Biotech Daily

Tuesday August 19, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: BIOTRON UP 17%, LIVING CELL DOWN 14%**

*** BIONOMICS $3m MAIDEN PROFIT ON REVENUE UP 133% TO $28m**

*** REGENEUS REGISTER SHOWS 2-YEAR HIQCELL JOINT BENEFIT**

*** INNATE READY TO START PHASE IIb MIS416 MS TRIAL**

*** MEDLINE'S FIRST US COMMERCIAL ORDER OF SIMAVITA DIAGNOSTIC**

*** ANTISENSE HIRES DESTUM FOR PARTNERING, LICENCING DEALS**

*** ANALYTICA APPOINTS US CLINICAL ADVISORY BOARD**

MARKET REPORT

The Australian stock market climbed 0.66 percent on Tuesday August 19, 2014 with the S&P ASX 200 up 36.7 points to 5,623.8 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and six were untraded. All three Big Caps were up.

Biotron was the best, up two cents or 16.7 percent to 14 cents with 635,975 shares traded, followed by Analytica up 12.5 percent to 3.6 cents with 956,659 shares traded.

Impedimed and Tissue Therapies climbed more than six percent, Compumedics rose 4.2 percent; Bionomics was up 3.9 percent; Prana and Prima rose more than two percent; Acrux, Atcor, Cochlear, CSL, Neuren and Phosphagenics were up more than one percent; with Psivida and Resmed up by less than one percent.

Living Cell led the falls, down 0.8 cents or 13.6 percent to 5.1 cents with 409,829 shares traded.

Benitec and Pharmaxis lost five percent or more; Avita, GI Dynamics, Medical Developments and Starpharma fell more than four percent; Admedus, Anteo and IDT were down more than three percent; Universal Biosensors shed 2.8 percent; Clinuvel fell 1.3 percent; with Mesoblast and Sirtex down by less than one percent.

BIONOMICS

Bionomics has declared a maiden net profit after tax for the 12 months to June 30, 2014 of $3,206,616 on revenue up 132.9 percent to $27,545,996.

Bionomics said that $18,046,709 was received as collaboration income and $3,267,589 recorded as “unearned income” relating to the payment of a $US20 million ($A21.4 million) upfront fee from the US based Merck & Co for the licencing of BNC375.

In June, Bionomics said that Merck, known as Merck Sharp and Dohme outside the US and Canada, would pay the $US20 million upfront payment for the collaboration with for its BNC375 cognitive dysfunction program.

Bionomics said the BNC375 collaboration was targeting Alzheimer’s disease and other central nervous system conditions and could be worth up to $US506 million ($A536.8 million) including milestones, but not royalties on product sales (BD: Jun 24, 2014).

Today, Bionomics said that the funds were received after June 30, 2014 and not included in earlier Appendix 4C announcements, BUT could be included in the full year accounts.

Bionomics said it received a further $1,095,356 for services rendered, a 6.1 percent improvement on the previous year.

Last year, Bionomics said it would licence a compound to Merck to discover and develop small molecule candidates for chronic pain, including neuropathic pain (BD: Jul 31, 2013).

Bionomics said at that time that the two-year agreement with Merck provided option exercise fees and development and regulatory milestone payments of up to $US172 million ($A190.4 million), and could be eligible for undisclosed royalties on net sales.

Today, the company said it received a further $7,505,598 from the Federal Government’s R&D Tax Incentive program as well as $118,892 from a Federal Government grant.

Bionomics said that research and development expenditure increased 6.3 percent to $17,785,002.

The company said that net tangible assets per share was up 16.9 percent from 5.9 cents to 6.9 cents and diluted earnings per share was 0.8 cents compared to the previous year’s loss of 2.7 cents a share, and it had $10,501,307 in cash and cash equivalents at June 30, 2014, compared to $22,452,089 at June 30, 2013.

Bionomics was up two cents or 3.9 percent to 53 cents.

REGENEUS

Regeneus says that 63 patients (73.3%) of 86 patients at 12 months post-treatment have responded to its Hiqcell fat stem cell treatment for osteoarthritis.

Regeneus said that data from its voluntary registry included 386 patients at July 21, 2014 with 14 of 17 assessed at 24 months, reporting more than a 30 percent reduction in pain, with an average pain reduction of 84 percent at two years.

The company said that patients also reported significant improvements in knee function, sleep quality and reduced pain medication.

In March, Regeneus reported that 56 patients (72.7%) of 77 patients at 12 months post-treatment responded to its Hiqcell treatment (BD: Mar 26, 2012).

Regeneus chief executive officer Prof Graham Vesey said that the registry data was demonstrating that Hiqcel had a therapeutic benefit for more than two years.

“We are now also beginning to see very encouraging data from patients that have had cells frozen for future injections,” Prof Vesey said.

“This combination of the long-term effect from Hiqcell and the successful storage of cells for repeat injections in the future, means that Hiqcell can be used to treat joint pain for many years,” Prof Vesey said.

Regeneus was up 1.5 cents or 5.9 percent to 27 cents.

INNATE IMMUNOTHERAPEUTICS

Innate says it expects to dose the first of up to 90 patients in its phase IIb trial of MIS416 for secondary progressive multiple sclerosis, in the coming three weeks.

Innate said that the private, independent Bellberry Human Research Ethics Committees approved the Western Australian Neuroscience Research Institute to begin patient recruitment.

The company said that the approval enabled the Institute to begin patient recruitment immediately with the first patients expected to be dosed within the next two to three weeks following baseline measurements of their present multiple sclerosis-related symptoms.

Innate said that the Western Australian Neuroscience Research Institute was selected as the study's lead site “due to its strong focus on investigating the causes and improving the therapy and management of patients suffering from multiple sclerosis”.

The Institute’s professor of neuro-immunology Prof Allan Kermode said that secondary progressive multiple sclerosis affected 30 percent of the multiple sclerosis population at any moment in time, with no approved long term effective treatment options.

“We all hope that MIS416 might be the drug to address this urgent need,” Prof Kermode said.

Innate said that the double blinded, randomized phase IIb study would treat patients with either MIS416 or placebo once weekly for 12 months, with a primary goal to determine the efficacy and safety of MIS416 compared to placebo.

The company said that previous non-placebo controlled MIS416 studies found that 80 percent of patients with secondary progressive multiple sclerosis had shown a 30 percent or greater improvement in at least one measure of their multiple sclerosis-related symptoms.

Innate said that patient stakeholder groups such as Multiple Sclerosis Research Australia and the US National Multiple Sclerosis Society had expressed support for its pursuit of an effective treatment for secondary progressive multiple sclerosis.

Multiple Sclerosis Research Australia chief executive officer Dr Matthew Miles said that Australia had “a strong cohort of world-leading [multiple sclerosis] neurologists who are highly experienced clinical trial investigators and strongly committed to supporting the development of new treatments for their patients”.

Innate said it expected trial sites in the Eastern states to obtain ethics approval over the next month with other centres to follow.

Innate was up half a cent or 2.5 percent to 20.5 cents.

SIMAVITA

Simavita says its US distributor Medline has begun the commercial roll-out of the smart incontinence management (SIM) diagnostic with its “first significant order”.

Simavita said that Australian residential aged-care provider Arcare Pty Ltd had committed to roll-out the SIM diagnostic across the remaining 17 facilities in its network.

The company said that Arcare had introduced SIM into six of its facilities and has decided to expand its use into all 23 of its facilities across Victoria and Queensland.

Simavita said that Arcare owned more than 2,100 beds.

Simavita chief executive officer Philippa Lewis said that Arcare’s decision to adopt SIM throughout its entire network was a strong endorsement of the many benefits provided by the diagnostic.

Simavita was up seven cents or 15.6 percent to 52 cents.

ANTISENSE THERAPEUTICS

Antisense says it has engaged the San Diego, California-based advisory firm Destum Partners to advance project partnering plans and consider other opportunities.
Antisense said it intended to capitalize on the development progress made and positive data generated on compounds ATL1103 and ATL1102 by out-licencing them to suitable partners.
The company said that with Destum it would seek to partner its projects with pharmaceutical companies who would also provide funding for the phase III development of ATL1103 and a phase IIb trial of ATL1102 in multiple sclerosis patients.
Antisense said that in parallel with partnering discussions, it would continue to develop its compounds to support the further clinical development of ATL1103 and ATL1102.
The company said that the results from the phase II trial of ATL1103 in acromegaly patients was due by the end of August 2014 and successful results would position ATL1103 to move to phase III stage of development.
Antisense said that in view of the good tolerability seen in the current phase II trial it would conduct a small study of ATL1103 at a higher dose trial for potential use in phase III trials.
The company said that animal toxicology results on ATL1102 provided an opportunity to resume its plans for the further clinical development of ATL1102 and the company submitted a request for the US Food and Drug Administration assessment of its plans for a phase IIb trial of ATL1102 in multiple sclerosis patients.
Antisense said that at the same time, it was looking into accessing additional existing clinical supplies of ATL1102 for use in the phase IIb trial, which would add further value to any potential partnering interactions and will speed development.
The company said it might consider other clinical applications of ATL1103 and ATL1102 and/or adding new compounds to its development pipeline.
Antisense managing director Mark Diamond said the company's objective was "to out-licence all of its compounds, which may occur at various stages in their development, but with the clear intention to add and realize value for shareholders".
Antisense was unchanged at 14 cents.

ANALYTICA

Analytica said that it has appointed a US clinical advisory board for the development of its intra-vaginal Pericoach pelvic floor diagnostic and training tool.
Analytica said that the US board comprised the Cleveland Clinic's Dr G Willy Davila, Shenandoah University's Dr Francie Bernier, Chicago's Loyola University's Prof Elizabeth Mueller, Dr Beth Shelly, physiotherapist Dawn Sandalcidi and fitness trainer Mary Drill.
The company said that the Australian advisory board had been meeting for about 12 months and each member was "a thought leader in their specialty, their opinions are respected by peers and colleagues in Australia and internationally".
Analytica said that the Australian board had been instrumental in designing the clinical trial protocol, with four of its members providing patient recruitment sites.
The Australian board consists of Townsville Mater Hospital's Prof Ajay Rane, urologic surgeon Dr Ailsa Wilson Edwards, Melbourne's Royal Women's Hospital's Dr Margaret Sherburn, Newcastle University's Prof Pauline Chiarelli, Australian Urology Associates nurse Kay Talbot and fitness trainer Marietta Mehanni.
Analytica was up 0.4 cents or 12.5 percent to 3.6 cents.