Biotech Daily

Friday November 16, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PATRYS UP 9%, IMPEDIMED DOWN 9%**

*** BENITEC EXPECTS US HEP C ddRNAi MONOTHERAPY TRIAL IN 2013**

*** BIOTRON PRESENTS PHASE IIa '100% HEP C CURE' DATA**

*** NZ ETHICS APPROVAL FOR LIVING CELL PARKINSON'S TRIAL**

*** IOOF TAKES 6% OF MAYNE PHARMA**

*** AGENIX COMPLETES 1-FOR-25 CONSOLIDATION**

*** NOVOGEN DISTRIBUTES MEI SHARES**

*** PRIMA FACES 21% AGAINST REMUNERATION, 24% INCENTIVES**

*** BLUECHIIP TAKES CAPITAL RAISING HALT TO SUSPENSION**

*** LIVING CELL APPOINTS CEO DR ANDREA GRANT M-D**

MARKET REPORT

The Australian stock market fell 0.29 percent on Friday November 16, 2012 with the S&P ASX 200 down 12.4 points to 4,336.8 points.

Nine of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and nine were untraded.

Patrys was the best, up 0.3 cents or 9.4 percent to 3.5 cents with 1.7 million shares traded.

Phylogica and Reva climbed more than four percent; Bionomics and Pharmaxis rose more than three percent; with Acrux, Alchemia, CSL, Mesoblast and QRX up by less than one percent.

Impedimed led the falls, down one cent or 8.7 percent to 10.5 cents with 565,760 shares traded.

Viralytics lost 5.3 percent; Allied Health and Clinuvel both fell 4.35 percent; Prima was down 3.85 percent; Neuren and Prana shed more than two percent; Anteo, Resmed and Tissue Therapies were down more than one percent; with Cochlear, Nanosonics, Sirtex and Starpharma down by less than one percent.

BENITEC BIOPHARMA

Benitec hopes to take its recently reacquired Tacere in-house lead compound TT-034 into US human clinical trials as a monotherapy for hepatitis C in 2013 (BD: Oct 11, 2012).

In a presentation to media and investors following the company's annual general meeting, former Tacere research and development director, now Benitec's head of research and development, Dr David Suhy said that Pfizer has spent a significant amount of money preparing for clinical trials prior to its merger with Wyeth in 2009 and the closing of the Tacere program, along with many others.

Dr Suhy said that all the preclinical work had been done and Tacere had had extensive discussions with the US Food and Drug Administration and European authorities.

Dr Suhy said that TT-034 was targeting three different sections of the hepatitis DNA and would be delivered with adeno associated virus 8 (AAV8) which "has a particularly high affinity with liver cells, providing thorough coverage of the liver …thus preventing the generation of viral escape mutants".

He said that interferon and ribavirin worked in about 50 percent of their trial populations and with direct acting anti-virals like Telaprevir, the success rate rose to 75 percent.

Dr Suhy said that TT-034 had been tested in 520 mice and 80 cynomolgus (macaque) monkeys as well as in-vitro studies showing non-toxic knock-down of hepatitis C virus.

Dr Suhy said TT-034 was "ready for the clinic" and the phase I/II trial, of hepatits C genotype 1 patients who had failed previous therapies, would involve a single dose of the compound as a monotherapy, without the standard of care of interferon and ribavirin.

Dr Suhy said the preclinical data would be presented to the FDA's Recombinant Advisory Committee in January 2013, for a public hearing in March 2013 with an investigational new drug application expected to be filed soon after, for trials to begin by mid-2013.

Dr Suhy said that if the trial went well, the program to treat hepatitis B virus would have a shorter, faster and better defined path and that using the same AAV8 delivery mechanism Benitec would swap the hepatitis C sequences to be shut down by its DNA-directed RNA interference (ddRNAi) construct for hepatitis B sequences.

Dr Suhy described the potential for the short hairpin RNA (shRNA) based approach of TT-211 for use in age-related macular degeneration and said that 1.75 million people in the US had the disease.

Dr Suhy said that the existing monoclonal antibody drugs needed to be injected into the eye on a monthly basis and although stabilizing vision loss in 95 percent of cases, there were only marginal improvements in up to 40 percent of the population.

He said an shRNA approach would hopefully be a single dose.

Stanford School of Medicine's Dr David Yeomans described the potential use of ddRNAi for pain, especially neuropathic pain and said the intention was to shut down the genetic changes that were caused by chronic pain, injecting the compound directly into the spine and targeting the PKC-gamma protein involved in pain.

Dr Yeomans said that the approach would treat the neuropathic pain without masking protective pain responses such as awareness of heat.

Benitec said it licenced its ddRNAi technology to Calimmune for a drug in clinical trials for HIV and to Genable for retinitis pigmentosa and had in-house programs including drug-resistant lung-cancer and ocupharyngeal muscular dystrophy.

Benitec chief business officer Carl Stubbings said the business model was to licence early and the company needed to de-risk programs by advancing towards the clinic.

"If we are successful with any of these programs it will validate all of our ddRNA platform," Mr Stubbings said.

Benitec was unchanged at 1.6 cents.

BIOTRON

Biotron says it has presented data showing that all eight high dose patients in its 24-patient phase IIa trial of BIT225 for hepatitis C had no detectable virus at week 48.
The poster, entitled 'High sustained viral response with a HCV p7 inhibitor, BIT225: Antiviral activity and tolerability of BIT225 plus pegylated interferon alfa 2b and weight-based ribavirin for 28 days in HCV treatment-naïve patients' was presented at the American Association for the Study of Liver Diseases meeting in Boston, Massachusetts, November 9-13, 2013.
The poster said that the trial in Thailand examined the safety and efficacy of two doses of BIT225 (200mg and 400 mg) delivered orally twice a day for 28 days compared to placebo with standard of care of interferon and ribavirin in genotype 1 patients that had not previously received antiviral therapy.
The poster said that after the 28 day treatment all subjects remained on standard of care and were followed for an additional 44 weeks.
The poster said that the 400mg group had a 100 percent sustained virological response (eight patients), compared to seven in the 200mg group (88%) and six in the standard of care group (75%).
Biotron said that analysis of blood samples taken from the patients after dosing with BIT225 indicated that the drug did not induce antiviral resistance.
The company said that the 48-week data extended the previous three-month data, and demonstrated that BIT225 appeared to continue to provide additional benefit to patients after the conclusion of dosing.
Biotron chief executive officer Dr Michelle Miller said the data was "very encouraging".
"To see no detectable virus at the 48 week follow-up is a good outcome for the patients, who are infected with the hard-to-treat genotype 1 version of the virus," Dr Miller said.
"During preclinical development of BIT225, laboratory studies indicated that BIT225 could potentially improve the activity of interferon and ribavirin, and this trial has confirmed that this has translated into benefit for the patients," Dr Miller said.
"In addition, the drug does not appear to readily generate resistance, which can be a problem with some of the other new classes of anti-HCV drugs in development," Dr Miller said.
Biotron said that BIT225 targeted the hepatitis C viral protein p7, which had crucial roles in virus replication and reproduction, which was a new target, with BIT225 a first-in-class direct acting antiviral for hepatitis C.
The company said that BIT225 was also in development for treatment of HIV and for HIV and hepatitis C co-infected patients.
Biotron was unchanged at 13 cents.

LIVING CELL TECHNOLOGIES

Living Cell says the New Zealand Ministry of Health's Health and Disability Ethics Committee has approved its phase I clinical trials of NTCell for Parkinson's disease.
In October, Living Cell said the Minister of Health authorized the phase I clinical trials, involving a pig-to-human brain cell transplant, to investigate the safety and clinical effect of the NTCell encapsulated pig choroid plexus cells in people with Parkinson's disease, expected to begin by April 2013 and last up to 60 weeks (BD: Oct 4, 2012)
Living Cell chief executive officer Dr Andrea Grant said the ethical approval meant the company was on-track to begin NTCell's first in-human trials by April 2013.
Living Cell was untraded at 5.1 cents.

MAYNE PHARMA

IOOF Holdings has become a substantial shareholder in Mayne Pharma with the acquisition of 26,895,569 shares or 5.796 percent.
The initial substantial shareholder notice said that the Collins Street Melbourne-based company (formerly known as the Independent Order of Odd Fellows) bought and sold shares between October 8 and November 13, 2012, primarily acquiring 24,974,886 shares for $4,994,977 or 20 cents a share in Mayne's recent $65 million capital raising to acquire Metrics Inc (BD: Oct 4, Nov 15, 2012).
Mayne Pharma was up one cent or 3.8 percent to 27.5 cents.

AGENIX

Agenix says it has completed its one-for-25 share consolidation and has 36,589,615 shares on offer and 261,853 unlisted options.
Agenix said that all trades conducted on a deferred settlement basis and first settlement of trades conducted on a T+3 basis would be on November 22, 2012.
Agenix was up 0.2 cents or five percent to 4.2 cents.

NOVOGEN

Novogen says it started trading on an ex-return of capital basis on November 14, 2012 following a capital reduction through the distribution to its MEI Pharma holdings.
Novogen said it returned six shares of US common stock in MEI for every 35 Novogen shares held by them on the record date of November 20, 2012.
Novogen fell four cents or 25 percent to 12 cents.

PRIMA BIOMED

Prima came close to a first strike on its remuneration report with 20.76 percent opposition, despite the resolution being "passed unanimously by a show of hands".
Prima said that all resolutions to the annual general meeting were "passed unanimously by a show of hands" despite 27,919,637 proxy votes or 23.8 percent opposing the company's executive incentive plan, 17.31 percent of proxy votes against the issue of 1,200,000 options to chief executive officer Matthew Lehman and 7.30 percent of proxy votes against the re-election of director Albert Wong.
There were more than 8.5 million proxy votes described as 'proxy discretion' not counted by the company as for or against for the latter three results, with 172,544 or 0.26 percent of proxy discretion votes for the remuneration report.
Prima's most recent Appendix 3B share issue announcement said there were 1,066,063,388 shares on issue, meaning that the strongest opposition came from 2.6 percent of all shares on issue, which is not sufficient to requisition extraordinary general meetings.
Prima fell half a cent or 3.85 percent to 12.5 cents with 2.2 million shares traded.

BLUECHIIP

Bluechiip has requested a voluntary suspension to follow the trading halt it requested on November 14, pending a capital raising (BD: Nov 14, 2012).
Bluechiip last traded at 25 cents.

LIVING CELL TECHNOLOGIES

Living Cell says chief executive officer Dr Andrea Grant has been appointed managing director.

Living Cell said Dr Grant joined the company as chief executive on December 28, 2011 and had extensive experience in the biotechnology and pharmaceutical fields, most recently at Roche Products New Zealand.

The company said that Dr Grant held a Doctorate of Philosophy in molecular neurobiology and a Bachelor of Arts in biochemistry from Cambridge University.

Living Cell said Dr Grant's had led the company to achieve significant milestones including the completion of pre-clinical studies of NTCell for Parkinson's disease, raising $1 million through a share purchase plan, completing implants in the Argentine phase I/IIa Diabecell type 1 diabetes clinical trial, announcing the main findings of the New Zealand phase I/IIa Diabecell trial and gaining authorization for a phase I clinical trial of NTCell for Parkinson's disease.