Biotech Daily

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Daily news on ASX-listed biotechnology companies

* **ASX UP, BIOTECH EVEN: ACTINOGEN UP 36%, VIRALYTICS DOWN 14%**

*** CSIRO, BERGHOFER, ANU MALARIA BREATH TEST**

*** WEHI: 'COMBINATION THERAPY COULD CURE HEPATITIS B'**

*** VIRALYTICS: 'MELANOMA EXTENSION TRIAL IMMUNE ACTIVITY'**

*** PRESCIENT PTX-100 REDUCES MULTIPLE MYELOMA TUMORS IN MICE**

*** PRO MEDICUS $9.5m US IMAGING DEAL**

*** COMPUMEDICS $2.2m CHINA NEURO-MONITORING CONTRACT**

*** IMUGENE FILES HER-VAXX REFORMULATION PATENT**

*** COCHLEAR US PATENT CASE GOES TO APPEAL COURT**

*** MEDIBIO TO PAY $3m FOR US, CANADA PATENTS**

*** PROTEOMICS TO RELEASE 75k ESCROW SHARES**

*** NOVOGEN $15m PLACEMENT, $15m RIGHTS ISSUE**

*** BIOTRON RECEIVES $1.7m FEDERAL R&D TAX REFUND**

*** ANTEO BRANCHES INTO BATTERY TECHNOLOGY**

MARKET REPORT

The Australian stock market climbed 0.67 percent on Tuesday April 21, 2015 with the S&P ASX 200 up 39.2 points to 5,872.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and one was untraded.

Actinogen was the best, up four cents or 36.4 percent to 15 cents with 4.7 million shares traded. Anteo climbed 11.6 percent; Compumedics and Uscom were up 10 percent or more; Antisense and Neuren rose more than nine percent; GI Dynamics was up 7.1 percent; Clinuvel climbed 6.4 percent; Admedus was up 5.2 percent; Benitec, Biotron and Resmed were up more than three percent; with Cochlear, Living Cell, Osprey and Sirtex up more than one percent.

Viralytics led the falls, down seven cents or 14 percent to 43 cents with 911,407 shares traded. Pharmaxis fell 10 percent; Genetic Technologies lost 6.7 percent; Analytica and Medical Developments fell more than four percent; Cellmid, Circadian and Nanosonics were down more than three percent; Reva shed 2.8 percent; with Atcor, IDT, Mesoblast and Oncosil down more than one percent.

THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation says it is developing a breath test for malaria.

A CSIRO media release said the Organisation was working with researchers at the Queensland's Berghofer Medical Research Institute and the Australian National University on tests for diagnosing malaria by identifying distinctive chemicals detected in the breath of patients infected with the disease.

The CSIRO said that volunteers were given a controlled malaria infection as part of existing studies to develop new treatments and found that the levels of some normally almost undetectable chemicals increased markedly in the breath of the volunteers during the malaria infection.

CSIRO research group leader Dr Stephen Trowell said that "the increase in these chemicals were present at very early stages of infection, when many other methods would have been unable to detect the parasite in the body of people infected with malaria".

"In addition to its potentially better sensitivity, human breath offers an attractive alternative to blood tests for diagnosing malaria," Dr Trowell said.

The media release said that the study, entitled 'Biomarkers of infection with Plasmodium falciparum detected in human breath' was published in the Journal of Infectious Diseases and was at: http://jid.oxfordjournals.org/content/early/2015/03/25/infdis.jiv176.full.pdf.

The Organisation said that two independent studies tested experimental drug treatments in volunteers who had been given a very small dose of infection.

CSIRO said that researchers identified four sulphur-containing compounds whose levels varied across the time course of the malaria infection.

Berghofer senior scientist Prof James McCarthy said that the sulphur-containing chemicals had not previously been associated with any disease and their concentrations changed in a consistent pattern over the course of the malaria infection.

"Their levels were correlated with the severity of the infection and effectively disappeared after they were cured," Prof McCarthy said.

"Malaria continues to place a huge health and economic burden on many of the poorest people in the world," Prof McCarthy said.

CSIRO said that researchers detected foul-smelling compounds, at levels too low for humans to smell, in the breath of people with malaria.

The Organisation said that until now, the chemicals had only been detected using very expensive, laboratory based instruments, and only in the breath of volunteers experiencing a controlled malaria infection in the clinic.

"Now we are collaborating with researchers in regions where malaria is endemic, to test whether the same chemicals can be found in the breath of patients," Dr Trowell said.

"We are also working with colleagues to develop very specific, sensitive and cheap biosensors that could be used in the clinic and the field to test breath for malaria," Dr Trowell said.

CSIRO said that in 2013 there were about 200 million cases and more than half a million deaths due to malaria.

The Organisation said that malaria diagnosis was mostly based on using powerful microscopes to look for parasites in blood using a method discovered in 1880.

CSIRO said that as the world started to work towards eliminating malaria, there was an urgent need for more sensitive and convenient tests to detect early and hidden cases.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says a phase I/IIa trial of birinapant with entecavir in up to 60 patients hopes to completely eliminate the hepatitis B virus.

WEHI said that the combination was “100 percent successful in eliminating the infection in preclinical models” and hepatitis B was currently incurable.

The Institute said that its scientists developed the combination treatment using birinapant, a drug developed by the Malvern, Pennsylvania-based Tetralogic Pharmaceuticals for cancer, and found that in mouse models, that the combination with the anti-viral drug entecavir, the infection was cleared twice as fast compared with birinapant alone.

WEHI said the human clinical trial was underway in Melbourne, Perth and Adelaide.

The Institute said that Dr Marc Pellegrini, Dr Greg Ebert and colleagues used their studies of the behavior of hepatitis B virus in infected cells as a basis for the treatment, developed in collaboration with Tetralogic, and targeting the cell-signaling pathways that the hepatitis B virus uses to keep host liver cells alive.

WEHI said that the research was published in two papers in the journal Proceedings of the National Academy of Sciences.

'Cellular inhibitor of apoptosis proteins prevent clearance of hepatitis B virus' is available at: http://www.pnas.org/content/early/2015/04/15/1502390112.abstract and the second paper, 'Eliminating hepatitis B by antagonizing cellular inhibitors of apoptosis' is available at: http://www.pnas.org/content/early/2015/04/15/1502400112.abstract.

Dr Pellegrini said the treatment was successful in curing infections in mouse models, leading to a human trial that began in December 2014.

“We were 100 per cent successful in curing [hepatitis B] infection in hundreds of tests in preclinical models,” Dr Pellegrini said.

Dr Pellegrini said birinapant enabled the destruction of hepatitis B-infected liver cells while leaving normal cells unharmed and when administered in combination with the anti-viral drug entecavir, the infection was cleared twice as fast compared with birinapant alone.

He said that chronic infectious diseases such as hepatitis B lived within the host’s cells, enabling them to persist within the body for many months or years.

“Normally, liver cells would respond to infection by switching on a signal that tells the cell to destroy itself for the greater good, preventing further infection,” Dr Pellegrini said.

“However our research showed that the virus commandeers the liver cells’ internal communications, telling the cells to ignore the infection and stay alive,” Dr Pellegrini said.

“Birinapant flips the cell survival switch used by the virus, causing the infected cell to die,” Dr Pellegrini said. “Treatments that enabled the host cell to rid itself of the virus, rather than targeting the virus itself, might prevent drug-resistant strains of hepatitis B emerging.”

“It is relatively easy for an organism to adapt to a drug, but it is very difficult to adapt to a change in the host cell,” Dr Pellegrini said.

“The virus relies on the survival mechanisms of the host, so if it can’t exploit them, it dies,” Dr Pellegrini said.

“Such a monumental change in the virus’ environment may be too big a hurdle for it to adapt to,” Dr Pellegrini said.

WEHI said that Dr Pellegrini and his colleagues would investigate if the same strategy could be applied to other chronic infectious diseases such as HIV, herpes simplex and dengue fever, as well as bacterial infections such as tuberculosis.

WEHI said that more than two billion people worldwide were infected with hepatitis B and about 400 million have a chronic hepatitis B infection.

The Institute said that the virus infected liver cells and could lead to complications including cirrhosis and liver cancer, resulting in more than 780,000 deaths a year.

VIRALYTICS

Viralytics says preliminary results from a 13-patient melanoma extension study show that Cavatak induces anti-cancer immune activity in tumor tissue biopsies.

Viralytics also presented previously published data from its late stage melanoma (CALM) study showing that 22 of 57 patients achieved the six-month immune-related progression-free survival endpoint prior at the American Association for Cancer Research meeting, in Philadelphia, Pennsylvania (BD: Sep 29, 2014).

The company said that preliminary results from the 13-patient CALM extension study demonstrated that Cavatak, or Coxsackievirus A21, was able to induce anti-cancer immune activity in tumor tissue biopsies taken from melanoma lesions prior to and after Cavatak administration.

Viralytics said that evidence from the study included the tumor infiltration of immune cells, such as T lymphocytes, and up-regulation of receptors such as PDL1 on cancer cells, signaling the potential for complementary activity when combined with other immunotherapies such as checkpoint inhibitors.

Viralytics said that chief scientific officer Dr Darren Shafren reported on the intravenous delivery of Cavatak in clinical and preclinical studies, including early results from the UK 30-patient, phase I/II trial of intravenous Cavatak for late stage melanoma, prostate, lung or metastatic bladder cancer, known as the Storm study.

The company said that initial results from the first six patients demonstrated that multiple intravenous doses of Cavatak had been well tolerated, with no grade 2, 3 or 4 product-related adverse events.

Viralytics said that four patients exhibited signs of secondary viral replication and the escalating dose was associated with indications of anti-tumor activity in some lesions and the third cohort was being studied with the highest dose of Cavatak and would include assessment of tumor tissue biopsies.

Viralytics fell seven cents or 14 percent to 43 cents.

PRESCIENT THERAPEUTICS (FORMERLY VIRAX HOLDINGS)

Prescient says that PTX-100, formerly GGTI-2418, reduces multiple myeloma tumors and increases median survival times in mice.

Prescient said the research, conducted by the Tampa, Florida-based Moffitt Cancer Center, was in a presentation entitled ‘The geranylgeranyltransferase I inhibitor GGTI-2418 suppresses multiple myeloma malignancy in the 5TMG1 mouse model’ to the American Association for Cancer Research meeting, in Philadelphia, Pennsylvania.

The company said that Moffitt scientists examined the effect of PTX-100, a GGT-1 inhibitor that targeted one of the rat sarcoma (RAS) signaling pathways, in a mouse model relevant to multiple myeloma and found that PTX-100 “significantly decreased the percentage of multiple myeloma tumors within the bone and also offered a substantial improvement on mouse median survival times”.

Prescient managing director Dr Rob Crombie said the data suggested that PTX-100 was “a promising new therapeutic approach to treating multiple myeloma and warrants further clinical investigation”.

“We are planning to commence a phase Ib/II trial in multiple myeloma in the second half of 2015 at the Moffitt Cancer Center and look forward to exploiting the full potential of this highly promising compound,” Dr Crombie said.

Prescient said that multiple myeloma was the second most common haematological cancer and had low survival rates with new treatments urgently needed.

Prescient was up 0.8 cents or 9.8 percent to nine cents with 1.65 million shares traded.

PRO MEDICUS

Pro Medicus says its US subsidiary Visage Imaging has a $9.5 million seven-year contract with University of Florida Health for its medical imaging services.

Pro Medicus said the Visage 7 technology would be used for primary diagnosis across the University of Florida Health service, as well as clinical distribution of diagnostic images to thousands of physicians throughout the University of Florida Health network.

University of Florida College of Medicine chairman Prof Anthony Mancuso said that after analysis by a team of technologists, physicists, radiologists and clinical providers “we are happy to be working with Visage to provide the visualization component of our new enterprise imaging [system]”.

“We are extremely pleased with Visage's server-side rendering architecture, which allows for the transfer and manipulation of images by all those with a need to access images to rapidly and completely arrive at proper medical decisions,” Prof Mancuso said.

“These images can be securely accessed using handheld devices, as well as fixed workstations,” Prof Mancuso said. “This will serve our most sophisticated clinical providers, as well as it does those who just wish to simply view images or share them with their patients,”

Dr Mancuso said he expected Visage would “markedly improve the efficiency of our clinical providers in their outpatient environment and will allow more effective radiologist to clinical provider communication in high acuity situations”.

Pro Medicus chief executive officer Dr Sam Hupert said the deal was “another significant milestone for us in the enterprise university hospital market and is further proof that our Visage 7 technology has the functionality, scalability and flexibility to meet even the most demanding requirements of a large, distributed university health system”.

Pro Medicus climbed 16 cents or 10.6 percent to $1.67.

COMPUMEDICS

Compumedics says it has a $2.2 million three-year contract with China partner Beijing Bestmed to distribute its neurological monitoring systems across South East China.

Compuedics said that the contract was complementary to its existing arrangements for the distribution of its sleep diagnostics in China and included an order for $700,000 of neurological monitoring systems to be shipped in the current financial year.

Compumedics executive chairman Dr David Burton said the company had spent many years with its Chinese partners “building a foundation for future growth in one of the worlds most challenging but highest growth markets and is now the number one premium supplier of sleep diagnostic and neurological research systems in China”.

“Compumedics is well positioned to capture growth, not only in sleep diagnostics, but also in neurological monitoring, a relatively new and untapped market for the company in China and other parts of Asia,” Dr Burton said.

Compumedics was up two cents or 10 percent to 22 cents with 1.2 million shares traded.

IMUGENE

Imugene says it has filed a provisional patent entitled ‘A Vaccine Composition and Uses Thereof, potentially extending HER-Vaxx patent life to 2036.

Yesterday, Imugene said that a new HER-Vaxx formulation increased the production of cancer fighting antibodies in mice by up to 10 times (BD: Apr 20, 2015).

Imugene was unchanged at 1.1 cents with 12.4 million shares traded.

COCHLEAR

Cochlear says the US District Court in California has entered judgment in the Alfred E Mann Foundation and Advanced Bionics patent case (BD: Jan 24, Apr 1, 2015).

Earlier this month, Cochlear said that a jury verdict was disclosed in 2014 relating to four expired US patent claims and a US District Court in Los Angeles judge determined that three of the four claims that the jury found Cochlear had infringed were invalid.

The company said that the judge sustained the jury's verdict on direct and contributory infringement of the one remaining patent claim, overturned the jury's verdict of wilful infringement by Cochlear and overturned the $US131.2 million ($A171.75 million) in damages awarded by the jury.

Cochlear said that a new trial on damages for infringement of the one remaining patent claim would be held at a future date to be determined by the Court and the findings would not disrupt its business or customers in the US.

Today, Cochlear said that all parties jointly requested the Court to enter Judgment without a determination on monetary damages to allow an immediate appeal to the US Court of Appeals for the Federal Circuit following the rulings.

The company said that the Court acted on the request and entered Judgment on terms consistent with the rulings except for the requirement for a new trial on damages.

Cochlear chief executive officer Dr Chris Roberts said the company "strongly believe the facts and law do not support the Judgment on infringement entered against Cochlear and as previously stated, Cochlear will now appeal this Judgment to the US Court of Appeals".

The company said that the Alfred E Mann Foundation and Advanced Bionics were expected to appeal the Judgment in favor of Cochlear on invalidity, rejection of the jury's damages award and non-willful infringement.

Cochlear was up $1.19 or 1.4 percent to $88.79 with 206,808 shares traded.

MEDIBIO

Medibio says it will acquire the US and Canadian patents covering its circadian heart rate diagnosis for mental health disorders for $US2.5 million ($A3.25 million).

Medibio said that the patents entitled 'Method for diagnosing psychiatric disorders' also covered the use of the technology to determine the effectiveness of therapeutic interventions.

The company said the two patents completed the consolidation of the suite of granted intellectual property targeted to support commercialization of its mental health diagnostic technologies.

Medibio said the patents would be acquired form the British Virgin Isles-based Ifem-Ctac with payment due in three years and Medibio able to extend the payment to five years, while Ifem-Ctac could elect to be paid in cash or Medibio shares at 31 cents a share.

The company said that it could make an early payment and interest would be payable at eight percent a year half-yearly on the outstanding acquisition price.

Medibio fell half a cent or 1.6 percent to 30.5 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says that 75,000 shares will be released from ASX escrow on May 5, 2015.

A Proteomics executive told Biotech Daily that following the release from escrow there would be 18,125,000 shares available for trading, with a further 32,531,453 shares in ASX escrow of the total of 50,581,453 shares on issue.

Proteomics was up half a cent or 2.6 percent to 19.5 cents.

NOVOGEN

Novogen says it will raise $15,525,000 through the placement of 51,750,000 shares at 30 cents a share to US institutional investors and a further $15 million in a rights issue.
Novogen said that each placement and rights issue share would come with one attaching six-month option exercisable at 30 cents and half of one attaching five-year option exercisable at 40 cents.
The company said that placement was expected to close on or about April 24, 2015 and was subject to satisfaction of customary closing conditions and the issue of the attaching options under the placement was subject to shareholder approval.
Novogen said that HC Wainwright & Co was the exclusive placement agent.
The company said shareholders at the record date of May 1, 2015 could participate in a one-for-six non-renounceable rights issue at 30 cents a share to raise up to $15,000,000.
Novogen said the rights issue was expected to close on May 29, 2015.
The company said that Lodge Partners and HC Wainwright & Co would co-manage the placement of any shortfall in the rights Issue.
Novogen fell 12.5 cents or 30.1 percent to 29 cents with 81.3 million shares traded.

BIOTRON

Biotron says it has received $1.7 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Biotron said the rebate related to research and development expenditure for the year to June 30, 2014 on its HIV and hepatitis C virus drug development programs.
Biotron managing director Dr Michelle Miller said that while the company was “fully funded for its current activities ... this [research and development] cash rebate will strengthen the company's cash position and support ongoing underlying expenditure”.
Biotron was up half a cent or 3.85 percent to 13.5 cents.

ANTEO DIAGNOSTICS

Anteo says it has created a third subsidiary company Anteo Energy and filed a patent to develop its nanometer thin coating technologies for batteries.
Anteo said that from the company’s inception chief scientific officer Dr Joe Maeji saw potential for its molecular adhesive technology platform in diverse fields.
Anteo chief executive officer Dr Geoff Cumming said the scientific team had worked on a research project led by “a highly regarded scientific expert in new batteries technologies, Dr Quansheng Song”
“The project has been completed, and proved fruitful,” Dr Cumming said. “It is clear that there is significant potential in the energy field, which we aim to realize”.
Anteo said that Dr Song would lead a research and development team into the application of Anteo’s platform technology in batteries.
Anteo was up one cent or 11.6 percent to 9.6 cents with 1.6 million shares traded.