



Biotech Daily

Wednesday January 27, 2016

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH UP: LIVING CELL UP 34%, ANTISENSE DOWN 11%
- * MEDICAL DEVELOPMENTS PENTHROX LAUNCH, RESPIRATORY FDA OK
- * LIVING CELL: 'NTCELL STOPS PARKINSON'S, SAFE AT 58 WEEKS'
- * ADMEDUS TO SELL CORONEO PRODUCTS
- * RECCE CLAIMS ANTIBIOTIC KILLS TUBERCULOSIS, GONORRHOEA
- * PRIMA READY FOR TACTIMEL PHASE I IMP321 FOR MELANOMA TRIAL
- * POLYNOVO APPOINTS LEON HOARE DIRECTOR
- * MEDIBIO APPOINTS DR FRANKLYN G PRENDERGAST DIRECTOR
- * SIENNA APPOINTS DR JOHN CHIPLIN DIRECTOR
- * WEHI 'CURES' AML IN MICE
- * MCRI, JUPITER COLLABORATE ON JOT101 FOR FRIEDREICH'S ATAXIA
- * NOHLA RAISES \$30m, APPOINTS LAWRENCE GOZLAN DIRECTOR
- * RECCE IPO RAISES \$5m FOR 'SUPERBUG' ANTIBIOTICS
- * GORDAGEN COLLABORATION WITH JAPAN'S MATSUMOTO
- * ANATARA, ZOETIS LICENCE OPTION
- * MEDADVISOR, EPILEPSY QUEENSLAND COLLABORATIONS
- * CLINICAL NETWORK SERVICES OPENS WASHINGTON DC OFFICE
- * IMUGENE APPOINTS STUART ROBERTS FOR CORPORATE DEVELOPMENT

MARKET REPORT

The Australian stock market lost 1.2 percent on Wednesday January 27, 2016 with the ASX200 down 60.2 points to 4,946.4 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 15 fell, three traded unchanged and one was untraded.

Living Cell was the best, up 34.15 percent to 5.5 cents with 3.4 million shares traded. Medical Developments rose 14.4 percent; Clinuvel and Compumedics climbed more than 10 percent; Benitec was up 9.8 percent; Actinogen and Tissue Therapies were up more than seven percent; Prana was up 6.6 percent; Genetic Technologies, Uscom and Viralytics were up five percent or more; with Ellex up 4.1 percent.

Antisense led the falls, down 0.7 cents or 11.3 percent to 5.5 cents with 336,242 shares traded. Oncosil lost 9.3 percent; Pharmaxis fell 7.25 percent; Prima shed 6.25 percent; Orthocell was down 5.3 percent; with Anteo, Avita, Cellmid and Neuren down by more than four percent.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that its inhaled analgesic Pentrox has been launched in the UK, with full reimbursement in Ireland and US approval for its respiratory devices.

Medical Developments said that distributor Galen launched the Pentrox product on January 25, 2016.

Medical Developments chief executive officer John Sharman said the company had "received substantial orders from Galen for the UK market and the recent pricing approval in Ireland is another step forward for our business".

"As a result of pricing approval in Ireland, Galen has placed a number of bigger than expected forward orders for Pentrox to facilitate the planned launch of Pentrox in Ireland during March," Mr Sharman said.

Separately, Medical Developments said it had US Food and Drug Administration approval for its new range of anti-static respiratory devices.

The company said that the approval was "a significant opportunity to build [its] global respiratory business".

Medical Developments said that the approval was anticipated and it expected to achieve new sales in the near term.

Medical Developments climbed 48 cents or 14.4 percent to \$3.82.

LIVING CELL TECHNOLOGIES

Living Cell says that at 58 weeks post implant, all four patients in its phase I/IIa study of NTCell for Parkinson's disease were well, with no safety concerns.

Living Cell 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".

The company said that after 58 weeks there was a clinically and statistically significant improvement in all the patients' neurological score from their pre-implant baseline.

Living Cell said that the Unified Parkinson's Disease Rating Scale score increased by about four to five points each year as Parkinson's disease progressed and "NTCell's ability to decrease UPDRS by an average of 16 points after 58 weeks is clinically significant, representing a three to four year reversal of neurological deterioration".

The company said that in the first patient, the improvement was maintained at 74 weeks after NTCell implant.

Living Cell chief executive officer Dr Ken Taylor said the sustained improvement was "pleasing, particularly as no other treatment has been able to maintain long term reversal of the effects of Parkinson's disease".

"We are delighted with the continued positive outcome of the study," Dr Taylor said.

"It certainly adds anticipation and motivation to our authorised phase IIb study, which we plan to initiate on February 24, 2016," Dr Taylor said.

Living Cell said the 18-patient trial of the encapsulated pig brain cells aimed to confirm the most effective dose, define any placebo component of the response and further identify the initial target Parkinson's disease patient sub-group (BD: Nov 12, 2015) .

"Our goal is to obtain provisional consent and launch NTCell as the first disease modifying treatment for Parkinson's disease in 2017," Dr Taylor said.

Living Cell climbed 1.4 cents or 34.15 percent to 5.5 cents with 3.4 million shares traded.

ADMEDUS

Admedus says it will sell the Coroneo's aortic annuloplasty ring and surgical instruments for heart valve surgery in Germany and the UK from April 2016.

Admedus said that the Montréal, Quebec-based Coroneo's extra-aortic ring was complementary to its bio-scaffold Cardiocel for the repair of aortic heart valves and would be managed and sold through its existing sales and marketing infrastructure.

Admedus chief executive officer Lee Rodne said that the agreement "expands our product portfolio in the cardiovascular space, as well as adding to our on-going sales growth and generating increased revenue from our existing in-house resources".

The company said that the distribution agreement was initially for the German and UK markets, with the option to extend to other regions.

Admedus was up one cent or 1.5 percent to 66.5 cents.

RECCE

Recce says that laboratory tests have shown that its antibiotic can kill the bacteria in tuberculosis and gonorrhoea.

Recce said that the antibiotic could kill *Mycobacterium fortuitum*, a model for TB disease and *Neisseria gonorrhoeae* which caused gonorrhoea.

The company said that in 2012, 8.7 million people developed tuberculosis and 1.3 million died from the disease and that the World Health Organisation estimated that there were 106 million new cases of gonorrhoea globally.

Recce said that its antibiotics were part of a technology targeted at a variety of applications, against a variety of diseases and "the technology in contrast to a lone product gives the investor security should unexpectedly negative results cause a particular application to lose favor".

Recce was up 3.5 cents or 8.9 percent to 43 cents with 1.6 million shares traded.

PRIMA BIOMED

Prima says it has initiated the first clinical trial site for its 24-patient multicentre, open label phase I trial of IMP321 for melanoma at the Greenslopes Private Hospital in Queensland.

Prima said the 'Two active immunotherapeutics in melanoma' or 'Tactimel' trial was a study in which patients with unresectable or metastatic melanoma would be dosed with IMP321 in combination with an approved checkpoint inhibitor.

The company said that the study would evaluate safety as the primary endpoint and anti-tumor activity and the immune response to the combination as secondary endpoints.

Prima said that Dr Victoria Atkinson was the principal investigator for the trial, with the first patients expected to be dosed by April 2016.

Prima fell 0.3 cents or 6.25 percent to 4.5 cents with 3.8 million shares traded.

POLYNOVO

Polynovo says that former Smith & Nephew Australia and New Zealand managing director Leon Hoare has been appointed as a non-executive director.

Polynovo said that Mr Hoare retired from Smith & Nephew in December 2015 after 24 years with the company.

The company said that Mr Hoare was previously a senior executive at Bristol-Myers Squibb and vice-chair of Medical Technology Association of Australia.

Polynovo was up one cent or 3.9 percent to 26.5 cents.

MEDIBIO

Medibio says it has appointed Dr Franklyn G Prendergast as a director.

Medibio said that Dr Prendergast was formerly the Rochester, Minnesota-based Mayo Clinic's chair of the Department of Biochemistry and Molecular Biology and director for research and a member of the Mayo board of governors.

The company said Dr Prendergast had been a director of Eli Lilly since 1995 and served extensively for the US National Institutes of Health on numerous review groups, had worked for the US National Cancer Advisory Board and was a director of the Translational Genomics Research Institute and the Infectious Disease Research Institute.

Medibio fell one cent or 3.6 percent to 27 cents.

SIENNA CANCER DIAGNOSTICS

Sienna says it has appointed Dr John Chiplin as a director.

Sienna said that Dr Chiplin was an experienced healthcare executive with capital markets experience, was most recently the chief executive officer US cancer immunotherapy company Polynoma and was formerly the founding chief executive officer Arana Therapeutics prior to its acquisition by Cephalon, now Teva.

Sienna said that Dr Chiplin was currently a director of Benitec, Cynata and Adalta and was the founder and managing director of investment fund Newstar Ventures.

Sienna is a public unlisted company.

Summer Catch-Up Addendum

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers have shown they can stop leukaemia by targeting a protein that stops cancer cell growth in mice.

The Institute said that targeting the Hhex protein "could cure acute myeloid leukaemia in preclinical disease models and could be a key target for new therapies for human leukaemia".

WEHI said that Dr Ben Shields and Dr Matt McCormack discovered that the loss of the Hhex protein put the handbrake on leukaemia cell growth and division.

The Institute said that the protein was "a critical factor enabling [acute myeloid leukaemia] cells to grow uncontrollably, a hallmark of cancer.

WEHI said that acute myeloid leukaemia was an aggressive blood cancer that appeared suddenly, grew quickly, had a poor prognosis, existing treatments were associated with serious side-effects and about three quarters of patients relapsed after a short period of treatment, with a five-year survival rate of 24 percent.

Dr McCormack said that discovering how acute myeloid leukaemia (AML) overcame normal cellular controls on growth and division was "a breakthrough in the search for new therapies".

"We showed blocking the Hhex protein could put the brakes on leukaemia growth and completely eliminate AML in preclinical models," Dr McCormack said.

Dr McCormack said Hhex was a particularly attractive therapeutic target because it was overproduced in leukaemia and, while essential for leukaemia cell growth, was not needed by healthy blood cells.

"We now hope to identify the critical regions of the Hhex protein that enable it to function, which will allow us to design much-needed new drugs to treat AML," Dr McCormack said.

MURDOCH CHILDRENS RESEARCH INSTITUTE

The Murdoch Childrens Research Institute says it has a development and licence agreement with Jupiter Orphan Therapeutics for JOT101 for Friedreich's ataxia.

The Institute said the agreement with the Jupiter, Florida- based organization would see the parties jointly develop an appropriate delivery system and conduct clinical trials for a product for the inherited life-shortening disease that caused progressive damage to the nervous system.

The Institute said that those affected became increasingly unsteady until they required the use of a wheelchair and there were no proven treatments.

The MCRI said that Prof Martin Delatycki was the head of the largest Friedreich's ataxia clinic in the southern hemisphere and design of clinical trials was central to the agreement.

The Institute said that JOT101 would be a new formulation of the active ingredient of resveratrol, a natural compound present in grapes and red wine, developed by Jupiter.

The MCRI said that its initial studies showed that resveratrol increased the frataxin protein, which was deficient in the cells of people with Friedreich's ataxia.

The Institute said that an open-label clinical trial in Friedreich's ataxia patients found improvement of neurological symptoms but there were also adverse side effects that limited dosing, meaning a more appropriate formulation and delivery system needed to be devised.

"If we can show that JOT101 ... is safe, well-tolerated and slows the progression or even reverses some of the symptoms, this would be a significant advancement for people with Friedreich's ataxia," Prof Delatycki said.

NOHLA THERAPEUTICS

Nohla says it has raised \$US21 million (\$A29.9 million) from several institutional investors and appointed Lawrence Gozlan as a director.

Nohla was established by Melbourne's-based Cytomatrix last year for a phase IIb collaboration with the Seattle, Washington-based Fred Hutchinson Cancer Research Centre, relating to an ex-vivo expanded umbilical cord blood platform, along with two US investigational new drug applications for the use of a non-human leukocyte antigen (HLA)-matched, expanded-cord blood product (BD: Dec 4, 2015).

Today, Nohla said that Mr Gozlan was the founder of the Melbourne-based Scientia Capital with 15 years experience in investing and banking and previously worked as the biotechnology analyst at Foster Stockbroking, as well as Deloitte, was currently a director of Prana and held a Bachelor of Science degree from the University of Melbourne.

Nohla is a private company.

RECCE

Recce says it has raised \$5 million in an oversubscribed initial public offer at 20 cents a share and listed on the ASX on January 13, 2016 to develop synthetic antibiotics.

Last year, Recce chairman Dr Graham Melrose said the company hoped to develop antibiotics that targeted otherwise antibiotic-resistant bacteria that would be "exceptionally economic in comparison to present day antibiotics" (BD: Oct 9, 2015).

The company said it had synthesised two particular antibiotics, Recce-327 and Recce-355 and early testing had shown that both were effective in treating a wide range of disease-causing gram-positive and gram-negative bacteria.

GORDAGEN PHARMACEUTICALS

Gordagen says it has a product development agreement with Japan's Matsumoto Trading Co for a functional food product using its Melt3 tocotrienol delivery technology.

Gordagen said that product development would focus initially on an unspecified functional food product with the proof-of-concept phase to be implemented by July 2016.

The company said that Matsumoto would have the option to an exclusive licence to manufacture, market and distribute the product for markets to be agreed between the two parties, but did not disclose specific commercial terms for the agreement.

Gordagen said that Matsumoto was a private company, founded in 1663, and was established in the supply of high value-added cosmetic ingredients, and undertook extensive work in formulation research.

Gordagen chief executive officer Dr Glenn Tong the collaboration "will show the diversity of our platform and the opportunity for product extensions".

The company said it was developing tocotrienol-based food additives backed by research, for muscle soreness, exercise endurance and heart health and its melt-then-swallow technology was combined with tocotrienols to enable improved bioavailability.

Gordagen is a private company.

ANATARA LIFESCIENCES

Anatara says it has an exclusive licence option with the Florham Park, New Jersey-based Zoetis for its Detach non-antibiotic treatment for diarrhoea in farm animals.

Anatara said that Zoetis was "the world's leading animal health company" and it had the exclusive right to evaluate potential applications of Detach for use in production animals.

The company said it had granted Zoetis an option to licence Detach for development and commercialization worldwide, while retaining rights to Australian and New Zealand.

Anatara chairman Dr Mel Bridges said the company had "significant international partnering interest in Detach and ... selected Zoetis as our ideal partner".

MEDADVISOR

Medadvisor says it has a memorandum of understanding with Epilepsy Queensland to improve medication management of epilepsy patients and their carers.

Medadvisor said the that Epilepsy Queensland would promote the use of its free medication management mobile telephone application and it would create a number of tailored products to assist Epilepsy Queensland.

The company said that epilepsy was the world's most common serious brain disorder, affecting 3.5 percent of Australians, with up to 800,000 people in Australia to be diagnosed with epilepsy at some stage in life and currently more than 250,000 Australians were living with epilepsy.

Medadvisor said its software platform helped individuals monitor their medication use, connecting to their pharmacy of choice, automatically retrieving medication records and activating a training, information and reminder system to ensure correct and reliable medication use.

Medadvisor chief executive officer Robert Read said that Australian medication adherence in epilepsy was "quite low, with just 60 percent of medication doses taken as prescribed".

"Epilepsy patients using the Medadvisor [application] are 15 to 20 percent more adherent, meaning they are taking more of their prescribed doses of medication," Mr Read said.

CLINICAL NETWORK SERVICES

Brisbane's Clinical Network Services says it has established an office in Washington DC for its expanded Biodesk consultancy division.

Clinical Network Services said that it had an office in San Francisco and the expansion to Washington extended its US footprint, enabling it to better support clients seeking to engage with the US Food and Drug Administration.

The company said that principal medical consultant Dr Bryan Smith would lead the Washington team with Sally Yang appointed as a regulatory consultant.

Clinical Network Services is a private company.

IMUGENE

Imugene says that Stuart Roberts has been appointed as its head of corporate development.

Imugene said that Mr Roberts would oversee its investor relations program and be involved in business development and corporate strategic planning.

The company said that Mr Roberts was formerly Prima's head of investor relations and previously was a sell-side analyst at Southern Cross Equities, Bell Potter Securities and Baillieu Holst.

Imugene said that Mr Roberts held a Masters Degree in Finance from the Financial Services Institute of Australasia.

Imugene