Biotech Daily

Friday November 11, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BENITEC UP 9.5%, UNIVERSAL BIO DOWN 16%**

*** ANTEO JOINS DMTC FOR NPLEX MEDICAL COUNTERMEASURE TESTS**

*** LIVING CELL 2nd PARKINSON'S NTCELL COHORT APPROVED**

*** MASS GENERAL OKAYS RESAPP PIVOTAL KIDS RESPIRATORY TRIAL**

*** REDHILL FDA MEETING FOR 2nd RHB-105 PHASE III HELICOBACTER TRIAL**

*** BOTANIX PREPARES HUMAN CANNABIDIOL BTX-1503 FOR ACNE TRIAL**

*** USPTO ISSUES 3rd LBT APAS PATENT**

*** MONASH ANTIBODIES FOR PROTEOMICS PROMARKERD KIDNEY TEST**

*** CE MARK FOR NEUROTECH'S EEG MENTE AUTISM**

*** PRIME DEMANDS MEMPHASYS $5m PAYMENT**

MARKET REPORT

The Australian stock market was up 0.79 percent on Friday November 11, 2016 with the ASX200 up 41.9 points to 5,370.7 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and three were untraded.

Benitec was the best on a corporate presentation, up one cent or 9.5 percent to 11.5 cents with 156,862 shares traded.

Factor Therapeutics climbed eight percent; Living Cell and Mesoblast were up more than six percent; Atcor rose 5.3 percent; Compumedics, Oncosil and Viralytics improved more than four percent; Bionomics and Clinuvel were up more than three percent; Actinogen and Resmed rose more than two percent; Acrux, Anteo and Ellex were up more than one percent; with CSL, Opthea, Pro Medicus, Sirtex and Starpharma up less than one percent.

Universal Biosensors led the falls, down two cents or 6.25 percent to 30 cents with 3,759 shares traded.

Admedus and Uscom fell more than five percent; Genetic Signatures, Osprey and Prana were down more than three percent; IDT shed 2.4 percent; Airxpanders, Cochlear, Impedimed, Medical Developments, Nanosonics and Polynovo were down more than one percent; with Reva down 0.8 cents.

ANTEO DIAGNOSTICS

Anteo says as a “supporting participant” of the Australian Defence Materials Technology Centre it will develop Planet Innovation’s Nplex point-of-care platform.

Anteo said that Planet Innovation, Deakin University and the Defence Materials Technology Centre Medical Countermeasures Program were funding the development of the Nplex point-of-care platform.

The company did not specify the level of funding but said that “the full integration and commercialization of the technology across a range of clinical indications [was] beyond the scope of the current project”.

Anteo said the funds would be used “to further the technology readiness of Planet Innovation’s novel [point-of-care] platform by bringing together Anteo’s surface coating technology with Deakin University’s frontier materials expertize”.

The company said that Planet Innovation’s wholly-owned subsidiary Nplex had developed a low-cost, high sensitivity, point-of-care diagnostic system using break-through reader technology.

Nplex general-manager Dr Sacha Dopheide said that “Anteo and Deakin’s chemistry and materials expertize coupled with our proprietary reader, cartridge and assay technologies will lead to meaningful improvements in point-of-care diagnostics”.

Anteo chief operating officer Tamara Mills said that Anteo expected to provide Nplex with a commercial solution to the challenges of controlling the surface interface between synthetic materials and biological reagents.

“This is critical for development of highly sensitive and specific diagnostics irrespective of platform configuration,” Ms Mills said.

Anteo chief executive officer Dr Jef Vangenechten said the partnership followed an initial paid feasibility study with Nplex which showed the technology benefits of Anteo’s metal-ion based nanometre-thin chemistry in the Nplex system.

“Developing cutting edge [point-of-care] platforms integrating novel technologies is increasingly complex and requires integration of technologies from a broad range of scientific disciplines,” Dr Vangenechten said.

Anteo said the Australian Defence Materials Technology Centre was a collaborative venture for advanced materials manufacturing.

The company said that the Centre facilitated industry-led research and commercialization projects targetting areas of Defence priority that could be transitioned into service in the Australian Defence Force through commercialization or building and enhancing defence industry capabilities.

Anteo said that the Defence Materials Technology Centre facilitated research into a broad range of areas including new generation composite materials, advanced coatings and joining technologies.

Dr Vangenechten said the Centre’s “proven collaborative model” had brought together 41 projects delivering new technologies and manufacturing processes in the year to June 30, 2015.

The company said it would benefit from leveraging the Centre’s support through linking supporting participants to research expertise and networks, actively embedding supporting participants into supply chains, participation in research and development activities of relevance to Defence and cost efficient access to research and development.

Dr Vangenechten said it was “the first step in moving into the Medical Countermeasures Program that is administered through the [Centre]” with the ancillary benefit of the visibility of Anteo’s coating technology in other application areas and industries outside medical devices.

Anteo was up 0.1 cents or 1.9 percent to 5.3 cents.

LIVING CELL TECHNOLOGIES

Living Cell says it has approval to treat six patients in the second group of its phase IIb trial of NTCell encapsulated pig brain choroid cells for Parkinson's disease.
Living Cell said the data safety monitoring board approved continuing the 18-patient continued trial at New Zealand's Auckland City Hospital (BD: Mar 24, 2016).
The company said four patients would have 80 NTCell microcapsules implanted into the putamen on each side of their brain and two patients would have sham surgery.
Living Cell said approval was earlier than planned after a protocol change, removing a review of magnetic resonance imaging of patients eight weeks after surgery, to reviewing the last three patients at four weeks post-surgery and one at eight weeks post-surgery.
The company said it planned to complete the second group by the end of 2016 and the six patients in group three by the end of March 2017.
Living Cell said the trial aimed to confirm the most effective NTCell dose, define any placebo component and identify the initial target patient sub-group and if successful, it would apply to treat paying patients in New Zealand by the end of 2017.
Living Cell was up 0.5 cents or 6.25 percent to 8.5 cents.

RESAPP HEALTH

Resapp says the Boston Massachusetts General Hospital has approved its large-scale, pivotal, prospective, paediatric, respiratory disease Smartcough-C study.
The company said the study was a multi-site, double-blind study evaluating the efficacy of its Resappdx software application for the diagnosis of childhood pneumonia and other respiratory conditions from cough sounds, with the primary endpoint the diagnosis of pneumonia with secondary endpoints the diagnosis of upper respiratory tract infection, croup, bronchiolitis and asthma.
Resapp fell two cents or 4.55 percent to 42 cents with 3.6 million shares traded.

REDHILL BIOPHARMA

Israel's Redhill says that it expects to begin a 440-patient confirmatory phase III trial of RHB-105 for Helicobacter pylori by July 2017.
Redhill said a US Food and Drug Administration type B meeting, discussed the chemistry, manufacturing and controls aspects of the RHB-105 phase III development program.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Today, Redhill said that RHB-105 was a proprietary, fixed-dose, oral combination therapy for the eradication of Helicobacter pylori infection.
The company said that subject to final minutes of the meeting, the FDA accepted its manufacturing plan towards filing the package as part of a potential new drug application.
Redhill said the two-arm, randomized, double-blind, active comparator confirmatory phase III study, comparing RHB-105 against a high-dose amoxicillin and omeprazole regimen, would follow completion of the pharmacokinetic program.
The confirmatory Phase III study is planned to enroll approximately 440 patients in up to 55 clinical sites in the U.S.
Redhill said the first phase III study showed that RHB-105 met its primary endpoint of superiority over historical standard-of-care with an eradication rate of 70 percent, with high statistical significance ($p<0.001$).
On the Nasdaq, Redhill fell 0.21 US cents or 1.72 percent to $US11.98 ($A15.72) with 30,636 shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it expects to begin its first human safety and irritation studies of its synthetic cannabidiol drug BTX-1503 for acne this month.
Botanix said the trials would be split so that the trials of the Permetrex drug delivery compound, which made up the majority of the formulation, would be separated from the safety studies for the formulation which include synthetic cannabidiol.
Botanix executive director Matt Callahan said that “given that synthetic cannabidiol has already been dosed to patients at 20-30 times higher dosages in other studies than what we will be using in our clinical studies, establishing the safety and irritation profile of the Permetrex formulation before we combine it with synthetic cannabidiol in the next study, will help de-risk the whole clinical program”.
Botanix said it completed manufacturing of the Permetrex formulation at US Food and Drug Administration quality standard for its study late last week and it had ethics approval for the study, with data potentially available before the end of December, 2016.
Botanix was up 0.7 cents or 17.95 percent to 4.6 cents.

LBT INNOVATIONS

LBT says the US Patent and Trademark Office has issued a third patent relating to its automated plate assessment system (APAS) technology.
LBT said the patent, citing former chief executive officer Lusia Guthrie as a co-inventor and entitled ‘Image capture and lighting apparatus’ would provide coverage until 2032.
The company said the patent was the third successful application for US patents and were part of a portfolio of four inventions related to APAS.
The company said that APAS had been licenced to the Hedditch AG joint venture Clever Culture Systems AG, which was integrating it with laboratory robotic instrumentation.
LBT said that Clever Culture Systems, whose chief executive officer was Ms Guthrie, expected to bring APAS to market as an automated stand-alone plate reader, called APAS Independence, followed by the integrated incubator, APAS Incubot.
LBT fell one cent or 2.1 percent to 47.5 cents with two million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says Melbourne’s Monash University will produce the antibodies for an enzyme-linked immunosorbent assay for its Promarkerd kidney disease test.
Proteomics said the contract with the Monash Antibody Technologies Facility was “a strategic milestone” in its commercialization pathway for its Promarkerd predictive in-vitro diagnostic for diabetic kidney disease.
The company said that custom antibodies would be designed to recognize diabetic kidney disease, following the manufacture of synthetic analogs of the biomarkers that make up the protein ‘fingerprints’ used to diagnose disease, with antibodies designed to recognise the fingerprints and provide the basis for a sensitive pathology lab assay.
Proteomics managing director Dr Richard Lipscombe said “the best path to market for the predictive test is as an additional item on the menu of existing pathology lab [in-vitro diagnostic] platforms”.
“Progressing our own go-to-market option gives significant additional bargaining power in the negotiations,” Dr Lipscombe said.
The company said it had multiple commercialization pathways for Promarkerd as a laboratory test, clinical pathology in-vitro diagnostic test and companion diagnostic.
Proteomics was up four cents or 16.0 percent to 29 cents.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says it has Conformité Européenne (CE) mark for its Mente Autism device to help children with autism spectrum disorder.
Last week, Neurotech raised $7 million and listed on the ASX to commercialize medical products for the management of neurological disorders including autism spectrum disorder, epilepsy, anxiety and depression (BD: Nov 4, 2016).
The company said at that time that Mente Autism was a clinical-quality electro-encephalogram device that uses neuro-feedback technology to help children with autism spectrum disorder, designed for home use.
The company said it would present at the Medica International Trade Fair in Düsseldorf, Germany, November 14 to 17, 2016.
Neurotech was up 6.5 cents or 23.2 percent to 34.5 cents with 4.9 million shares traded.

MEMPHASYS (FORMERLY NUSEP)

Memphasys says it has received a statutory demand from Prime Biologics for the repayment of the third party debt that Prime paid as guarantor of a third party debt.
In 2014, Memphasys spun out its Singapore-based Prime subsidiary and agreed to take responsibility for a payment to A-Bio Pharma Pte Ltd for Prime B-class non-voting shares.
The company said that A-Bio had used the manufacturing facility in Singapore for manufacturing and Prime had taken over the site from A-Bio.
Memphasys said Prime was spun-out from the then Nusep to use the technology developed by Nusep for plasma fractionation.
In September, Memphasys said it had received a letter of demand from Pulau Manukan Ventures Labuan relating to Prime Biologics, of which Manukan was the key investor, demanding it repay within seven days the debt paid by to A-Bio, plus legal costs and interest charges (BD: Sep 12, 2016).
Today, Memphays said the debt had been repaid by Prime as guarantor of the loan, and Memphasys owned 43 percent of Prime with other shareholders including JP Asia Prime Capital Pte Ltd and Manukan, which was part of Xeraya Capital, part of the portfolio of the Malaysian Sovereign Wealth Fund, Khazanah National.
Memphasys said it was in litigation against Prime and its major investor, Manukan, and the litigation involved two separate actions in the Singapore High Court: the means of payment by Memphasys against the debt pay-out by Prime; and the ownership of a GF100 machine, a key part of Prime's plasma processing facility and for which Prime had paid rent to Memphasys.
Memphasys said it had taken steps to defend the actions but was also making efforts to resolve the conflict to preserve shareholder value.
The company said that in the process of determining an outcome and to counter the Memphasys legal actions against Prime, Prime had served statutory demand for the payment of $4,895,598 which comprised the debt that Prime repaid, interest accrued and legal costs, which Memphasys would vigorously defend.
Memphasys said the value of its Prime B-class shares would exceed the pay-out and was hopeful that a negotiated settlement would be reached.
Memphasys was untraded at half a cent.