Biotech Daily

Thursday March 8, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: PSIVIDA UP 14%; OSPREY DOWN 7%**

*** IMMURON UP 65% ON MIXED RESULTS FOR IMM-124E FOR NASH**

*** RECCE, FDA MEET TO DISCUSS RECCE-327 ANTIBIOTIC**

*** GI DYNAMICS COMPLETES $2m PRIVATE PLACEMENT**

*** SUDA COMPLETES $1.7m WEST COAST MEDICAL SUPPLIES SALE**

*** RACE REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** ALCHEMIA-RELATED SANDON CAPITAL TAKES 5% OF IDT**

MARKET REPORT

The Australian stock market climbed 0.69 percent on International Women's Day, Thursday March 8, 2018, with the ASX200 up 40.9 points to 5,942.9 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and two were untraded.

Psivida was the best on no news, up 19.5 cents or 13.9 percent to $1.60 with 2,700 shares traded. Bionomics climbed 9.3 percent; Cyclopharm and Immutep improved eight percent or more; Pharmaxis was up 6.45 percent; Medical Developments and Volpara were up more than four percent; Oncosil was up 3.7 percent; Ellex and Resmed rose more than two percent; Cochlear, CSL, ITL, Opthea and Polynovo were up one percent or more; with Neuren and Pro Medicus up by less than one percent.

Osprey led the falls, down two cents or 7.4 percent to 25 cents with 821,562 shares traded, followed by Mesoblast down 7.3 percent to $1.77 with 4.6 million shares traded and Universal Biosensors down 7.1 percent to 26 cents with 270,957 shares traded.

Dimerix and Optiscan lost more than six percent; Avita retreated five percent; Impedimed fell 4.55 percent; Airxpanders, Acrux, Actinogen and LBT were down more than three percent; Compumedics shed 2.8 percent; with Nanosonics, Starpharma and Viralytics down by less than one percent.

IMMURON

Immuron says its 133-patient, phase II IMM-124E for non-alcoholic steatohepatitis trial, had mixed results, missing its primary endpoint but showing mechanism of action.

Immuron said that the proof-of-concept, multinational, randomized, double-blind study compared 600mg and 1200mg doses of IMM-124E to placebo for the treatment of non-alcoholic steatohepatitis, or fatty liver disease (BD: Oct 15, 2014; Feb 3, 2015).

The company said “the established primary endpoints of the study were improvement of liver steatosis” with secondary endpoints including a reduction in aspartate aminotransferase (AST) and alanine aminotransferase (ALT) as well as other liver enzymes and metabolic markers.

Immuron interim chief executive officer Dr Jerry Kanellos told Biotech Daily that the mechanism of action for IMM-124E was shown to be anti-inflammatory and the oral cow colostrum-derived, polyconal antibody targeted the endotoxin lipo-poly-saccharide (LPS) and other bacterial components.

Dr Kanellos said the trial showed “a statistically significant reduction of serum LPS levels in patients with NASH”.

“Considering the published association of serum LPS in the progression of NASH, Immuron believes the outcome of the trial is an important milestone toward commercialization of IMM-124E,” the company said.

The company said serum ALT was significantly reduced in the six-month treatment period with a more than 30 percent reduction in serum ALT compared to placebo ($p = 0.048$), with additional biomarkers reduced by IMM-124E including AST and cytokeratin-18.

Immuron said that twice as many subjects treated with high dose IMM-124E showed a 15 percent or greater decrease in serum CK-18 levels compared to placebo, 38.89 percent compared to 18.18 percent ($p = 0.0494$).

Principle investigator and Richmond, Virginia Commonwealth University gastroenterology and hepatology professor Prof Arun Sanyal said the results were “truly a proof of concept for this first-in-class drug candidate".

“The IMM-124E drug candidate has been developed to target LPS in the gut and prevent it translocating into the portal circulation,” Prof Sanyal said.

“The study results clearly demonstrate a statistically significant reduction of serum LPS levels in the treatment groups when compared to placebo and provides us with a proof of concept that metabolic endotoxemia can indeed be decreased using this drug candidate which targets the endotoxin LPS,” Prof Sanyal said.

Immuron said that no safety concerns or serious adverse events were associated with the study drug, both doses were well-tolerated, supporting the use of higher doses and extended treatment periods in future clinical trials.

The company said that 64.29 percent of patients treated with IMM-124E showed a 15 percent or more decrease in serum LPS levels compared with 34.48 percent in the placebo group ($p = 0.01843$), while 58.62 percent of placebo patients had a 15 percent or greater increase in serum LPS levels, compared with 25.0 percent of IMM-124E treated patients ($p = 0.0062$).

Immuron head of medical Dr Dan Peres said that “the proof for IMM-124E’s non-absorbable nature and excellent safety profile … will allow us to conduct further clinical research aimed at maximizing the effect with potentially higher doses and longer treatment times”.

Dr Kanellos said the trial showed “excellent safety and significant efficacy signals for our novel [mechanism of action] in a relatively short treatment trial [of 24 weeks] and small numbers of patients”.

Immuron climbed 18.5 cents or 64.9 percent to 47 cents with 5.4 million shares traded.

RECCE PHARMACEUTICALS

Recce says that it will meet with the US Food and Drug Administration in May to discuss its synthetic antibiotic compound Recce-327.

Recce said that the meeting would involve face-to-face discussion of the proposed clinical and regulatory pathway for Recce-327, including a proposed phase I clinical trial, and involve members of Recce's technical and manufacturing teams, its FDA consultants Parexel International and infectious disease representatives of the FDA.

The company said its Recce-327 was awarded FDA qualified infectious disease product (QIDP) designation in late-2017, providing five years of market exclusivity, starting from the date of a new drug application approval, extended for another five years through Hatch-Waxman exclusivity, with additional protection from the company's patents (BD: Nov 16, 2017).

Recce chairman Dr Graham Melrose said that "given the urgent medical need for new antibiotics, in the face of rising incidence of drug resistant superbugs, we look forward to meeting with the FDA to explore the most efficient regulatory pathway for Recce-327".

Recce was unchanged at 16.5 cents.

GI DYNAMICS

GI Dynamics says it has raised $2,057,321 in a private placement of 52,690,100 chess depository interests (CDIs) at 3.5 cents per CDI.

In January, GI Dynamics said that it had raised $996,347 in the first tranche of its placement on January 23, 2018 and today announced it had raised $1,060,974 in the second tranche of its placement to sophisticated and professional investors in Australia, the US and the UK.

The company said the capital would fund the continued development of the Endobarrier and general working capital purposes.

GI Dynamics was up 0.1 cents or 3.7 percent to 2.8 cents.

SUDA PHARMACEUTICALS

Suda says it has completed the $1,728,757 sale of its wholly owned subsidiary Westcoast Surgical & Medical Supplies to Perth's Medical Sales and Services.

Last week, Suda said it intended to completed the sale in March but did not specify the sale price (BD: Feb 27, 2018).

Today, the company said the sale price was subject to further reconciliation.

Last year, Suda said that its revenue to June 30, 2017 was $7,221,000, primarily from Westcoast Surgical & Medical Supplies and in 2016, the company had revenue for the year to June 30, 2016 of $5,872,000 (BD: Sep 1, 2016; Aug 31, 2017).

Suda fell 0.1 cents or 6.7 percent to 1.4 cents.

RACE ONCOLOGY

Race has requested a trading halt "pending an announcement regarding a capital raising".

Trading will resume on March 12, 2018 or on an earlier announcement.

Race last traded at 37 cents.

IDT AUSTRALIA

Sandon Capital says it has become a substantial shareholder in IDT acquiring 12,885,055 shares or 5.3 percent.

In a substantial shareholder notice signed by director Gabriel Radzyminski, the Sydney-based Sandon Capital said that between November 2, 2017 and March 5, 2018 bought 12,885,055 shares for $6,669,505 or 7.5 cents a share.

Last month, IDT announced that it had appointed Dr David Sparling as its interim chief executive officer, following the 2017 departure of chief executive officer Dr Paul MacLeman (BD: Jul 14, 2017; Feb 16, 2018).

Last year, IDT shareholders voted a remuneration report first strike at the annual general meeting (BD: Oct, 25, 2017).

In 2015, Sandon bought 13.2 percent of Alchemia following its phase III HA-irinotecan metastatic colorectal cancer trial failing to meet its primary endpoint, followed by the sale of its revenue-generating fondaparinux to Dr Reddy's Laboratories and its market capitalization falling from $216 million on September 30, 2014 to $31 million on October 31, 2014 (BD: Jun 1, 2015; Feb 25, 2016).

Sandon requisitioned an extraordinary general meeting to replace Alchemia directors Tim Hughes and Dr Tracie Ramsdale with Dinimus Capital principal Ken Poutakidis and Sandon Capital founder and managing director Gabriel Radzyminski, which was withdrawn one week later when Alchemia appointed Mr Poutakidis as a director and liquidated its substantial holding in March, 2016 (BD: July 7, 2015; Mar 1, 2016).

Dinimus Capital principal Simon Gennari continues as Alchemia's chairman.

Asked about the share purchase Mr Radzyminski said "no comment".

IDT was up half a cent or 7.7 percent to seven cents.