Biotech Daily

Monday April 10, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ORTHOCELL UP 37.5%, OPTHEA DOWN 7%**

*** BLUECHIIP WINS 1st MAJOR US CONTRACT**

*** US WALLMART, KMART TO SELL MEDICAL DEVELOPMENTS' SPACERS**

*** MESOBLAST PHASE III HEART TRIAL PASSES FUTILITY ANALYSIS**

*** ORTHOCELL PLEADS SCHULTZ TO ASX 28% QUERY, CLOSES UP 37.5%**

*** NOVOGEN PREPARES GDC-0084 GLIOBLASTOMA MULTIFORME TRIAL**

*** MEDICINES AUST 'BRIDGE PROGRAM' TAKES RESEARCH TO MARKET**

*** AUSCANN MARIJUANA CROP YIELDS 300kg DRIED BUDS**

*** MGC STARTS SLOVENIA CANNABINOID EXTRACTION OPERATIONS**

*** MEDIBIO JOINT VENTURE FOR PAEDIATRIC MENTAL HEALTH**

*** NOXOPHARM STARTS IDRONOXIL-C PATENT PROCESS**

*** SIRTEX APPOINTS EX-COCHLEAR CFO NEVILLE MITCHELL DIRECTOR**

*** IMPEDIMED APPOINTS JUDITH DOWNES DIRECTOR**

*** IQ'S FARMAFORCE APPOINTS HARRY SIMEONIDIS GENERAL-MANAGER**

MARKET REPORT

The Australian stock market was up 0.86 percent on Monday April 10, 2017 with the ASX200 up 50.4 points to 5,912.9 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and one was untraded.

Orthocell was the best, up 13.5 cents or 37.5 percent to 49.5 cents with 1.4 million shares traded. Mesoblast climbed 9.9 percent; Dimerix and Uscom were up more than seven percent; Actinogen, Avita and Neuren rose more than five percent; Factor Therapeutics improved 4.8 percent; Living Cell was up 3.85 percent; ITL, Osprey and Starpharma rose more than two percent; with Airxpanders and Polynovo up more than one percent.

Opthea led the falls, down 8.5 cents or 7.2 percent to $1.09 with 196,285 shares traded. Genetic Signatures lost seven percent; both IDT and Oncosil fell 3.85 percent; Benitec, Bionomics, Cyclopharm and Universal Biosensors shed more than two percent; with Acrux, Cochlear, Compumedics, Ellex, Medical Developments and Pro Medicus down one percent or more.

BLUECHIIP

Bluechiip says its first US “major supply and licence agreement” for its wireless sample tracking technology will return fees over the next 18 months.
Bluechiip said that the San Francisco Bay, California-based Labcon North America would pay a technology access fee with upfront and on-going fees.
The company said that Labcon was “the world’s leading manufacturer of Earth-friendly laboratory consumables”.
Labcon’s website said it was a wholly-owned subsidiary of the privately-owend Beaumont, Texas based Helena Laboratories.
Bluechiip said that in 2016 Labcon molded more than 1.4 billion products for major companies in the life sciences sector, including centrifuge tubes, pipet tips, microbiology disposables, organization tools, and specialty items.
The company said that the agreement allowed Labcon to buy, use, sell, market and promote its wireless sample tracking intellectual property, technology and products.
Bluechiip said that Labcon had undertaken full technical and business due diligence and had identified customers to proceed with pilot programs of Bluechiip-integrated products in the near term.
Labcon president Jim Happ said the “partnership and the advanced technology it provides, allows us to differentiate our products and provide a series of value-added solutions for latent customer needs that no other technology available can solve”.
“We are looking forward to integrating the Bluechiip technology into a collection of data-enabled products that we can sell across multiple customer segments,” Mr Happ said.
Bluechiip managing-director Andrew McLellan said the partnership was “pivotal”.
“It is our first in North America, our primary target market,” Mr McLellan said.
“Our relationship with Labcon started last year with their purchase of a starter kit, which they tested extensively,” Mr McLellan said.
Mr McLellan said that Labcon would buy an initial series of our multi-vial readers, micro-electro-mechanical systems (Mems) chips and software to use in customer trials, with volume to build over time.
“This agreement represents an important inroad into high-value markets,” Mr McLellan said.
Bluechiip was up half a cent or 16.7 percent to 3.5 cents with 3.8 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that Walmart and Kmart will distribute its Compact Anti-Static Space Chamber respiratory devices in the US.
Medical Developments said that both companies had placed their first orders.
The company said that Walmart operated more than 4,600 pharmacies across the US and Kmart operated 1,000 pharmacies in the US.
Medical Developments chief executive officer John Sharman said the company was selling its respiratory devices in more than 7,000 US pharmacies.
“This is a milestone event for our strategy for sales of our respiratory devices in the US,” Mr Sharman said. “It is not every day that an Australian company achieves ranging of product with Walmart”.
“We have a world class respiratory device product range and we have a significant price advantage over competitor products in the US,” Mr Sharman said.
“We are confident our US business will deliver the expected sales growth in the months to come,” Mr Sharman said.
Medical Developments fell nine cents or 1.8 percent to $5.00.

MESOBLAST

Mesoblast says the independent data monitoring committee has approved continuing its phase III trial of mesenchymal precursor cells for congestive heart failure.

Mesoblast said the committee conducted a pre-specified interim futility analysis of the efficacy endpoint for the first 270 patients, with the trial expected to enrol 600 patients.

The company said that the committee said it had “no safety concerns” relating to MPC-150-IM and formally recommended that the trial should continue as planned.

A lead investigator in the trial, the Texas Heart Institute’s Dr Emerson Perin said it was “very pleasing to see that this large and rigorously conducted phase III trial of Mesoblast's cell therapy was successful in the pre-specified interim futility analysis for the trial's efficacy endpoint in the first 270 patients”.

Mesoblast chief executive Prof Silviu Itescu said that passing the interim futility analysis was “an important milestone ….and This validates our strategy and our prioritization of this valuable program”.

Mesoblast said that the double-blinded, randomized, trial was being conducted at multiple study sites in the US and Canada, evaluating MPC-150-IM in adult patients with moderate to advanced New York Heart Association class II and III congestive heart failure with left ventricular systolic dysfunction.

The company said that the primary efficacy endpoint was a comparison of recurrent non-fatal, heart failure-related major adverse cardiac events in moderate to advanced heart failure patients receiving either MPC-150-IM by catheter injection into the damaged left ventricular heart muscle or sham control.

Mesoblast said that it, the US Food and Drug Administration and trial investigators were blinded to grouped safety and efficacy data for the on-going trial as well as the numerical results of this interim analysis.

The company said that in a phase II trial, a single injection of MPC-150-IM into the myocardium of patients with moderate to advanced chronic heart failure prevented any heart failure-related hospitalizations or cardiac deaths over three years of follow-up.

Mesoblast said that non-clinical studies showed that intra-myocardial administration of mesenchymal precursor cells in animal models of heart failure improved cardiac function and attenuated pathological ventricular remodelling, attributable, at least in part, to mesenchymal precursor cell secretion of biomolecules that stimulated reparative processes in the failing heart including new blood vessel formation, cardiac muscle cell survival, and reduction in tissue fibrosis.

The company said that MPC-150-IM was also being studied in a phase IIb trial in 159 patients with class IV end-stage heart failure in conjunction with implantation of a left ventricular assist device, to assess the ability of MPC-150-IM to help wean patients from a device-dependent existence for survival.

Mesoblast said that the FDA had approved a 24-patient trial being sponsored by Boston’s Children’s Hospital combining the allogeneic MPC-150-IM product with corrective heart surgery in children under the age of five with hypo-plastic left heart syndrome.

Mesoblast climbed 24 cents or 9.9 percent to $2.67 with 1.5 million shares traded.

ORTHOCELL

Orthocell 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 rose 27.8 percent from 36 cents on April 7 to 46 cents today, April 10, 2017, and noted a significant increase in trading volume.

Orthocell closed up 13.5 cents or 37.5 percent to 49.5 cents with 1.4 million shares traded.

NOVOGEN

Novogen says it expects to begin a 200-patient, phase II, US, Europe and Australia study of GDC-0084 for glioblastoma multiforme by the end of the year.

Novogen said that glioblastoma multiforme was the most common and most aggressive form of primary brain cancer in adults, and the randomized, two-arm design trial would enrol patients largely resistant to temozolomide the most widely-used treatment, with patients receiving either GDC-0084 or temozolomide as maintenance therapy after completion of standard radiotherapy treatment.

The company said that glioblastoma multiforme affected about 130,000 patients worldwide each year and had one of the poorest outcomes, with only three to five percent of patients alive five years after diagnosis.

Novogen said that it expected to take 18 months to reach full recruitment, with progression-free survival data available 12 months later.

The company said that oral GDC-0084 was licenced from Roche's Genentech last year and was designed to inhibit tumor growth by targeting a biochemical control mechanism thought to be critical to growth of the tumor (BD: Oct 31, Nov 2, 2016).

Novogen said that Genentech had completed a phase I study in 47 patients with advanced brain cancer, which had shown the drug to be generally well-tolerated and provided signals of clinical efficacy supporting further development.

The company said it had transferred the FDA investigational new drug application and taken possession of 48.8kg of drug substance, prepared by Genentech in anticipation of a phase II study, which was being formulated into oral capsules for the phase II trial.

Novogen said the phase II study was intended to measure the efficacy of GDC-0084 in recently diagnosed patients, who had undergone surgical resection and radiotherapy in accordance with usual treatment practice in this disease, which was a different and less advanced population than the phase I study, which was in patients with recurrent disease.

The company said that the study would recruit only patients who have a confirmed unmethylated MGMT promoter, which was associated with limited response to temozolomide, the pharmacological standard of care for glioblastoma multiforme.

Novogen said that the study would be open-label, with patients and clinicians aware of which drug was being administered, but the key efficacy assessments would be performed in a blinded fashion by independent adjudicators, with the primary endpoint progression-free survival and patients followed for overall survival.

The company said that the FDA could provide accelerated approval to hasten the delivery of products appearing to provide a benefit for serious or life-threatening illnesses lacking satisfactory treatments, allowing new drugs to be approved prior to completion of the requisite phase III trials.

Novogen said that Avastin (bevacizumab) was initially approved for recurrent glioblastoma multiforme following two single-arm, phase II studies which enrolled 141 patients in total.

The company said that it hoped GDC-0084 might also be considered by the FDA for accelerated approval if the phase II study was successful, given the unmet medical need in this patient population.

Novogen chief executive officer Dr James Garner said that "glioblastoma remains an area of significant unmet need in the treatment of cancer".

"It is the most common and most aggressive malignant primary brain tumour in adults," Dr Garner said. "Unfortunately, median overall survival is very short at only about 12 months."

"We are hopeful that GDC-0084 could become a valuable new treatment option for these patients," Dr Garner said.

Novogen was up 0.1 cents or 1.85 percent to 5.5 cents with 1.4 million shares traded.

MEDICINES AUSTRALIA

Medicines Australia says the collaborative Bridge Program will translate innovation and discovery research to the market.

Medicines Australia said the consortium backing the Program included pharmaceutical companies, Queensland University of Technology and the Medical Technologies and Pharmaceutical Growth Centre, or MTP Connect.

The industry organization said that the Bridge Program commercialization training would begin in June 2017 with 100 participants, of which two would be granted travel scholarships to visit offshore pharmaceutical research facilities and develop experience and business networks.

Medicines Australia said the initiative would create commercialization opportunities for Australia's bioscience research sphere and Australia's pharmaceutical and biotechnology sectors.

Medicines Australia chief executive Milton Catelin said the Bridge Program would "foster opportunities for researchers to make the connections necessary for commercialization and to ultimately deliver better health outcomes for Australian patients by leveraging the extensive knowledge of the innovative pharmaceutical sector".

"The Bridge program provides, through training and networking, the knowledge transfer that happens naturally in other countries," Mr Caitlin said.

AUSCANN GROUP

Auscann's says its first marijuana crop is being harvested in Chile with 400 plants expected to yield more than 300 kilograms of dried cannabis buds.

Auscann said the marijuana would be processed into medicinal cannabis formulations for clinical trials in Chile and sale to third parties.

The company said that the crop was planted by its Dayacann 50-50 joint venture with Fundacion Daya in November 2016 at a 30-hectare facility south of Santiago, Chile.

Auscann said that the greenhouse-grown plants included various strains selected for specific medical use.

The company said that the dried cannabis would be sent to a good manufacturing practice-certified facility for processing into medicinal cannabis formulations and, pending successful clinical trials in Chile, the formulations would be registered through the Chilean National Institute of Public Health and made available for sale to Chilean patients and export markets.

Auscann managing-director Elaine Darby said the company was "delighted with the harvest of our first crop with our partner Fundacion Daya and we're confident we have selected the strongest and most appropriate strains for effective medicine formulations and further cultivation in the next harvest".

Auscann was up three cents or 3.9 percent to 80.5 cents with 1.5 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has commenced cannabinoid extraction operations at its Slovenian extraction facility, ahead of schedule.

MGC said that the first cannabinoid extracts confirmed the operational status of the facility, as well as its ability to produce high quality extracts for its various projects, with commercial production targeted to begin by October 2017, once good manufacturing practice (GMP) certification was granted.

MGC was unchanged at 7.6 cents with 22.5 million shares traded.

MEDIBIO

Medibio says it has a joint venture with Partnerships for Health Intelligence director Prof Paul Porter to develop diagnostic products for the up-to 18 years age group.

Medibio said that the joint venture with Joondalup, Perth Western Australia based Partnerships for Health Intelligence would focus on a range of paediatric mental disorders including depression, anxiety disorder, attention deficit hyperactivity disorder (ADHD), schizophrenia and post-traumatic stress disorder.

The company said that Prof Porter was as adjunct associate professor in the Faculty of Health Science at Perth's Curtin University.

Medibio said that Partnerships for Health Intelligence conduct and fund 100 percent of the clinical trials up until the completion of proof-of-concept, defined as the pre-submission meeting for the purposes of submitting the product to the US Food and Drug Administration or for Conformité Européenne (CE) mark approval.

The company said that Partnerships for Health Intelligence would manage all day-to-day activities of the joint venture including data collection and clinical trials.

Medibio said it would undertake all necessary algorithmic, statistical and analytical work and take responsibility for the registration of worldwide patents.

The company said the joint venture was a 50-50 agreement with it having the right to move from to 75 percent in relation to paediatric depression, anxiety disorder and schizophrenia at the completion of proof-of-concept, but to do so would have to refund 100 percent the Partnership's expenditure and a further 200 percent of expenditure on receipt of first revenue.

Prof Porter said he had "long identified the need for a better diagnostic system along with an accurate measure of improvement with treatment".

"We believe that the Medibio technology will revolutionize existing mental health diagnostic methods which is reliant upon subjective assessment; and in so doing, will potentially improve outcomes for children, families and communities," Prof Porter said.

Medibio was unchanged at 39.5 cents.

NOXOPHARM

Noxopharm says it has begun the process of applying for a patent for its idronoxil-C technology for cancer, by lodging a patent co-operation treaty application.

Noxopharm said that the international patent treaty covered 152 countries and was designed to facilitate global patent grant.

The company did not state the title or expected duration of the patent but said that "idronoxil-C accounts for a significant part of the idronoxil in animal blood after dosing with NOX66" and was a form of idronoxil not previously identified with "smart drug-like properties" and was a new drug in its own right.

Noxopharm chief executive officer Dr Graham Kelly said that "in the test-tube, idronoxil is an extraordinarily effective drug in sensitizing cancer cells to standard cancer therapies".

"The challenge always has been with patients to get idronoxil into the bloodstream in exactly that same form in order to deliver the same potent anti-cancer effect," Dr Kelly said.

"That has proved difficult to date," Dr Kelly said.

"NOX66 was developed with that aim in mind and it is an aim that we are confident we have achieved," Dr Kelly said.

Noxopharm was up 3.5 cents or 8.75 percent to 43.5 cents.

SIRTEX MEDICAL

Sirtex says it has appointed former Cochlear chief financial officer Neville Mitchell as an independent non-executive director, effective from today April 10, 2017.

Sirtex chairman Richard Hill said that Mr Mitchell was "one of the most experienced senior executives in the Australian medical device industry, with a demonstrated track record of success and achievement".

The company said that Mr Mitchell had more than 25 years' experience as Cochlear's former chief financial officer and company secretary and was "a key member of Cochlear's executive team responsible for the setting and execution of the company's growth strategy since its listing on the ASX in 1995 with a market capitalisation of $125 million".

Sirtex said that in his time at Cochlear, Mr Mitchell was responsible for all financial aspects of the business, including ASX compliance and governance, banking, acquisitions and mergers, together with forecasting/budgetary management and responsibility for accounting data, legal and company secretarial and facilities.

The company said that Mr Mitchell was a director of Osprey,a director of the South East Sydney Local Health District and a member of the Board of Taxation.

Sirtex was up 15 cents or 0.9 percent to $17.58 with 246,715 shares traded.

IMPEDIMED

Impedimed says it has appointed Judith Downes as a non-executive director.

Impedimed said that Ms Downes had more than 20 years' experience in accounting and management with a focus on financial management and audit and risk management, with ASX listed companies, as an executive and director.

The company said that previously Ms Downes was Alumina chief financial officer and the ANZ Bank's Institutional Division chief financial officer and chief operating officer.

Impedimed was currently the chair of Bank Australia, a member of the Financial Reporting Council of Australia and previously was a Director of Devine, Alcoa Australia, ING Australia and the ANZ Staff Superannuation Fund.

The company said that Ms Downes was an honorary fellow of the University of Melbourne's Faculty of Business and Economics and a member of the University's finance committee.

Impedimed fell half a cent or 0.7 percent to 73.5 cents.

IQ GROUP

IQ Group wholly-owned contract sales organization subsidiary Farmaforce has appointed Harry Simeonidis as general-manager.

IQ Group said that Mr Simeonidis had more than 20 years' experience in management roles in healthcare, pharmaceutical and life sciences businesses in Australia, New Zealand and South East Asia.

The company said that most recently Mr Simeonidis was GE Healthcare's Asia Pacific surgery general-manager and previously was the chief executive officer of GE Healthcare for Australia and New Zealand for nine years.

IQ3 was untraded at 29 cents.