Biotech Daily

Tuesday October 27, 2015

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: LIVING CELL UP 77%; COMPUMEDICS DOWN 7%**

*** MONASH CHANCELLOR DR ALAN FINKEL APPOINTED CHIEF SCIENTIST**

*** LIVING CELL: 'NTCELL STOPS PARKINSON'S DISEASE'**

*** MMJ PHYTOTECH STARTS ISRAEL MARIJUANA TRIAL FOR MS**

*** BELGIUM OK FOR PRIMA PHASE IIb IMP321 BREAST CANCER TRIAL**

*** REGENEUS TREATS 1st RGSH4K TUMOR VACCINE PATIENT**

*** US, AUSTRALIAN PATENTS FOR PROTEOMICS KIDNEY TEST**

*** CELLMID Q1 ÉVOLIS HAIR LOSS PRODUCTS EARN $1m**

*** SIRTEX DISSENT AGAINST CEO PERFORMANCE RIGHTS**

*** TISSUE THERAPIES 1.6m 100% PREMIUM OPTIONS-FOR-PAY AGM**

*** GENETIC TECHNOLOGIES 14m CEO EUTILLIO BUCCILLI OPTIONS AGM**

*** GENERA 2m CEO RICHARD HANNEBERY 'RIGHTS' AGM**

*** ISONEA 2m DIRECTOR OPTIONS, NAME CHANGE AGM**

*** GOLDMAN SACHS BELOW 5% OF NANOSONICS**

MARKET REPORT

The Australian stock market slipped 0.03 percent on Tuesday October 27, 2015, with the ASX200 down 1.8 points to 5,346.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and four were untraded. All three Big Caps rose.

Living Cell was the best, up three cents or 76.9 percent to 6.9 cents with 16.9 million shares traded, followed by Cellmid up 14.3 percent to 3.2 cents with 8.4 million shares traded. Oncosil climbed 9.7 percent; Biotron and Uscom were up more than five percent; IDT was up four percent; Ellex rose 2.9 percent; with Admedus, Cochlear, CSL and Universal Biosensors up more than one percent.

Compumedics led the falls, down 2.5 cents or 6.85 percent to 34 cents with 581,567 shares traded. Circadian fell 5.8 percent; Atcor and Prana lost four percent or more; Acrux, Orthocell and Osprey were down more than three percent; Anteo, Clinuvel, Mesoblast, Nanosonics and Pharmaxis shed more than two percent; with Actinogen, Bionomics, Neuren, Prima and Tissue Therapies down more than one percent.

FEDERAL GOVERNMENT

The Federal Government has appointed Monash University chancellor Dr Alan Finkel as Australia's chief scientist.

A media release from Prime Minister Malcolm Turnbull and the Minister for Industry, Innovation and Science Christopher Pyne said that Dr Finkel would begin his duties in January 2016, succeeding Prof Ian Chubb who had the job since May 2011.

Biotech Daily welcomes the appointment of a scientist and entrepreneur and a member of the Biotech and Related Industry Leadership Group, who has formulated innovation and commercialization policy for many years (BD: Jul 6, 2009; June 30, 2014).

Dr Finkel told Biotech Daily that he was "a passionate advocate for science education, a passionate advocate for the environment and importantly the health and wealth and well-being of Australia".

Dr Finkel noted the trifecta of having a Prime Minister who was an entrepreneur, the head of the Commonwealth Scientific and Industrial Research Organisation Dr Larry Marshall who was an entrepreneur and now the chief scientist.

"But I am also a scientist, first," Dr Finkel said.

Dr Finkel's family office shares rooms with biotechnology doyen and Circadian founder Leon Serry, Dr Finkel's brother-in-law.

Earlier this year, Dr Finkel was appointed a director of Cogstate and today the company said that due to the appointment he would resign as a director (BD: May 12, 2015).

Dr Finkel said that in 2004, he sold his Axon company, built around the invention of a method of detecting the current and voltage of deep tissue neurons to measure ion channel activity, to the Sunnyvale, California-based Molecular Devices for $140 million.

Dr Finkel said the work began while he was a Monash University doctoral student and was developed at the Australian National University's John Curtin School of Medical Research.

The Prime Minister's media release said that Dr Finkel was "a prominent engineer, respected neuroscientist, successful entrepreneur and philanthropist with a personal commitment to innovation and commercialisation" and president of the Australian Academy of Technological Sciences and Engineering.

The Prime Minister's office said that Dr Finkel's experience in science and the commercial sector meant that he was "uniquely qualified to act as one of the Government's key advisers on science and innovation and on ways to translate our great scientific research into tangible outcomes for Australians and our economy".

Dr Finkel is a signatory to the BRIL Group call for 25 percent of the proposed $20 billion Medical Research Future Fund to be set aside for commercialization (BD: Jul 30, 2014).

Mr Turnbull said science and innovation were at the centre of the Government's agenda and key to Australia remaining a prosperous, first world economy with a generous social welfare safety net.

"The Australian Government recognises the importance of science, innovation and technology to our future prosperity and economic security in an increasingly competitive and diverse global economy," Mr Turnbull said.

"Dr Finkel is renowned for his outstanding research, industrial and entrepreneurial achievements in Australia and overseas, his leadership and service in the university and education sector, the academies and national science bodies, and his experience in providing high-quality expert advice to government," Mr Pyne said.

"His will be a vital role in shaping Australia's economic future and leading our national conversation on science, innovation and commercialisation," Mr Pyne said.

The media release said that the chief scientist would provide independent advice to the government on science, innovation and commercialisation and lift the profile of Australian scientific endeavor domestically and internationally.

LIVING CELL TECHNOLOGIES

Living Cell says that at 42 weeks post-implant NTCell “has stopped the progression of Parkinson’s disease” in the four patients in its phase I/IIa clinical study of NTCell.
Living Cell said that its NTCell was composed of encapsulated clusters of neonatal pig choroid plexus cells, transplanted into the brains of Parkinson’s disease patients.
Living Cell said that all four patients were well, with no safety concerns.
The company said that “in all four patients NTCell treatment has stopped the progression of Parkinson’s disease as measured by globally accepted and validated neurological rating scales”.
Living Cell said that in all four patients the 42-week post-implant data showed there was a clinically and statistically significant improvement in the patients’ neurological score from their pre-implant baseline.
The company said that the improvement was equivalent to about five years of Parkinson’s disease remission and was maintained 74 weeks after NTCell transplant in the first patient.
Living Cell said that data from the on-going monitoring of the four patients was measured by validated neurological rating scales and questionnaires, including the Unified Parkinson’s Disease Rating Scale, the Unified Dyskinesia Rating Scale and the Parkinson’s Disease Quality of Life Questionnaire, which were scales and questionnaires used to assess improvements in patients’ movement abnormalities, other physical symptoms, well-being and ability to perform everyday tasks.
Living Cell chief executive Dr Ken Taylor said that the continued improvement of the patients was pleasing.
“We are delighted with the continued positive outcome of the study to date,” Dr Taylor said. “It certainly adds anticipation and motivation to the planned phase IIb study.”
The phase IIb study will confirm the effective dose of NTCell, define any placebo component of the response and further identify the Parkinson’s disease patient sub group we would initially target,” Dr Taylor said.
Living Cell climbed three cents or 76.9 percent to 6.9 cents with 16.9 million shares traded.

PHYTOTECH MEDICAL

Phytotech says that its 15 patient phase I trial of medical marijuana for multiple sclerosis has begun in Israel.
In July, Phytotech said that it had filed documents to Israeli authorities for phase I and II trials including the clinical study protocol and investigative brochure for trials of its oral tetrahyrocannabidiol (THC) and cannabidiol (CBD combination capsules to Israel's National Clinical Trial Committee and to an institutional review board for the trials, which were expected to begin by the end of 2015 (BD: Jul 6, 2015).
Phytotech Israel chief executive officer Dr Daphna Heffetz told Biotech Daily at that time that the study would be “a cross-over study [in] 15 healthy volunteers” and each volunteer would receive several treatments with a washout period between treatments.
In July, Phytotech said the phase I study, at the Tel Aviv, Israel-based Sourasky Medical Clinical Research Center, would be a single-centre, randomized, crossover study to compare the safety, tolerability and pharmacokinetics in healthy volunteers of the two oral formulations administered as single doses and the study objectives included the selection of the optimal THC and CBD formulations and was expected to conclude after nine weeks.
Phytotech fell four cents or 11.3 percent to 31.5 cents with 3.3 million shares traded.

PRIMA BIOMED

Prima says that Belgium's Federal Agency for Medicines and Health Products has approved its 211-patient phase IIb trial of IMP321 for in metastatic breast cancer.

Prima said it was the first approval for the active immunotherapy paclitaxel (Aipac), multi-national, randomized, double-blind, placebo-controlled study.

The company said that institutional review board ethics approvals at Belgium study sites would be the final step before trial initiation.

Prima chief scientific and medical officer Dr Frédéric Triebel said the approval was "a big step forward … and we are on track to commence the study by the end of 2015".

The company said that IMP321 was a first-in-class antigen presenting cell activator based on the immune checkpoint s lymphocyte activation gene 3 (LAG-3), one of the first proposed active immunotherapy drugs in which the patient's own immune system was harnessed to respond to tumor antigenic debris created by chemotherapy.

Prima said that as an antigen presenting cell activator, IMP321 boosted the network of dendritic cells in the body that could respond to tumor antigens for a better anti-tumour CD8 T-cell response.

The company said that IMP321 had been shown in a phase I study1 to double the expected six-month response rate in HER-2 negative metastatic breast cancer patients receiving standard-of care paclitaxel, from a 25 percent historic response rate to 50 percent when combined with IMP321 (BD: Oct 2, 2014; Feb 27, 2015).

Prima said the phase IIb trial had been designed to confirm this expected response and evaluate its effect on patient survival with progression-free survival the primary endpoint, response rates and overall survival among the secondary endpoints.

The company said that the trial would recruit women with metastatic breast cancer where the tumor was HER-2-negative but hormone receptor positive.

Prima said the patients would receive paclitaxel as first line chemotherapy after having failed on hormone therapy and be administered subcutaneous doses of IMP321 on days two and 16 of a weekly regimen of paclitaxel, the day after their paclitaxel infusion.

The company said that the trial would aim to initially recruit 15 patients for a smaller safety run-in in three different countries, testing the combination of paclitaxel with IMP321 in doses up to 30mg per dose, which had been shown to be safe as a monotherapy was significantly higher than the maximum 6.25mg dose in the phase I metastatic breast cancer trial.

Prima said the first part of the trial was expected to provide safety, pharmaco-kinetic and pharmaco-dynamic data to be reported by the end of 2016.

The company said that following the 15-patient safety trial, investigators would proceed to recruit 196 patients, randomizing them equally to either standard-of-care paclitaxel with placebo or paclitaxel with IMP321 for six months as per the phase I dosing regimen, after which the responding or stable patients would be maintained for another year with monthly IMP321 injections.

Prima said that the study had been powered to show a four-month progression-free survival advantage for the treatment group.

The company said that allowing for recruitment and follow-up, the trial was expected to take about three years.

Prima said that independent data monitoring for patient safety, survival rates and demographics would be conducted at regular intervals, but with no interim statistical analysis planned.

The company said it expected to establish at least 30 study sites in six European countries, starting with Belgium, France and the Netherlands.

Prima fell 0.1 cents or 1.7 percent to 5.7 cents with 2.6 million shares traded.

REGENEUS

Regeneus says the first of 21 patients has been safely treated in the first clinical trial of its RGSH4K autologous tumor vaccine for solid tumors.
Regeneus said that a review of the first patient's safety data identified no safety concerns, following two vaccinations, administered three weeks apart.
The company said that dosing the first patient was "a significant milestone".
In May, Regeneus said the open label, first in-human, phase I dose escalating 'Activate' study of RGSH4K at the St Leonards, Sydney-based private hospital the Northern Cancer Institute would evaluate the safety, tolerability and preliminary efficacy of RGSH4K, produced from a patient's own cancer cells and combined with a proprietary immuno-stimulant to activate the immune system against the cancer cells to initiate a body-wide response (BD: May 25, 2015)
Today, the company said that patients would be enrolled into three dose cohorts of seven patients each.
Regeneus said that patients would be on the study for 24 weeks with an option to continue dosing and long-term follow-up in an open-ended extension phase.
The company said that it had established an ethics-approved tumor bank and participants in the trial would store a tumor sample to produce an autologous cancer vaccine for the individual patient's use in the trial and so far, nine patients had banked tumors with a view to trial enrolment.
Regeneus was unchanged at 11.5 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has been granted a US patent for its Promarkerd test for the early diagnosis of diabetic kidney disease.
Proteomics said that the patent entitled, 'Method of assessing diabetic nephropathy using CD5 antigen-like" provided protection for the use of Promarkerd as both a predictive, or prognostic, and diagnostic test in the US until September 20, 2031.
The company said that the US patent was "a critical milestone in the development and commercialisation pathway for [its] diagnostic test in the US".
Proteomics said the patent was significant, as there was "an increasing level of stringency being applied to diagnostic patent applications".
The Australian High Court has determined that DNA sequences can no longer be patented, which follows an earlier finding by US Federal Courts, the company said.
Proteomics managing director Dr Richard Lipscombe said the company was "delighted to have this protein based patent granted in the US in such a challenging diagnostic patent environment".
The company said that the patent contained the core claims within its international patent application 'Biomarkers associated with pre-diabetes, diabetes and diabetes related conditions' designating a patient as having an increased risk of developing diabetic kidney disease by measuring a panel of protein biomarkers.
Proteomics said its test was developed from its proteomics-based technology platform, using protein biomarkers in blood to provide an early and accurate detection of the presence of disease.
The company said that an Australian patent, entitled 'Biomarkers associated with pre-diabetes, diabetes and diabetes related conditions' was granted on September 3, 2015 and was also valid until September 2031.
Proteomics said it had patent applications for Promarkerd in Europe, China and India.
Proteomics climbed nine cents or 26.5 percent to 43 cents with 1.2 million shares traded.

CELLMID

Cellmid says that record cash receipts for the three months to September 30, 2015 was up 318.9 percent to $1,022,000, compared to the same period last year.

Cellmid chief executive officer Maria Halasz told Biotech Daily that while there was a “non-material payment” for the company’s midkine-enzyme-linked immunosorbent assay (Elisa) diagnostic kits, more than $1 million was from sales of its Évolis hair loss products.

The company said that strong sales exceeded internal projections reaching $713,000 for the three months compared to $180,000 for the same period last year, which was “especially pleasing as the pharmacy distribution, a precursor to sales, is rapidly growing towards the target 2,000 stores in Australia”.

Cellmid was up 0.4 cents or 14.3 percent to 3.2 cents with 8.4 million shares traded.

SIRTEX MEDICAL

The Sirtex annual general meeting passed all resolutions but with 11.9 percent opposition against the issue of 45,930 ‘performance rights’ to chief executive officer Gilman Wong.

Sirtex said the issue of the performance rights at no cost and exercisable as shares at no cost to Mr Wong was supported by 26,389,973 proxy votes (88.1%) with 3,577,883 proxy votes against (11.9%).

In 2013, the Sirtex annual general meeting passed voted 5.5 percent opposition against the issue of 115,000 ‘performance rights’ to Mr Wong and last year up to 23.8 percent of the meeting opposed the increase in the pool of directors remuneration from $625,000 to $1,000,000 (BD: Oct 29, 2013; Oct 28, 2014).

Today, Sirtex said that the meeting adopted the remuneration report, re-elected directors Grant Boyce and Dr Katherine Woodthorpe and approved the executive rights plan, overwhelmingly.

The company’s most recent Appendix 3B said that Sirtex had 57,157,977 shares on issue meaning that the opposition to Mr Wong’s performance rights amounted to 6.25 percent of the company’s total shares on issue, sufficient to requisition extraordinary general meetings.

Sirtex was up 16 cents or 0.5 percent to $34.60 with 706,083 shares traded.

TISSUE THERAPIES

Tissue Therapies will vote to grant 1,600,000 options to executive director Dr Christian Behrenbruch, chairman Dr Cherrell Hirst and Tim Hughes in partial lieu of pay.

Tissue Therapies said that all options would be exercisable at 11 cents each within five years, with Dr Behrenbruch’s options vesting on issue and the options for Dr Hirst and Mr Hughes vesting in four tranches over 12 months.

The company said that the annual general meeting would vote on the election of Dr Hirst, Dr Behrenbruch and Mr Hughes, as well as the ratification of the prior issue of placement and consultancy shares and approving the 10 percent placement capacity.

The meeting will be held at the offices of McCullough Robertson, Level 11 Central Plaza Two, 66 Eagle Street, Brisbane on November 25, 2015 at 12.30pm (AEST).

Tissue Therapies fell 0.1 cents or 1.9 percent to 5.1 cents.

GENETIC TECHNOLOGICS

Genetic Technologies will vote to grant chief executive officer Eutillio Buccilli 14,236,111 options exercisable at two cents each within five years from issue.
The Genetic Technologies notice of annual general meeting said the options would vest in three tranches pending the company meeting three month volume-weighted average prices of five cents, 10 cents and 20 cents.
The company said that shareholders would vote to refresh the $20.96 million Kentgrove Capital standby equity placement facility, ratify the prior placement of 26,500,000 shares to Kentgrove, ratify the prior placement of 107,329,800 shares, elected directors Dr Malcolm Brandon and Mr Buccilli and adopt the remuneration report.
The meeting will be held at Treetops, Melbourne Museum, 11 Nicholson Street, Carlton on November 25, 2015 at 10.30am (AEDT).
Genetic Technologies was unchanged at 1.7 cents with 1.1 million shares traded.

GENERA BIOSYSTEMS

Genera will vote to grant chief executive officer Richard Hannebery 2,000,000 "performance rights" vesting in three tranches between June 2015 and March 31, 2016.
The Genera notice of annual general meeting said the rights were pending the achievement of total seek shareholder return milestones.
The company said the meeting would vote on the ratification of the prior issue of convertible notes and shares and to approve the 10 percent placement capacity and the employee share option plan.
Genera said shareholders would vote on the re-election of directors Richard Hannebery and David Symons.
The meeting will be held at Grant Thornton, Level 30, The Rialto, 525 Collins Street, Melbourne on November 26, 2015 at 1pm (AEDT).
Genera was untraded at 26 cents.

ISONEA

Isonea will vote to grant director Ross Blair-Holt and Wall Partnership 2,000,000 options each and change the company's name to Respiri.
Isonea's notice of meeting said that the options would be exercisable at 28 cents each by February 3, 2017.
The company said that the Wall Partnership "supported the chairman [Leon L'Huillier] in the build of Isonea's new technology platform, clinical trial development and in the project management of all outsourced partners".
The Melbourne-based Wall Partnership's website says it is "a marketing and communications firm" and cites Isonea as a client.
Isonea said that the change of name was "proposed so that the company's name better reflects its current activities in the respiratory health market" (BD: Aug 6, 2015).
The company's notice of meeting said shareholders would vote on the remuneration report, the 10 percent placement capacity and the re-election of directors Dr Timothy Oldham and Mr Blair-Holt.
The meeting will be held at Giorgios Restaurant Function Room, 1235 High Street, Armadale on November 26, 2015 at 3.30pm (AEDT).
Isonea was untraded at 5.6 cents.

NANOSONICS

The Delaware-based Goldman Sachs Group says it has ceased its substantial shareholding in Nanosonics, again.

Following the notice on October 23 that it had again become substantial in Nanosonics with 14,728,433 shares or 5.20 percent Goldman Sachs today said it had reduced its holding below the five percent substantial shareholder threshold (BD: Oct 2, 5, 15, 16, 20, 21, 23, 2015).

Goldman Sachs said that subsidiary Rothesay Life returned 1,099,720 shares “to the counterparty under a repurchase agreement” for no applicable consideration.

Previously, under a counterparty agreement, Goldman Sachs said it had returned, lent and borrowed shares held by subsidiaries, Rothesay Life, JP Morgan Chase, RBC Dexia Australia, HSBC Custody Nominees and the Bank of New York Mellon (BD: Apr 13, 2015).

Nanosonics fell three cents or 2.1 percent to $1.40.