Biotech Daily

Wednesday November 22, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRIMA UP 9%; BIONOMICS DOWN 7%**

*** SPAIN REIMBURSES SIRTEX SIR-SPHERES**

*** PRO MEDICUS ADDS ARTIFICIAL INTELLIGENCE TO VISAGE 7 IMAGING**

*** INDIA OKAYS ADMEDUS CARDIOCEL; SYNCRONEI DISTRIBUTOR**

*** STUDY BACKS USCOM BP+**

*** EUROPEAN PATENT FOR PRIMA'S IMP321**

*** MMJ TO RAISE $21m, LEASE FOR 35 TONNES MARIJUANA BUDS**

*** MEMPHASYS RIGHTS, NOTES, PLACEMENT FOR $3.75m**

*** CRYOSITE CORD BLOOD CLOSURE TO COST $1m, H1 PROFIT WARNING**

*** CORRECTION: RECCE**

*** AUSCANN DAYACANN WINS 2nd CHILE MARIJUANA GROWING**

*** MGC TO SUPPLY MARIJUANA EXTRACT TO MACEDONIA'S MABSUT LIFE**

*** KAZIA (NOVOGEN) 'IP LEGAL DISCUSSIONS WITH DR GRAHAM KELLY'**

*** CRESO APPOINTS HEALTH HOUSE CANNAQIX 50 DISTRIBUTOR**

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

*** DR YACOV GEVA DILUTED TO 58% IN G MEDICAL**

*** IDT: ALAN FISHER CHAIR, GRAEME KAUFMAN EXEC DIRECTOR**

*** MEDIGARD APPOINTS DR IAN DIXON EXECUTIVE DIRECTOR ON $240k**

*** PROTEOMICS APPOINTS PAUL HOUSE DIRECTOR; US, JAPAN CONSULTANTS**

MARKET REPORT

The Australian stock market was up 0.38 percent on Wednesday November 22, 2017, with the ASX200 up 22.9 points to 5,986.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell and eight traded unchanged.

Prima was the best, up 0.2 cents or 8.7 percent to 2.5 cents with 5.0 million shares traded. Actinogen and Admedus climbed more than seven percent; Avita, Benitec, Orthocell and Pro Medicus improved more than five percent; Psivida was up 3.9 percent; Cyclopharm rose 2.6 percent; with Compumedics, Medical Developments, Osprey and Volpara up more than one percent.

Bionomics led the falls, down three cents or 7.3 percent to 38 cents, with 2.6 million shares traded. Cellmid, Living Cell and Reva lost five percent or more; Factor Therapeutics fell four percent; Dimerix, LBT, Nanosonics, Neuren and Uscom were down more than three percent; Impedimed, Opthea, Starpharma and Universal Biosensors shed more than two percent; with Airxpanders down 1.4 percent.

SIRTEX MEDICAL

Sirtex says Spain has included selective internal radiation therapy with SIR-Spheres in its Basic Portfolio of Services, allowing reimbursement by hospitals and regions.

Sirtex said that the Spanish Ministry of Health, Social Services and Equality included SIR-Spheres yttrium-90 resin microspheres in the Portfolio and the Ministry's evaluation agency said that SIR-Spheres had "shown therapeutic effectiveness and safety in patients with hepatic metastases from colorectal cancer, refractory or intolerant to other treatments".

Sirtex chief executive officer Andrew McLean said the company was "delighted to receive this product specific reimbursement in Spain, with similar pricing structures to other more established European markets".

"This is the second Western European market after France earlier this year to grant national reimbursement specifically for Sirtex's SIR-Spheres Y-90 resin microspheres only," Mr McLean said.

"Although SIR-Spheres microspheres are available across a small number of treatment centres in Spain, to date funding for the product has been sporadic and determined at the hospital level, or for self-pay patients only," Mr McLean said.

"With this new national reimbursement in place, we expect an acceleration in dose sales growth in this market, commencing [in early 2018]," Mr McLean said.

"Accordingly, we will … expand the number of treatment centres certified to use our product, coupled with increased sales and marketing activity to drive new referrals for treatment under this reimbursement to eligible [metastatic colorectal cancer] patients," Mr McLean said.

Sirtex said the incidence of colorectal cancer in Spain was about 32,000 cases in 2012 and it was the country's second most common cause of cancer mortality, accounting for approximately 15,000 deaths each year.

The company said that the Instituto Nacional de la Salud (the Spanish national healthcare system) provided universal healthcare coverage to all Spanish nationals, with close to 100 percent population coverage.

Sirtex was up seven cents or 0.5 percent to $13.89 with 252,896 shares traded.

PRO MEDICUS

Pro Medicus says it has integrated artificial intelligence into its Visage 7 Enterprise Imaging system.

Pro Medicus said its Visage 7 medical imaging platform was the only platform that combined artificial intelligence research and artificial intelligence assisted diagnostic imaging in one system.

The company said that Visage 7 had the capability to provide radiologists with faster access to multi-dimensional images, improving productivity and clinical accuracy and US subsidiary Visage Imaging would launch the system at the Radiological Society of North America meeting in Illinois, Chicago on November 26 to 30, 2017, with the first of its Visage 7 artificial intelligence systems scheduled to be released by July 2018.

Pro Medicus chief executive officer Dr Sam Hupert said that artificial intelligence was "evolving rapidly and has the potential to transform health imaging in ways previously not imagined".

"We are well placed to capitalize on this transformation as we look to leverage our three key assets, namely our [research and development] capability, our technology platform and our growing base of blue chip clients," Dr Hupert said.

Pro Medicus was up 38 cents or 5.25 percent to $7.62 with 196,914 shares traded.

ADMEDUS

Admedus says that India has approved the launch of its Adapt treat bovine cardiac tissue Cardiocel, with Syncronei Medical India Pvt Ltd appointed its distributor.
Admedus said that Syncronei Medical would manage all Cardiocell sales, marketing and distribution.
The company said that India had about 50 million cardiac patients and 28 million births a year with about 280,000 babies born with a congenital heart defect.
Admedus chief executive officer Wayne Paterson said that “providing life-changing outcomes for these patients and their families is the purpose of Cardiocel”.
Admedus was up two cents or 7.4 percent to 29 cents with 2.4 million shares traded.

USCOM

Uscom says a study has shown its BP+ central blood pressure monitor detected significant changes in blood pressure which a leading competing device did not.
Uscom said that seven universities in Austria, England, New Zealand and the United States conducted a 517-patient, double-blind, placebo-controlled study on the use of vitamin D treatment for hypertension.
The company said the study showed that the Uscom BP+ identified significant changes in central systolic blood pressure ($p = 0.03$) over the course of treatment, while a leading competitor detected changes in brachial systolic blood pressure but did not achieve statistical significance ($p = 0.11$) over the course of treatment.
The study, entitled ‘Effect of Monthly, High-Dose, Long-Term Vitamin D Supplementation on Central Blood Pressure Parameters: A Randomized Controlled Trial Substudy’ was published in the Journal of the American Heart Association.
An abstract is at: https://www.ncbi.nlm.nih.gov/pubmed/29066444.
Uscom executive chairman Prof Rob Phillips said the evidence was “exciting” and came from “some of the most influential academics in the global hypertension field, indicating the Uscom BP+ is more effective for detecting the [blood pressure] changes associated with treatment benefits than a conventional device from the current leading manufacturer”.
“The authors also recommended the routine adoption of Uscom BP+ central [blood pressure] measures in future hypertension trials,” Prof Phillips said.
Uscom fell half a cent or 3.1 percent to 15.5 cents.

PRIMA BIOMED

Prima says it has been granted a European patent covering its IMP321, formally known as LAG-3Ig and to be known as eftilagimod alpha.
Prima said that the patent, entitled ‘Use of Recombinant LAG-3 or the Derivatives thereof for Eliciting Monocyte Immune Response’ would provide intellectual property protection until October 3, 2028 and was filed as a divisional patent with the European Patent Office and followed the grant of the European parent patent, which was issued in August 2013.
The company said that the patent claims targeted the use of IMP321 in combination with a chemotherapeutic agent for the treatment of cancer.
Prima said that according to the patent claims IMP321 elicited a monocyte-mediated immune response and was administered before, with, or subsequent to administration of the chemotherapeutic agent.
The company said that the granted claims supported the application of IMP321 in its European metastatic breast cancer trial.
Prima was up 0.2 cents or 8.7 percent to 2.5 cents with 5.0 million shares traded.

MMJ PHYTOTECH

MMJ says that subsidiary Harvest One Cannabis hopes to raise up to $C20,125,000 ($A20,785,010)and lease a property to 35,000kg of dried marijuana buds a year.
MMJ said that the funds raised through the issue of 17,500 convertible debenture units at $C1,000 each would be used by its 59 percent Harvest One for working capital and general corporate purposes.
The company said that Mackie Research Capital Corp would be the lead underwriter and sole book-runner for a syndicate of underwriters, with the right to offer up to an additional 2,625 debenture units.
MMJ said the debentures would carry an interest rate of eight percent a year, to be paid twice yearly, convertible within five years at 84 cents a share and each $C1,000 debenture would come with 458 warrants exercisable at $C1.09 within 36 months.
The company said the offer was expected to close about December 11, 2017.
MMJ said that Harvest One wholly-owned subsidiary United Greeneries had a letter of intent with an unnamed third party for the lease of a property in Chemainus, British Columbia “to accelerate and expand production capacity”.
MMJ said the Chemainus facility was previously and industrial timber kiln-drying plant and was “extremely well-suited for a retrofit into a cannabis indoor cultivation facility”.
The company said that cultivation was expected to begin in 2018 with a capacity of about 8,000kg marijuana buds and a lease option on a further eight acres would take production to more than 35,000kg a year.
MMJ said the expansion was “fully funded with the company’s current cash balance”.
MMJ fell three cents or 5.5 percent to 51.5 cents with 7.3 million shares traded.

MEMPHASYS

Memphasys says it hopes to raise $3.75 million in a combination non-renounceable entitlement offer, convertible note issue and placement at 0.1 cents a share.
Memphasys said that subject to shareholder approval at an extraordinary general meeting on December 21, 2017, the raising would “significantly strengthen its balance sheet” as it developed its Felix sperm separation product for male infertility.
The company said that about $1.78 million of existing debt would be settled by the entitlement issue and placement.
Memphasys said that the placement was expected to raise $2.75 million, the entitlement issue about $700,000, and $300,000 from the convertible notes, which would be at no interest until December 31, 2017 then incurring a 20 percent premium and with one free option for every two shares converted, exercisable at 0.2 cents within two years.
The company said that the record date for the one-for-one entitlement issue would be November 28, the offer would open on December 1 and close on December 15, 2017.
Memphasys said that Patersons Securities was the lead manager to the raising.
Memphasys executive chairman Alison Coutts said the capital raising would enable the company “to significantly advance the development of its program for the Felix device for human [in-vitro fertilization]”.
“Together with our partners at the University of Newcastle, we are currently fine-tuning operating parameters for the current Felix re-usable prototype cartridge,” Ms Coutts said.
“We are poised to carry out further tests in a clinical [in-vitro fertilization] setting at [the University of New South Wales] over the next couple of months and are finalizing the design specification for the next generation clinical device for [in-vitro fertilization] centres which will use sterile single-use disposable cartridges,” Ms Coutts said.
Memphasys fell 0.05 cents or 20 percent to 0.2 cents.

CRYOSITE

Cryosite says that restructure costs of about $1 million will lead to “a substantial” loss for the six months to December 31, 2017.

Cryosite said the decision to cease its cord blood and tissue business incurred restructuring costs, and with assets write downs, legal fees and costs, the company would expend about $1 million in the six month period, and no interim dividend would be paid.

“The board’s decision to re-energize, refocus and reinvest in our remaining businesses of clinical trial logistics and bio-repository services will see them post a trading profit for the period,” Cryosite said.

The company said it had identified “significant opportunities to build on [its] expertize in long term cold, frozen and cryogenic storage, logistics and distribution through potential acquisitions and organic growth initiatives”.

Cryosite was untraded at 15 cents.

RECCE

Last night’s article on the Recce annual general meeting remuneration report second strike and board spill misreported the total number of shares in the company.

The figures on the board spill and remuneration report were correct, but the article quoted only the shares currently on issue on the ASX and missed 42,810,081 shares in escrow until January 15, 2018, further down the most recent Appendix 3B document.

The total number of Recce shares according to the Appendix 3B is 86,148,875, meaning that the largest dissenting vote, 4,035,644 votes, amounted to 4.7 percent of the company, not sufficient to requisition extraordinary general meetings, compared to the 9.3 percent incorrectly stated last night.

Biotech Daily apologizes for the error, which was made by a junior AGMs sub-editor confused by the numbers.

Recce fell one cent or 5.1 percent to 18.5 cents.

AUSCANN GROUP

Auscann says its Chilean joint venture Dayacann has secured a further licence for the cultivation of marijuana for medical purposes.

Auscann said that Chilean medical cannabis cultivation licences were awarded for a one year period the joint venture partner Fundacion Daya was the only company to be awarded the licence every year for the past four years.

The company said that Dayacann would begin planting crops immediately at its 30-hectare facility south of Santiago, Chile, with the harvest expected by July 2018.

Auscann said the licence followed the harvest of 400 plants earlier this year that provided a range of chemotypes to be used in initial trial formulations.

The company said that Dayacann was the only licenced producer in Chile, giving it a competitive advantage in a growing market whose patient demographics were similar to Australia.

Auscann said that Chile allowed the export of products once registered as medicines with the Chilean National Institute of Public Health and Dayacann was well-positioned to leverage the growing opportunity across Latin America, where medical cannabis was legal in Brazil, Argentina, Peru, Columbia, Uruguay, Panama, Puerto Rico and Mexico.

The company said it was focused on the production of final dose forms of cannabinoid medicines for chronic pain.

Auscann was up 13.5 cents or 18.2 percent to 87.5 cents with 5.8 million shares traded.

MGC PHARMACEUTICALS

MGC says it has a multi-year supply agreement with Skopje, Macedonia-based distributor Mabsut Life to supply cannabidiol extract from its European facility.
MGC said it would supply a specialized industrial-grade cannabidiol to Mabsut Life which would commercialize it through its own electronic cigarette brand and distributed throughout its sales network in Central and Eastern Europe.
The company said it would supply at least 12kg of extract every three months which would generate about $1 million in annual sales, about $83.33 a gram or $2,362 an ounce.
MGC said an initial purchase order for 2kg of extract had been placed by Mabsut Life, with an upfront payment of $US40,000 which it expected to receive within two weeks.
The company said the deal was for an initial two years and would automatically renew each year on mutual agreement.
MGC was up 0.6 cents or 6.4 percent to 10 cents with 100.3 million shares traded.

KAZIA THERAPEUTICS (FORMERLY NOVOGEN)

Kazia says it is in legal discussions on intellectual property with founder and former executive chairman Dr Graham Kelly and his new company Noxopharm.
Kazia said the announcement was to make a “clarification to shareholders” regarding a November 20, 2017 media report referring to Noxopharm and Dr Kelly.
The company said that the media report stated that Noxopharm's lead program NOX66 was designed by Dr Kelly when he was an employee of Novogen.
Kazia said that following that report it became “aware of speculation among certain of its shareholders regarding the company's intellectual property position”.
The company said that “protection of its intellectual property [is] among its highest responsibilities to shareholders and in this regard is in ongoing discussions with both Dr Kelly and Noxopharm through the parties' respective lawyers”.
“The matters under discussion with Noxopharm have no bearing on the intellectual property associated with the company's own development programs,” Kazia said.
Kazia was up 0.5 cents or 1.45 percent to 35 cents.

CRESO PHARMA

Creso says Perth-based Health House International will import and distribute its first cannabinoid-based human health product Cannaqix 50 in Australia from 2018.
Creso said that the prescription Cannaqix 50 would be available through the Therapeutic Goods Administration’s special access scheme.
The company said the Switzerland-produced Cannaqix 50 would be imported and distributed by Health House International to pharmacies across Australia.
Creso said Cannaqix 50 was a proprietary buccal, or cheek) formulation cannabidiol lozenge product was designed for chronic pain and each pack contained 30 tablets containing 50mg of cannabidiol, along with niacin, vitamins B6, B12, C and zinc in a standardized pharmaceutical-grade formulation.
Creso chief executive officer Dr Miri Halperin Wernli said the deal “cements our position in the Australian market and enhances our competitive position after being the first Australian company to import medicinal cannabis into Australia earlier this year”.
The company said that it was finalizing distribution agreements for other products from the Cannaqix range for Germany, the UK, Italy, Spain, Netherlands, Belgium, Sweden and Switzerland, Canada and Latin America.
Creso was up 10 cents or eight percent to $1.345 cents with 8.0 million shares traded.

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 30.0 percent from 9.0 cents to 11.7 cents on November 21, 2017 and noted a significant increase in trading volume.
Zelda said it was in discussions in relation to ethics approvals for planned trials and new collaborations, but no agreements have been completed and it did "not reasonably expect that this would explain the trading in the company's shares".
Zelda fell half a cent or 4.55 percent to 10.5 cents with 16.4 million shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical chief executive officer Dr Yacov Geva says his 193,469,154 shareholding in his company has been diluted from 63.43 percent to 57.51 percent.
Dr Geva said that the dilution followed last week's $13.5 million placement at 43 cents a share (BD: Nov 15, 2017).
G Medical fell one cent or 2.3 percent to 43 cents with 3.1 million shares traded.

IDT AUSTRALIA

IDT says that Alan Fisher will replace executive chairman Graeme Kaufman who will continue as an interim executive director.
IDT said that Mr Fisher had extensive business, corporate and finance experience as well as in operational restructuring and had been an IDT director since 2015.
IDT was untraded at 7.8 cents.

MEDIGARD

Medigard says it has appointed Dr Ian Dixon as an executive director starting on $240,000 a year, effective from November 21, 2017.
Medigard said it had conducted a review of business and technology opportunities and engaged with Dr Dixon and his private Altnia Group to broaden its research and development and commercialization activities while maintaining and expanding its syringe technology and strategic alliance with Sol-Millennium.
Medigard chairman Dr Chris Bishop said that Dr Dixon and Altnia had "a track record of building value in innovative medical-related products and technologies".
The company said that Dr Dixon was a non-executive director of Noxopharm and a major shareholder of its spin-out company Nyrada (BD: Sep 25, Nov 21, 2017).
Medigard said that Dr Dixon was a co-founder of Cynata Inc in 2011, which became Cynata Therapeutics.
Dr Dixon holds a Bachelor of Engineering and a Masters of Business Administration from Swinburne University and a Doctorate of Philosophy from Monash University.
"We have identified some significant opportunities in the syringe field and intend to move into higher-value products such as prefilled-syringes," Dr Dixon said.
Medigard said that Dr Dixon would be paid a base salary of $240,000 a year and, subject to shareholder approval, a sign-on incentive of 40,000,000 options exercisable at 10 cents within five years and 40,000,000 options exercisable at 20 cents within five years.
Medigard was up 1.6 cents or 114.3 percent to three cents.

PROTEOMICS INTERNATIONAL

Proteomics says that Paul House has been appointed as a non-executive director, effective immediately.

Proteomics said Mr House had 25 years of commercial and management experience most recently as certification company SGS India's managing-director.

The company said that Mr House previously held chief financial officer and chief operating officer roles.

Proteomics said that Neomark Ventures's Eric Button had been appointed as a US consultant and Phama BDL's Dr Masafumi Yoshimoto as a Japan consultant.

Proteomics fell 1.5 cents or 8.6 percent to 16 cents.