Biotech Daily

Monday October 17, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ADMEDUS UP 60%; DIMERIX DOWN 9%**

*** ADMEDUS JUMPS 68% ON FDA ADAPT VASCUCEL CLEARANCE**

*** ITL SAMPLOK GLOBAL DISTRIBUTION AGREEMENT WITH BIOMÉRIEUX**

*** CYNATA STEM CELLS NORMALIZE ASTHMA MODEL IN MICE**

*** OPTHEA RECEIVES $2.6m FEDERAL R&D TAX INCENTIVE**

*** BIOXYNE 60-PATIENT PCC PROBIOTIC GUT HEALTH TRIAL**

*** COGSTATE HAS LESS THAN TWO QUARTERS CASH**

*** DORSAVI EARNS $1m FOR SECOND QUARTER IN A ROW**

*** REGENEUS DELAY IN SIGNING JAPAN PARTNER**

*** LBT AGM FOR 1.5m CEO OPTIONS**

*** UP TO 17% DISSENT AGAINST COGSTATE DIRECTORS OPTIONS, FEES**

*** MEDADVISOR REQUESTS 'CAPITAL RAISING' TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.83 percent on Monday October 17, 2016 with the ASX200 down 45.3 points to 5,388.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and two were untraded. All three Big Caps fell.

Admedus was the best, closing up 19.5 cents or 60 percent at 52 cents with 38.5 million shares traded. IDT climbed five percent; Actinogen, Avita and Oncosil rose more than four percent; Clinuvel and Prima improved more than two percent; Acrux, Anteo, Genetic Signatures, Living Cell, Polynovo and Viralytics were up more than one percent; with Compumedics up 0.75 percent.

Dimerix led the falls, down 0.1 cents or 9.1 percent to one cent with 3.6 million shares traded. Universal Biosensors lost 6.9 percent; Opthea fell five percent; Impedimed and Nanosonics were down more than four percent; Bionomics, Mesoblast and Osprey shed more than two percent; Airxpanders, Atcor, Cochlear, CSL, Factor Therapeutics, Pharmaxis, Pro Medicus and Uscom were down more than one percent; with Medical Developments, Resmed, Sirtex and Starpharma down by less than one percent.

ADMEDUS

Admedus climbed as much as 67.7 percent on US Food and Drug Administration 510(k) clearance to market its Vascucel collagen scaffold for restorative vascular repair.
Admedus said that in November it would launch two sizes of Vascucel, 2.0cm by 8.0cm and a 0.8cm by 8.0cm, with the latter designed for carotid endarterectomy procedures, removing plaque from inside the carotid artery to prevent strokes.
The company said it had finalized several process improvement projects and ample product inventory had been manufactured to support the launch through its existing US sales team into the peripheral vascular market, in which about 250,000 vascular repair procedures were performed each year.
Admedus interim executive chairman Wayne Paterson said that the FDA clearance for Vascucel was “important … as we build on the existing Adapt product portfolio”.
“It adds to the new company strategy of focusing on products that are near to market, refining the product range and driving sales growth,” Mr Paterson said.
Admedus said Vascucel could “take significant market share in the US vascular market as it offers a premium next generation collagen scaffold for restorative vascular repair”.
The company said Vascucel provided improved handling because it was supple, strong and remained pliable and conformable; enhanced procedural efficiency as it was available off the shelf with no rinse required; had ease of suturing while remaining resistant to suture line bleeding; had improved biocompatibility with zero aldehyde toxicity; optimized healing with no stimulus for thrombosis, inflammation, or foreign body reaction, enabling rapid endothelialisation and native tissue growth; and reduced the risk of infection.
Admedus climbed as much as 22 cents or 67.7 percent to 54.5 cents before closing up 19.5 cents or 60 percent at 52 cents with 38.5 million shares traded.

ITL

ITL says it has a global, multi-year distribution agreement for its Samplok blood sampling kit with Biomérieux.
ITL said that it partnered with Biomérieux for more than five years to supply of Samplok sampling kit (SSK) in the UK, generating $11.5 million in revenue and the new agreement would expand the distribution to a non-exclusive global contract for three years with annual renewal options.
The company said that Biomérieux had been “a world leader in in-vitro diagnostics for more than 50 years” with a distribution existing network in more than 150 countries.
ITL said the Samplok kit was used in blood banking to transfer platelet samples during bacterial detection testing and had “state of the art product design that facilitates product sampling for laboratory testing process efficiencies, safety in reducing potential for needle-stick injuries and reduced biohazard waste, among other benefits” and Samplok was compatible with standard blood component storage bags and culture bottles.
ITL said the agreement built on Samplok’s inclusion in Biomérieux’s multi-year tender with the UK National Health Service, implementation by the Orlando, Florida-based Oneblood, a contract extension with an unnamed US blood bank, the grant of the SSK patent in the US and Taiwan Food and Drug Administration approval (BD: Mar 21, Jul 8, Aug 8, 2016).
ITL executive chairman Bill Mobbs said the global distribution contract was “an excellent achievement by ITL Biomedical”.
“Biomérieux is a highly respected company and its global reach will facilitate expansion of SSK sales,” Mr Mobbs said. “The agreement is in line with ITL’s stated strategy at the start of the year to expand sales of SSK around the globe.”
ITL was unchanged at 22.5 cents.

CYNATA THERAPEUTICS

Cynata says a 48-mouse model of asthma has provided “compelling data” for its Cymerus mesenchymal stem cells.

Cynata said that its partnership with Melbourne’s Monash University investigated the Cymerus technology as a potential alternate treatment for asthma sufferers.

The company said that Monash University’s Department of Pharmacology and the Monash Biomedicine Discovery Institute’s Prof Chrishan Samuel and Dr Simon Royce induced human-like asthma symptoms by sensitizing and challenging mice with the ovalbumin protein.

Cynata said that subjecting mice to the ovalbumin sensitization regime caused them to exhibit significantly increased airway hyper-responsiveness compared to the saline treated control group ($p < 0.001$).

The company said that intravenous administration of its mesenchymal stem cells caused a statistically significant of 60 percent to 70 percent decrease in airway hyper-responsiveness ($p < 0.01$) relative to untreated, sensitized animals.

Cynata said that intra-nasal administration of the mesenchymal stem cells “completely normalized [airway hyper-responsiveness] to a level that was no longer different to healthy animals, in which the asthma model had not been induced”.

The company said that no adverse safety findings were observed during the study.

Cynata head of product development Dr Kilian Kelly said the results “indicate that Cymerus [mesenchymal stem cells] could have a profound effect in the treatment of asthma”.

“This is a debilitating condition, which affects about 10 percent of the population, resulting in close to 40,000 hospitalizations and several hundred deaths each year, in Australia alone,” Dr Kelly said.

“Although a number of drugs are approved for the treatment of asthma, studies have shown that conventional treatments result in as few as five percent of asthma patients achieving full control of their condition,” Dr Kelly said.

“Consequently, there is a widely recognized need for novel treatments that address and potentially eliminate the underlying disease,” Dr Kelly said.

Prof Samuel said the study “clearly demonstrated that Cynata’s [mesenchymal stem cells] have a dramatic effect on [airway hyper-responsiveness] in our model, particularly when directly administered into the allergic lung,” Prof Samuel said.

“We look forward to continuing our analysis of the effects of these unique cells on markers of inflammation and airway remodeling and we are optimistic of building on the very positive data we have generated so far,” Prof Samuel said.

Cynata was up three cents or 5.45 percent to 58 cents.

OPTHEA

Opthea says it has received $2,643,552 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Opthea said the rebate related to Australian and eligible overseas expenditure on the development of OPT-302 for the year to June 30, 2016.

Opthea chief executive officer Dr Megan Baldwin said that “the receipt of $2.6 million represents a significant increase in our resources as we advance OPT-302 through a phase IIa clinical trial for the treatment of wet [age-related macular oedema] and plan to commence a larger, randomized controlled phase IIb clinical trial in wet [age-related macular oedema] patients in 2017.”

Opthea fell 3.5 cents or five percent to 66 cents.

BIOXYNE

Bioxyne says it will run a 60-subject, placebo-controlled trial of its PCC Lactobacillus fermentum VRI-003 probiotic on gastro-intestinal health and general well-being.

Bioxyne said that the primary outcome of the randomized, double-blind trial of its human-isolated probiotic strain probiotic in healthy adult volunteers was "to determine the effect of daily consumption of PCC in capsules for six months on the composition of the gut bacteria.

The company said that the types of bacteria in the gastro-intestinal tract had significant effects on human health, and PCC's ability to positively influence these bacteria would be examined in this trial.

Bioxyne said that the secondary outcomes included effects on bowel function, weight loss and general well-being through a self-assessment questionnaire.

The company said that the effect of PCC on the composition of the gut microbiome would be analyzed using kits from the Melbourne-based Smartdna Pty Ltd, which used nucleic acid analysis to identify the thousands of species present in the gastro-intestinal tract and each volunteer's microbiome would be analyzed before, during and at the end of the six month trial.

Bioxyne said PCC, or Lactobacillus fermentum VRI-003, had been sold as a capsule and powder dietary supplement for more than 10 years with no reported adverse effects and "several clinical studies … demonstrated its ability to boost immune health in people".

Bioxyne scientific director Dr Peter French said the company believed it was "the first time that a probiotic has been tested for its long term effect on the gut microbiome in healthy humans".

"PCC has been demonstrated in previous trials to have beneficial effects on boosting the immune system of elite male athletes and infants, as well as boosting the immune response to the flu vaccine," Dr French said.

"Scientific studies have previously indicated that PCC exerts its potent effect on the immune system via the gastrointestinal tract," Dr French said.

"This study is designed to confirm that mechanism," Dr French said.

Bioxyne said that data from the study would be used to promote the gastro-intestinal benefits of PCC and the soon-to-be-launched, Progastrim probiotic product.

Bioxyne chairman Tony Ho said the company was "committed to demonstrating the clinical efficacy of PCC to assist in the marketing of its current products as well as new products in new markets".

Bioxyne was untraded at 2.1 cents.

COGSTATE

Cogstate says its net operating cash burn for the three months to September 30, 2016 was $2,506,221 with cash at the end of the quarter of $4,696.848.

In a cover note to its Appendix 4C Quarterly Report, Cogstate said that the three months to September 30, 2016 "saw record revenue of $11.1 million up 82 percent on [the] previous corresponding period [and was] the largest quarter of new contract signings at $US17.3 million".

The company said that cash receipts from customers in the three months to September 30, 2016 amounted to $6,903,182 while staff costs including research and development was $7,455,335, with administration and corporate costs of $958,435, travel costs of $215,604 and advertising and marketing costs $153,607.

Cogstate climbed 13 cents or 14.4 percent to $1.03.

DORSAVI

Dorsavi has reported customer revenue of more than $1,000,000 for the second quarter in a row.
Dorsavi said that receipts from customers for the three months to September 30, 2016 was up 135.5 percent to $1,328,000 compared to three months to September 30, 2015 with revenue booked up 65.1 percent to $1,004,000.
The company said that for the three months to June 30, 2016 it had customer revenue booked of $1,008,000 and receipts from customers of $610,000.
Dorsavi said it had $5,769,000 in cash and cash equivalents.
Dorsavi was unchanged at 51 cents.

REGENEUS

Regeneus says it has been delayed meeting its manufacturing and development collaboration with a Japanese partner for its Progenza stem cell technology in Japan.
Regeneus said it expected to complete the collaboration by October 2016 “but unexpected delays in the sign-off process has impacted completion”.
The company said it was “confident of completing and announcing the collaboration shortly”.
Regeneus said it had completed a week of presentations and business meetings in Japan.
Regeneus chief executive officer John Martin told Biotech Daily that he had previously told shareholders that he expected the partnering contracts to be signed by now but the finalization had been delayed.
On July 1, 2016 in a quarterly update Regeneus said that following a May 2016 visit by executives to Japan to advance discussions with potential manufacturing and commercial partners for Progenza in Japan, meetings went well and “we are on track to enter into our first significant partnering agreement in Japan by the end of September 2016”.
In a media release today, Mr Martin said the company was “very encouraged by the quality of the parties interested in our technologies and clinical assets and hope to convert this interest into partnering opportunities for Japan”.
Regeneus said that it planned a phase II trial for Progenza for osteoarthritis in Japan and was “in active discussions with potential Japanese manufacturing, clinical development and marketing partners for Progenza”.
Regeneus fell 1.5 cents or 10 percent to 13.5 cents.

LBT INNOVATIONS

LBT will vote to grant chief executive officer Brent Barnes 1,500,000 options vesting on August 8, 2018 and exercisable at 15.7 cents by August 8, 2026.
Mr Barnes joined LBT as chief executive officer on August 9, 2016 and last week the company won US Food and Drug Administration approval for its automated plate-reading system, leading to a share price jump from 19 cents before the announcement by 68 cents or 357.9 percent to 87 cents at the close on Friday (BD: Oct 10, 2016).
LBT said the company would vote on the remuneration report, the approval of the 10 percent placement facility, the approval of the employee share option plan and the re-election of chairman Bob Finder.
The meeting will be held at Thomson Geer lawyers, Level 7, 19 Gouger Street, Adelaide on November 16, 2016 at 2pm (ACDT).
LBT retreated 12 cents or 13.8 percent to 75 cents, from last week’s 357.9 percent rise, with 8.6 million shares traded.

COGSTATE

Cogstate's annual general meeting passed all resolutions but with dissent of up to 17.1 percent against 1,250,000 director options and a 28.6 percent directors fees hike.
The proposed issues of 200,000 options to chairman Martin Myer and 100,000 options each to David Simpson, Richard van den Broek and David Dolby were opposed by 5,400,177 votes (17.11 %) and supported by 26,150,245 votes (82.89%).
The company said that the options, exercisable at 84 cents within five years of issue would vest over three years.
Cogstate said that the 28.6 percent increase in the total directors' remuneration pool from $350,000 a year to $450,000 a year was passed by a slightly larger margin with the issue of 750,000 options to chief executive officer Brad O'Connor passed overwhelmingly, as were resolutions to approve the 10 percent placement facility and the remuneration report.
The re-election of directors Mr Myer and Mr Dolby was opposed by 4,828,466 votes with 70,183,298 votes and 50,411,909 votes in favor, respectively.
The company's most recent Appendix 3B said that Cogstate had 111,880,182 shares on issue meaning that the opposition to the directors' options amounted to 4.83 percent of the company's total shares on issue, not sufficient to requisition extraordinary general meetings.

MEDADVISOR

Medadvisor has requested a trading halt "for the company to conduct the capital raising which was approved by shareholders on October 10, 2016".
Trading will resume on October 19, 2016 or on an earlier announcement.
Medadvisor last traded at 4.4 cents.