Biotech Daily

Wednesday February 8, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: BENITEC UP 29%, LIVING CELL DOWN 13%**

*** LIVING CELL HIGH-DOSE NTCELL FOR PARKINSON'S APPROVED**

*** OVENTUS CRC PROJECT WINS $3m; QUALITY SYSTEM APPROVED**

*** MEDICAL DEVELOPMENTS PENTHROX IN FRANCE, BELGIUM; $2.6m**

*** ORTHOCELL FILES FDA CELGRO DENTAL APPLICATION**

*** PROTEOMICS: 'ARTICLE BACKS PROMARKERD KIDNEY DISEASE TEST'**

*** BARD1 LUNG CANCER TEST FEASIBILITY STUDY**

*** PFIZER TERMINATION TAKES PSIVIDA H1 REVENUE UP 520% TO $8m**

*** NUHEARA READY FOR IQBUD CONCENTRATION, HEARING TRIALS**

*** LANG WALKER GROUP TAKES 19.99% OF MEDICAL AUSTRALIA**

*** MM ASSET MANAGEMENT TAKES 5% OF MMJ PHYTOTECH**

*** MICHAEL AARONS BELOW 5% IN RECCE**

*** ANTISENSE TRADES 3.8m UNMARKETABLE SHARES**

MARKET REPORT

The Australian stock market climbed 0.52 percent on Wednesday February 8, 2017 with the ASX200 up 29.5 points to 5,651.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and three were untraded. All Big Caps rose.

Benitec was the best, up 4.5 cents or 29.0 percent to 20 cents with three million shares traded. Pharmaxis climbed 7.1 percent; Medical Developments improved five percent; Impedimed and Orthocell were up more than four percent; Anteo, IDT and Viralytics rose more than two percent; with Bionomics, Cochlear and Neuren up more than one percent.

Living Cell led the falls, down 1.5 cents or 13.0 percent to 10 cents with 1.5 million shares traded. Uscom lost 8.3 percent; Genetic Signatures and Reva fell more than four percent; Cellmid was down 3.1 percent; Oncosil shed two percent; with Acrux, Admedus, Atcor, Compumedics, Nanosonics, Opthea, Polynovo, Sirtex and Universal Biosensors down by more than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says it has approval to treat the six patients in group 3 of its phase IIb trial of NTCell encapsulated pig brain choroid cells for Parkinson's disease.

Group 3 is the final group in the 18 patient trial, which dosed the first group with 40 NTCell microcapsules and the second group with 80 NTCell microcapsules implanted into the putamen on each side of their brain (BD: Oct 5, Dec 22, 2016).

Today, Living Cell said that four patients at Auckland City Hospital would have 120 NTCell microcapsules implanted into the putamen on each side of their brain, with two patients having sham surgery without NTCell implantation.

The company said it would be blind to the results until 26 weeks after the last patient in group 3 had been treated, at which point the patients who received the placebo may receive the optimal dose of NTCell.

Living Cell said that the trial aimed to confirm the most effective dose of NTCell, define any placebo component of the response and further identify the initial target Parkinson's disease patient sub-group.

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

Living Cell fell 1.5 cents or 13.0 percent to 10 cents with 1.4 million shares traded.

OVENTUS MEDICAL

Oventus says it is the lead participant in a co-operative research centre project which will receive a Federal Government grant of $2,950,000 over three years.

Oventus said that the project was entitled 'Targeted therapy for sleep apnoea: A novel personalised approach' and aimed to improve the efficacy, compliance and monitoring of sleep apnoea therapy using a suite of treatments to suit the individual patient.

The company said that the range of therapies, to be used alone or in combination, included oral appliances with mandibular advancement and an airway, with or without a positive airway pressure machine, supplemental oxygen delivery and/or a sleep consolidation aid.

Oventus said it was the lead participant with Medical Monitoring Solutions Pty Ltd, Neuroscience Research Australia, Western Sydney University and the Commonwealth Scientific and Industrial Research Organisation.

Oventus chief executive officer Neil Anderson said there was a large opportunity for easier, better and more personalized therapy for people with sleep apnoea.

"The grant will focus on new technologies evaluated in the recently completed pilot trial," Mr Anderson said.

"These early results indicated that our appliances with an airway may be a viable alternative to [continuous positive airway pressure or CPAP] in many patients and for those that do need CPAP, at much lower pressures with a smaller pump," Mr Anderson said.

"It also allows us to evaluate an innovative monitoring technology from Medical Monitoring Solutions that can be used on-going at relatively low cost, for treatment optimisation and clinical feedback," Mr Anderson said.

Separately, Oventus said it had received a certificate of registration certifying that the company's quality management system complied with the requirements of the medical device single audit program for the design, development and manufacture of oral appliances, certifying its quality system for Australia, Europe, the US, Canada, Japan and Brazil.

Oventus was unchanged at 79 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says Mundipharma has launched the Penthrox inhaled analgesic in France and Belgium, triggering a $US2 million ($2.6 million) payment.
Medical Developments chief executive officer John Sharman said the launch of Penthrox in France was “an exciting achievement”.
Medical Developments climbed 25 cents or five percent to $5.25.

ORTHOCELL

Orthocell says it has submitted a 510(k) application to the US Food and Drug Administration for its Celgro collagen medical device.
Orthocell said the application followed the Conformité Européenne (CE) mark application, which was “in its final stages”.
The company said that Celgro was a tissue support and barrier membrane for dental guided bone and tissue regeneration procedures and could be used as a scaffold for a variety of orthopaedic and general reconstructive surgical applications.
Orthocell chief executive officer Paul Anderson said the application was “a very important milestone”.
The company said that the US market for dental barrier membranes used in conjunction with bone graft substitutes was up to 800,000 units a year, with a total value of up to $US320 million.
Orthocell was up two cents or 4.35 percent to 48 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says a journal article backs its Promarkerd diabetic kidney disease diagnostic.
Proteomics said the article, entitled ‘Comprehensive mass spectrometry based biomarker discovery and validation platform as applied to diabetic kidney disease’ was published in the European Proteomics Association journal Open Proteomics and was available at: www.sciencedirect.com/science/article/pii/S2212968516300393.
The company said that the article, co-written by Proteomics managing-director Dr Richard Lipscombe, “proves the efficacy of the process used to develop and test [the] Promarkerd protein fingerprint that detects the onset of kidney disease in patients with diabetes, to produce a novel diagnostic test that outperforms the current gold standards”.
Dr Lipscombe said that publication of the diagnostics platform technique was “an important validation step”.
“Going through the peer review process in this way means our method is independently verified,” Dr Lipscombe said.
The company said that Promarkerd could predict the onset of disease before clinical symptoms appeared and in an extension of the published work 576 patients were followed in a four year prognostic clinical study, with Promarkerd correctly predicting 95 percent of the previously kidney disease-free diabetic patients who developed chronic kidney disease.
Proteomics said there was no test available for predicting the onset of diabetic kidney disease.
Proteomics was unchanged at 21 cents.

BARD1 LIFE SCIENCES

Bard1 says its lung cancer assay feasibility study has been evaluated on a commercial instrument platform for research use.

Bard1 said that the Rockville, Maryland-based Meso Scale Diagnostics conducted the analyses and confirmed the test could be performed on a commercial-scale instrument platform using a standardized method.

The company said that Meso tested 40 lung cancer and control samples across 40 Bard1 peptides using various coating methods and dilution factors to determine the best assay method for further development of a clinical-grade test.

Bard1 said that statistical analysis and modelling by the University of Geneva showed that at least one method reproduced a similar receiver operating characteristic to that previously reported in the proof-of-concept study.

The company said that Meso's final report confirmed the reproducibility of the test in an independent laboratory on a commercial research use-only instrument platform and confirmed the feasibility of transferring the research-grade Bard1 test to the platform.

Bard1 said that further assay optimisation and validation testing of defined specifications would be required to develop a final Bard1 lung cancer test on the Meso instrument platform.

Bard1 chief scientific officer Dr Irmgard Irminger-Finger said the results "demonstrate the potential of developing a standardised … test that can be performed on a commercial instrument platform to enable fast, accurate and reliable testing across centralised laboratories".

The company said that a confirmation study to further develop and optimize the test on 530 samples of lung cancer and healthy controls had been completed, with results expected by end of March 2017.

Bard1 said it was focused on developing the test for screening and diagnosis of lung cancer and planned to conduct a prospective study to demonstrate the accuracy, sensitivity and specificity of the test compared to computed tomography scans for early detection of lung cancer in high-risk individuals, expected to begin by the end of 2017.

Bard1 was unchanged at 3.1 cents with 1.8 million shares traded.

PSIVIDA

Psivida says that revenue for the six months to December 31, 2016 was up 520 percent to $US6.2 million ($A8.1 million) compared to the six months to December 31, 2015.

Psivida said the increase "was primarily attributable to the $US5.6 million of revenue recognized upon termination of the Pfizer agreement" with operating expenses up from $US11.2 million to $US13.5 million, primarily attributable to severance costs and professional fees related to the change from former chief executive officer Dr Paul Ashton to chief executive officer Nancy Lurker and other executive team changes as well as regulatory consulting services, partially offset by lower contract research organization costs.

In 2007, Psivida and Pfizer signed a $203 million collaborative research and licence agreement for Psivida's drug delivery technologies, including Medidur in ophthalmic applications (BD: Apr 4, 2007).

The company said that net loss for the six months to December 31, 2016 was $US7.2 million, compared to $US10.1 million, for the previous corresponding period.

Psivida said that cash, cash equivalents and marketable securities at December 31, 2016 totalled $US17.5 million.

Psivida was untraded at $2.17.

NUHEARA

Nuheara says it is exploring collaborations to research on its Iqbuds sound filtering and device ear buds for people with concentration and auditory processing difficulties.
Nuheara said it was awaiting ethics approval from an unnamed Australian university for two studies.
The company said that Iqbuds could have application for auditory processing disorder, autism, sensory processing disorder and attention deficit hyperactivity disorder.
Nuheara said it had seen “promising results in the positive effect on young children and adults who have a range of concentration and auditory processing challenges”.
Nuheara chief executive officer Justin Miller said the Iqbuds could “help people on this spectrum more easily access the world around them and allow them to personally customise how they hear the world for their comfort level”.
“This experience now includes children with auditory processing disorder using Iqbuds in the classroom, to benefit concentration by reducing the distraction of background noise while enhancing their ability to focus on what they need to focus on,” Mr Miller said.
“While the results are still anecdotal, the initial responses are very encouraging,” Mr Miller said.
Nuhear said about 10 percent of the population had a range of concentration and auditory disorders and up to three percent of children had auditory processing disorder, in which the ears process sound normally but the hearing centres and circuits of the brain don’t correctly process incoming information, affecting understanding, especially in challenging listening situations such as in the presence of other distracting sound, or when listening to complex information or instructions.
“We started Nuheara with a vision to change people’s lives, in particular people who struggled to hear what they want to hear in the world around them,” Mr Miller said.
“This applied not only to people with slight hearing loss but also to people with good hearing who wanted to control their audio experience in this ever increasingly noisy world,” Mr Miller said.
Nuheara was up half a cent or 4.35 percent to 12 cents.

MEDICAL AUSTRALIA

The Lang Walker Group says it has increased its substantial holding in Medical Australia from 23,641,007 shares (17.29%) to 27,341,007 shares (19.99%).
The substantial shareholder notice said that Auckland Trust Co as trustee for the Second Pacific Master Superannuation, and Walker Group acquired 3,700,000 shares for $199,800 or 5.4 cents a share on February 6, 2017.
Land Walker executive and Medical Australia director Bruce Hancox told Biotech Daily that the purchase was an off-market transaction.
Last night, Medical Australia has not seen 5.4 cents since last October, with a 30-day average closing price of 4.8 cents.
Medical Australia was untraded at 4.6 cents.

MMJ PHYTOTECH

The Toronto, Ontario New York MM Asset Management says it has become a substantial shareholder in MMJ Phytotech with 9,652,632 shares (5.04%).
The notice was signed by director Hillel Meltz and said the shares were acquired on February 6, 2016 at 20.84 cents a share, when the company was trading around 27 cents.
MMJ was up 3.5 cents or 13.7 percent to 29 cents with 2.3 million shares traded.

RECCE

Michael Aarons says he has ceased his substantial shareholding in Recce, selling 3,476,262 shares for $760,823 or 21.9 cents a share.
Last year, the Perth, Western Australia-based Mr Aarons said he held 6,099,999 shares in Recce or 8.91 percent, implying he retained 2,623,737 shares or 3.4 percent.
Recce fell three cents or 12 percent to 22 cents.

ANTISENSE THERAPEUTICS

Antisense says that 1,164 unmarketable parcels of shares totalling 3,783,086 shares were sold in an off-market transaction at 3.8 cents a share.
Antisense said that following the purchase the shareholder base was reduced to about 1,504 shareholders.
Antisense chief executive officer Mark Diamond said that the share sale would reduce administrative costs and “provided an opportunity for a significant number of shareholders to sell their relatively small shareholdings with no commission payable”.
Antisense was unchanged at 3.7 cents.