
- \* MESOBLAST TAKES \$21m FROM HERCULES CREDIT FACILITY
- \* FIL TAKES 5% OF STARPHARMA
- \* ZELDA DIRECTOR JASON PETERSON TRANSFERS, REDUCES TO 9.6%
- \* ANATARA RECEIVES \$1.25m R&D TAX INCENTIVE
- \* CEO RICHARD HANNEBERY TAKES 13.4% OF GENERA
- \* MEMPHASYS: BOSTON IVF, UNIVERSITY OF MUNSTER TEST FELIX
- \* PHARMAUST: 'MONEPANTEL SHOWS ANTI-CANCER ACTIVITY'
- \* CARDIEX, ANTHEM TO CO-MARKET INHEALTH
- \* IMMURON OFFERS WARRANTS OVER 701.5k US SHARES
- \* RESONANCE: ENVOYAI TO DISTRIBUTE FERRISMART IN US

- \* KAZIA RECEIVES \$2.2m R&D TAX INCENTIVE
- \* PRESCIENT RECEIVES \$939k R&D TAX INCENTIVE
- \* MARK FORTUGNO REPLACES THC CFO JARROD WHITE
- \* INVION: LYNDA SPELMAN, LOUIS IRVING, NATHAN LAWRENSTCHUK ADVISORS
- \* PAINCHEK WORKS WITH ALLITY AGED CARE, WARD MEDICATION
- \* INVITROCUE APPOINTS PROF JESÚS GARCÍA-FONCILLAS CLINICAL ADVISOR
- \* IMPEDIMED SIGNS ASCENSION FOR SOZO
- \* PHARMAXIS READY FOR PHASE II LOXL2 TRIALS
- \* PHOSPHAGENICS, FDA DISCUSS TPM-OXYMORPHONE PATH
- \* EMA APPROVES MEDLAB SME QUALIFICATION
- \* GENERA RECEIVES \$438k R&D TAX INCENTIVE
- \* ANTEO WORKS WITH SONA NANOTECH, ELLUME
- \* ESENSE-LAB SHIPS 2L CANNABIDIOL VAPE PRODUCT TO E-QUITS
- \* MALAYSIA APPROVES POLYNOVO BTM; BUYS PRODUCTION FACILITY
- \* CARDIEX TELLS ASX: 'JANUARY 5 ANTHEM NEWS PUBLISHED JANUARY 15'
- \* INVITROCUE ROLLS-OUT ONCO-PDO SCREENING GERMANY
- \* ANTISENSE: ATL1102 FOR DMD TRIAL RECRUITMENT HALF-WAY
- \* BIOXYNE LOSES DIRECTOR MAXWELL PARKIN
- \* AUSCANN TO RELEASE 133m ASX ESCROW SHARES

Detailed summaries continue on the following pages

The following articles appear in date order

**Late on Friday December 21, 2018**

### **BENITEC LATE BB-401 HEAD, NECK CANCER TRIAL CLOSURE**

#### **[BENITEC BIOPHARMA](#)**

At 6.10pm, after the market closed for the Christmas break, Benitec said BB-401 for head and neck cancer did not meet the objective response rate to continue enrollment in the phase II study.

The company said that BB-401 was “fundamentally different” from its other DNA-directed-RNA-interference drugs.

## **RHINOMED SHARE PLAN RAISES \$95k OF HOPED-FOR \$1m**

### **[RHINOMED](#)**

At 6.26pm, after the market closed for the Christmas break, Rhinomed said its share plan at 21 cents a share raised \$95,000 of a hoped for \$1 million.

In November, Rhinomed said it raised \$5 million in a placement at 21 cents a share and hoped to raise a further \$1 million in a share plan (BD: Nov 2, 2018).

**Monday December 24, 2018 (Christmas Eve)**

## **PHOSPHAGENICS ANNA LEGG OUT, MELANIE LEYDIN, MICHAEL SAPOUNTZIS IN PHOSPHAGENICS**

Phosphagenics says it has appointed Melanie Leydin company secretary and chief financial officer and Michael Sapountzis as joint company secretary replacing Anna Legg who has resigned after six years with the company.

## **PHYLOGICA LOSES CSO DR ROBERT HAYES**

### **[PHYLOGICA](#)**

Phylogica says Dr Robert Hayes has resigned after a year and a half as chief scientific officer, effective from December 24, 2018.

The company said it would not be appointing a replacement chief scientific officer "in the near term".

## **ASX 'VERBAL CONFIRMATION' QUEENSLAND BAUXITE RELISTING QUEENSLAND BAUXITE**

Queensland Bauxite says it has received "verbal confirmation" from the ASX that it will receive a formal letter approving relisting upon lodging its ninth revised prospectus.

In August, the ASX said Queensland Bauxite had been suspended for failing to lodge its quarterly report and because it intended to amend the terms of re-compliance.

## **RACE CEO PETER MOLLOY INCREASES, DILUTED TO 5%**

### **[RACE ONCOLOGY](#)**

Race chief executive officer Peter Molloy says his substantial holding has increased and been diluted from 4,020,000 shares (6.27%) to 4,278,593 shares (5.20%).

## **FIL BELOW 5% IN STARPHARMA, AGAIN**

### **[STARPHARMA](#)**

FIL Investments says it has again reduced its shareholding in Starpharma below the five percent substantial threshold to 18,578,111 shares (4.99%).

The Bermuda based FIL said it sold 298,792 shares for \$1.40 a share.

## **TELIX COMPLETES \$8.3m AMNI SA ACQUISITION**

### **[TELIX PHARMACEUTICALS](#)**

Telix says it has completed the acquisition of the Belgium-based Advanced Nuclear Medicine Ingredients SA (ANMI) for EUR5.15 million (\$A8.29 million).

## **MGC EXPORTS CANNEPIL FROM SLOVENIA**

### **[MGC PHARMACEUTICALS](#)**

MGC says it imported its first Cannepil cannabinoid veterinary investigational medicinal product from Slovenia to Australia.

## **MICRO X RAISES \$2m**

### [MICRO X](#)

Micro X says it has raised \$2,000,000 in a private placement at 27 cents a share.

## **ALTIUM TAKES 7.5% OF IMMUTEP**

### [IMMUTEP](#)

Altium Growth says it has become a substantial shareholder in Immuteq with 250,000,000 shares (7.48%).

The Altium notice listed the New York-based Mark and Jacob Gottfried as holders of the relevant interest and said that they purchased the shares on December 21, 2018 for \$US5,000,000 (\$A7,087,000) or two US cents a share.

## **MEDIBIO LOSES CHRISTOPHER INDERMAUR, APPOINTS CLAUDE SOLITARIO**

### [MEDIBIO](#)

Medibio says chairman Christopher Indermaur will resign and it has appointed major shareholder Claude Solitario as a director.

Medibio said Mr Indermaur would step down from December 31, 2018 to focus on other business interests.

## **CANN PAYS CSIRO 91k SHARES**

### [CANN GROUP](#)

Cann says the Commonwealth Scientific and Industrial Research Organisation (CSIRO) received 91,164 shares as settlement of an invoice for services rendered.

## **DORSAVI CEO DR ANDREW RONCHI DILUTED BELOW 5%**

### [DORSAVI](#)

Dorsavi chief executive officer Dr Andrew Ronchi says that with AR BSM Pty Ltd, he has again ceased to be a substantial shareholder (BD: Jan 21, 2018, Sep 16, 2016). Dr Ronchi said he was diluted below substantial after the company's recent \$2.1 million one-for-three rights offer at 5.8 cents a share (BD: Dec 18, 2018).

**Thursday December 27, 2018**

## **PRUDENTIAL (M&G) TAKES 5% OF MEDICAL DEVELOPMENTS**

### [MEDICAL DEVELOPMENTS INTERNATIONAL](#)

Prudential PLC with its subsidiaries including M&G Investment Funds says it has become a substantial holder in Medical Developments with 3,284,528 shares (5.02%). The London-based Prudential said it bought shares between August 20 and December 20, 2018, with the largest purchase of 100,000 shares for \$391,575, or \$3.92 a share.

## **ELIXINOL RELEASES 52k ASX ESCROW SHARES**

### [ELIXINOL GLOBAL](#)

Elixinol says that 52,559 shares were released from ASX escrow on December 27, 2018.

## **MMJ MEDIPHARM RECEIVES CANADA APPROVAL MARIJUANA PRODUCTION**

### [MMJ](#)

MMJ says its 4.5 percent owned Medipharm has received approval from Health Canada to increase its annual dried cannabis production by 50 tonnes to 150 tonnes.

## **RACE CHAIR DR BILL GARNER TAKES 17.5%**

### **[RACE ONCOLOGY](#)**

Race chairman Dr William Garner says he has increased his substantial holding from 11,398,338 shares (14.76%) to 14,405,916 shares (17.52%).

The San Juan, Puerto Rico-based Dr Garner said that on December 20, 2018, a total of 9,951,301 shares were transferred off-market to him by “non-related shareholders” with the financial consideration for the shares listed as “nil”.

The substantial shareholder notice said that on December 21, 2018 Dr Garner acquired a further 5,000,000 shares through the conversion of performance rights.

## **RACE CEO PETER MOLLOY INCREASES, DILUTED TO 5.2%**

### **[RACE ONCOLOGY](#)**

Race chief executive officer Peter Molloy says he has increased his holding and been diluted from 4,020,000 shares (6.27%) to 4,278,593 shares (5.20%).

## **FDA REQUESTS ‘CLINICAL DATA’ TO APPROVE STARPHARMA VIVAGEL BV**

### **[STARPHARMA](#)**

Starpharma says the US Food and Drug Administration has requested “confirmatory clinical data” for regulatory approval of Vivagel BV for bacterial vaginosis.

Starpharma said it planned to meet with the US FDA “as soon as possible” to discuss the clinical data required for approval and it was discussing regulatory steps with its US partner ITF Pharma.

## **Friday December 28, 2018**

## **PRANA RAISES \$44.6m FROM LIFE BIOSCIENCES, INVESTORS**

### **[PRANA BIOTECHNOLOGY](#)**

Prana says that Life Biosciences has agreed to invest up to \$US29.4 million (\$A41.8 million) and that it expected to raise a further \$US2 million (\$A2.8 million).

Prana said that the Boston, Massachusetts-based Life Biosciences would initially invest \$US7.5 million (\$A10.6 million), after which Prana would raise an additional US\$2 million from other investors.

The company said a further amount of up to \$US21.9 million (\$A31.1 million) would be invested by Life Biosciences and other investors on the exercise of short-term warrants being issued as part of the transaction, giving a total of approximately \$US31.4 million (\$A44.6 million) in investments.

Prana chief executive officer Geoffrey Kempler said the funds would “potentially allow us to accelerate our drug development programs”.

## **Monday December 31, 2018**

## **LANSTEAD REDUCES BELOW 5% IN NEUREN**

### **[NEUREN PHARMACEUTICALS](#)**

Lanstead Capital says it has ceased its substantial shareholding in Neuren, reducing its holding by 4,337,509 shares.

The London-based Lanstead said it sold shares on and off market between May 17 and December 27, 2018 with the single largest sale of 4,164,223 shares for \$5,829,912, or \$1.40 a share.

**Wednesday January 2, 2019**

**GI DYNAMICS EXTENDS \$6.6m CRYSTAL AMBER LOAN**

[GI DYNAMICS](#)

GI Dynamics says it will extend the maturity date of its 2017 senior secured convertible promissory note with Crystal Amber Fund from December 31, 2018 to March 31, 2019. GI Dynamics said that in June last year it first announced the \$US5,000,000 (\$A6,595,767) convertible note financing with major shareholder Crystal Amber Fund for working capital for 2017 (BD: Jun 16, 2017).

Today, the company said that without the extension of the maturity date all outstanding principal and interest was due and payable to Crystal Amber on December 31, 2018. GI Dynamics said that it did not currently have sufficient cash reserves to repay the total amount outstanding under the note.

The company said that in exchange for the extension of the maturity date it had agreed to pay by January 7, 2019 to all outstanding interest that had accrued until December 31, 2018 totalling \$US393,836 (\$A561,279).

**RESAPP SUBMITS CE MARK TECH FILE FOR SMARTPHONE DIAGNOSTIC**

[RESAPP HEALTH](#)

Resapp says it has submitted a CE Mark technical file for its mobile telephone application for respiratory illnesses diagnosis to the British Standards Institution. Resapp said it planned to file a de-novo pre-market submission for its smartphone application with the US Food and Drug Administration by April, 2019.

**JAPAN APPROVES STARPHARMA VIVAGEL CONDOM**

[STARPHARMA](#)

Starpharma says the Japan Pharmaceuticals and Medical Devices Agency has approved the Vivagel-coated condom.

Starpharma said its Japan partner, the Tokyo-based Okamoto Industries had begun "key launch preparations" to launch the Vivagel condom by July, 2019.

**TOTAL BRAIN RELEASES 474k SHARES FROM ESCROW**

[TOTAL BRAIN \(FORMERLY BRAIN RESOURCE\)](#)

Total Brain says 474,000 shares will be released from ASX escrow on January 17, 2019.

**CRESO 'TAKES ADVANTAGE' OF ISRAELI MARIJUANA EXPORT RULES**

[CRESO PHARMA](#)

Creso says it will "take advantage" of the Israeli Parliament's agreement to allow the export of medicinal cannabis from Israel.

**Thursday January 3, 2019**

**IMMURON RECEIVES \$1.19m FEDERAL R&D TAX INCENTIVE**

[IMMURON](#)

Immuron says it has received \$1.19 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Immuron said that the tax incentive was for research and development programs for the year to June 30, 2018.



## **RESONANCE LICENCES WISCONSIN FAT-DISEASES PATENTS**

### **[RESONANCE HEALTH](#)**

Resonance says it has licenced patents owned by the Wisconsin Alumni Research Foundation for the diagnosis and management of fat-related diseases.

Resonance said the agreement would give the company the rights to use the patents to develop and commercialize new and alternative methods for measuring proton density fat fraction (PDFF) from magnetic resonance images.

The company said the commercial terms were confidential but it would pay the Foundation an annual licence fee, by December 31 each year.

**Friday January 4, 2019**

## **BIONOMICS PHASE II BNC105 COMBINATION CANCER TRIAL UNDERWAY**

### **[BIONOMICS](#)**

Bionomics says that last September, it began a 90-patient phase II trial of BNC105 in combination with nivolumab for metastatic colorectal cancer.

Bionomics said that the Australasian Gastro-Intestinal Trials Group would conduct the trial, supported by nivolumab owner Bristol-Myers Squibb.

The company said 45 patients would receive BNC105 and the programmed cell death-1 (PD-1) inhibitor nivolumab and a second group of 45 patients would receive nivolumab in combination with a signal activator of transcription (STAT3) inhibitor.

Bionomics said the first patient visit was conducted on September 21, 2018.

## **LEIGH ELKOLLI REPLACES REVA CFO, CO SEC BRANDI ROBERTS**

### **[REVA MEDICAL](#)**

Reva says it has appointed Leigh Elkolli as company secretary and chief financial officer, replacing Brandi Roberts, who was appointed in August 2017.

## **GI DYNAMICS APPOINTS STEPHEN LINHARES CLINICAL, REGULATORY HEAD**

### **[GI DYNAMICS](#)**

GI Dynamics says it has appointed Stephen Linhares as its head of clinical and regulatory affairs.

**Monday January 7, 2019**

## **AUSTRALIA ACCEPTS CYNATA STEM CELL PATENT APPLICATION**

### **[CYNATA THERAPEUTICS](#)**

Cynata says that IP (Intellectual Property) Australia has accepted its patent application covering its Cymerus mesenchymal stem cell technology.

Cynata said the patent, titled 'Methods and materials for haemato-endothelial differentiation of human pluripotent stem cells under defined conditions' was owned by the University of Wisconsin-Madison's Wisconsin Alumni Research Foundation and was expected to provide coverage until March 12, 2034.

## **MESOBLAST PHASE III TRIAL COMPLETES RECRUITMENT**

### **[MESOBLAST](#)**

Mesoblast says it has completed recruitment of 570 patients for its phase III trial of Revascor, or MPC-150-IM, for advanced chronic heart failure.

## **STARPHARMA TELLS ASX: FDA DATA MATERIAL, JAPAN APPROVAL NOT STARPHARMA**

Starpharma has told the ASX aware that a US request for “confirmatory clinical data” is material but Japan approval of its Vivagel condom is not material.

The ASX said that Starpharma announced the US Food and Drug Administration data request on Thursday December 27, 2018 and the share price fell 29.6 percent from \$1.44 to 99 cents.

The ASX said that chairman Robert Thomas, chief executive officer Dr Jackie Fairley and director Peter Turvey bought shares on that day and on Monday December 31, 2018 the company’s share price rose from \$1.00 to \$1.19.

The ASX said that following the New Year’s Day holiday, on Wednesday January 2, 2019 Starpharma announced the approval of the Vivagel-coated condom in Japan and the share price fell from \$1.19 to \$1.06.

The ASX asked a series of question relating to when the company became aware of the information in the announcements, whether they were material, and whether the directors were compliant with prohibitions on trading securities while in possession of inside information or price sensitive information.

Starpharma told the ASX the FDA announcement was material, but did not say whether a “confirmatory clinical data” meant a new trial of Vivagel BV.

The company said that the Japan condom approval was “not a material part of Starpharma’s business ... [with] the incremental revenue from the Japanese Vivagel condom market opportunity ... not expected to be material in the context of anticipated revenues from the [dendrimer-enhanced product] platform and Vivagel BV product”.

Starpharma said the approval required translation and was received after the market closed on December 28, 2018 “subsequent to the trading by directors on the day”.

## **NUHEARA LAUNCHES IQBUDS MAX**

### **NUHEARA**

Nuheara says it has launched Iqbuds Max, tripling the hearing capability using three microphones in each ear, with five times the processing power.

Nuheara said Iqbuds Max would become its flagship product.

## **IMUGENE APPOINTS PROF MICHAEL CALIGIURI SCIENTIFIC ADVISOR**

### **IMUGENE**

Imugene says it has appointed Prof Michael Caligiuri to its scientific advisory board.

Imugene said Prof Caligiuri was the president of the City of Hope National Medical Center in Los Angeles.

## **IMMUTEP \$6m COLLABORATION WITH CYTLIMIC**

### **IMMUTEP**

Immutep says Cytlimic will pay up to \$US5 million (\$A6.3 million) to trial its IMP321 with Cytlimic’s CYT001 cancer peptide vaccine.

Immutep said Cytlimic was a subsidiary of the Tokyo, Japan-based NEC Corp.

## **REVA EXPANDS INTO SEVEN EUROPEAN COUNTRIES**

### **REVA MEDICAL**

Reva says it has four new distribution partnerships to cover commercial operations in seven European countries.

Reva said it would expand commercial distribution into the Czech Republic, Slovakia, Poland, Russia, Lithuania, Estonia and Latvia.

## **CRESO TO DISTRIBUTE MEDICAL MARIJUANA IN SRI LANKA**

### [CRESO PHARMA](#)

Creso says it has signed a letter of intent with Ceyoka Health to distribute medical marijuana in Colombo, Sri Lanka.

## **FIL REDUCES TO 6.5% IN IMPEDIMED**

### [IMPEDIMED](#)

Impedimed says FIL Limited has reduced its substantial shareholding in the company, from 28,013,479 shares (7.46%) to 24,443,264 shares (6.45%).

## **POLYNOVO: H1 NOVOSORB BTM SALES UP 320%**

### [POLYNOVO](#)

Polynovo says sales of its Novosorb biodegradable temporizing matrix for the six months to December 31, 2018 are up 319.5 percent compared to the prior corresponding period.

**Tuesday January 8, 2019**

## **PATRY'S RECEIVES \$556k R&D TAX INCENTIVE**

### [PATRY'S](#)

Patry's says it has received \$556,129 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Patry's said that the tax incentive was for research and development programs for the year to June 30, 2018.

## **TELEX: HUIJ591 DATA SUPPORTS PHASE III PROSTATE CANCER TRIAL**

### [TELEX PHARMACEUTICALS](#)

Telex says further analysis of previous data supports a phase III trial of the monoclonal antibody HuJ591 for prostate cancer.

The company said it had high-level data from several academic phase I and phase II studies, but much of the clinical data remained undisclosed.

## **AVITA US LAUNCH OF RECELL SYSTEM**

### [AVITA MEDICAL](#)

Avita says it has begun the US launch of its Recell spray-on-skin for the treatment of acute burns in patients 18 years or older.

Avita said it had been training staff in support of the launch of the Recell system.

The company described Recell as an "autologous cell harvesting device".

## **ELIXINOL CFO RON DUFFICY TO US, KIM BRADLEY-WARE CO SEC**

### [ELIXINOL GLOBAL](#)

Elixinol says chief financial officer and company secretary Ron Dufficy will relocate to the US, with the Sydney-based Kim Bradley-Ware appointed joint company secretary.

## **OVENTUS LAUNCHES NYLON O2VENT OPTIMA FOR SLEEP APNOEA**

### [OVENTUS MEDICAL](#)

Oventus says it has developed a nylon version of its O2Vent Optima oral device for the treatment of sleep apnoea.

Oventus said it will be lighter and cheaper than the original titanium O2Vent.

## **ITL HEALTH VOTES TO QUIT ASX**

### [ITL HEALTH GROUP](#)

ITL says its extraordinary general meeting overwhelmingly passed resolutions for an on-market buyback and to delist from the ASX.

ITL said it expected to delist about February 8, 2019.

## **MMJ APPOINTS MICHAEL CURTIS DIRECTOR**

### [MMJ GROUP](#)

MMJ says it has appointed the Toronto Canada-based Michael Curtis as a non-executive director, effective immediately.

## **ZELDA PLEADS SCHULTZ TO ASX 20% QUERY**

### [ZELDA THERAPEUTICS](#)

Zelda 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 20.0 percent from 5.5 cents on January 7 to 6.6 cents on January 8, 2019 and noted a significant increase in trading volume.

**Wednesday January 9, 2019**

## **MEDLAB: 'NANOSTAT IMPROVES ATORVASTATIN'**

### [MEDLAB CLINICAL](#)

Medlab says its Nanocelle version of atorvastatin, Nanostat, is a "significant improvement" over atorvastatin tablets for lowering cholesterol drug.

Medlab said the preliminary results from the bioequivalence trial showed Nanostat orobuccal spray showed a two or more times better blood level of free atorvastatin in about 30 minutes, compared to the 20mg oral tablet of Atorvastatin after 53 minutes.

## **NUHEARA LAUNCHES IQSTORE SERVICES SOFTWARE**

### [NUHEARA](#)

Nuheara says it has launched Iqstore, a subscription-based hearing services application for hearing healthcare.

Nuheara said it launched two featured applications, Soundscape for sleep support and tinnitus masking, and Autocros for unilateral hearing difficulties.

## **JENCAY CAPITAL TAKES 8% OF UNIVERSAL BIOSENSORS**

### [UNIVERSAL BIOSENSORS](#)

Sydney's Jencay Capital Pty Ltd says it has increased its holding in Universal Biosensors from 13,061,444 shares (7.39%) to 14,925,509 shares (8.44%).

The notice, signed by director Brett Rock, said that between November 29, 2018 and January 4, 2019 Jencay acquired 1,864,065 shares for \$431,795 or 23.2 cents a share.

## **CRESO, MEDLEAF PARTNER FOR NZ MEDICAL MARIJUANA**

### [CRESO PHARMA](#)

Creso says it will partner with Medleaf Ltd to build a comprehensive medical marijuana business, expanding the range of products offered in New Zealand.

## **CANCER TRIALS JOINS SHAREROOT'S MEDIA CONSENT**

### **[SHAREROOT](#)**

Shareroot says that Cancer Trials Australia will work with the Media Consent project rights management software program.

Social Science founder Michelle Gallagher told Biotech Daily that Shareroot acquired her communications company last year and the Media Consent project aimed "to give researchers access to real world data and real-world evidence".

Ms Gallagher said that regulators, biotechnology and pharmaceutical companies were "increasingly interested in accessing [the data] in a compliant manner".

**Thursday January 10, 2019**

## **FDA: JULY 8 PDUFA DATE FOR CLINUVEL'S SCENESSE FOR EPP**

### **[CLINUVEL PHARMACEUTICALS](#)**

Clinuvel says the US Food and Drug Administration has set July 8, 2019 as the Prescription Drug User Fee Act (PDUFA) date for a decision on Scenesse for the prevention of phototoxicity and anaphylactoid reactions in adult patients with erythropoietic protoporphyria.

## **NIV DAGAN, FREEDOM TRADER TAKE 5.5% OF LIFESPOT**

### **[LIFESPOT HEALTH](#)**

Niv Dagan and Freedom Trader Pty Ltd say they have become substantial shareholders in Lifespot Health with 4,241,719 shares (5.47%).

In a substantial shareholder notice signed by Freedom Trader director Niv Dagan, the company said it bought 600,000 shares between December 12 and 14, 2018 for \$38,300 or 6.4 cents a share.

## **INVITROCUE APPOINTS DR STEVEN FANG CHAIRMAN**

### **[INVITROCUE](#)**

Invitrocue says it has appointed executive director Dr Steven Fang as chair, replacing Jamie Khoo Gee Choo, director Koh Chow Yee resigning from the board.

Invitrocue said Ms Choo would continue as a non-executive director and Mr Koh would continue as company secretary.

## **NUHEARA LAUNCHES IQCONNECT**

### **[NUHEARA](#)**

Nuheara says it has launched Iqconnect, a "hearing screening kiosk" in shops, as well as a customer relationship management platform to monitor customer hearing health.

Nuheara said Iqconnect would offer two-minute in-store screening hearing tests, determining whether customers have good, moderate or mild hearing loss.

**Friday January 11, 2019**

## **INVITROCUE APPOINTS PROF MASAKAZU TOI CLINICAL ADVISOR**

### **[INVITROCUE](#)**

Invitrocue says it has appointed Prof Masakazu Toi as a clinical advisor.

Invitrocue said Prof Toi was a Professor of the Graduate School of Medicine at Kyoto University.

## **MEMPHASYS: UNI OF FLORENCE, ISFAHAN CLINIC TEST FELIX**

### **[MEMPHASYS](#)**

Memphasys says that Italy's University of Florence in Italy and the Iran-based Isfahan Fertility and Infertility Clinic will assess its Felix sperm separation device.

**Monday January 14, 2019**

## **FEDERAL \$25m FOR WEHI DRUG DISCOVERY CENTRE**

### **[FEDERAL GOVERNMENT, WALTER AND ELIZA HALL INSTITUTE](#)**

The Federal Government says it will provide \$25 million for a new national Drug Discovery Centre at the Walter and Eliza Hall Institute of Medical Research.

A media release from Health Minister Greg Hunt said the Centre "aims to turn scientific discoveries into new medicines faster" with the help of advanced robotics equipment and would open in June 2019, with funds from philanthropic support and \$32.1 million from the sale of royalty rights for the venetoclax anti-cancer treatment.

## **MESOBLAST TAKES \$21m FROM HERCULES CREDIT FACILITY**

### **[MESOBLAST](#)**

Mesoblast says it has drawn a further \$US15 million (\$A20.8 million) from its \$US75 million (\$A103.9 million) Hercules Capital credit facility.

Last year, Mesoblast said it drew \$US35 million of the facility when it was established (BD: Mar 7, 2018).

## **FIL TAKES 5% OF STARPHARMA**

### **[STARPHARMA HOLDINGS LIMITED](#)**

FIL Limited says it has become a substantial shareholder in Starpharma with 18,729,813 shares or 5.04 percent of the company.

FIL said that between October 10, 2018 and January 9, 2019, it acquired 1,134,789 shares at prices ranging from \$1.12 to \$1.56.

## **ZELDA DIRECTOR JASON PETERSON TRANSFERS, REDUCES TO 9.6%**

### **[ZELDA THERAPEUTICS](#)**

Zelda director Jason Peterson says he has reduced his substantial shareholding in the company from 80,292,388 shares (10.64%) to 72,207,773 shares (9.56%).

The substantial shareholder notice said he transferred and sold shares off-market including 1,642,105 shares off-market for \$78,821 or 4.8 cents a share.

## **ANATARA RECEIVES \$1.25m R&D TAX INCENTIVE**

### **[ANATARA LIFESCIENCES](#)**

Anatara says it has received \$1,249,299 from the Australian Taxation Office under the Federal Government Research & Development Tax Incentive program.

Anatara said that the funds were for expenditure to the year to June 30, 2018.

## **CEO RICHARD HANNEBERY TAKES 13.4% OF GENERA**

### **[GENERA BIOSYSTEMS](#)**

Genera chief executive officer Richard Hannebery says he has increased his holding from 11,827,755 shares (11.01%) to 14,709,519 shares (13.37%).

Mr Hannebery said that on January 11, 2019, he acquired 2,595,577 loan shares for \$337,425 or 12.9 cents a share.

## **MEMPHASYS: BOSTON IVF, UNIVERSITY OF MUNSTER TEST FELIX**

### [MEMPHASYS](#)

Memphasys says Boston IVF and the German University of Munster's Centre of Reproductive Medicine and Andrology will assess its Felix sperm separation device.

## **PHARMAUST: 'MONEPANTEL SHOWS ANTI-CANCER ACTIVITY'**

### [PHARMAUST](#)

Pharmaust says its monepantel major metabolite, monepantel sulfone, has shown anti-cancer activity and had little effect on non-cancer cells.

Pharmaust did not disclose whether the study was in-vivo or in-vitro.

**Tuesday January 15, 2019**

## **CARDIEX, ANTHEM TO CO-MARKET INHEALTH**

### [CARDIEX](#)

Cardiex says it has a co-marketing agreement with the Indianapolis, Indiana-based health insurer Anthem Inc to co-promote its Inhealth tele-health services and plans.

## **IMMURON OFFERS WARRANTS OVER 701.5k US SHARES**

### [IMMURON](#)

Immuron says it has issued a US Securities and Exchange Commission document offering warrants or options over 701,500 American depository shares (ADSs).

Immuron said the warrants were exercisable at \$US10 each (\$A13.84) by June 13, 2022, five years from their first issue and each ADS represented 40 Australian shares, or 28,060,000 Australian shares if exercised

## **RESONANCE: ENVOYAI TO DISTRIBUTE FERRISMART IN US**

### [RESONANCE HEALTH](#)

Resonance says the Durham, North Carolina-based Envoyai Inc will distribute its Ferrismart magnetic resonance imaging liver-iron concentration diagnostic.

## **KAZIA RECEIVES \$2.2m R&D TAX INCENTIVE**

### [KAZIA THERAPEUTICS](#)

Kazia says it has received \$2,191,258 from the Australian Taxation Office under the Federal Government Research & Development Tax Incentive program.

Kazia said that the funds were for expenditure for the year to June 30, 2018.

## **PRESCIENT RECEIVES \$939k R&D TAX INCENTIVE**

### [PRESCIENT THERAPEUTICS](#)

Prescient says it has received \$939,423 from the Australian Taxation Office under the Federal Government Research & Development Tax Incentive program.

Prescient said that the funds were for expenditure for the year to June 30, 2018.

## **MARK FORTUGNO REPLACES THC CFO JARROD WHITE**

### [THC GLOBAL \(FORMERLY THE HYDROPONICS COMPANY\)](#)

THC says it has appointed Mark Fortugno as chief financial officer, replacing Jarrod White.

**Wednesday January 16, 2019**

**INVION: LYNDA SPELMAN, LOUIS IRVING, NATHAN LAWRENSTCHUK ADVISORS**

[INVION](#)

Invion says it has appointed Dr Lynda Spelman, Prof Louis Irving and Prof Nathan Lawrenstchuk to its scientific advisory board.

**PAINCHEK WORKS WITH ALLITY AGED CARE, WARD MEDICATION**

[PAINCHEK](#)

Painchek says it will work with Melbourne's Allity Aged Care and Ward Medication Management on its facial recognition technology for aged care pain management.

**INVITROCUE APPOINTS PROF JESÚS GARCÍA-FONCILLAS CLINICAL ADVISOR**

[INVITROCUE](#)

Invitrocue says it has appointed Prof Jesús García-Foncillas as a clinical advisor.

**IMPEDIMED SIGNS ASCENSION FOR SOZO**

[IMPEDIMED](#)

Impedimed says it has a multi-year purchasing agreement with US Catholic health system Ascension Health Resources, for its Sozo digital health platform.

Impedimed said Ascension was "the largest non-profit health system in the US".

**Thursday January 17, 2019**

**PHARMAXIS READY FOR PHASE II LOXL2 TRIALS**

[PHARMAXIS](#)

Pharmaxis says following toxicity studies, it is ready to begin a phase II trials of its two lysyl oxidase like 2 (LOXL2) inhibitors for fibrotic diseases.

Pharmaxis said it was ready for phase II trials for indications such as non-alcoholic steato-hepatitis, cardiac fibrosis and idiopathic pulmonary fibrosis.

**PHOSPHAGENICS, FDA DISCUSS TPM-OXYMORPHONE PATH**

[PHOSPHAGENICS](#)

Phosphagenics says the US Food and Drug Administration has provided guidance on approval of its three-day tocopheryl phosphate mixture (TPM)-oxymorphone patch.

Phosphagenics said it the FDA required a "safety database of at least 750 patients".

**EMA APPROVES MEDLAB SME QUALIFICATION**

[MEDLAB CLINICAL](#)

Medlab says it has received formal small to middle size enterprise qualification from the European Medicines Agency for drug registration and approval.

Medlab chief executive officer Sean Hall said "this qualification allows us to start the process into Europe".

**GENERA RECEIVES \$438k R&D TAX INCENTIVE**

[GENERA BIOSYSTEMS](#)

Genera says it has received \$438,087 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.

Genera said that the funds were for the year to June 30, 2018.



## **ANTEO WORKS WITH SONA NANOTECH, ELLUME**

### **[ANTEO DIAGNOSTICS](#)**

Anteo says it will collaborate with the Halifax, Nova Scotia-based Sona Nanotech to develop products to improve the performance of lateral flow immunoassays. Anteo said that Brisbane-based collaborator Ellume had projects using its Anteobind molecular glue with London's Glaxosmithkline for respiratory care and the Venlo, Netherlands-based Qiagen NV for tuberculosis.

## **ESENSE-LAB SHIPS 2L CANNABIDIOL VAPE PRODUCT TO E-QUITS**

### **[ESENSE-LAB](#)**

Esense-Lab says it has shipped two litres of its cannabidiol infused terpene vaping product to the Equits group.

**Friday January 18, 2019**

## **MALAYSIA APPROVES POLYNOVO BTM; BUYS PRODUCTION FACILITY**

### **[POLYNOVO](#)**

Polynovo says Malaysia has approved its Novosorb biodegradable temporizing matrix (BTM) wound treatment and it has bought an adjoining facility to expand production.

## **CARDIEX TELLS ASX: 'JANUARY 5 ANTHEM NEWS PUBLISHED JANUARY 15'**

### **[CARDIEX](#)**

Cardiex has told the ASX that its subsidiary Inhealth told it of an agreement with Anthem Inc on Saturday January 5 and published it on Tuesday January 15, 2019. The ASX said the announcement, titled 'Cardiex's Inhealth executes major co-marketing agreement [with Anthem]' was released at 9:30am on January 15, 2019 and asked the company if the co-marketing agreement would be information that a reasonable person would expect to have a material effect on the price or value of its securities and if so "when did CDX first become aware of the information"?

Cardiex said it believed the information would be material and it first became aware of the decision on January 5, 2019.

The company said that it believed that it "required approval from Inhealth for such announcement".

"Authority to announce was delayed due to the hospitalization of Inhealth's CEO Aubrey Jenkin's [sic] over early January and the availability of other executives due to travel schedules and the holiday period generally," Cardiex said.

"[An] announcement was immediately made on January 15 prior to market opening," the company said.

In December, Cardiex said it had raised \$5.5 million at three cents a share to acquire the Los Angeles-based Inhealth Medical Services (BD: Dec 6, 2018).

In October, Cardiex said it would pay more than \$4.6 million for up to 50.5 percent of Inhealth for its "health coaching and Telehealth services" (BD: Oct 16, 2018).

## **INVITROCUE ROLLS-OUT ONCO-PDO SCREENING GERMANY**

### **[INVITROCUE](#)**

Invitrocue says it has begun the German roll-out of its cancer patient-derived organoid (Onco-PDO) personalized screening, through Munich's Systasy Bioscience GmbH.

## **ANTISENSE: ATL1102 FOR DMD TRIAL RECRUITMENT HALF-WAY**

### **[ANTISENSE THERAPEUTICS](#)**

Antisense says it has recruited five of the expected nine patients in its phase II trial of ATL1102 for Duchenne muscular dystrophy.

Antisense said that no serious adverse events had been reported to date.

## **BIOXYNE LOSES DIRECTOR MAXWELL PARKIN**

### **[BIOXYNE](#)**

Bioxyne says director Maxwell Parkin resigned, effective from January 17, 2019.

## **AUSCANN TO RELEASE 133m ASX ESCROW SHARES**

### **[AUSCANN GROUP](#)**

Auscann says it will release 132,707,146 shares and 7,827,639 unquoted options from ASX escrow on February 3, 2019.

According to the company's most recent Appendix 3B new share issue announcement, following the release from escrow, Auscann would have a total of 309,089,848 shares available for trading.