Biotech Daily

Wednesday October 5, 2016

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: UNIVERSAL BIOSENSORS UP 15%**
- GENETIC SIGNATURES DOWN 8%

*** AUSBIOTECH OCTOBER INTERNATIONAL BIOFEST**

*** FDA OKAYS UNIVERSAL BIOSENSORS, SIEMENS COAGULATION TEST**

*** LIVING CELL DOSES 1st PHASE IIb NTCELL FOR PARKINSON'S COHORT**

*** PSIVIDA BEGINS 2nd PHASE III MEDIDUR UVEITIS TRIAL**

*** FDA APPROVES AVITA RECELL 'CONTINUED ACCESS'**

*** CELLMID: 'ANTI-MIDKINE ANTIBODIES HELP THC FOR GLIOBLASTOMA'**

*** MACH7 SIGNS MICROSOFT FOR CLOUD IMAGING, GOSHEN HOSPITAL**

*** RACE APPOINTS SAI LIFE SCIENCES TO MANUFACTURE BISANTRENE**

*** ALLAN GRAY TAKES MORE PROFIT TO BELOW 5% OF NANOSONICS**

*** PETER CORR, INOV8 TAKE 12% OF ANALYTICA**

*** ACTINOGEN CHAIR MARTIN ROGERS RETIRES, PENDING SHARE PLAN**

MARKET REPORT

The Australian stock market fell 0.57 percent on Wednesday October 5, 2016 with the ASX200 down 31.1 points to 5,452.9 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and two were untraded.

Universal Biosensors was the best, up 4.5 cents or 15.25 percent to 34 cents with 788,330 shares traded. Cellmid climbed 12.5 percent; Actinogen was up 11.1 percent; Clinuvel and Compumedics were up more than six percent; Ellex and Oncosil improved more than four percent; Avita and Living Cell rose more than two percent; Acrux, Atcor, Osprey and Pharmaxis were up more than one percent; with Airxpanders, Cochlear, Medical Developments and Mesoblast up by less than one percent.

Genetic Signatures led the falls, down four cents or eight percent to 46 cents with 33,862 shares traded. IDT fell 4.55 percent; Prana lost 3.1 percent; Orthocell, Prima and Viralytics shed more than two percent; Anteo, Bionomics, Nanosonics, Pro Medicus and Resmed were down more than one percent; with CSL, Impedimed, Sirtex and Starpharma down by less than one percent.

AUSBIOTECH

Ausbiotech says it will host three conferences in Melbourne in October under the banner of an International Biofest.

Ausbiotech said that the conferences included its annual major Ausbiotech conference, the Australia Biotech Invest life science investment showcase and the International Biotechnology Symposium, which would present issues in biotechnology green chemistry and related fields.

The US Environmental Protection Agency defined green chemistry as “the design of chemical products and processes that reduce or eliminate the generation of hazardous substances”.

The industry organization said that there was “a refreshing focus on innovation in Australian public policy … [and] both industry and researchers are building an exciting environment for the Australian life sciences, of which there has been no better time to take part”.

Despite paraphrasing Prime Minister Malcolm Turnbull’s public statements about innovation, Ausbiotech recently criticized the Federal Government’s 1.5 percent cut to the R&D Tax Incentive along with concerns about the Tax Review (BD: Oct 3, 2016).

The organization said that the International Biofest would feature more than 270 biotechnology experts and include 100 exhibitors representing industry, research and investment in the life sciences, with about 40 percent of delegates from nearly 40 countries.

Ausbiotech said that a number of pharmaceutical companies would attend the conference, including Bristol-Myers Squibb which is seeking investment opportunities in Australia.

The organization said that its Auspartnering business matching program would facilitate meetings between delegates and satellite events would valuable networking opportunities.

Ausbiotech chief executive officer Glenn Cross said that the International Biofest offered “a holistic view of the global biotechnology ecosystem with events dedicated to academia, industry and investment”.

“Drawing researchers, industry leaders, investors and companies to Melbourne, it facilitates valuable discussion in life sciences innovation and offers outstanding networking opportunities to delegates,” Mr Cross said.

Ausbiotech said that speakers at the Biofest included CSL chief executive officer Paul Perreault, University of Auckland organic chemistry chair and medicinal chemistry director Prof Margaret Brimble and Swisse Wellness Pty Ltd chief executive officer Radek Sali, who would present ‘The Science of Swisse’.

Swisse and its vitamin and natural remedy capsule products have been the subject of extensive public discussion as has the role of Australian Therapeutic Goods Administration in approving the products (BD: Mar 22, 2013).

Ausbiotech said that Prof Ian Gust would deliver the Prof Nancy Millis Oration reflecting on the biotechnology industry past and New Zealand’s chief science advisor to the Prime Minister Prof Peter Gluckman would discuss ‘Biotechnology and innovation: risk and precaution: social license or not?’

The organization said the Atlanta, Georgia-based Emory Institute for Drug Development executive director Prof Dennis Liotta would discuss ‘A new model for drug development in academic institutions; the Milano-Bicocca University’s Prof Laura Cipolla would present on nanostructured biomaterials for tissue regeneration; and Monash University senior research scientist Dr Kade Roberts would talk on ‘Improving last resort antibiotics’.

Registration has opened for the conferences which will be held at the Melbourne Convention Centre, October 24 to 27, 2016.

For the full program and registration go to: www.internationalbiofest.org.

UNIVERSAL BIOSENSORS

Universal Biosensors says the US Food and Drug Administration has cleared its Xprecia Stride coagulation analyzer produced by Siemens Health.

Universal Biosensors said that the Xprecia Stride was a handheld device which delivers prothrombin time international normalized ratio (PT/INR) testing for point-of-care monitoring and assessment of patients taking oral anticoagulation therapy warfarin and used test strips produced at its Rowville, Victoria facility.

The company said that the Xprecia Stride analyzer was launched in Europe in May 2015 and has won international design awards.

Universal Biosensors said that the device was designed to meet the demand for fast and accurate analysers that could be used in clinics or doctors' offices where quick, informed patient-care decisions could be made.

Universal Biosensors executive chairman Andrew Denver said the company was "thrilled for Siemens that the Xprecia Stride analyzer has received clearance from the FDA and that patients and medical professionals in the US will now have access to this exceptional device".

Universal Biosensors said that the point-of-care market for coagulation testing was be worth about $US1 billion in 2014 and was dominated by PT/INR testing, which had about 65 percent of the market.

Universal Biosensors climbed 4.5 cents or 15.25 percent to 34 cents.

LIVING CELL TECHNOLOGIES

Living Cell says it has completed treatment of the first group of six patients in its phase IIb trial of NTCell for Parkinson's disease at Auckland City Hospital.

Living Cell said that it planned to complete the second group of six by the end of 2016 and the third group of six patients by the end of February 2017.

The company said that the phase IIb trial aimed to confirm the most effective dose of NTCell encapsulated pig choroid brain cells, define any placebo component of the response and further identify the initial target Parkinson's disease patient sub-group.

Living Cell said that four patients had 40 NTCell microcapsules implanted into the putamen on each side of their brain and two patients had sham surgery.

The company said that to date there were no safety issues in any of the six patients.

Living Cell said it was blind to the results until 26 weeks after completion of the trial, at which point the patients who received the placebo will receive the optimal dose of NTCell.

The company said that the next step was for the data safety monitoring board to review the patients' results and approve the second group of six patients with the next dose of NTCell, which would be 80 microcapsules implanted into the putamen on each side of their brain.

Living Cell said that principal investigator Dr Barry Snow presented data from the earlier four-patient, phase I/IIa trial to prospective patients and their partners and supporters at meetings organised by Parkinson's New Zealand (BD: Jun 7, 2016).

The company said that the meetings were oversubscribed and assisted patient recruitment for the clinical trial.

Living Cell said that Auckland City Hospital had invested in additional equipment and arranged extra surgical sessions dedicated to treating multiple patients in the trial and the measures would accelerate trial progress.

The company said that if the trial was successful it would apply for provisional consent to treat paying patients in New Zealand by the end of 2017.

Living Cell was up 0.2 cents or 2.5 percent to 8.3 cents.

PSIVIDA CORP

Psivida says it has competed enrolment of the targeted 150 patients in its second phase III trial of Medidur for chronic, non-infectious posterior segment uveitis.
Psivida said that the trial was being conducted in India, with the same study design and endpoints as the first phase III trial in the US, EU and India (BD: Jun 28, 2016).
The company said that the results of both phase III trials would support US product registration, with US Food and Drug Administration a new drug application to be filed by the end of 2017.
Psivida said that European Union registration was expected to be filed by April 2017.
Psivida chief executive officer Nancy Lurker said that the second phase III trial was “on target”.
“Both phase III trials are generating efficacy and safety data critical to regulatory filings in support of product registration,” Ms Lurker said.
Psivida was unchanged at $3.95.

AVITA MEDICAL

Avita says the US Food and Drug Administration has approved access to Recell for patients in its US trial, while the marketing application is under preparation and review.
Avita said that up to 60 new patients could be treated under the FDA approval of an application for Continued Access to Investigational Devices.
The company said that continued access provision allowed doctors to access a medical device while the marketing application was under preparation and review, if “there is a public need for the device [and] there is preliminary evidence that the device is likely to be effective and no significant safety concern have been identified for the proposed indication”.
Avita said that the FDA principles on granting the continued access stated that “it could be contrary to public health to prevent access to potentially safe and effective new devices during an evaluation period”.
The company said that it had treated all 30 patients required for its US approval trial and they were in a safety observation period.
Avita said that once that was completed in early 2017 it would submit a pre-market approval application and hoped Recell would be approved by the end of 2017.
The company said it had FDA approval for an investigational device exemption for compassionate use for burn patients to be treated with Recell if their life was in danger and there was no other treatment alternative.
Avita said that more than 30 American burn and trauma victims, most with very large-scale injuries, had been treated under this protocol.
The company said that under Continued Access the surgeons who participated in the trial would be able to access Recell, for their patients who required grafting, but whose injuries do not meet the criteria for compassionate use.
Avita said that the surgeons would record the treatment in compliance with the approval trial protocols, which would contribute to the body of clinical data.
Avita chief executive officer Adam Kelliher said the approval was a positive step to enter the US healthcare market.
“It is a very positive step that the FDA have decided that we comply with the guiding criteria for Continued Access, under which eligible devices must be assessed as safe, effective and meeting a real public need,” Mr Kelliher said.
Avita was up 0.2 cents or two percent to 10 cents.

CELLMID

Cellmid says its anti-midkine antibodies improve tetrahydrocannabinol (THC) treatment response in mouse models of cannabinoid-resistant glioblastoma multiforme.
Cellmid said that the pre-clinical study was conducted in collaboration with the Madrid, Spain-based Complutense University.
The company said that glioblastoma multiforme was one of the most common and aggressive forms of brain cancer, with no effective treatment and tumors recurring after the most intensive combination of surgery, radiotherapy and chemotherapy.
Cellmid said that existing treatments extended survival “from three months to just over a year, with very few glioblastoma patients surviving beyond three years”.
The company said that Complutense University had previously shown that high levels of midkine were associated with aggressive tumors and poor survival in glioblastoma patients.
Cellmid said that medicinal cannabis had benefits in cancer treatment including relieving pain and nausea and improving appetite and there was evidence that distinct chemical components of cannabis called cannabinoids were potent anti-cancer agents, with direct anti-tumor actions including induction of cancer cell death, but tumors could develop resistance to cannabinoids.
The company said that the study led by Prof Guillermo Velasco observed that midkine antibodies in combination with THC inhibited tumor growth in gliomas resistant to THC.
Cellmid said that overcoming THC-resistance highlighted a potential treatment strategy using midkine antibodies to enhance glioblastoma sensitivity to treatment and provided “a strong rationale for the continued clinical development of [midkine] antibodies to treat brain cancer in combination with cannabinoids”.
The company said that the study results provided “additional collaboration opportunities with companies focused on improving their existing therapeutic approaches using cannabinoids in the treatment of glioblastoma multiforme”.
Cellmid was up 0.4 cents or 12.5 percent to 3.6 cents with 36.0 million shares traded.

RACE ONCOLOGY

Race says the Hyderabad, India-based Sai Life Sciences will manufacture and supply bisantrene for its European named-patient program for acute myeloid leukaemia.
Race said that Sai would supply sufficient bisantrene active pharmaceutical ingredient to support at least the first year of sales under the program and would be expected to provide enough bisantrene for the additional clinical studies that might be required to support its US Food and Drug Administration approval.
The company said that beyond the initial manufacturing program, Sai was intended to be its long-term active pharmaceutical ingredient manufacturer to support sales of bisantrene.
Race managing-director Peter Molloy said that Sai was “an important strategic supply partner”.
“The decision to commence manufacturing is an important one for the company overall,” Mr Molloy said.
“It signals our full commitment to now drive forward towards the launch of bisantrene,” Mr Molloy said.
Race said that manufacturing would take several months to complete and was the first step in the production of the final bisantrene product for sale or clinical use.
The company said that once produced the active pharmaceutical ingredient would be shipped to a yet-to-be selected manufacturer for final drug formulation and packaging.
Race was up 0.5 cents or 2.2 percent to 23.5 cents.

MACH7 TECHNOLOGIES

Mach7 says it has partnered with Microsoft Azure to bring its medical imaging products to the internet and has signed its first US hospital customer on a five-year contract.
Mach7 said the Microsoft Azure managed service provided hospitals and healthcare systems with a product to meet their clinical, business, technical and patient care needs, with the security to safeguard hospital and patient data.
The company said that Indiana University Health's Goshen Hospital would be the first customer using the Enterprise Imaging Platform through the Microsoft Azure internet infrastructure and as well as software implementation and data migration fees, it would earn a monthly subscription-based fee levied on each study managed by the Mach7 Enterprise Imaging Platform for at least the next five years.
Mach7 said that it expected a minimum of $115,000 a year in subscription revenue.
The company said that Goshen Hospital selected its system based on its "ability to achieve the specific workflow requirements that their legacy [picture archive communication] system Pacs could not fulfil".
Mach7 said that the Enterprise Imaging Platform would provide Goshen Hospital with internet-based image storage and archiving, electronic medical record image-enablement with Mach7 Clinical Viewer and the ability for authorized clinicians to search, access, view and share medical imaging procedures.
The company said that the suite of enterprise imaging products could be deployed at the enterprise, through the internet 'cloud' or through a hybrid model.
Mach7 chief executive officer Albert Liong said that "a cloud solution is a strategic undertaking for us, especially with Microsoft as a partner".
"We expect this innovation will be highly valued by hospitals and radiology groups as they address today's changing data storage and access needs," Mr Liong said.
Mach7 was up 0.4 cents or 8.2 percent to 5.3 cents with 2.975 million shares traded.

NANOSONICS

Allan Gray Australia has reduced its substantial holding in Nanosonics from 16,184,022 shares (5.47%) to 14,774,231 shares (4.96%).
Allan Gray said it sold 1,409,791 shares for $4,494,295 or an average price of $3.19 a share.
Earlier this year, Allan Gray said it sold 3,106,741 shares at an average price of $2.40 a share, 2,067,647 shares for an average price of $2.29 a share and 2,933,635 shares for an average price of $2.04 a share (BD: Apr 14, May 31, Jul 27, 2016).
Allan Gray last bought Nanosonics shares at about 40 cents (BD: Aug 11, 2014).
Nanosonics fell five cents or 1.5 percent to $3.38 with 574,419 shares traded.

ANALYTICA

Inov8 LLC and Peter Corr have increased their substantial holding in Analytica from 238,038,923 shares (10.81%) to 273,753,209 shares (12.24%).
In a substantial shareholder notice signed by owner and director Peter B Corr, the St Thomas, US Virgin Islands-based Inov8 said the 35,714,286 shares were bought on October 4, 2016 for $250,000 or 0.7 cents a share.
Separately, Analytica said that the acquisition was the second tranche of its $500,000 placement to Inov8 (BD: Jul 27, 2016).
Analytica was unchanged at 0.7 cents.

ACTINOGEN MEDICAL

Actinogen says that chairman Martin Rogers will retire from the board with effect from the November 2016 annual general meeting.

Actinogen said that Mr Rogers had been chairman since the 2014 acquisition of the Xanamem dementia asset, then known as UE2343, from the University of Edinburgh spin-out Corticrine (BD: Aug 27, 2014).

Today, the company said that Mr Rogers resignation was “effective from and conditional on shareholders approving certain amendments to the terms of Mr Rogers’ participation in the Actinogen Medical employee share plan”.

According to Actinogen’s annual financial statements for the year to June 30, 2016, of 25,000,000 loan shares approved for issue to Mr Rogers, 20,000,000 loan shares valued at two cents a share or $400,000 had vested in three tranches.

The document said that the fourth tranche would vest on recruitment of the phase II trial which was currently being discussed with the US Food and Drug Administration.

Actinogen said that the loans for the shares were repayable under certain conditions including within one month of resignation from the company.

Actinogen did not disclose the required “certain amendments to the terms of Mr Rogers’ participation in the Actinogen Medical employee share plan”.

The company said that a search would begin for a replacement chairman, but if the process was not concluded by the annual general meeting Dr Jason Loveridge would be appointed interim chairman until a replacement was found.

Actinogen was up 0.5 cents or 11.1 percent to five cents with 2.5 million shares traded.