Biotech Daily

Tuesday October 13, 2015

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: CIRCADIAN, TISSUE THERAPIES UP 9% - IMPEDIMED DOWN 6%**

*** DR CHRIS NAVE TELLS WEHI MEETING: 'BIOTECH CURVE IS UP, STEEP'**

*** TAIWAN WATERPARK DISASTER REPORTS POSITIVE AVITA RECELL USE**

*** REGENEUS RECEIVES $3.4m FEDERAL R&D TAX REFUND**

*** RETT FOUNDATION COMMITS $1.4m TO NEUREN TRIALS**

*** PRIMA RAISES $1.6m FROM NETHERLANDS NYENBURGH**

*** SOMNOMED Q1 SALES UP 30% TO $9.6m**

*** CELLMID AGM FOR 8m DIRECTOR OPTIONS**

*** LIVING CELL AGM FOR 3m DIRECTOR OPTIONS**

*** MMJ HIRES GAELAN BLOOMFIELD PR, IMPLIES VICTORIA LICENCE BID**

MARKET REPORT

The Australian stock market fell 0.57 percent on Tuesday October 13, 2015, with the ASX200 down 30.0 points to 5,202.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and two were untraded.

Circadian and Tissue Therapies were the best, the latter for the second trading day in a row, both up 9.1 percent to 24 cents and six cents, respectively, with 62,590 shares and 418,436 shares traded, respectively.

Compumedics and Ellex climbed six percent or more; Acrux was up 5.3 percent; Starpharma improved four percent; Bionomics, Neuren and Oncosil were up more than three percent; Admedus, Antisense, Medical Developments and Optiscan rose more than two percent; Actinogen and Pro Medicus were up more than one percent; with CSL and Resmed up by less than one percent.

Impedimed led the falls, down 5.5 cents or 5.8 percent to 89.5 cents with 377,535 shares traded. Genetic Technologies and IDT fell five percent or more; Orthocell and Osprey fell more than four percent; Prana and Viralytics were down more than three percent; Pharmaxis and Universal Biosensors shed more than two percent; Anteo, Benitec, Clinuvel, Mesoblast, Nanosonics and Sirtex were down more than one percent; with Cochlear down 0.3 percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH
MEDICAL RESEARCH COMMERCIALIZATION FUND

Brandon Capital and Medical Research Commercialization Fund principal Dr Chris Nave says Australian biotechnology is “trending upwards at a steep incline”.

Opening the Walter and Eliza Hall Institute ‘Catalyzing Commercialization Symposium’ in Melbourne, Dr Nave said that translation and commercialization were gaining momentum.

“We’re at the bottom of the curve and the curve is trending upwards at a steep incline,” Dr Nave said.

Dr Nave said the recent successes of Fibrotech, Spinifex and Hatchtech demonstrated that home-grown technologies could have world-standard licencing and acquisition deals.

“It gives us confidence that we actually can do this,” Dr Nave said.

He said the MRCF’s third fund was supported entirely by previously biotechnology-shy superannuation funds, with more interest than the $200 million capped fund could satisfy.

Dr Nave said the change in Australian leadership to Prime Minister Malcolm Turnbull who believed in innovation and technology was “great for our sector”.

The executive director of the Victoria Government innovation and industry program Cameron Boardman also acknowledged the change of Prime Minister as a benefit for innovation.

“The changing of the guard in Canberra is good for innovation,” Mr Boardman said.

Mr Boardman said that there had been strong bi-partisanship in Victoria, but the question for government was “What do we do to make sure every aspect is in sync to get the outcomes we want?”

He said that the two areas that needed further reform were the protection of intellectual property and tax incentives to innovative companies.

Mr Boardman said that the UK Patent Box was an opportunity for Australia, albeit with a different tax regime.

He said that IP Australia decided to abolish the small and medium sized enterprize patent with lower thresholds but “lobbying by Victoria Government to [Minister for Industry, Innovation and Science] Christopher Pyne resulted in him looking favourably at it”.

Mr Boardman suggested tax holidays for companies as well as positive changes to the R&D Tax incentive.

WEHI’s Dr Marc Pellegirini, Fibrotech and Occurx founder Prof Darren Kelly and Hatchtech founder Prof Vern Bowles gave detailed case studies of their respective companies’ technological development and commercialization processes.

WEHI

Dr Pellegrini said the Institute decided to try to attack infectious diseases by killing the disease cells like cancer rather than working on a vaccine or immune response and partnered with Tetralogic to trial a combination of birinapant and GT13072 which cleared hepatitis B infection and had been shown to create antibodies to hepatitis B in mice, with a phase I/IIb trial currently underway.

Dr Pellegrini said the combination could be translated to tuberculosis and had been shown in mice to clear “a lot of the virus … and we think it also acts on latent TB”.

FIBROTECH, OCCURX

Prof Kelly said that the drug tranilast had serious toxicity issues but had shown anti-fibrotic potential and his group reconstructed the molecule to reduce toxicity and increase potency creating FT011 and three separate patent families around the technology.

Prof Kelly said that in rats, tranilast had been shown to slow leakage in diabetic nephropathy and reduce fibrosis.

Prof Kelly said Fibrotech had to show FT011 was safer and more efficacious than tranilast and it had, with doses of up to 2,000mg/kg/day in rats, 600mg/kg/day in dogs and up to 1,000mg in a single dose in humans, as well as 500mg/day for 14 days with no adverse events.
He said that in myocardial infarction, or heart attack, FT1011 could prevent the progression of fibrosis.
Prof Kelly said that having proved safety and moved to human clinical trials in “15 to 16 years of research” Fibrotech, which received $3 million in seed funding from Uniseed, Brandon and the MRCF, reviewed previous deals and set minima of $US75 million upfront and $US500 million in milestones for a phase IIa technology, and agreed it would walk away from anything less.
Prof Kelly said Shire bought the phase Ib technology for $US75 million upfront and $US525 million in milestones, a 53-fold return on investment.
Prof Kelly said that the use of the non-lead compound was retained for eye diseases and that technology was contained within his new company Occurx.

HATCHTECH
Prof Bowles said that he began work on what would become Xeglyze at the University of Melbourne in 2003 having come from an agricultural background and looking for a technology to eliminate sheep blow-fly that laid eggs on the skin and in the wool and was responsible for the deaths of one million sheep a year.
“We wanted to disrupt the life-cycle and if proteases were involved in hatching can we interrupt the proteases and the hatching?”
Prof Bowles said that the market of treating sheep was about $50 million which was too small a target and following discussions, decided to use the same principles for killing human head lice eggs, which had poor compliance and increasing resistance.
Prof Bowles said there were over-the-counter remedies as well as prescription medicines and “if not for the prescription market, Hatchtech would not exist”.
He said that the active ingredient abamettapir had been shown to bind to multiple metal dependent proteins reducing the possibility of resistance.
Prof Bowles said that a single 10 minute application of the 200ml preparation had been shown in phase III trials to kill 81.5 percent of head lice at day 14.
He said that with patients treated at home, there was always the possibility of reinfection, but an examination of lice eggs pre and post treatment showed that 93 percent of untreated eggs hatched while 100 percent of treated eggs did not hatch.
Prof Bowles said that there had been a total of 1,200 participants in four phase I trials, four phase II trials and two pivotal phase III trials.
He said that the 50,000 page new drug application had been filed to the US Food and Drug Administration on September 14, 2015 and the company expected the review to take about 12 months.
Prof Bowles said Hatchtech had an experienced board and management with a track record of phase III trial success as well as filing a new drug application and partnering experience.
He said that $6.2 million of $39 million invested in the company came for State and Federal Government with 67 percent from venture capital including One Ventures, GBS Partners, Uniseed, QBF and Blue Sky, with 14 percent from the University of Melbourne, 12 percent from high net worth individuals and seven percent from management.
Prof Bowles said that the Dr Reddy’s licence covered specified territories not including Europe and China nor the use of the technology for non-human use and would return milestone payments up to $279 million (BD: Sep 14, 2015).

AVITA MEDICAL

Avita says that doctors in Taiwan have reported superior wound closure and better outcomes in using Recell to treat burn victims of June's waterpark disaster.

Avita said 12 people died from burns sustained in the June 27, 2015 blast, triggered when a flammable starch-based powder ignited during a crowded music festival at the waterpark outside Taipei, with 498 people left with burn injuries, most of them teenagers, with the average wound size covering 43 percent of their bodies.

The company said that 107 patients remain hospitalized, of whom 12 were still in intensive care.

Avita said it donated 50 Recell devices and sent a team to support Taiwanese medical personnel, with all donated devices and a number of purchased devices distributed to 12 hospitals (BD: Jul 7, 2015).

The company said that about 76 patients had been treated with Recell and doctors contacted since the treatment began reported positive outcomes in their application of the regenerative epithelial suspension to both wounds and donor sites.

Avita said that definitive conclusions around the impact of Recell were difficult to draw in circumstances where multiple treatments were being provided to meet the challenges of a mass casualty, but when Recell was part of the care program, it was reported that better-than-expected outcomes are often being achieved.

Avita chief executive officer Adam Kelliher said that there was "a great range and variation of burn wounds, so it is heartening to hear directly from the doctors that the regenerative healing mechanism has performed as we hoped it would".

"Using Recell was a new approach for the surgeons and it was being applied in extreme circumstances, so we are pleased to be able to report benefits amongst these various anecdotal accounts," Mr Kelliher said.

Taipei Veterans General Hospital plastic surgeon Dr Yu-Ching Shih said he had conducted four treatments with Recell and reported positive outcomes in healing and better-resulting skin quality saying Recell was "important in accelerating healing, as we have seen that Recell does help wound closure".

Dr Shi said in one of the cases, donor skin shortages meant the patient could only receive Recell on one thigh, while the other thigh was given a dressing.

"After 14 days, we could see wound closure on the right [Recell-treated] thigh and no progress of wound healing on the left [untreated] thigh," Dr Shi said.

"We will keep monitoring results in the coming months and it will be of particular interest to see if Recell can help stop such typical scarring problems as contracture," Dr Shi said.

Changhua Christian Hospital head of plastic surgery Dr Wen-Pin Kao said that using Recell with other treatments such as grafts had boosted the survival rate of skin islands within the wound bed by up to 90 percent.

"The final result is better than we expected," Dr Kao said.

"Recell is showing that it can enhance the survival rate of skin grafts, Dr Kao said. "By using this, we are seeing that there is no need for another skin graft treatment."

Avita was unchanged at 11.5 cents.

REGENEUS

Regeneus says it has received $3,418,568 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Regeneus said the rebate related to research and development expenditure for the year to June 30, 2015.

Regeneus was up one cent or 9.1 percent to 12 cents.

NEUREN PHARMACEUTICALS

Neuren says the International Rett Syndrome Foundation has committed up to $US1 million ($A1.37 million) to continue its support its trials of trofinetide for Rett syndrome.
Neuren said the foundation, also known as rettsyndrome.org, supported the phase II trial in adults and adolescents with Rett syndrome, which showed clinical benefit from treatment with trofinetide, formerly known as NNZ-2566 (BD: Nov 12, 2014).
The company said the benefit seen in the trial "encompassed many of the core symptoms of Rett syndrome and was observed in both clinician and caregiver assessments".
Neuren said it had orphan drug designation in the US and the European Union for trofinetide in Rett syndrome and the US Food and Drug Administration had granted fast track designation for the development program.
Neuren said it would conduct a paediatric trial in 2016, with higher doses of trofinetide in children below the age of 16 years, to confirm the optimum dose for the subsequent phase III trial, as well as generating data on the treatment of children and younger adolescents.
The company said that it was working with the FDA to agree the phase III study design that would support potential approval of a new drug application in the US.
International Rett Syndrome Foundation chief science officer Dr Steven Kaminsky said that "the work by Neuren provides one of the brightest opportunities to change the quality of life for those suffering with Rett syndrome".
Neuren was up 0.3 cents or 3.45 percent to nine cents with 1.7 million shares traded.

PRIMA BIOMED

Prima says it has raised EUR1 million ($A1.55 million) through a placement of shares at five cents a share to Nyenburgh Investment Partners.
Prima said that the Amsterdam, Netherlands-based Nyenburgh was a specialist healthcare investor, taking long-term positions in life sciences companies.
The company said that proceeds from the placement would be used to fund its IMP321 clinical trial program and provide additional working capital.
Prima was unchanged at 5.6 cents with 1.2 million shares traded.

SOMNOMED

Somnomed says that revenue for the three months to September 30, 2015 was up 30.1 percent to $9.64 million mainly on sales of its sleep apnoea mouth-guard.
Somnomed said that direct US sales were up 37.8 percent compared to the three months to September 30, 2014 with a record 6,888 devices sold, which "more than compensated for the drop in sales to licencees".
Somnomed climbed 20 cents or 8.85 percent to $2.46.

CELLMID

Cellmid will vote to grant chairman Dr David King 4,000,000 options with 2,000,000 options each for directors Dr Fintan Walton and Bruce Gordon.
The company said the options would be exercisable at six cents each with three years of the date of issue and shareholders would vote on the remuneration report and the re-election of chairman Dr King.
The meeting will be held at Clifton's, Level 13, 60 Margaret Street, Sydney, on November 12, 2015 at 11am (AEDT).
Cellmid was unchanged at 3.2 cents.

LIVING CELL TECHNOLOGIES

Living Cell will vote to grant five directors 600,000 unlisted options each to reduce the cash cost of directors to the company.

Living Cell said that chairman Roy Austin and directors Prof Robert Elliott, Laurie Hunter, Dr Bernard Tuch and Robert Willcocks would each receive 300 options exercisable at 7.5 cents and 300 options exercisable at 10 cents each, within three years of issue.

The company said that if approved the options would "comprise a component of the directors remuneration".

"Remunerating directors in this manner reduces the cash cost to the company and aligns the reward to directors with those to shareholders," Living Cell said.

The company's notice of meeting said shareholders would vote on the re-election of director Prof Elliott, the approval of the remuneration report and the amendment of the employee share option plan.

The meeting will be held at Pullman Auckland, Cnr Princes Street and Waterloo Quadrant, Auckland, New Zealand on November 12, 2015 at 2pm (NZDT).

Living Cell was unchanged at four cents.

MMJ PHYTOTECH

MMJ says it has appointed Gaelan Bloomfield as the manager of marketing and public relations and implied that it might apply for licence to grow marijuana in Victoria.

MMJ said that Mr Bloomfield's appointment was "the first step in an updated strategy to encourage sustainable growth with a focus on corporate maturity".

The company said that Mr Bloomfield had experience with established and emerging companies working in investment banking and management consulting and had has worked in London, Singapore, Australia and the Philippines.

MMJ said it was encouraged by the Victoria Government decision to introduce legislation before the end of 2015 to enable access to locally manufactured medicinal cannabis products for a limited number of patients to treat various serious medical conditions.

"The Victorian Government's acceptance of the Victorian Law Reform Commission's review provides the company with the opportunity to establish its operating presence in Australia and management are currently investigating opportunities within the Australian market place," MMJ said.

MMJ chief executive officer Andreas Gedeon said the company was "encouraged by the Victorian Government's move towards the legalisation of medical cannabis cultivation and as a viable method of treatment for a number of serious conditions including cancer, multiple sclerosis, HIV/AIDS, epilepsy and chronic pain".

"Through our investigations into the opportunity in the market we hope to one day become one of the leading providers of safe and secure medical cannabis in the state of Victoria," Mr Gedeon said.

MMJ was up 1.5 cents or 4.8 percent to 33 cents.