Biotech Daily

Monday October 12, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: TISSUE THERAPIES UP 10%; ONCOSIL DOWN 6%**

*** CLOVER LICENCES OMEGA OIL TO PREMNEO, DR BRIAN MCNAMEE**

*** CYCLOPHARM ULTRALUTE BOOSTS Mo-99 BY 50%**

*** FDA APPROVES OSPREY DYEVERT AUTOMATIC DYE MODULATION**

*** WEHI IMAGES TRIB1 FOR BLOOD CANCER DRUGS**

*** ANTISENSE MANUFACTURES MS EARLY ACCESS ATL1102, STUDY**

*** MEDIBIO CANADA STUDY COMPARES MENTAL, SLEEP DISORDERS**

*** USPTO ALLOWS NEUREN TROFINETIDE (NNZ-2566) RETT PATENT**

*** AVEXA TO ACQUIRE TALI FOR DEVELOPMENT DISABILITIES, TO RAISE $4m**

*** ONCOSIL EXPECTS BSI FAST-TRACK REVIEW IN NOVEMBER**

*** PHOSPHAGENICS CUTS STAFF, EARLY STAGE PROGRAMS**

*** LBT TO LOSE FOUNDING CEO LUSIA GUTHRIE**

*** TISSUE THERAPIES APPOINTS PROF CHRISTIAN BEHRENBRUCH DIRECTOR**

*** NUSEP DIRECTOR ANDREW GOODALL REDUCES TO 36%**

MARKET REPORT

The Australian stock market fell 0.89 percent on Monday October 12, 2015, with the ASX200 down 46.8 points to 5,232.9 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and one was untraded. All three Big Caps fell.

Tissue Therapies was best, up half a cent or 10 percent to 5.5 cents with 84,144 shares traded. Osprey and Universal Biosensors climbed more than nine percent; Antisense and Compumedics rose more than eight percent; Atcor, Ellex and Pro Medicus improved more than four percent; Neuren, Orthocell and Uscom were up more than three percent; Living Cell and Nanosonics rose more than two percent; with Bionomics up 1.85 percent.

Oncosil led the falls, down one cent or 6.1 percent to 15.5 cents with 3.1 million shares traded. Actinogen was down 5.3 percent; Avita and Optiscan fell more than four percent; Impedimed, Medical Developments and Polynovo were down more than three percent; Admedus, Anteo, CSL, Pharmaxis, Reva and Sirtex shed two percent or more; Acrux, Benitec, Biotron, Clinuvel, Prima and Viralytics were down more than one percent; with Cochlear, Resmed and Starpharma down by less than one percent.

CLOVER CORP

Clover says it has a licence agreement with Premneo Pharmaceuticals to accelerate development its docosahexaenoic acid (DHA) emulsion for premature babies.

Clover said that Premneo was a newly formed company with former CSL chief executive officer Dr Brian McNamee as executive chairman.

Dr McNamee told Biotech Daily that Premneo Pharmaceuticals Pty Ltd and Premneo Pty Ltd were “family owned companies” with his daughter Natalie McNamee also a director of the company.

According to the US Patent and Trademark Office, the name Premneo was filed by Clover Corp on April 7, 2015, covering “chemical additives for food; chemical ingredients for use in the manufacture of foods; chemical preparations for use as ingredients for foods; chemical preparations for use in the food industry, nutritive substances; dietetic foods and supplements; medicated food additives and supplements; dietary supplements; all of the aforesaid goods including omega-3 (DHA) oils, oils from fish, algae and plant sources including those in oil or microencapsulated form”.

Today, Clover Corp said that a phase III clinical trial was “nearing completion” to test the effectiveness of its DHA emulsion in reducing the incidence of broncho-pulmonary dysplasia, a lung condition common in infants born prematurely.

Dr McNamee said that the trial was a 1,250 neo-natal patient trial in Australia, New Zealand and Singapore and was one of the largest trials funded by the National Health and Medical Research Council (NHMRC).

According to the Australian New Zealand Clinical Trials Registry the trial, entitled ‘Docosahexaenoic acid for the reduction of bronchopulomonary dysplasia in preterm infants born at less than 29 weeks gestational age: a randomised controlled trial’ also known as: ‘DHA for the reduction of bronchopulmonary dysplasia in premature babies’ would compare tuna oil emulsion containing 120mg/mL of DHA to provide 60mg/kg/day of DHA (0.17ml/kg three times a day) against the placebo of soy oil emulsion with no additional DHA given at 0.17mL/kg three times a day.

The Registry said that primary sponsor was the Adelaide, South Australia-based Women's and Children's Health Research Institute with Dr Carmel Collins the principal investigator.

Dr McNamee said that the trial was expected to publish results about the middle of 2016.

Clover chief executive officer Peter Davey said that while awaiting the outcome of the clinical trial, his company had been “searching for the right partner to drive the product through to marketing and sales”.

“With specialised regulatory, manufacturing and marketing skills needed to move the product forward at optimal pace, Clover required a partner with a proven track record in the pharmaceutical field,” Mr Davey said.

“We are confident that Premneo will provide the best possible support in rolling out our product to the market,” Mr Davey said.

“Dr McNamee and his team have significant expertise in the pharmaceuticals sector having delivered successful programs for CSL,” Mr Davey said.

Clover said that Premneo would “gain an exclusive worldwide licence to develop and commercialise the emulsion product for use in premature babies” and Clover would earn milestone payments as product development advances and royalties on future sales.

Dr McNamee said he was “impressed by the excellent properties and market potential of this product”.

“We will be moving quickly to establish a full development plan as the clinical results become available in the first half of next year, with a focus on rapid access and exclusivity in both Australian and international markets,” Dr McNamee said.

Clover Corp climbed five cents or 16.95 percent to 34.5 cents.

CYCLOPHARM

Cyclopharm says it has launched its Ultralute which boosts the longevity of Molybdenum-99, the most commonly used medical isotope, by 50 percent.

Cyclopharm said that Ultralute was a device that attached to the Molybdenum-99 generator and through an in-line extraction process allowed the technician to harvest a more highly concentrated yield of Technetium-99m used to produce its Technegas.

The company said that the technology "potentially gives nuclear medicine departments the ability to dramatically improve their operating efficiencies, cost of materials and health outcomes for patients".

Cyclopharm said that it launched Ultralute at the European Association of Nuclear Medicine congress in Hamburg Germany and expected sales in Europe by July 2016.

The company said that Molybdenum-99 (Mo-99) had a half-life of 2.75 days and when it decayed it produced Technetium-99m (Tc-99m) with a half-life of six hours.

Cyclopharm said the isotope Tc-99m was harvested from the Mo-99 generator and used in about 80 percent of all nuclear medicine diagnostic imaging procedures worldwide, but the short half-life of the Mo- 99 generator was a challenge faced by nuclear medicine departments and the constantly decaying inventory meant new Mo-99 generators had to be bought to ensure that the Tc-99m activity and concentration was sufficient to manufacture the radiopharmaceuticals used in nuclear medicine procedures.

Cyclopharm chief executive officer James McBrayer said that Ultralute would be a productive tool for hospitals, clinics and nuclear pharmacies.

"When I was a practising nuclear pharmacist I would have loved to have had the convenience this technology provides," Mr McBrayer said.

Mr McBrayer said Ultralute could increase the life of a Mo-99 generator by several days, save hospitals time and money and benefit an industry that often faced Mo-99 shortages.

Cyclopharm fell one cent or 1.8 percent to 54 cents.

OSPREY MEDICAL

Osprey says the US Food and Drug Administration has cleared its Dyevert contrast modulation system automating contrast dye modulation.

Osprey has been developing products to reduce the quantities of dye used in cardiac procedures, to reduce contrast-induced nephropathy (BD: Mar 1, 2012; Jun 17, 2014).

Osprey said that the Dyevert system further automated contrast modulation during manual injections as it self-adjusted for catheter and contrast type without requiring user adjustments of the pin on the external control box.

The company said that the product was easier to set up and provided more seamless integration into the catheter lab workflow.

Osprey said that a trial of the Dyevert system was currently underway in Australia and Germany to demonstrate the ease of use and dye savings in a range of clinical cases.

The company said its research and development group was developing its contrast monitoring, or Smart Syringe, compatibility with the Dyevert system, expected by mid-2016, extending its research and development pipeline and patent portfolio.

Osprey chief executive officer Mike McCormick said that with FDA clearance of the Dyevert system "we will now gain real-world physician use to gauge market acceptance of the product's additional automation and ease-of-use benefits."

Osprey said that its primary product, the Avert Plus system was currently in limited commercialization in Texas and it planned to begin full US commercialization of Avert Plus after the Avert trial results for additional marketing claims expected later this year.

Osprey climbed 6.5 cents or 9.7 percent to 73.5 cents.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it has created the first three-dimensional image of the Trib1 protein involved in the development of blood and other cancers.

WEHI said that the discovery showed that Trib1 played "a vital role in controlling how and when other proteins are degraded, which is essential for managing protein levels in the cell [and the finding could be used to develop new drugs to treat cancers such as leukaemia, caused by malfunctioning of the Trib1 protein".

The Institute said that Trib1 was part of the protein family Tribbles which played diverse roles in cell signalling and development and were named after fictional furry creatures from Star Trek that reproduced uncontrollably.

WEHI said that excess Tribbles drove the abnormal production of immune cells, causing the acute myeloid leukemia (AML) blood cancer.

The Institute said that researchers Dr James Murphy and Dr Isabelle Lucet, in collaboration with Dr Peter Mace from the University of Otago, New Zealand, characterized the human Tribbles protein Trib1.

Dr Murphy said the research showed how Trib1 played an important role in controlling protein levels within the cell.

"The amount of protein in a cell depends on the balance between production and degradation," Dr Murphy said.

"Defects in protein degradation, or in the controllers of protein degradation, disrupt this balance and can lead to diseases such as cancer," Dr Murphy said.

The Institute said that using the Australian Synchrotron, Dr Mace, Dr Murphy and colleagues were able to obtain detailed three-dimensional images of Trib1.

"The structure of Trib1 is really exciting," Dr Murphy said.

"We can now see how Trib1 is able to trigger protein destruction, which will provide critical clues for developing drugs that target Trib1 to treat cancers," Dr Murphy said.

Lead investigator Dr Mace said Trib1 acted as a scaffold to bring many proteins together, forming a large complex that caused specific proteins to be degraded.

"As well as explaining how Trib1 functions, our research could help us design novel therapeutic agents for the treatment of AML," Dr Mace said.

"For example, some AML patients have too much Trib1, which causes a loss of proteins that would normally inhibit cancer," Dr Mace said.

"Understanding the structure of Trib1 provides critical clues about how we could block Tribbles for the treatment of AML," Dr Mace said.

Dr Murphy said that Trib1 was an unusual type of protein called a pseudokinase.

"Pseudokinases were once thought to be evolutionary dead ends, but we now know that they play critical roles in cells," Dr Murphy said.

"Precisely how Trib1 lost its old activity and gained other functions has been a real mystery," Dr Murphy said.

WEHI said that visualising Trib1 allowed the team to answer that question.

"The powerful X-ray beams created by the synchrotron enabled us to see that Trib1 has undergone huge contortions compared to its ancestors," Dr Murphy said.

"These structural changes prevent Trib1 from driving chemical reactions, and instead allow it to act as a scaffold to bring proteins together," Dr Murphy said.

The Institute said that the research, entitled 'Molecular Mechanism of CCAAT-Enhancer Binding Protein Recruitment by the TRIB1 Pseudokinase' was published in the journal Structure.

An abstract is at: http://www.cell.com/structure/abstract/S0969-2126(15)00367-6.

ANTISENSE THERAPEUTICS

Antisense says manufacture of ATL1102 for its multiple sclerosis early access program is expected this year with partner Mytomorrows funding an observational study.
Antisense said the European earl access program was to help multiple sclerosis patients who had no other treatment options and Mytomorrows would seek approvals in Germany, Austria, Denmark, Sweden, Finland and several East European countries and the reimbursement for drug supply from bodies such as relevant healthcare insurers.
The company said that it was expected that the timeline for individual country approvals would be staggered with approval in Germany by July 2016.
Antisense said that Mytomorrows was preparing a pre-registration observational study in Germany with the support of the University of Cologne's Prof Volker Limmroth, who was the principal investigator of the ATL1102 phase IIa study (BD: Jun 30, 2008).
The company said that Mytomorrows would bear the costs for the observational study, expected to start by July 2016, including the approvals process, data management and doctors' fees.
Antisense said that the study would collect data of the type collected in clinical practice including information on the safety of ATL1102, which may be supportive in the further clinical development of the drug and would provide "first-hand experience of the use of ATL1102 in order to enhance the drug's future prospects".
The company said that the initial manufacture of ATL1102 for the early access program would be sufficient to supply about 30 patients for their first year of treatment and a significant proportion of the cost of manufacture was expected to be reimbursed through the program.
Antisense was up 0.7 cents or 8.75 percent to 8.7 cents.

MEDIBIO

Medibio says it has a research agreement with the Institute of Mental Health Research on a study entitled 'Detailed Analysis of Sleep Physiology in Mental Disorders'.
Medibio said that the aim of the retrospective study was to assess the validity and specificity of its circadian heart rate technology to discriminate between individuals with mental disorders, individuals with sleep disorders and healthy controls.
The company said that the study at the Ottawa, Ontario-based Institute would be the first to expand beyond depression, evaluating subjects with anxiety, bipolar and psychotic disorders in addition to depression and was part of a larger program investigating sleep biomarkers of mental disorders across multiple age groups.
Medibio said that the main aim of the sub-study was to compare patients with anxiety, depression, bipolar and psychotic disorders in terms of variations in heart rate during transitions across wake and sleep states; evaluate the relative associations between heart rate variations, age, psychiatric symptoms severity and psychotropic medications; and assess the validity and specificity of its diagnostic algorithms using heart rate variations during sleep to discriminate between individuals with mental disorders, with and without comorbid sleep disorders, individuals with sleep disorders without psychiatric illnesses, and healthy controls.
The company said that participants would be divided into subgroups of mental disorders, sleep disorders and healthy controls.
Medibio said that the retrospective study would use data to be extracted from the Royal Ottawa Mental Health Centre sleep clinic database, allowing results "to be generated quickly for peer review and publishing".
Medibio fell two cents or 4.4 percent to 43 cents.

NEUREN PHARMACEUTICALS

Neuren says the US Patent and Trademark Office has allowed a new patent for the use of trofinetide, formerly NNZ-2566, for Rett syndrome.
Neuren said the patent was entitled 'Treatment of Rett syndrome using glycyl-L-2-methylprolyl-L-glutamic acid' and would provide coverage until January 2032.
The company said that trofinetide was being developed as a therapy for Rett syndrome and other neurological disorders and the Rett syndrome program had been granted fast track designation by the US Food and Drug Administration and had orphan drug designation in both the US and the European Union.
Neuren said that in the US, trofinetide was covered by an issued composition of matter patent, which would expire in 2022, with the potential to extend to 2026.
The company said that orphan drug designation provided and additional market exclusivity period of seven years following marketing authorization and in Europe orphan designation provided 10 years of market exclusivity following marketing authorization.
Neuren said that it had similar patent applications pending in other territories.
Neuren was up 0.3 cents or 3.6 percent to 8.7 cents.

AVEXA

Avexa says it will acquire Tali Health Pty Ltd in exchange for scrip for its technology for diagnosing and treating developmental disabilities, including autism.
Avexa said the transaction was conditional on completing a $4 million placement and Tali shareholder approval and it would ask shareholders to approve a 20-to-one consolidation.
The company said that two Tali directors Jefferson Harcourt and Benjamin Yeo would be appointed as directors, with Prof Kim Cornish remaining as chair of Tali's scientific advisory board and Hannah Kirk to be appointed chief technical officer.
Tali said that Tali Health had the exclusive global licence to the Tali technology together with the option to acquire the Tali technology outright.
Avexa said that the training attention and learning initiative (Tali) process was the result of research by Monash University's Prof Kim Cornish, and a collaboration with Grey Innovation and Torus Games, developed the product to address the limited awareness and treatment of intellectual disabilities, including autism.
The company said that the front-end was an attention measuring and training game, accessed by downloading a mobile telephone application and the back-end was an internet cloud-based, centralized secure data collection, analysis and report back function.
In 2012, Avexa said it would invest $10 million for a share of a coal mine in Alabama with hoped-for profits to fund its Apricitabine HIV drug programs (BD: Nov 5, 2012).
In 2009, Avexa raised $17 million for its phase III trial of Apricitabine but closed the trial early before raising a further $11 million (BD: Apr 30, Oct 2, Nov 30, 2009).
In 2010 Avexa said the trial showed a non-significant benefit (BD: Feb 4, 2010).
Avexa was unchanged at one cent with 3.1 million shares traded.

ONCOSIL MEDICAL

Oncosil says that it expects its Conformité Européenne (CE) mark fast track review notified body, the British Standards Institute, will make a decision in November 2015.
Oncosil said it was granted fast track review for its brachysil radiation product for pancreatic and primary liver cancer, the face-to-face review had been completed and it was awaiting the outcome of the review over the coming weeks. (BD: Sep 9, 2015).
Oncosil fell one cent or 6.1 percent to 15.5 cents with 3.1 million shares traded.

PHOSPHAGENICS

Phosphagenics says a reduction of up to 10 staff positions and a change to a more outsourced model for previously in-house activities would extend its funds to 2017.
Phosphagenics said that it would reduce its early phase, higher risk research activities and redirect resources towards delivery of its short to medium term, later stage, development projects with higher probability of success.
Phosphagenics chief executive officer Dr Ross Murdoch said that “not all of the changes we have made to the business over the past few months have been easy, particularly those that involve reducing staff numbers, but all have been made with the same goal in mind [to] optimize the delivery of value from our key assets”.
The company said that the changes would improve its ability to deliver high priority, short to medium term later phase projects, such as the opioid patch development programs, the animal health and nutrition trials and the tocopheryl phosphate mixture (TPM) manufacturing expansion project and would focus its resources on delivering its human health and nutrition business, its phase II clinical development of the TPM-oxycodone patch, reformulation of the TPM-oxymorphone patch and development of the unnamed TPM antibiotic injectable with Mylan.
Dr Murdoch said that a number of projects were “set to deliver key milestones over the remainder of 2015 into 2016 and we expect this to lead to greater news flow”.
Phosphagenics was unchanged at 1.4 cents.

LBT INNOVATIONS

LBT says that long-standing chief executive officer Lusia Guthrie will retire from the company in 2016 due to health reasons.
LBT said that Ms Guthrie had been the chief executive officer of the Adelaide-based company since she co-founded the company in 2004, steering it through its formative years, negotiating the licence of its first technology, the Microstreak automated culture plate streaking system marketed as the Previ Isola and more recently, the development of its plate analysis technology, the automated plate assessment system (APAS).
LBT chairman Bob Finder said that the company would miss Ms Guthrie’s pivotal leadership, but that it understood her reasons for stepping down.
“This is a sad day for LBT, as we are losing our leader just as the company is about to realise the fruits of some of her greatest labours,” Mr Finder said.
“However, we do understand why Lusia has to leave and we fully support her,” Mr Finder said.
LBT said that Ms Guthrie would continue to support and advise the company through the transition to the new chief executive officer and potentially beyond.
“The past 11 years have been demanding and challenging, but at the same time they have been some of the most rewarding years of my professional career,” Ms Guthrie said.
“The team we have assembled are some of the brightest and most inspiring people I have worked with,” Ms Guthrie said.
“To say that I have been proud to lead this team would be a serious understatement,” Ms Guthrie said.
Mr Finder said the company was in the process of recruiting a new chief executive officer, while Ms Guthrie continued with her full duties and authority in company matters.
LBT fell one cent or 6.7 percent to 14 cents.

TISSUE THERAPIES

Tissue Therapies says it has appointed 'The Long Tail' publisher Prof Christian Behrenbruch as an executive director, effective today (BD: Jun 25, 2015).

Dr Behrenbruch has written a large number of web-logs, or blogs, on ASX-listed biotechnology companies.

Tissue Therapies chairman Dr Cherrell Hirst said Prof Behrenbruch had "extensive experience in a wide range of roles in development-stage companies including as [chief executive officer], mentor, director and investor and has a significant international biopharma network".

"The company has fundamentally excellent technology that has been challenged by a number of product and regulatory issues over the past 12 months," Prof Behrenbruch said. "My mission is to help the board to rebuild a solid foundation for the company and work together closely with the management team to review the skills and capabilities required to deliver durable performance to shareholders," Prof Behrenbruch said.

Tissue Therapies said that Prof Behrenbruch held a Bachelor of Engineering from Monash University, a Doctorate of Philosophy in biomedical engineering from the University of Oxford, a Masters of Business Administration jointly from New York University Stern School of Business and the London School of Economics and a Doctorate of Jurisprudence from the University of Melbourne.

The company said that Prof Behrenbruch was formerly a chief executive officer and executive director of Mirada Solutions, CTI Molecular Imaging now Siemens Healthcare, Fibron Technologies and Imaginab Inc.

Tissue Therapies said that Prof Behrenbruch was a former director of Momentum Biosciences, Siemens Molecular Imaging, Radius Health now Adaptix, Peter MacCallum Cancer Centre's Cell Therapies and the Oncidium Foundation and was currently a member of the Monash Engineering Foundation Board and held adjunct appointments at Monash University and the Royal Melbourne Institute of Technology University.

Tissue Therapies was up half a cent or 10 percent to 5.5 cents.

NUSEP

Nusep director Andrew Goodall says he has reduced his shareholding from 94,638,261 shares (38.24%) to 88,538,261 shares (35.77%).

Mr Goodall said that he held a direct interest in Nusep, as well as an indirect interest through Marjorie Goodall, Ti Rakau Developments and Aemagood Pty Ltd.

The substantial shareholder notice said that in two off-market transfers Mr Goodall and Aemagood sold 6,100,000 shares for $152,500 or 2.5 cents a share.

Nusep was untraded at three cents.