Biotech Daily

Friday June 5, 2015

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: VIRALYTICS UP 15%, GI DYNAMICS DOWN 13%**

*** CSIRO SEASHELLS FOR DRUGS, VACCINE DELIVERY**

*** MESOBLAST RECEIVES $6m FEDERAL R&D TAX REFUND**

*** FEDERAL GOVERNMENT: 'NEW CHIEF SCIENTIST WANTED'**

*** ADMEDUS HSV-2 PHASE II TRIAL 'ON-TRACK'**

*** NOVOGEN: 'TRXE-009 CROSSES BLOOD-BRAIN BARRIER IN MICE'**

*** CLINUVEL BEGINS EU TRAINING FOR SCENESSE PRESCRIPTIONS**

*** NUSEP DIRECTORS TO TAKE $215k CONVERTIBLE NOTES**

*** BVF PARTNERS, MARK LAMPERT TAKE 5% OF PHARMAXIS**

*** BERGEN SELLS 64m PRIMA SHARES TO 2%**

*** OPTISCAN REQUESTS FUNDRAISING TRADING HALT**

*** IMUGENE APPOINTS PROF URSULA WIEDERMANN CSO**

MARKET REPORT

The Australian stock market slipped 0.11 percent on Friday June 5, 2015 with the S&P ASX 200 down 5.8 points to 5,498.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, nine fell, 13 traded unchanged and three were untraded. All three Big Caps rose.

Viralytics was the best, up 10 cents or 15.4 percent to 75 cents with 1.5 million shares traded. Biotron climbed 5.7 percent; Compumedics, Sirtex and Universal Biosensors were up more than four percent; Circadian and Clinuvel were up more than three percent; Acrux, Avita, Bionomics and Genetic Technologies rose more than two percent; Cochlear, CSL, Medical Developments, Mesoblast and Starpharma were up more than one percent; with Benitec and Resmed up by less than one percent.

GI Dynamics led the falls, down two cents or 13.3 percent to 13 cents with 54,737 shares traded, followed by Tissue Therapies down 11.4 percent to 3.9 cents with 1.9 million shares trade. Admedus and Prima lost more than three percent; Actinogen, Impedimed and Nanosonics shed more than two percent; Neuren was down 1.2 percent; with Psivida down 0.6 percent.

THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation says its staff have developed a seashell-based capsule to preserve active biological ingredients in drugs.
CSIRO said that the development overcame “a critical challenge in biomedicine by ensuring important proteins remain effective in hostile environments”.
The Organisation said that the shell, developed with the University of Adelaide and the Australian Synchrotron, could hold the key to cost-effectively preserving and extending the shelf-life of vaccines in extreme temperatures without refrigeration and could significantly benefit healthcare in developing countries where life-saving vaccines often need to be transported over long distances to reach everyone who needs them.
The research, entitled ‘Biomimetic mineralization of metal-organic frameworks as protective coatings for biomacromolecules’ was published in Nature and an abstract is at: http://www.nature.com/ncomms/2015/150604/ncomms8240/full/ncomms8240.html
CSIRO lead researcher Dr Kang Liang said that living organisms were made up of proteins which played a critical role in the body, but proteins were fragile and their function altered or perished when exposed to heat, pressure and pollutants.
“Inspired by a sea urchin’s outer shell, which supports and protects its fragile body, we’ve come up with a porous shell that grows around important proteins such as enzymes to protect them on the inside,” Dr Liang said.
“Our shell offers a low-cost solution to protecting proteins for making and enhancing drugs and other products where sensitivity has long been an issue,” Dr Liang said.
“The shell is made of an extremely porous material called metal organic frameworks that has a flexible and customizable cage-like structure,” Dr Liang said.
“The shell’s tiny cage holes are similar to a sea creature’s pores and are designed to capture, trap or release specific bio-molecules,” Dr Liang said.
CSIRO said the development paved the way to making new and improved consumer products, with shell-encapsulated enzymes in laundry washing powder performing better.
CSIRO research team leader Dr Paolo Falcaro said they were seeking industry partners to develop the technology for specific applications including pharmaceuticals, manufacturing, chemical and food processing, water decontamination and screening for genetic disease.
“We are currently investigating important bio-molecules including DNA, antibodies and those used in vaccines,” Dr Falcaro said.
“Based on our laboratory trials, the shell could protect a vaccine vial for only a few dollars and at a commercial scale we would work to make it even cheaper,” Dr Falcaro said. “This cost is insignificant when a vaccine dose can cost up to hundreds of dollars.”
CSIRO said it was developing a range of technologies for making and using metal organic frameworks that spanned capturing carbon dioxide from the atmosphere, separating and storing gases, and decontaminating water and soils, offering industry significant productivity and environmental benefits.
The Organisation said that companies interested in developing the shell technology should contact enquiries@csiro.au.

MESOBLAST

Mesoblast says it has received $5.8 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Mesoblast said the rebate related to research and development expenditure for the year to June 30, 2014 and it expected to receive further reimbursement of funds for ongoing research and development activities in the year to June 30, 2015.
Mesoblast was up five cents or 1.3 percent to $3.95 with 444,442 shares traded.

FEDERAL GOVERNMENT

The Federal Government says it has begun the process to select Australia's next chief scientist, with Prof Ian Chubb whose tenure concludes at the end of the year.
The Minister for Industry and Science Ian Macfarlane said that choosing the best candidate was an extremely important process, given the integral role science plays in Australia's future prosperity and economic competitiveness.
"The Australian Government places the highest priority on science," Mr Macfarlane said.
"We have put science at the centre of industry policy as it is integral to supporting Australia's future growth and prosperity," Mr Macfarlane said.
"We have announced national science and research priorities of food, soil and water, transport, cyber-security, energy, resources, advanced manufacturing, environmental change and health to ensure our high performing science, research and innovation system delivers maximum benefit," Mr Macfarlane said.
Mr Macfarlane said the successful applicant would have a substantial scientific track record and reputation, be a passionate and effective communicator across disciplines and have significant policy advisory experience.
He said that the chief scientist reported to the Prime Minister providing independent advice across all levels of government and agencies with responsibilities on science, research, technology and innovation matters.
The Government has contracted the Sydney office of the London-based Odgers Berndtson to conduct an international search for a replacement.
Further information about the selection process is available by contacting Odgers Berndtson Australia managing director Julie Steiner on +612 9460 4505 or be email to chiefscientistaustralia@odgersberndtson.com.
Applications close on July 17, 2015.

ADMEDUS

Admedus says its 40-patient phase II herpes simplex 2 (HSV-2) trial is on-track with enrolment expected to be completed "by mid-year" and results by the end of the year.
Admedus said that patients in the therapeutic vaccine program had started receiving their second vaccination dose and the study was on track to recruit the required number of participants, "with hundreds already registered to participate".
Admedus chief executive officer Lee Rodne said the study was "progressing extremely well and we anticipate it will be fully enrolled in the coming weeks, with interim results scheduled for later this year".
"To date, the safety profile of the study has been very positive," Mr Rodne said.
Admedus said about 25 percent of the target study numbers had received their initial dose of the HSV-2 therapeutic vaccine, which was well-tolerated with no safety issues reported.
"The first study participants have now received their second dose of the vaccine," Mr Rodne said. "Currently 70 percent of the required study participants have either begun screening or received their initial dosing regimen, so we're on track."
Admedus said that each participant would receive three monthly intra-dermal injections, followed by a fourth injection six months after the initial dose.
The company said that the primary objective was to explore both the safety of the therapeutic vaccine in people with HSV-2 and assess efficacy through evaluating changes in T-cell counts, HSV-2 viral shedding and viral load.
Admedus said that about one in six people in the US between the ages of 14 and 49 were infected with HSV-2 with about 776,000 new infections annually.
Admedus fell 0.2 cents or 3.1 percent to 6.3 cents with 8.2 million shares traded.

NOVOGEN

Novogen says that a lipid formulation of TRXE-009 dosed intravenously to mice was able to deliver therapeutic concentrations to brain tissue, crossing the blood-brain barrier.
Novogen said that the blood-brain barrier was a defence mechanism intended to protect the brain from the unwanted toxic effects of drugs and food chemicals, preventing 98 percent of all drugs used in humans from reaching the brain.
The company said that the blood-brain barrier, along with the inherent resistance of primary brain cancers to chemotherapies, was the reason for the poor survival prospects of adults and children with brain cancer.
Novogen glioblastoma multiforme program manager Dr Eleanor Ager said that TRXE-009 showed “remarkably potent killing in the test tube against a wide range of cancer types, but it has been its particularly potent activity against brain cancers including glioblastoma and [diffuse intrinsic pontine glioma] that has marked it as a potential treatment of primary brain cancers in both adults in children”.
“These are tumors that show high levels of resistance to standard of care drugs, so even if it was possible to get those drugs into the brain, they may not offer clinical benefit,” Dr Ager said. “We know TRXE-009 kills these highly resistant cancer cells in vitro, with toxic effects on normal brain cells only occurring at very high doses ... so a vital step forward for us was to see whether we could get the drug to cross the blood-brain barrier.”
“Today’s data shows that it does,” Dr Ager said. “The next key step is to confirm that the drug is effective against brain cancer cells growing in the brain.”
Novogen executive chairman Dr Graham Kelly said that TRXE-009 was expected to be in clinical trials next year “.
“What marks this agent as particularly exciting is its particular ability to kill the full range of cells within a tumor, including the tumor-initiating or cancer stem cells,” Dr Kelly said.
“Today’s data is important in showing that the compound now will also be able to proceed into the clinic for testing as a therapeutic for brain cancer and where others in this field are focusing on the development of treatments just for cancers that arise in the brain, the much larger problem is cancers that arise elsewhere in the body and spread to the brain, so-called secondary brain cancers,” Dr Kelly said.
Novogen was up three cents or 12.2 percent to 27.5 cents with 11.9 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will begin training physicians and their staff on the use of Scenesse (afamelanotide 16mg) for erythropoietic protoporphyria to enable prescriptions to begin.
Clinuvel said that last year’s the EU marketing authorization last year, included a number commitments agreed with the European Medicines Agency under a long-term risk management plan, including specific training sessions (BD: Jan 18, 2015).
Clinuvel said it was required to train physicians and their staff prior to prescribing Scenesse and on June 5, 2015 in Paris 33 physicians from 23 centres across 15 countries would be instructed on the use of the disease registry and the administration of Scenesse.
The company said that it would host a number of these expert meetings.
Clinuvel acting chief scientific officer Dr Dennis Wright said the company was “putting all the required processes in place in accordance with the EMA’s principles and we have progressed our distribution of Scenesse”.
Clinuvel clinical affairs director Dr Emilie Rodenburger said that “while EMA progress is taking longer than we wish for, our team is clearly excited by the approaching landmark of treating [erythropoietic protoporphyria] patients,” Dr Rodenburger said
Clinuvel was up 10 cents or 3.4 percent to $3.05.

NUSEP HOLDINGS

Nusep says that directors Mark Gell, Andrew Goodall and Alison Coutts have subscribed for $215,000 in convertible notes, pending shareholder approval.
Nusep said that Mr Gell, Mr Goodall and Ms Coutts provided $100,000, $40,000 and $40,000 respectively, with Mr Goodall subscribing for $35,000 in convertible notes for payment of director fees and expenses incurred on behalf of the company.
The company said that all funds would be for working capital.
Nusep said that the notes had a coupon of five percent a year, convertible to shares on the same terms as the notes of 3.8 cents a share by July 31, 2018.
Nusep was untraded at 5.5 cents.

PHARMAXIS

BVF Partners and Mark Lampert say they have become substantial shareholders in Pharmaxis with 15,841,327 shares (5.04%).
The San Francisco, California-based BVF Partners and Mr Lampert said they acquired the shares between May 22 and June 1, 2015at 23 cents a share.
BVF Partners and Mr Lampert also hold 13.12 percent of Circadian and 13.55 percent of Viralytics (BD: Nov 25, 28, 2014).
Pharmaxis was unchanged at 23 cents.

PRIMA BIOMED

New York's Bergen Global Opportunity Fund, Bergen Asset Management and Eugene Tablis have sold 64,237,850 shares reducing their holding to 34,495,771 shares (1.98%).
The Bergen group said the shares were sold for $6,312,353 or an average price of 9.8 cents a share.
Earlier this week, the Bergen group sold 102,379,152 shares for $14,147,137, or an average price of 13.8 cents a share, reducing their holding to 98,733,621 shares (5.73%) (BD: Jun 3, 2015).
Last week the Bergen group became substantial shareholders in Prima with 201,112,773 shares (12.04%) acquiring the shares through the issue of a monthly tranche of 15,215,510 shares for $US360,000, the exercise of 19,800,000 options for $1,084,050 and the conversion of a $US2,500,000 note for 168,097,263 shares or 1.93 cents per converted share. (BD: May 28, 2015.
Prima fell 0.3 cents or 3.5 percent to 8.3 cents with 10.6 million shares traded.

OPTISCAN

Optiscan has requested a trading halt pending an announcement "concerning fundraising, upon finalization of the arrangements".
Trading will resume on June 10, 2015 or on an earlier announcement.
Optiscan last traded at 5.2 cents.

IMUGENE

Imugene says it has appointed the University of Vienna's Prof Ursula Wiedermann as its chief scientific officer.

Imugene said that Prof Wiedermann had worked as the principal Investigator for the preclinical development of its HER-Vaxx technology with Prof Christophe Zielinski and was currently a member of the scientific advisory board.

The company said Prof Wiedermann and Prof Zielinski worked together on the phase I trial of HER-Vaxx in metastatic breast cancer patients.

Imugene said that Prof Wiedermann was the professor of vaccinology at the Medical University of Vienna and had more than 110 publications in peer reviewed scientific journals to her credit.

Imugene managing director Charles Walker said that Prof Wiedermann was "a founding inventor of HER-Vaxx and her resume reflects her extraordinary prowess as a scientist, physician and educator and confirms her status as one of the leading lights in immuno-oncology globally".

Imugene was unchanged at 1.2 cents with 1.6 million shares traded.