Biotech Daily

Tuesday February 16, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MESOBLAST UP 16%, ANTISENSE DOWN 8%**

*** MESOBLAST CLAIMS RHEUMATOID ARTHRITIS SAFETY, RESPONSE**

*** CSL RECORD H1 REVENUE UP 10% TO $4.4b, PROFIT UP 4% TO $1b**

*** BIOTRON JUMPS 45% ON ZIKA STUDY CONTRACT**

*** WEHI: 'LEAFY GREENS, E COLI, SULPHUR CYCLE AND GUT HEALTH'**

*** MMJ PREPARES FOR PHASE II MS TRIAL, CAPITAL RAISING**

*** GOLDMAN SACHS TAKES 10% OF REVA**

*** CYNATA RECEIVES $930k FEDERAL R&D TAX INCENTIVE**

*** SIMAVITA: BELTS TIGHTEN, DIRECTORS GO, $80k CHAIRMAN REVIEW**

*** NOVOGEN EGM FOR 7.5m CEO OPTIONS, 61% DIRECTORS POOL HIKE**

*** CREDIT SUISSE TAKES 5% OF ADHERIUM**

*** CSL APPOINTS DR MEGAN CLARK DIRECTOR**

MARKET REPORT

The Australian stock market was up 1.37 percent on Tuesday February 16, 2016 with the ASX200 up 66.5 points to 4,910.0 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 10 fell, six traded unchanged and three were untraded. All three Big Caps rose.

Mesoblast was the best, recovering from a low base, up 18.5 cents or 15.9 percent to $1.35 with 1.5 million shares traded, followed by Biotron up 10.2 percent to 5.4 cents with 2.9 million shares traded and Polynovo up 10.17 percent to 32.5 cents with 2.8 million shares traded. Orthocell climbed 9.9 percent; IDT was up eight percent; Starpharma was up 6.4 percent; Genetic Technologies improved 5.3 percent; Viralytics was up 4.4 percent; Osprey and Pharmaxis were up more than three percent; Anteo, Benitec, Nanosonics, Opthea, Prima, Pro Medicus and Sirtex rose two percent or more; with Acrux, Bionomics, Clinuvel, Cochlear, CSL and Universal Biosensors up more than one percent.

Antisense led the falls, down 0.4 cents or 8.2 percent to 4.5 cents with 10,000 shares traded. Living Cell fell 5.2 percent; Actinogen lost 3.5 percent; Medical Developments and Oncosil shed more than two percent; with Admedus, Compumedics, Ellex and Impedimed down more than one percent.

MESOBLAST

Mesoblast says that a single intravenous infusion of the lower dose of MPC-300-IV for rheumatoid arthritis is safe and resulted in early and sustained clinical responses.

Mesoblast said that the top-line results came from the first cohort of 24 rheumatoid arthritis patients who had previously failed one or more biologic agents showed that a single intravenous infusion of the one million mesenchymal precursor cells per kilogram (MPCs/kg).

The company said that cell infusions were well tolerated with no cell-related adverse events and the 12 week, pre-specified American College of Rheumatology 20 percent improvement (ACR20) efficacy endpoint was achieved by 47 percent of all MPC-treated patients and by 60 percent of MPC-treated patients who had failed one or two biologics, compared to 25 percent and 17 percent, respectively, of matched placebo-treated controls.

Mesoblast said that 71 percent of MPC-treated patients who achieved ACR20 responses did so as early as week 1 and at week 12, 27 percent of MPC-treated patients, but no placebo-treated controls, achieved improvements of 50 percent or 70 percent on the American College of Rheumatology scale.

The company said that remission at week 12, as defined by an established disease activity score was seen in 20 percent of MPC-treated patients but in no controls.

Mesoblast said that the mesenchymal precursor cell product candidate MPC-300-IV, which had the US Adopted Names designation of “rexlemestrocel-L” was being evaluated in a US double-blind, randomized, placebo-controlled, two-dose escalating trial designed to evaluate safety and explore efficacy in 48 patients with active rheumatoid arthritis randomized two-to-one to either placebo or a single intravenous infusion of one million or two million MPCs/kg.

The company said that all patients were on a stable regimen of methotrexate and had previously failed or had an adverse or inadequate clinical response to at least one biologic agent.

Mesoblast said the lower dose was evaluated in the first cohort of 24 patients, of whom 16 had failed one or two biologics and the second cohort of 24 patients, evaluating the higher dose was actively recruiting, with results expected by October 2016.

The company said that the primary endpoint was safety, with pre-specified efficacy endpoints at 12 weeks including the American College of Rheumatology 20 percent, 50 percent and 70 percent response criteria.

Mesoblast said that ACR20 was a key validated primary endpoint in clinical trials accepted by the US Food and Drug Administration for product approval in rheumatoid arthritis.

Mesoblast chief executive Prof Silviu Itescu said the company was “encouraged by the efficacy signals seen in the initial results using the lower dose of Mesoblast’s cell therapy in biologic refractory patients with rheumatoid arthritis.”

“They suggest that a single intravenous administration of our cell therapy may result in rapid and sustained responses in patients with active disease where disease remission remains the clear goal,” Prof Itescu said.

Mesoblast said that in 2014, rheumatoid arthritis affected more than 5.3 million people in the US, Japan and the five major European markets, with 2.4 million patients in the US alone.

The company said that advances using biologic agents for rheumatoid arthritis increased the market size to $15.7 billion in 2014, with the market expected to grow to $18.4 billion in 2024, and despite advances in the use of biologic agents, about one third of patients either did not sufficiently respond or could not tolerate these agents.

Mesoblast climbed 18.5 cents or 15.9 percent to $1.35 with 1.5 million shares traded.

CSL

CSL's net profit after tax for the six months to December 31, 2015 was up 3.8 percent to a record $US718.8 million ($A1,007.8 million) on revenue up 10.4 percent to $US3,136 million ($A4,396.7 million).

CSL said that research and development expenditure increased 21.6 percent from $US233.4 million in the six months to December 31, 2014 to $US283.9 million for the six months to December 31, 2015 or as a percentage of total revenue, research and development expenditure increased from 8.5 percent for the half year to December 31, 2014 to 9.05 percent for the six months to December 31, 2015.

The company said that diluted earnings per share was up 6.25 percent to $US1.546 and the interim unfranked dividend of 58 US cents, was unchanged from the previous corresponding period and would be paid on April 15, with a record date of March 24, 2016.

CSL said it had cash and cash equivalents of $US1,092.0 million at December 31, 2015.

In a media release and teleconference, CSL chief executive officer Paul Perreault said that the "R&D engine remained strong and a key advantage for CSL".

Mr Perreault said that the company would have its Centenary in April, that "few organizations have such a rich heritage and such a bright future" and plans to celebrate the 100 years were underway.

Mr Perreault said he expected 2016 to be "an extraordinary year" with approvals expected in the US and Europe for the recombinant factor IX Idelvion or CSL654 and factor VIII Afstyla or CSL627.

Mr Perreault said the company had "double digit growth in all plasma groups" with Hizentra sales up 31 percent, Privigen sales up 13 percent, albumin sales up 10 percent, haemophilia products up 13 percent and speciality products up 14 percent.

He said revenue from the Seqirus business created by the acquisition of the Novartis influenza business was $US519 million "in a very mild 'flu season", CSL was the second largest provider of influenza vaccines and he intended CSL to be the market leader.

Mr Perreault said the influenza business would make an overall loss of $US90 million to $US120 million but the overall profit guidance for the year to June 30, 2016 remained at a five percent increase over the previous year's $US1,379.0 million (BD: Aug 12, 2015).

CSL was up $1.57 or 1.5 percent to $106.00 with 1.4 million shares traded.

BIOTRON

Biotron jumped as much as 44.9 percent to 7.1 cents on news that it is investigating its compounds for efficacy against the Zika virus.

Biotron said that it had contracted the Frederick, Maryland-based Imquest Biosciences laboratory to test the activity of specific compounds against Zika virus.

The company said that a number of viruses including Ebola, Middle East respiratory syndrome, coronavirus and Zika had viroporins as a part of their infection regime and it had been developing an anti- platform technology targeting these viral-encoded viroporins.

Biotron said it had developed a library of viroporin-targeting compounds.

Biotron chief executive officer Dr Michelle Miller said there had been "increasing interest in Biotron's broad antiviral platform".

"This first round of screening is a starting point for Biotron's Zika program, noting that additional compounds may need to be screened, or additional chemistry undertaken to design compounds with targeted activity against this virus," Dr Miller said.

Biotron said that Zika virus was similar to Dengue fever, against which it had several compounds with promising antiviral activity.

Biotron closed up half a cent or 10.2 percent at 5.4 cents with 2.9 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that the YihQ enzyme in leafy green vegetables feeds “good gut bacteria, limiting … bad bacteria”.

The Institute said that the previously unknown enzyme was used by bacteria, fungi and other organisms to feed on the unusual but abundant sugar sulfoquinovose found in green vegetables.

WEHI said that the research, entitled ‘YihQ is a sulfoquinovosidase that cleaves sulfoquinovosyl diacylglyceride sulfolipids’ was published in Nature Chemical Biology, and was led by the Institute’s Dr Ethan Goddard-Borger, with Bio21 Institute’s Prof Spencer Williams and the University of York’s Prof Gideon Davies and an abstract is at: http://www.nature.com/nchembio/journal/vaop/ncurrent/full/nchembio.2023.html.

Dr Goddard-Borger said the discovery could be exploited to cultivate the growth of ‘good’ gut bacteria.

“Every time we eat leafy green vegetables we consume significant amounts of [sulfoquinovose] sugars, which are used as an energy source by good gut bacteria,” Dr Goddard-Borger said.

Dr Goddard-Borger said that bacteria in the gut, such as crucial protective strains of Escherichia coli (E coli), used sulfoquinovose as a source of energy.

“E coli “provides a protective barrier that prevents growth and colonisation by bad bacteria, because the good bugs are taking up all the habitable real estate,” Dr Goddard-Borger said.

“We speculate that consumption of this specific molecule within leafy greens will prove to be an important factor in improving and maintaining healthy gut bacteria and good digestive health,” Dr Goddard-Borger said.

Prof Williams said the team had discovered the enzyme YihQ, which was used by bacteria to absorb and metabolise sulphur-containing sugars as food.

“Sulphur is critical for building proteins, the essential components of all living organisms,” Prof Williams said.

“[Sulfoquinovose] is the only sugar molecule which contains sulphur, and digestion of the molecule by bacteria releases sulphur into the environment, where it re-enters the global sulphur cycle to be reused by other organisms,” Prof Williams said.

Prof Williams said the pathway was unusual, but abundant in biological organisms.

“This work answers a 50-year mystery that has surrounded how sulphur, an element essential for life on Earth, was used and recycled by living organisms,” Prof Williams said.

“What is remarkable is that the YihQ enzyme was hiding in plain sight and is produced by the humble bacterium E coli, present in nearly every biologist’s laboratory,” Prof Williams said.

Dr Goddard-Borger said that the discovery provided “crucial insights that may one day be exploited to develop an entirely new class of antibiotics”.

“New antimicrobial strategies are desperately needed as more and more bacteria acquire resistance to existing classes of antibiotics,” Dr Goddard-Borger said.

“We think it will be possible to use these widespread enzymes to enable highly specific delivery of antibiotics to harmful forms of E coli and other pathogens, such as Salmonella, responsible for food poisoning, while leaving the good gut bacteria untouched,” Dr Goddard-Borger said.

WEHI said that the research was supported by the National Health and Medical Research Council, Australian Research Council, Ramaciotti Foundation, Veski, the Victorian Government Operational Infrastructure Support Program, UK Biotechnology and Biological Sciences Research Council and the European Research Council.

MMJ PHYTOTECH

MMJ Phytotech says it is creating a vertically integrated medicinal cannabis company and will need to raise capital ahead of a planned phase II multiple sclerosis trial.
MMJ managing director Andreas Gedeon told an investor briefing in Melbourne that the company planned to be the first company to grow, refine and market medical marijuana.
Mr Gedeon said that with Health Canada ready to approve the 10,000 square feet (about 929 square metres) facility in Duncan, Vancouver, the company should be able to produce one tonne of flowering buds a year worth about $5 million to $6 million at a wholesale level but about $25 million when refined into its gel capsules.
Mr Gedeon said the company had spent about $8 million so far on the facility with most of the spending on security measures including computers and monitoring equipment, to meet Canadian regulatory requirements.
He said that once operational the plant would cost about $2.2 million a year to operate.
Mr Gedeon said that medical marijuana was not led by industry but by patients and physicians and spoke of juvenile epilepsy patients who had reduced their 100 seizures a day by 50 percent while taking medical cannabis.
He said results published last week showed that MMJ's 7mg and 10mg oral capsule doses were comparable with, if not better than, the $US958 million Cambridge UK-based GW Pharmaceuticals' Sativex (BD: Feb 11, 2016).
Mr Gedeon said that MMJ's aim was to produce a standardized safe reliable delivery of its tetrahydrocannabinol and cannabidiol (CBD) compounds.
He said the 10mg and 100mg CBD capsules, which were not psychoactive, were available on-line as "a dietary supplement" and were earning $2,000 a day in Europe.
The Israel-based Phytotech Therapeutics chief executive officer Dr Daphna Heffetz told the meeting that the planned 60-patient, phase II, multiple sclerosis trial would be randomized, controlled and using a cross-over design with an efficacy endpoint of the impact on spasticity, or muscle contraction and pain.
Dr Heffetz said the trial was expected to begin by the end of 2016 and take about 12 weeks.
MMJ was up half a cent or 1.7 percent to 29.5 cents.

REVA MEDICAL

Reva says that Goldman Sachs International has become a substantial shareholder in the company, with the equivalent to 43,750,000 Chess depository instruments (10.3%).
Reva said that Goldman Sachs exercised options issued on November 14, 2014, resulting in proceeds of $US11,406,938 ($A15,953,741) or cents 36.5 cents per exercised option.
Reva fell one cent or 0.8 percent to $1.18.

CYNATA THERAPEUTICS

Cynata says it has received $932,581 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Cynata said that Federal R&D Tax Incentive refund related to expenditure in the year to June 30, 2015.
Cynata chief executive officer Dr Ross Macdonald said that "the R&D Tax Incentive … provides a very useful addition to the company's balance sheet and extends our operating runway at a time when we plan to soon commence the clinical trial of our first proprietary Cymerus mesenchymal stem cell product CYP-001".
Cynata fell two cents or 5.6 percent to 34 cents.

SIMAVITA

Simavita says a strategy review has identified cost containment, revenue uplift and capital management as priorities.
Simavita chairman Michael Brown said the company needed to extend “its global resources and reach through licensing agreements with large global players”.
The company said that “in-line with initiatives to further streamline the business” directors Ari Bergman and Damien Haakman would retire on February 29, 2016.
Simavita said that Mr Bergman had been a director for 15 years and was the son of the late Dr Fred Bergman, whose original concept led to the precursor to Simavita.
The company said that it had begun “a systematic program of cost reduction beginning with the board and [the chief executive officer]” with Philippa Lewis setting an example reducing her annual salary by 30 percent until the company has secured its first major licencing agreement.
Simavita said that as part of its global strategic review, it had retained the Melbourne-based corporate advisory firm Integrated Equity Pty Ltd and chairman Michael Brown, was also the founder and executive chairman of Integrated Equity.
The company said that Integrated Equity held 519,410 common share purchase warrants exercisable at 41 cents by December 3, 2016, issued in connection with services provided for the December 2013 initial public offer.
Simavita said that Integrated Equity also owned 500,000 options exercisable at 62 cents by July 1, 2017 for corporate advisory services and Mr Brown currently owned, exercised control or direction over, directly or indirectly, 210,000 shares.
The company said that the engagement of Integrated Equity was for two months, and allows for up to 16 consulting days per month, at a fee of $2,500 per day.
Simavita said that the engagement would “not attract any other fees, and no securities of the company will be issued to Integrated Equity in connection with the engagement”.
Simavita fell half a cent or 4.35 percent to 11 cents.

NOVOGEN

Novogen will vote to grant chief executive officer Dr James Garner 7,500,000 options and increase the directors remuneration pool by 60.7 percent to $900,000.
Novogen said that Dr Garner’s options would be issued in two tranches, with the first tranche of 5,000,000 options exercisable at 19.88 cents, vesting at six months, one year, 18 months, two years and three years from commencement; and the second tranche of 2,500,000 options exercisable at 26.05 cents each vesting at four from commencement.
The company said that the maximum aggregate non-executive directors’ remuneration of $560,000 had not increased since the 2005 annual general meeting.
Novogen said that shareholders would also vote on the election of director of Iain Ross.
The meeting will be held at Level 5, 20 George Street, Hornsby, Sydney on March 18, 2016 at 10.30am (AEDT).
Novogen fell half a cent or 4.8 percent to 10 cents.

ADHERIUM

Credit Suisse Australia on behalf of Credit Suisse Group AG says it has become a substantial shareholder in Adherium with 7,173,182 shares (5.01%).
The substantial shareholder notice said that 4,669,425 shares were acquired under a securities lending agreement.
Adherium was unchanged at 50 cents.

CSL

CSL says that former Commonwealth Scientific and Industrial Research Organisation chief executive Dr Megan Clark has been appointed a director.

CSL said that Dr Clark's appointment was, effective from today, February 16, 2016.

The company said that Dr Clark was the chief executive of CSIRO from 2009 to 2014 and was currently a director of the mining group Rio Tinto and a member of the Australian advisory board of the Bank of America Merrill Lynch.

CSL said that prior to CSIRO, Dr Clark was a director at NM Rothschild and Sons (Australia) and a senior executive at BHP Billiton.

The company said that Dr Clark held a Bachelor of Science from the University of Western Australia and a Doctorate of Philosophy from Queen's University, Canada.