



Biotech Daily

Wednesday November 28, 2018

Daily news on ASX-listed biotechnology companies

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- * **DIMERIX TO EXPAND USE, LICENCE RECEPTOR-HIT PLATFORM**
- * **MACH7 REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **ADMEDUS ENDS 4-MONTH SUSPENSION TO RAISE \$20m; FALLS 57%**
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- * **GLENN GILBERT REPLACES RHYTHM CEO DR TREVOR LOCKETT, ON \$260k**

MARKET REPORT

The Australian stock market slipped 0.06 percent on Wednesday November 28, 2018 with the ASX200 down 3.2 points to 5,725.1 points. Seventeen of the Biotech Daily Top 40 stocks were up, 16 fell and seven traded unchanged.

Factor was the best, up 0.1 cents or 50 percent to 0.3 cents, with 17.5 million shares traded. Avita climbed 11.8 percent; Ellex was up 10.1 percent; Actinogen rose 9.8 percent; Genetic Signatures was up eight percent; Cynata climbed 5.15 percent; Prescient was up four percent; Polynovo and Uscom were up more than three percent; Compumedics, LBT and Orthocell rose more than two percent; with Dimerix, Nanosonics and Resmed up one percent or more.

Admedus led the falls, down 7.7 cents or 57.04 percent to 5.8 cents with 16.8 million shares traded. Airxpanders lost 11.1 percent; Paradigm fell 8.7 percent; Prana shed 7.3 percent; Immutep was down 5.3 percent; Benitec, Impedimed, Optiscan and Osprey were down more than three percent; Cyclopharm and Reva shed more than two percent; with Clinuvel, Opthea and Telix down more than one percent.

[OPTHEA \(FORMERLY CIRCADIAN\)](#)

Opthea says that 99.4 percent of its 2014-issued 27 cent options have been exercised raising \$13,345,857.

Opthea said that in 2014, the then Circadian raised \$17.4 million at 17.5 cents a share with one option attaching to every two new shares purchased, exercisable at 27 cents by November 25, 2018 (BD: Oct 6, 2014).

Today, Opthea chief executive officer Dr Megan Baldwin said the company was “pleased to have delivered significant shareholder value since the 2014 capital raising which is reflected in the impressive number of options that were exercised by the expiry date”. The company said that along with a \$12.0 million Federal Research and Development Tax Incentive it had more \$37 million in cash.

Opthea fell one cent or 1.7 percent to 57 cents.

[DIMERIX](#)

Dimerix says it hopes to use its Receptor-HIT drug discovery platform as a service provider for external companies and potentially licence its use.

Dimerix chief executive officer Dr Nina Webster told Biotech Daily that with two phase II trials underway and results not expected until the end of 2019, the company was looking to better utilize the receptor-heteromer investigation technology (Receptor-HIT) platform. On Monday, the company said it had been awarded a \$50,000 Federal Innovation Connections Grant to work with the Harry Perkins Institute of Medical Research and University of Western Australia on targets of interest, with Perkins Institute head of molecular endocrinology and pharmacology Prof Kevin Pflieger leading the 10-month program (BD: Nov 26, 2018).

Dimerix said it would match the grant, which would use Recepto-HIT to profile molecular biology targets.

The company has previously said that the Receptor-HIT system was used to develop the DMX-200 propagermanium with irbesartan combination therapy which was in a 10-patient phase IIa trials for focal segmental glomerulo-sclerosis and a 40-patient phase IIb trial for diabetic kidney disease.

Today, Dr Webster said that Receptor-HIT could be used internally to develop new combinations for Dimerix or for other companies, the platform could be used for external contracts or potentially licenced for specific targets and indications.

Dr Webster referred to her annual general meeting address, in which she said that the Receptor-HIT platform “enables us to understand the ways receptors interact” and helps rapid screening and identification of new drug opportunities.

“Dimerix is currently assessing ways of leveraging this asset for potential near term opportunities,” Dr Webster told the meeting.

“There are two ways of looking at this opportunity,” Dr Webster said. “One is to provide a service to other parties in screening candidates on their behalf and the other is to licence out the proprietary platform so other parties might screen their own compounds.

Dimerix was up 0.1 cents or 1.1 percent to 9.3 cents.

[MACH7 TECHNOLOGIES \(FORMERLY 3D MEDICAL\)](#)

Mach7 has requested a trading halt pending “regarding the outcome of the company’s planned institutional capital raising placement”.

Trading will resume on November 30, 2018 or on an earlier announcement.

Mach7 last traded at 22.5 cents.

ADMEDUS

Admedus fell 7.7 cents or 57.04 percent to 5.8 cents when it emerged from its four-month suspension to announce a \$20.2 million rights offer at eight cents a share.

Admedus said it hoped to raise a minimum cash amount of \$12 million after the payment of underwriter fees and repayment of a \$5 million loan to major shareholder Star Bright through the partly-underwritten, five-for-seven rights issue.

The company said that each new share would have an attaching listed option exercisable at eight cents each within three years and the combined issue of shares and options would raise up to \$20.2 million, with a record date of December 3, the offer would open on December 4 and close on December 13, 2018.

Admedus said the eight cents offer price was a 40.7 percent discount to the 13.5 cents last traded price on August 1 and a 38.6 percent discount to the average price paid by Hong Kong's Star Bright Holding in the September placement (BD: Sep 3, 2018).

Admedus said that the New York hedge fund SIO Partners LP would underwrite up to \$6 million with Star Bright underwriting \$1 million and also taking up its full entitlement of about \$4 million.

The company said that SIO would provide "up to a further \$6.3 million in underwriting" if the offer did not raise a minimum net cash amount after underwriting fees and repayment of the Star Bright loan of about \$12 million, with SIO to be paid 3.0 percent for the initial \$6 million underwriting, but if SIO was required to provide more than \$6 million because the offer did not raise a net \$12 million, it would be paid 12.5 percent on the initial underwriting instead of the 3.0 percent and 25 percent on any amount SIO takes up over \$6 million.

Admedus said Star Bright would receive a fee of 3.0 percent on the underwritten amount of \$1 million and the proceeds would be used to repay a \$5 million Star Bright loan.

The company said that the Cayman Islands-based CVI Investments Inc would underwrite the offer for \$2 million for a 3.0 percent fee, with Admedus chairman John Seaberg and chief executive officer Wayne Paterson taking up their entitlements and underwriting the offer for \$50,000 each, without an underwriting fee.

Mr Paterson said the offer "marks an important step in Admedus' re-capitalization plan that it has been working towards since August 2018".

"The capital raised from this rights issue will provide funding for Admedus to consolidate and further develop the Adapt portfolio and position itself for the development of new products in 2019," Mr Patterson said.

In September, Admedus said that Star Bright would lend it \$5 million at 5.0 percent a year to repay the Partners For Growth loan, invest \$7,685,527 at 11.1 cents a share, take its holding to 19.99 percent and have up to four directors on the board (BD: Sep 3, 2018).

Last year, Admedus said that San Francisco's Partners for Growth provided a \$5,000,000 "revolving line-of-credit" at 9.75 percent and a \$5,000,000 loan at 11.75 percent, both repayable in 36 months, along with a seven-year warrant, or option, for the issue of 4,938,799 shares exercisable at 25 cents each (BD: Oct 26, 2017).

According to the Hong Kong-listed Vision Values 2017 Annual Report, Star Bright (HK) Holdings was acquired in 2016 by its Comet Eagle and Star Power Global subsidiaries for \$HK62,513,000 (\$A11,085,000) and "Star Bright owns solely an office premise and a car parking space located in Central, Hong Kong".

Biotech Daily has asked Admedus how Star Bright had the funds to invest in Admedus, but did not receive a response.

The company said it had a letter of intent with Star Bright for an \$18 million investment for 60 percent of Admedus Vaccines, the unit led by Prof Ian Frazer developing vaccines for herpes, glandular fever and human papillomavirus (BD: Apr 27, 2018).

Admedus lost 7.7 cents or 57.04 percent to 5.8 cents with 16.8 million shares traded.

NUHEARA

Nuheara says the UK National Health Service has selected its Iqbuds Boost hearing buds for adults and children with mild to moderate hearing loss.

Nuheara said it was the first time a smart hearing bud was able to be prescribed alongside traditional hearing aids.

Nuheara chief executive officer Justin Miller told Biotech Daily said that the Iqbuds Boost was the only ear bud to be selected by the NHS.

The company said that the tender contract would begin in April 2019 for an initial two-year period with provision for a further two-year extension.

Nuheara said the expected value for all NHS purchases for the mild to moderate hearing was GBP34.5 million (\$A60.8 million) in the first 12 months and GBP138 million for the full term of 48 months, if extended.

Mr Miller told Biotech Daily that he expected the Iqbuds Boost to be sold to the NHS at a discount to the Australian recommended retail price of \$649.

In a media release Mr Miller said the “tender and contract through one of the world’s leading government health care provider’s is a defining moment for Iqbuds Boost”.

“In a world first for any government body, Iqbuds Boost can be prescribed to suffers of mild to moderate hearing loss,” Mr Miller said.

“[The] NHS is leading the way in recognizing the value of smart hearing solutions, in providing more accessible and affordable hearing assistance,” Mr Miller said.

Nuheara said the tender application was submitted in partnership with its UK distributor, Puretone Ltd, which will supply and support Iqbuds Boost to the NHS.

Nuheara was up 0.9 cents or 11.4 percent to 8.8 cents with 51.5 million shares traded.

IMMUTEP

Immutep says that after three months of IMP321 with Keytruda, three of six metastatic melanoma patients in part B of its Tactimel had a partial response.

Earlier this month, Immutep said that its 24-patient, phase I, “two active immune-therapeutics in melanoma” Tactimel study had shown efficacy and safety from 18 patients in part A, and safety from six patients in part B (BD: Nov 12, 2018).

The company said that the part A patients were dosed with the checkpoint inhibitor pembrolizumab, or Keytruda, for four cycles, adding three different dose levels of IMP321, or eftilagimod alpha, in the fifth cycle; and the part B patients were receiving IMP321 30mg from the first cycle of pembrolizumab.

Immutep chief scientific officer Dr Frederic Triebel said the company was “very pleased by this initial data which further supports our hypothesis that the combination of [IMP321] and pembrolizumab may be a hopeful solution for cancer patients”.

Separately, Immutep said the European Patent Office had granted a patent protecting its intellectual property relating to combined preparations comprising its lead product candidate eftilagimod alpha and a programmed cell death-1 (PD-1) or programmed cell death-ligand-1 (PD-L1) inhibitor, and also the use of the combined preparations for the treatment of cancer or infection.

The company said that the patent, titled ‘Combined Preparations for the Treatment of Cancer or Infection’ provided coverage until January 8, 2036.

Immutep said that under the patent, Efti, or IMP321, and the PD-1 or PD-L1 inhibitor might be present in one combined dosage form, or as part of separate dosage forms for sequential administration of the respective active ingredients.

Immutep fell 0.2 cents or 5.3 percent to 3.6 cents with 5.2 million shares traded.

POLYNOVO

Polynovo says sales of its Novosorb BTM for the five months to November 27, 2018 were up 62.1 percent to \$2.82 million compared to the year to June 30, 2018.

Polynovo said the US dominated sales of the Novosorb biodegradable temporizing matrix (BTM) wound treatment with sales in Australia and New Zealand expected “to significantly increase” following Australian Therapeutic Goods Administration approval in August with South Africa, Israel and Saudi Arabia were expected to add to sales (BD: Aug 14, 2018). Polynovo chairman David Williams said that when company sales reached \$1 million per month “Polynovo will be close to or at breakeven”.

Polynovo was up two cents or 3.6 percent to 57 cents with 3.8 million shares traded.

ORTHOCELL

Orthocell says the last of 10 patients in a single-stage dental implant study of its Celgro scaffold has received treatment.

Orthocell said that single-stage performance study was designed “to further validate the versatility of Celgro in dental bone and soft tissue repair procedures and to demonstrate the potential for improved patient outcomes in a treatment process that traditionally requires two surgical procedures”.

Orthocell managing-director Paul Anderson said the company “previously demonstrated Celgro’s ability to deliver superior bone growth”.

“This study is designed to generate supplementary marketing data to assist in positioning Celgro as the best-in-class collagen membrane and support Orthocell’s ability to gain significant traction across key target markets,” Mr Anderson said.

Orthocell said that traditional dental implant procedures were often performed in two-stages, with patients receiving an initial implant placement, followed by a second surgery, up to six months later, to insert the implant abutment and dental crown.

The company said that advances allowed the potential for a single-stage procedure for some patients, eliminating the need for re-entry surgery, accelerating the healing process and potentially reducing the costs to patients and the health care system.

Orthocell was up half a cent or 2.4 percent to 21.5 cents.

CARDIEX

Cardiex says 50.5 percent US subsidiary Inhealth has partnered with healthcare provider Kaiser Permanente for a seven-year diabetes lifestyle intervention study.

In October, Cardiex said it would pay more than \$4.6 million for up to 50.5 percent of the Los Angeles-based Inhealth Medical Services for its “health coaching and Telehealth services” saying that Inhealth provided digital, electronic commerce and mobile telephone tools for patients to connect online with health coaches as part of a patient care management program (BD: Oct 16, 2018).

Today, the company said that with the California State University Long Beach, the study would assess the role of patient lifestyle intervention on diabetes management using Inhealth’s telehealth services, with its nutrition, exercise and lifestyle telehealth coaching programs forming a “key part of the patient’s intervention and treatment”.

Cardiex said the data and findings from the study would be used “to refine and validate Inhealth’s existing diabetes healthcare programs on an ongoing basis”.

The company said that Inhealth would receive service fees for the duration of the study for the provision of health programs and telehealth services.

Cardiex was up 0.2 cents or 6.45 percent to 3.3 cents.

GI DYNAMICS

GI Dynamics says that with the Hyderabad, India-based Apollo Sugar, it will study the safety and efficacy of its Endobarrier duodenal insert in India.

GI Dynamics said that Apollo Sugar was a collaboration between Apollo Health & Lifestyle founded by Dr Prathap Reddy and the Paris-based Sanofi.

The company said that Apollo Sugar was “focused on the treatment of metabolic disorders” and operated a network of centres for diabetes, obesity and endocrinology.

GI Dynamics said the Apollo Hospital Group was “the largest hospital system in India”.

The company said the agreement provided for a 100-patient, three-to-one randomized clinical trial of the Endobarrier for obesity and type II diabetes, pending approvals and GI Dynamics raising additional capital, with enrollment expected to begin by July 2019 and conclude by September 2019.

GI Dynamics chief executive officer Scott Schorer said the clinical trial was “a first part of a partnership with Apollo Sugar to study Endobarrier in India”.

GI Dynamics fell 0.1 cents or 5.3 percent to 1.8 cents.

LBT INNOVATIONS

LBT says its annual general meeting avoided a remuneration report first strike with 16,519,253 votes (24.0%) opposing the report.

LBT said that 40,995,569 votes were in favor and 11,298,817 votes were at the proxy’s discretion, adding to 76.0 percent.

LBT chief executive officer Brent Barnes told Biotech Daily that the discretionary votes were voted in favor of the report.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed by more than 50 percent of votes the directors must stand for re-election.

The company said that the largest opposition vote was 16,964,205 votes against the 10 percent placement capacity with 49,081,945 votes in favor.

LBT said director Kate Costello was re-elected with 48.2 million votes in favor and 16.0 million votes against, Caroline Popper was re-elected by a wider margin, as was a prior share issue.

The company’s most recent Appendix 3B said it had 200,927,025 shares on issue meaning that the opposition to the placement capacity amounted to 8.4 percent of the total shares on issue, sufficient to requisition extraordinary general meetings.

LBT was up 0.2 cents or 2.15 percent to 9.5 cents.

THC GLOBAL GROUP (FORMERLY THE HYDROPONICS COMPANY)

THC Global says it has exclusive rights to import Endoca’s marijuana-based products into New Zealand and has established a supply chain through Datapharm.

Last year, Hydroponics said it would distribute the Hoofddorp, Netherlands-based Endoca BV’s medical marijuana products in Australia, through its wholly-owned subsidiary Canndeo (BD: Nov 15, 2017).

Today, THC said that New Zealand regulations allowed prescriptions for cannabidiol to be made by doctors without Government approval as is required in Australia which would allow for access to products by “a far larger patient population”.

THC was unchanged at 50.5 cents.

[TPI \(TASMANIA POPPY INDUSTRIES\) ENTERPRISES](#)

The Melbourne-based Cooper Investors Pty Ltd says it has ceased its substantial holding in TPI, selling 891,292 shares for \$1,115,139 or \$1.25 a share.

Cooper Investors said it sold the shares between September 9, 2017 and November 28, 2018.

Last year the company said it became substantial with 4,091,292 shares or 5.046 percent, implying the company continued to hold 3,200,000 shares or 3.95 percent.

TPI fell one cent or 0.8 percent to \$1.20 with 1.4 million shares traded.

[TPI \(TASMANIAN POPPY INDUSTRIES\) ENTERPRISES](#)

TPI says it has appointed MTP Connect chair Sue MacLeman as a non-executive director with effect from November 27, 2018.

TPI said that Ms MacLeman had more than 30 years' experience as a pharmaceutical, biotechnology and medical technology executive including corporate, medical, commercial and business development.

The company said that Ms MacLeman had been a director and chief executive officer of several ASX and Nasdaq listed companies in the pharmaceutical sector and was currently the chair of Anantara, Novita, MTP Connect and a director of Oventus and the Victoria Government agency Veski.

[RHYTHM BIOSCIENCES](#)

Rhythm says it has appointed Glenn Gilbert as its chief executive officer, starting on \$260,000, replacing Dr Trevor Lockett who continues as technical director.

Rhythm said that Dr Lockett would remain a director and chair the company's clinical advisory board.

The company said that prior to joining Rhythm, Mr Gilbert was an executive at Medical Developments International and had business experience in the UK, Europe, Asia and North America, including mergers and acquisitions and managing intellectual property.

Rhythm said that previously, Mr Gilbert was an executive at CSL's biotherapeutics division, now known as Seqirus.

The company said that Mr Gilbert would start on \$260,000 a year plus 9.5 percent superannuation, with short-term incentives of up to 30 percent of the base salary and long-term incentives of up to 30 percent of the base salary.

Rhythm was unchanged at 16 cents.