Biotech Daily

Thursday February 19, 2015

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: ONCOSIL UP 14%, PATRYS DOWN 13%**

*** WANRI: 'PEPTIDES LIMIT STROKE BRAIN DAMAGE'**

*** CYNATA UP 146% PERCENT ON LARGE SCALE, LOW COST STEM CELLS**

*** CYCLOPHARM REVENUE UP 26% TO $15m, LOSS TO $4m PROFIT**

*** REGENEUS H1 REVENUE UP 46% to $1.1m, LOSS DOWN 10% TO $6m**

*** UNIVERSAL BIO REVENUE DOWN 37% TO $9.5m, LOSS DOWN 20% TO $9m**

*** ALCHEMIA FONDAPARINUX Q2 PROFIT SHARE DOWN 32% TO $1.9m**

*** CBA BORROWS, LENDS, BUYS, SELLS DOWN TO 6.5% OF CSL**

*** RA CAPITAL REDUCES TO 10% OF BENITEC**

MARKET REPORT

The Australian stock market slipped 0.19 percent on Thursday February 19, 2015 with the S&P ASX 200 down 11.5 points to 5,904.2 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and four were untraded.

Oncosil was the best, up 1.1 cents or 13.75 percent to 9.1 cents with 2.2 million shares traded.

Compumedics climbed 8.3 percent; Circadian was up 5.9 percent; Analytica and Optiscan were up more than four percent; Antisense, Neuren and Prima were up more than three percent; Benitec, Genetic Technologies and Prima rose more than two percent; Alchemia was up 1.6 percent; with Acrux, Cochlear, CSL and Psivida up by less than one percent.

Patrys led the falls, down 0.2 cents or 13.3 percent to 1.3 cents with 5.6 million shares traded.

Tissue Therapies lost six percent; Prana and Sirtex were down more than three percent; Impedimed and Mesoblast shed more than two percent; Anteo, Medical Developments, Osprey, Phosphagenics, Starpharma, Universal Biosensors and Viralytics lost more than one percent; with Clinuvel and Resmed down by less than one percent.

WESTERN AUSTRALIAN NEUROSCIENCE RESEARCH INSTITUTE

The Western Australian Neuroscience Research Institute says it has discovered that some peptides are highly neuro-protective and can limit brain damage after a stroke.

WANRI said that the research was supported by Sir Charles Gairdner Hospital and the Neurotrauma Research Program and was led by Prof Bruno Meloni and Prof Neville Knuckey, who was also the head of neurosurgery at Sir Charles Gairdner Hospital.

The Institute said that the discovery of neuro-protective peptides was “particularly exciting discoveries as there are currently no neuroprotective treatments available after a stroke”.

The research, entitled ‘Poly-arginine and arginine-rich peptides are neuroprotective in stroke models’ was published in the Journal of Cerebral Blood Flow & Metabolism with an abstract at: http://www.nature.com/jcbfm/journal/vaop/ncurrent/full/jcbfm201511a.html.

“It's an area that many researchers are no longer pursuing as everything has failed to date,” Prof Bruno Meloni said. “Some have lost hope that neuro-protection of this kind will ever become available”.

“We have a different view and believe there is immense value in pursuing these significant new findings,” Prof Meloni said.

“While some of the brain injury occurs within minutes of a stroke occurring, which is obviously difficult to prevent, there is still the opportunity to minimize ongoing damaging processes which persist several hours and even days after a stroke,” Prof Meloni said.

The Institute said the findings had the potential to provide stroke victims with benefits that both complemented and differed from a recently reported stroke treatment being trialed involving improved blood supply to the brain.

The Institute said that its Stroke Research Group began researching the neuro-protective properties of poly-arginine peptides in 2012 and recently completed the first laboratory-based animal stroke study with one of the peptides, R9, securing highly promising results.

The Institute said that the study showed how a particular peptide could reduce brain injury when administered 30 minutes after the onset of a stroke and more recent studies were returning similarly positive results when treatment was given one hour after a stroke.

“Results for new therapeutic compounds like these don't come along very often, so we're feeling very hopeful that we may have discovered a potential treatment to improve a patient's quality of life after a stroke,” Prof Meloni said.

WANRI said that the commercial development of the peptides was being explored with help from the University of Western Australia and Prof Meloni was confident the team would secure additional funding this year to examine how the peptides performed in other conditions, such as spinal cord injury and other forms of brain ischemia, for example cardiac arrest, traumatic brain injury, perinatal hypoxic-ischemia.

WANRI medical director Prof David Blacker said that the impact of stroke and the limited treatments currently available made the findings even more compelling.

“These promising discoveries by professors Meloni and Knuckey offer welcome news in the challenging field of stroke research, Prof Blacker said.

“We need to see more investment in research like this as the prevalence of stroke within our community continues to rise,” Prof Blacker said.

Prof Blacker said the WA Neuroscience Research Institute was expanding its research and treatment programs so that more could be done to help combat the effects of stroke on patients and their families.

Prof Blacker said that the Institute was well-placed to quickly translate the work that scientists such as Prof Meloni were doing, into human trials through its access to a high volume stroke unit at Sir Charles Gairdner Hospital.

The Institute said that the number of people having a stroke in Australia will rise from 50,000 a year to more than 130,000 by 2050.

CYNATA THERAPEUTICS

Cynata climbed as much as 146.3 percent to $1.01 on news that it can manufacture large-scale, low-cost mesenchymal stem cells for therapeutic use.

Cynata chief executive officer Dr Ross Macdonald told a teleconference that trials at the Madison, Wisconsin-based Waisman Biomanufacturing confirmed the Cymerus stem cell manufacturing process was capable of producing mesenchymal stem cells for therapeutic application, consistently, efficiently and economically.

"It's a major milestone for the company," Dr Macdonald said. "We are able to manufacture quality stem cells in virtually unlimited quantities."

In a media release, Cynata said that its Cymerus process used "an effectively limitless starting material, a bank of induced pluripotent stem cells, and a patent-protected process to derive [mesenchymal stem cells] for commercial use".

The company said that it was "a world-first breakthrough that sets Cymerus apart from all existing methods of [mesenchymal stem cells] production, which require a continuous supply of new tissue donations".

Cynata said that it expected to be able to produce all of the mesenchymal stem cells it would need from a single induced pluripotent stem cell bank, derived from a single blood donation, with no need to repeatedly source, screen and test new donors and the issues with donor-to-donor variability would not arise.

The company said the "essentially limitless starting material means that it will not be necessary for Cynata to excessively expand [mesenchymal stem cells] in culture in order to generate the vast numbers of cells required to provide commercially-viable treatments for major diseases", significantly reducing costs.

Cynata said it would expedite its clinical trial and collaboration programs, with a phase I trial for graft-versus-host disease in the planning stage.

The company said mesenchymal stem cells were thought to have two main mechanisms of action, an anti-inflammatory effect modulating the immune system and the ability to enhance tissue regeneration by protecting cells from damage and promoting healing.

Cynata said that mesenchymal stem cells were being investigated in more than 200 clinical trials in indications ranging from immune disorders to heart disease, stroke, arthritis, fractures, degenerative disc disease, diabetes, lung disorders and eye disease.

Cynata product development vice-president Dr Kilian Kelly told the teleconference that the company's Cymerus stem cells could be used as they were for all those indications, but they could also be driven down certain pathways for other indications.

Dr Macdonald said that one of the issues facing regenerative medicine companies was how to produce enough stem cells consistently, reproducibly and economically for clinical and commercial benefit.

"Our international manufacturing partner has now confirmed our proprietary process can achieve this," Dr Macdonald said.

"This is a key requirement for pharmaceutical companies as they move to capture the opportunities presented by stem cell medicine," Dr Macdonald said.

"An abundance of stem cells clears a path toward low cost, cutting edge cell therapy," he said.

Dr Kelly said that "demonstrating that we can make cells at industrial scale under [good manufacturing practice] positions us to be at the forefront of regenerative medicine globally".

"These results confirm the viability and scalability of our platform, creating a new paradigm for the economic and consistent manufacture of [mesenchymal stem cells] for therapeutic use," Dr Kelly said.

Cynata closed up 60 cents or 146.3 percent to $1.01 with 11.0 million shares traded.

CYCLOPHARM

Cyclopharm says that total revenue for the 12 months to December 31, 2014 was up 25.8 percent to $14,962,227 taking last year's loss to a net profit after tax of $4,065,563.
Cyclopharm said that sales revenue was up 1.4 percent to $12,046,797.
Cyclopharm managing director James McBrayer told Biotech daily that it was the first time the company had posted a profit since commercializing its cyclotron in 2010 and the year included four months loss of business.
Mr McBrayer said that the company would have "no more losses from the cyclotron business and was receiving good revenue for Technegas".
Last year, the Cyclopharm cyclotron at Macquarie University Hospital "suffered substantial water damage" following a fire in the floor above the facility (BD: Jun 20, 2014)
In a media release, Cyclopharm said that the combined sales of its Technegasplus generators and patient administration sets for medical imaging were up 10 percent to $11.59 million "assisted by an increase in sales of Generators in North America, local price increases and favorable foreign exchange impacts", with the patient administration sets comprising 82 percent of revenue.
The company said that settlement of the Cyclopet dispute with the Australian Nuclear Science and Technology Organisation and its Petnet Australia subsidiary resulted in a payment of $2.65 million.
Cyclopharm said it had strong growth in Technegas sales with Canada the largest market and had begun trials of Technegas for chronic obstructive pulmonary disease in China and had made progress in obtaining US Food and Drug Administration approval for Technegas in the US.
"This past year represents a fundamental change of fortunes for the company," Mr McBrayer said.
"Roadblocks that impacted our profitability have been removed, our core operations are profitable and we have seen significant sales growth in key markets," Mr McBrayer said.
Cyclopharm said that net tangible assets per share was up 140 percent form five cents to 12 cents.
The company said that diluted earnings per share was 7.03 cents compared to the previous year's loss of 17.56 cents per share.
Cyclopharm said it had $3,268,425 in cash and equivalents at December 31, 2014 compared to $1,220,646 for the previous corresponding period.
Cyclopharm was up 13.5 cents or 45.8 percent to 43 cents with 171,000 shares traded.

REGENEUS

Regeneus says that revenue for the six months to December 31, 2014, was up 45.7 percent to $1,141,000 reducing net loss after tax 9.7 percent to $5,749,230.
Regeneus chief financial officer John Bird told Biotech Daily that the revenue was composed of sales revenue from Hiqcell and Cryoshot as well as licencing fees and other technology-related income.
The company said that diluted loss per share fell 25 percent from 0.04 cents in the previous year to 0.03 cents for the six months to December 31, 2014, with net tangible assets per share decreased from negative 4.8 cents at December 31, 2013 to negative 4.3 cents at December 31, 2014.
Regeneus said it had cash and cash equivalents of $6,738,552 at December 31, 2014, compared to $2,507,497 at June 30, 2014.
Regeneus was up one cent or 6.7 percent to 16 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says its revenue for the 12 months to December 31, 2014 fell 36.8 percent to $9,529,684, reducing its net loss after tax 19.9 percent to $9,316,127.

Universal Biosensors chief executive officer Paul Wright told an internet broadcast that the reduction in revenue related to the end of the low-margin test strip manufacturing for Johnson and Johnson's Lifescan Veriotouch blood glucose meter, improving the company's bottom line loss.

Mr Wright said that with two products in the market and Lifescan quarterly service fees rising "cash break even is now in sight".

He said that revenue from the quarterly service fees was up 89 percent to $6.4 million and the Siemens Xprecia Stride coagulation analyzer would return between 50 US cents and $1.50 per test strip depending on sales volumes, with a gradual ramp-up of sales expected.

A presentation with the internet broadcast said that there were two more coagulation tests in development for Siemens as well as the company's own coagulation test as well as an immunoassay platform at the feasibility stage and a molecular diagnostic at the concept stage.

Universal Biosensors said that research and development expenses increased by 11 percent to $17.1 million.

The company said that net tangible asset per share fell 35.3 percent to 11 cents at December 31, 2014 and diluted loss per share fell 28.6 percent to five cents compared with a seven cents loss in the previous corresponding period.

Universal Biosensors said it had cash and equivalents of $16,329,829 at December 31, 2014 compared to $23,742,422 at December 31, 2013.

Mr Wright told Biotech Daily that the company had a long term $US15 million debt at 10.5 percent interest which did not need to be repaid until 2018.

Universal Biosensors fell half a cent or 1.7 percent to 29 cents.

ALCHEMIA

Alchemia says its profit share for generic fondaparinux for the three months to December 31, 2014 fell 31.8 percent to $1.92 million compared to December 31, 2013.

In the three months to December 31, 2014 the gross revenue was $US1.55 million compared to $US2.5 million for the three months to December 31, 2013.

Alchemia said that Dr Reddy's Laboratories reported increased market share from 33 percent from 37 percent in the three months to December 31, 2014, but overall fondaparinux volume fell three percent.

The company said that it would receive $US1.05 million ($A1.29 million) of the profit share, with the final payment of $US500,000 to Dr Reddy's as its "contribution to yield and cost of goods improvement".

Last November, Alchemia said that it would receive $US1.25 million ($A1.44 million) of the $US1.75 million profit share, for the three months to September 30, 2014, with the company receiving $1.62 million as its profit share for the three months to June 30, 2014 (BD: Aug 29, Nov 27, 2014).

Alchemia was up 0.1 cents or 1.6 percent to 6.5 cents.

CSL

The Commonwealth Bank of Australian and related entities have reduced their substantial holding in CSL from 36,096,229 shares (7.54%) to 30,811,401 shares (6.50%).

The Commonwealth Bank said the shares were bought, sold, borrowed and loaned in an extraordinary number of very small trades from June 20, 2014 to February 17, 2015, requiring more than 350 pages to document the share movements.

The Commonwealth Bank said the shares were held by companies and nominee firms including Citicorp, ASB Group, First State Investments (Hong Kong), HSBC UK, Avanteos Investments, Share Direct Nominees, Colonial First State, Citibank Hong Kong, Acadian, Northern Trust Co, UBS Nominees, JP Morgan, Realindex Investments, NAB Nominees, Nomura Bank (Luxembourg), State Street Global, BNP Paribas, First State Investments (Singapore), Bank of New York Melon, RBC Dexia and UBS Nominees.

CSL was up 17 cents or 0.2 percent to $88.67 with 2.9 million shares traded.

BENITEC

RA Capital Management has reduced its substantial shareholding in Benitec from 12,804,078 shares (11.14%) to 11,629,031 shares (10.05%).

The Sydney-based RA Capital said the shares were held by RA Capital Healthcare Fund and Blackwell Partners, gave Citigroup as its address, and said the two entities sold 1,175,047 shares on-market for $1,122,383 or an average of 95.5 cents a share.

In 2014, RA Capital acquired 7,009,346 shares at $1.07 a share and became a substantial shareholder in the $31.5 million placement at $1.07 a share (BD: Feb 24, Apr 17, 2014).

Benitec was up 2.5 cents or 2.8 percent to 92 cents.