Biotech Daily

Tuesday September 16, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 7%, PATRYS DOWN 8%**

*** DAVID MILES LEADS REVIEW OF COOPERATIVE RESEARCH CENTRES**

*** W.H.O. FUNDS VAXXAS POLIO NANOPATCH TRIALS**

*** FDA AGREES FASTER AVITA RECELL BURNS TRIAL**

*** FDA TO RESPOND TO ANTISENSE ATL1102 FOR MS; EURO PATENT**

*** AUSTRALIAN PATENT FOR ORTHOCELL ORTHO-ATI**

*** MEDLINE WINS $277k LORIEN CONTRACT FOR SIMAVITA SYSTEM**

*** BIOTA: 'LOSS OF BARDA CONTRACT DELAYS ANNUAL REPORT'**

*** CLINUVEL PLEADS RETROPHIN BID TO ASX 31.7% QUERY**

*** MINING INVEST, ELIAS LEO KHOURI BELOW 5% OF BIOPROSPECT**

MARKET REPORT

The Australian stock market fell 0.51 percent on Tuesday September 16, 2014 with the S&P ASX 200 down 28.1 points to 5,445.4 points. Ten of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and four were untraded.

Impedimed was the best, up 3.5 cents or 7.1 percent to 52.5 cents with 948,087 shares traded.

Genetic Technologies and Oncosil climbed four percent or more; Atcor and Cellmid were up more than three percent; Tissue Therapies and Universal Biosensors rose more than two percent; Viralytics was up 1.85 percent; with Benitec, Cochlear and Prana up by less than one percent.

Patrys led the falls, down 0.2 cents or 8.3 percent to 2.2 cents with 1.4 million shares traded.

Bionomics lost 7.3 percent, Ellex, Living Cell and Osprey fell more than four percent; Admedus was down 3.7 percent; Analytica, Clinuvel and Prima shed more than two percent; Alchemia, Mesoblast, Nanosonics, Pharmaxis, Phosphagenics and Resmed fell more than one percent more; with Acrux, CSL and Sirtex down less than one percent.

FEDERAL GOVERNMENT

The Federal Government has appointed David Miles to lead a review of the Cooperative Research Centres program.

A media release from the Minister for Industry Ian Macfarlane said Mr Miles was a ”prominent lawyer and innovation expert” and the former chair of Innovation Australia, who would bring experience, expertise and insight to the review.

“This year is the 25th anniversary of the CRC program and an important time to review the program and its role in supporting business and researchers to work together in industry-led partnerships,” Mr Macfarlane said.

The media release said that the CRC program began in 1991 under the Hawke Government and since then, 209 CRCs had been funded by the Australian Government which had committed more than $3.8 billion through the program.

The media release said that 36 CRCs continued ranging from cell therapy to space environment management.

“The CRC program has facilitated research and development in a range of areas by bringing together researchers, industry and the community,” Mr Macfarlane said.

“As Australia moves to consolidate its strengths and facilitate more frequent and targeted research connections between business and science, now is the ideal time to assess the program and ensure Australia is making effective investments in collaborative projects that will boost Australia’s productivity and international competitiveness,” Mr Macfarlane said.

The media release said the review would begin this month, the recommendations expected by early 2015, with the review’s terms of reference and information on how to make a submission available at: www.business.gov.au/CRC-Review.

VAXXAS

Vaxxas says that the World Health Organisation will fund its polio vaccine Nanopatch research program.

The Brisbane-based Vaxxas said that the Nanopatch induced “robust immune system activation by targeting vaccine to the abundant immunological cells immediately below the surface of the skin”.

The company said that the World Health Organization would provide funding to support its polio vaccination research, specifically for pre-clinical studies and good manufacturing practices.

A spokesman for the company told Biotech Daily that the funding would cover clinical trials in Australia.

Vaxxas said that polio was one of the most dreaded childhood diseases of the 20th Century, resulting in limb disfigurement and irreversible paralysis in tens of millions of cases and as recently as 1988, more than 350,000 cases occurred every year in more than 125 endemic countries.

Vaxxas said that concerted efforts to eradicate the disease have reduced incidence by more than 99 percent and efforts were being intensified to eradicate the remaining strains of transmission once and for all.

Vaxxas chief executive officer David Hoey said that the Nanopatch did not need to be kept refrigerated to maintain its efficacy, which was important for the transportation and application of polio vaccine in remote regions, where eradication efforts were most challenging.

“The research we are undertaking with WHO’s support aims to provide better vaccine solutions to reach all children anywhere,” Mr Hoey said.

Vaxxas is a private company.

AVITA MEDICAL

Avita says the US Food and Drug Administration has approved extensive changes to its US trial of Recell for burns, making it more accessible and broadening its scope.

Avita began the trial in 2009 and in 2012 reported that about 75 percent of the expected 106 patients had been enrolled (BD: May 27, 2009; Jan 28, 2010; Sep 28, 2012).

Today, the company said that an additional cohort of 25 patients would be recruited.

Avita said that the trial to date had been designed to demonstrate the superior expansion of donor skin achieved with Recell by comparing the use of the autologous cell suspension created with Recell to conventional mesh graft treatment.

The company said that the trial protocol specified an age range of 18 to 65 years, total body surface area injured to be less than 20 percent and treatment of only specific deep partial thickness second-degree burns.

Avita said that the changes would allow an age range of five years and older with up to 50 percent total body surface area burns.

The company said that the complementary use of Recell in combination with expanded mesh grafts allowed the product to be part of the treatment of injuries for which skin grafting was required, regardless of depth, a technique which was the clinical standard in Western Australia and was also how US surgeons used Recell for individual FDA-approved compassionate use cases.

Avita said that the changes would also improve Recell market penetration post-approval.

The company said that the revised program took advantage of US clinical experience in both the burns trial and compassionate use cases, allowing for evaluation of Recell as a complementary treatment to expanded meshed skin grafting in the 25-patient cohort.

Avita chairman Lou Panaccio said the changes were “a significant leap forward for the company and will provide better trial outcomes to enhance future commercial opportunities for Recell”.

The company said that Recell could improve clinical outcomes for burn patients primarily by reducing the amount of healthy donor skin harvested during surgical grafting.

Avita said that the previous study design was motivated to ensure limited confounding factors by enforcing narrow, homogeneous selection of study participants, but an unintended effect was great difficulty in recruitment, and burn patients who had the most to benefit from a reduction in requirement for graft donor skin were precluded.

The company said that harvesting donor skin was painful and the availability of healthy skin was limited, especially for paediatric cases and patients with extensive burns.

Avita’s head of research and technology Andrew Quick said the FDA approved changes would improve patient enrolment rates, which had been less than one subject per month and had stalled Avita’s regulatory progress in the US burns market.

Mr Quick said that revised trial criteria would result in a clearer and timelier path to market, and the opportunity to highlight the clinical benefits of using Recell for a greater range of patients.

“We have every confidence that Recell, when used to complement expanded mesh grafting, will demonstrate statistically superior patient outcomes versus mesh grafts alone,” Mr Quick said.

“The increase to the allowed [total body surface area] broadens the population who can participate, but more importantly will serve to highlight the benefit of reduced donor area in the larger burns,” Mr Quick said.

Avita said it expected to begin enrolling the 25 patient cohort in early 2015, with enrolment completed by the end of 2015, with each patient to be followed for 12 months, but a pre-market application could be made prior to all patients completing the 12 month follow-up.

Avita closed unchanged at 10.5 cents with 2.7 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it expects to receive the US Food and Drug Administration response for its ATL1102 multiple sclerosis clinical trials by October 17, 2014.

Antisense said that it had requested a pre-investigational new drug assessment, FDA guidance and agreement on the intended content of the planned submission, including the proposed phase IIb clinical study design and supporting non-clinical toxicology studies.

Antisense managing director Mark Diamond said that FDA guidance would be “a pivotal step in the continued development of ATL1102”.

“A positive outcome would underpin our partnering and commercialization plans for this drug and allow us to capitalize on the substantial development and investment made to date in this project asset,” Mr Diamond said.

The company said that the European Patent Office had allowed a patent application entitled ‘Methods for Treating Multiple Sclerosis using Antisense Oligonucleotides’ which extended coverage of the ATL1102 compound for the treatment of relapsing-remitting multiple sclerosis patients until 2029 with potential for a five-year extension to 2034.

Antisense said that granting of the European patent was a formality and would take place in the coming months.

The company said that global sales for drugs treating relapsing-remitting multiple sclerosis in 2013 was about $US14 billion.

Antisense was unchanged at 14 cents.

ORTHOCELL

Orthocell says an Australian patent covering the use of biological materials to repair damaged tendons, protects its Ortho-ATI autologous tenocyte implantation.

Orthocell said that the granted patent, entitled ‘Tenocyte Containing Bioscaffolds and Treatment Using the Same’, protected its intellectual property for the preparation of bio-scaffolds and tendon stem cells to treat rotator cuff tears in a patient’s shoulder and further protected Ortho-ATI.

Orthocell managing director Paul Anderson said the patent grant was “further validation of Orthocell’s innovation and leadership in the area of regenerative medicine and in particular the regeneration of human tendon tissue”.

The company said that the patents related to the methods it used to cultivate and grow a patient’s own tendon cells, known as tenocytes; seed a scaffold with the tenocytes; and implant the tenocyte-seeded bioscaffold close to the rotator cuff tear.

Orthocell said that the Australian patent followed patents granted in New Zealand, Singapore and China.

The company said that rotator cuff tendon tear was a common injury caused by the overuse of tendons in the shoulder, most commonly seen in athletes, as well as work-related and other overuse activities.

Orthocell said that surgical procedures could be effective in mechanically stabilizing rotator cuff tendon tears, but new ways to treat the injury were needed as success rates for mechanical stabilization alone to repair failed repairs were very low.

The company said that up to 40 percent of rotator cuff stabilization surgeries eventually failed as the underlying pathology of the tendon, including insufficient viable tendon repairing cells or tenocytes, were absent.

Orthocell said that its ATI technology in conjunction with stabilization would support repair and regeneration of the tendon.

Orthocell was unchanged at 38 cents.

SIMAVITA

Simavita says that US distributor Medline Industries has a $US250,000 ($A277,340) contract providing its smart incontinence management diagnostic to Lorien Health.
Simavita said that US aged care provider Lorien had more than 1,400 beds in its nine nursing facilities and five assisted living facilities in Maryland.
The company said the smart incontinence management (SIM) diagnostic would be rolled-out across all of Lorien's nursing facilities, replacing the numerous manual continence assessments which are currently being undertaken.
Simavita said it expected Lorien to conduct about assessments across its nine nursing facilities and that the value of this agreement to Medline over the one year life of the contract would be about $US250,000.
Simavita chief executive officer Philippa Lewis said the SIM system would "deliver a range of important economic benefits to Lorien's facilities ... [and] their residents".
Simavita was up one cent or 1.8 percent to 57 cents.

BIOTA PHARMACEUTICALS

Biota says its annual report will be late because it needs time to calculate the impact of the termination of its Biomedical Advanced Research and Development Authority contract.
Biota told the US Securities and Exchange Commission that it was "unable to file its annual report on Form 10-K for the year ended June 30, 2014 ... by the prescribed due date without unreasonable effort or expense because additional information and time is required to properly account for and disclose in its audited financial statements the impact of the recent termination by BARDA of its contract with the registrant for the development of laninamivir octanoate".
The company said that it was "continuing to work diligently on the completion of the annual report and anticipates filing the annual report on or before the 15th calendar day following the prescribed due date for the annual report".
Separately, Biota said it would host a conference call on September 26, 2014 at 9am (USEDT) to review the fourth quarter and year-end 2014 financial results and provide an update on recent corporate developments"
In April, BARDA halted work on the $US231 million contract and terminated it in May, refuting the company's claims that it had not been given reasons either for the stop-work order or the termination (BD: Apr 30, May 1, 9, 2014).
In August, Biota said that top-line data from its phase II 'Igloo' trial comparing 40mg and 80mg laninamivir octanoate to placebo showed no significant benefit (BD: Aug 4, 2014).
Biota said that the BARDA-funded 639-patient, randomized, double-blind, placebo-controlled, parallel-arm trial found that median time to alleviation of influenza symptoms was 102.3 hours for the 40mg cohort, 103.2 hours for the 80mg cohort and 104.1 hours for the placebo cohort.
In June, following the termination of its $US231 million 2011 BARDA contract, Biota said it would close its Australian operations and sack more staff (BD: Jun 3, 2014).
Biota was developing its long-acting neuraminidase inhibitor, laninamivir octanoate, when it merged with Nabi Pharmaceuticals to access its $US54 million in cash, eventually settling for $US27 million in cash (BD: Apr 1, 2011; Apr 23, Oct 30, 2012).
Last year, Biota sacked 30 percent of its workforce and closed its pre-clinical antibiotic programs (BD: Apr 17, Nov 22, 2013).
On the Nasdaq last night, Biota fell four US cents or 1.74 percent to $US2.26 ($A2.50 - equivalent to 31.25 cents prior to the Nabi merger, when it was trading around $A1.00), with 32,339 shares traded.

CLINUVEL

Clinuvel has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price climbed from $3.00 on September 9 to $3.95, a 31.7 percent increase, on September 15, 2014, but did not note an increase in trading volumes.
Clinuvel told the ASX that the New York-based Retrophin had made an unsolicited bid for the company and filed substantial shareholder notices disclosing that it held 6.70 percent on July 30 and 7.8 percent on September 11 (BD: Sep 12, 2014).
Clinuvel fell 12 cents or 2.8 percent to $4.18.

BIOPROSPECT

Mining Investments says it has reduced its holding in Bioprospect from to 298,909,928 shares (9.42%) to 129,695,833 shares (4.09%).
The Newport, Victoria-based Mining Investments substantial shareholder notice, signed by director Elias Khouri, said that 169,214,095 shares were sold for $676,856 or 0.4 cents a share, including the sale of 145,000,000 shares for $580,000, of which 40 percent was payable in cash and the balance as a loan.
Last week, Mining Investments reduced its holding from 735,000,000 shares (23.16%) to 298,909,928 shares (9.42%).(BD: Sep 10, 2014).
In June, Mining Investments increased but was diluted in Bioprospect from 700,000,000 shares (24.15%) to 735,000,000 shares (23.16%) (BD: Jun 11, 2014).
In 2010, Elias Leo (The Gun) Khouri resigned as a director of Bioprospect citing the company's dispute with Solagran over its pine needle extract cure-all for liver disease and Alzheimer's disease (BD: Sep 17, 2010).
Bioprospect said last week that it would acquire Invatec for its heart rate variability technology to diagnose depression and other mental illnesses and appointed former Chemgenex chief operating officer and Invion director Dr James Campbell as a director, along with several other appointments (BD: Sep 8, 2014).
Bioprospect said at that time that it proposed a 100-to-one consolidation and hoped to raise $4 million at a post-consolidation price of 30 cents a share.
Bioprospect was unchanged at 0.4 cents with 24.9 million shares traded.