Biotech Daily

Wednesday February 19, 2020

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: IMMUTEP UP 14%; USCOM DOWN 10%**

*** ZELIRA: 'MARIJUANA REDUCES INSOMNIA SEVERITY'**

*** IMMUTEP 8 OF 17 CANCER PATIENTS RESPOND TO IMP321, KEYTRUDA**

*** MEDICAL DEV H1 REVENUE UP 14% TO $11m, PROFIT UP 82% TO $240k**

*** AVITA H1 REVENUE UP 95% TO $13.5m, LOSS UP 35% TO $21m**

*** RESAPP REQUESTS CAPITAL RAISING TRADING HALT**

*** G MEDICAL RAISES $350k**

*** OPYL: CLINICAL TRIAL PREDICTOR 'PROOF OF CONCEPT'**

*** EXOPHARM: 'CEVARIS SIGNIFICANT FOR ERECTILE DYSFUNCTION EX-VIVO'**

*** REGAL FUNDS REDUCES TO 5.5% OF ONCOSIL**

*** MICRO-X APPOINTS KINGSLEY HALL CFO, CO-CO SEC**

*** MELBOURNE MARCH MEDICAL MARIJUANA MEETING**

MARKET REPORT

The Australian stock market fell 0.16 percent on Wednesday February 19, 2020, with the ASX200 down 11.4 points to 7,113.7 points. Nine of the Biotech Daily Top 40 stocks were up, 20 fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Immutep was the best, up 5.5 cents or 14.1 percent to 44.5 cents with 11.1 million shares traded. Cochlear climbed 11 percent; Prescient improved six percent; Kazia was up 4.35 percent; CSL, Mesoblast and Volpara were up three percent or more; Cynata, Opthea and Pro Medicus rose more than two percent; with Antisense, Avita, Medical Developments and Polynovo up by less than one percent.

Uscom led the falls, down 3.5 cents or 10 percent to 31.5 cents with 3.1 million shares traded. Oncosil lost 8.8 percent; Patrys was down 5.6 percent; Actinogen, Ellex and LBT were down more than three percent; Amplia, Imugene and Next Science shed two percent or more; Compumedics, Genetic Signatures, Neuren, Orthocell and Proteomics were down more than one percent; with Clinuvel, Nanosonics, Paradigm, Resmed and Starpharma down by less than one percent.

ZELIRA THERAPEUTICS (FORMERLY ZELDA THERAPEUTICS)

Zelira says its 24-patient phase Ib/IIa study of ZTL-101 marijuana therapy for chronic insomnia shows statistically significant improvement in insomnia severity scores.

Zelira said it administered either a placebo or a single 0.5ml dose of 11.5mg of cannabinoids or a double 1.0ml dose of 23mg of cannabinoids sublingually followed by a one-week washout period for a further 14-night trial period.

The company said 12 patients (52%) chose to increase from a single dose to a double dose and by the fourteenth night, 16 patients (69.5%) were taking a double dose.

Zelira said the randomized, double-blind, cross-over design for patients between 25 and 70 years of age assessed patients using a monitored sensitivity test to ZTL-101 and a placebo prior to dosing, in order to assess the primary endpoints of safety based on adverse event reporting and insomnia symptoms as measured by the insomnia severity index (ISI) at the end of each night.

The company said 36 non-serious adverse events possibly or likely related to ZTL-101 were recorded from 17 patients, with 22.2 percent of all events were dry mouth, 16.7 percent were dizziness, 11.1 percent headache and 11.1 percent from “feeling abnormal”.

Zelira said four non-serious adverse events were recorded from four patients during dosing of the placebo, 50 percent of which was headache, 25 percent was dizziness and 25 percent was variable mood.

The company said 97.5 percent of all adverse events were classified as mild and resolved overnight, soon after waking or at the end of the trial.

Zelira said there was a significant decrease in ISI scores following ZTL-101, from a baseline of 18 +/- 3.7 to 12.9 +/- 5.3 ($p < 0.001$) but not following a placebo, which had a score of 18.0 +/- 4.3 ($p > 0.05$).

The company said the magnitude of ISI score decreases was 5.2 +/- 4.3 for ZTL-101 and was 0.0 +/- 3.3 for the placebo and were significantly different ($p < 0.001$).

University of Western Australia Centre for Sleep Science director and principal investigator Prof Peter Eastwood said that the study was “the most rigorous clinical trial ever undertaken to assess the therapeutic potential of medicinal cannabis to treat the symptoms of chronic insomnia”.

“It’s also the first trial to use the Insomnia Severity Index, arguably the current gold standard in this field, to measure the efficacy of a medicinal cannabis product to treat insomnia symptoms,” Prof Eastwood said.

“The fact that ZLT-101 treatment achieved a statistically significant improvement in ISI scores is very impressive, particularly given the relatively short two-week dosing window,” Prof Eastwood said.

“The lack of serious adverse or persistent mild adverse events is also encouraging given the reported safety issues for several already approved insomnia therapies,” Prof Eastwood said.

“Taken together, these results suggest ZLT-101 has potential as a novel treatment for Insomnia,” Prof Eastwood said.

Zelira chairman Osagie Imasogie said the “positive outcome to this trial represents an important milestone for Zelira and its commitment to address the unmet need for clinically validated cannabis medicines and offer more treatment options to physicians and patients”.

Zelira said a final report on the study, including an analysis of secondary endpoints, would be provided by the end of March 2020.

Zelira fell 0.3 cents or 5.2 percent to 5.5 cents with 9.0 million shares traded.

IMMUTEP

Immutep says eight of 17 patients of up to 109-patients in its Tacti-002 trial have shown a response to eftilagimod alpha or IMP321 with Keytruda for cancers.

Immutep said that the further interim data from its phase II open label, single-arm study of IMP321 with Keytruda for cancers was presented at the German Cancer Congress in Berlin by principal investigator Dr Bernhard Doger.

Last year, Immutep said it had dosed the first of 109 patients in the phase II study to assess IMP321 in collaboration with the Kenilworth, New Jersey-based Merck & Co's programmed cell death-1 (PD-1) blocking antibody Keytruda, or pembrolizumab, on second line head and neck squamous cell carcinoma and non-small cell lung cancer patients (BD: Mar 7, 2019).

In September, the company said positive interim data in cohort one would take the study to a second cohort, following a partial response in seven of 17 patients in cohort one of part A of the study, with disease stabilization in six patients and a disease control rate of 76.5 percent (BD: Sep 26, 2019).

Today, Immutep said the study was in two stages and three parts, including 17 patients in stage one, part A and 19 patients in stage two, part A for first line non-small cell lung cancer (NSCLC), 23 patients in stage one, part B for second line NSCLC and 18 patients in stage one, part C and 19 patients in stage two, part C for second line head and neck squamous cell carcinoma.

The company said all patients received 200mg of Keytruda every three weeks, in combination with 30mg of IMP321 every two weeks for the first eight three-week cycles and every three weeks thereafter.

Immutep said it found that eight part A NSCLC patients showed an overall response (47%), no patients with a response had progressive disease and five of eight responders had a programmed death-ligand 1 (PD-L1) expression of less than 50 percent.

The company said that 10 of 17 patients (59%) were still under treatment and it had not yet reached a median progression free survival (PFS), with all patients passed the seven-month mark.

Immutep said second line head and neck squamous cell carcinoma patients in part C showed an interim overall response rate of 33 percent, with six of 18 patients reporting a response.

Immutep chief scientific and medical officer Dr Frederic Triebel said the results were "highly encouraging, with 47 percent of first line non-small cell lung cancer patients responding".

"These results are remarkable given that usually only 20 percent of patients respond to pembrolizumab monotherapy, if not preselected for high PD-L1 expression," Dr Triebel said. "Interestingly, patient responses are being seen in all three PD-L1 expression level groups, meaning the combination treatment seems to work even in patients not expected to respond to pembrolizumab monotherapy."

"The initial overall response rate of 33 percent [one of three patients] of second line head and neck squamous cell carcinoma patients is also very exciting, albeit from a smaller patient group," Dr Triebel said.

"It compares well to an expected pembrolizumab monotherapy response rate of 15 to 18 percent, especially taking into account that three patients could not yet be assessed," Dr Triebel said.

The company said more detailed data would be provided as patient treatment duration advanced, no new safety signals had been reported and recruitment was ongoing for stage one of part B of the study, as well as for stage two for both Part A and Part C.

Immutep was up 5.5 cents or 14.1 percent to 44.5 cents with 11.1 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says revenue for the six months to December 31, 2019 was up 14.4 percent to $10,895,000 with net profit after tax up 81.8 percent to $240,000.
Medical Developments said revenue was largely from sales of its Penthrox inhaled methoxyflurane analgesic, its respiratory medical devices and from contracts.
The company said it would pay a fully franked interim dividend of 2.0 cents a share for holders at the record date of March 6, to be paid on April 17, 2020.
Medical Developments said net tangible asset backing per share was down 77.2 percent to 3.07 cents, diluted earnings per share was up 71.4 percent to 0.36 cents and it had cash and cash equivalents of $23,153,000 at December 31, 2019 compared to $32,273,000 at December 31, 2018.
Medical Developments was up 12 cents or 1.1 percent to $10.96 with 378,699 shares traded.

AVITA MEDICAL

Avita says revenue for the six months to December 31, 2019 was up 95.3 percent to $13,529,787 with net loss after tax up 34.7 percent to $20,980,787.
Avita said revenue from sales of its Recell system for the treatment of burns was up 434.1 percent to $9,684,214.
The company said other revenue included funding from the Biomedical Research and Development Authority (BARDA) of $3,549,000, down 29.1 percent from the previous corresponding period.
Avita said net tangible asset backing per share rose 199.5 percent to 5.66 cents, diluted loss per share rose 1.9 percent to 1.62 cents and it had cash and cash equivalents of $124,658,116 at December 31, 2019 compared to $30,342,360 at December 31, 2018.
Avita was up 1.5 cents or 1.8 percent to 83 cents with 24.1 million shares traded.

RESAPP HEALTH

Resapp has requested a trading halt “pending the release of an announcement regarding a capital raising”.
Trading will resume on February 21, 2020 or on an earlier announcement.
Resapp last traded at 24 cents.

G MEDICAL INNOVATIONS HOLDINGS

G Medical says it has raised $350,000 through the set-off of 3,400,000 collateral shares issued to Acuity Capital at 10.3 cents a share.
G Medical said the price was a 17 percent premium to the last closing price of 8.8 cents a share.
The company said the collateral shares were issued to Acuity Capital under a controlled placement agreement.
G Medical said this set-off would reduce the total 17,000,000 collateral shares, which Acuity is otherwise required to return to the company upon termination of the agreement.
The company said the funds would be used for additional working capital.
G Medical fell 0.3 cents or 3.4 percent to 8.5 cents.

OPYL

Opyl says it has completed the proof-of-concept stage for artificial intelligence software to predict the probability of a clinical trial completing each phase.
Opyl said the algorithm-based technology used information from more than 300,000 published trials and more than 60 trial variables and it used “explainable” artificial intelligence to develop the algorithm.
The company said the tool would optimize clinical trials across study planning, protocol design, recruitment and site location, as well as selecting the best contract research organization for particular diseases in key geographic locations.
Opyl said its model had estimated that some trials had up to a 70 percent chance of success, while others were as low as less than one percent and its development represented a significant milestone.
The company said the tool would be commercialized on a subscription basis, with additional consulting services aimed at pharmaceutical, biotechnology, government, hospitals, universities and research institutes, medical device companies, contract research organisations and investment houses.
Opyl chief executive officer Michelle Gallaher said the algorithm had “the potential to dramatically disrupt the clinical trial feasibility sector, reducing risk and cost to global biopharma and medtech developers”.
“This technology has the potential to create more certainty in the typically risky clinical trial stage, which in turn means success worth millions if not billions to a biopharma or medtech company,” Ms Gallaher said.
Opyl said it expected to launch the product by October 2020.
Opyl was up half a cent or 4.55 percent to 11.5 cents.

EXOPHARM

Exopharm says ex-vivo models of erectile dysfunction shows that its Cevaris treatment provides “statistically significant improvement in muscle contraction and release”.
Exopharm said the cavernous smooth musculature contracted when in the flaccid or non-erect state and smooth muscle relaxation was essential for an erectile response.
The company said France’s Pelvipharm independently tested two of its exosome products Caveris and Plexaris, and found that Cevaris statistically significantly enhanced the nitrergic relaxations of isolated corps cavernosum strips compared to a control substance ($p < 0.01$).
Exopharm said this testing would provide a basis for further non-clinical testing of its products for erectile dysfunction and later, for human clinical trials.
Exopharm was up half a cent or 1.7 percent to 29.5 cents.

ONCOSIL MEDICAL

Regal Funds Management says it has reduced its substantial shareholding in Oncosil from 41,906,317 shares (6.64%) to 34,632,579 shares (5.49%).
The Sydney-based Regal Funds said that between January 30 and February 14, 2020, it sold 7,273,738 shares for $1,381,474.74 or an average of 19.0 cents a share.
Oncosil fell 1.5 cents or 8.8 percent to 15.5 cents with 3.3 million shares traded.

MICRO-X

Micro-X says it has appointed Kingsley Hall as chief financial officer and co-company secretary, effective from February 24, 2020.
Micro-X said Mr Hall had more than 25 years' experience in finance and operations, including previous roles as company secretary, and most recently was Scope Global chief financial officer and head of diversified business.
The company said that Mr Hall was previously Discovery Holiday Parks chief financial officer, DMG Radio Australia group finance director and Nova Entertainment Group chief operating officer.
Micro-X said Mr Hall held a Bachelor of Economics from Adelaide's Flinders University.
The company said that chief financial officer and company secretary Georgina Carpendale had advised "of her intention to explore new career directions during the year".
Micro-X fell one cent or 5.1 percent to 18.5 cents with 1.5 million shares traded.

MEDICINAL CANNABIS INDUSTRY AUSTRALIA

Medicinal Cannabis Industry Australia says it will hold a medical marijuana meeting, titled Acannabis, in Melbourne on March 3 and 4, 2020.
The industry association said the conference would discuss patient and doctor opportunities, the barriers to the use of medical marijuana and the ways to build confidence in cannabis as a medicine.
Medicinal Cannabis Industry Australia chair Peter Crock said the conference would offer a "platform to gain a deep understanding of ground-breaking research, an inside perspective on global trends and a unique opportunity for the agri-tech and med-tech sector to have the conversations required to leverage our advantages".
The Medicinal Cannabis Industry Australia (MCIA) said the inaugural Acannabis conference was "designed to help define and shape the future of the Australian medicinal cannabis sector".
MCIA said that the event would bring "professionals from across the medicinal cannabis sector together in one place, providing the exclusive opportunity for attendees to engage with thought leaders, change makers and industry authorities, that is unlikely to be found anywhere else".
Acannabis will be held at the Timber Yard, 351 Plummer Street, Port Melbourne.
For more information go to: www.acannabis.com.au.