Biotech Daily

Tuesday November 15, 2016

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: LIVING CELL UP 13%, DIMERIX DOWN 11%**

*** FDA APPROVES SIENNA'S 1st TELOMERASE IN-VITRO DIAGNOSTIC**

*** SIMAVITA LAUNCHES ASSESSPLUS FOR HOME CARE**

*** RMIT NEBULIZER WINS $663k JOHNSON & JOHNSON QUICKFIRE CHALLENGE**

*** PHARMAXIS, WOOLCOCK WORK ON ORBITAL INHALER FOR CF**

*** PROTEOMICS, LINEAR PARTNER FOR DIAGNOSTICS, CLINICAL TRIALS**

*** TBG TO DISTRIBUTE OMIXON'S HOLOTYPE HLA TYPING IN ASIA-PACIFIC**

*** CYNATA RECEIVES $1.75m FEDERAL R&D TAX INCENTIVE**

*** ANTISENSE RECEIVES $396k FEDERAL R&D TAX INCENTIVE**

*** ANTEO AGM SURVIVES REMUNERATION REPORT, UP TO 34% DISSENT**

*** UP TO 25% OPPOSE ANATARA PLACEMENT CAPACITY**

*** PERPETUAL TAKES 9% OF SIRTEX**

*** DRH, DAVID HANNON REDUCE TO 10% OF NOXOPHARM**

*** STEPHEN COUPE TAKES 5.5% OF NUHEARA**

*** ADALTA APPOINTS DR ROBERT PEACH A NON-EXECUTIVE DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.36 percent on Tuesday November 15, 2016 with the ASX200 down 19.5 points to 5,326.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and four were untraded. All three Big Caps fell.

Living Cell was the best up 1.1 cents or 13.4 percent to 9.3 cents with 2.1 million shares traded. Ellex climbed 7.3 percent; Benitec and Osprey improved five percent or more; Oncosil was up 4.55 percent; Cellmid and Cyclopharm were up more than three percent; Genetic Signatures and Viralytics rose two percent or more; with Clinuvel and Factor Therapeutics up more than one percent.

Dimerix led the falls, down 0.1 cents or 11.1 percent to 0.8 cents with 1.7 million shares traded. Bionomics fell 4.9 percent; Starpharma lost 3.5 percent; Actinogen, Cochlear, Compumedics, CSL, Prima and Pro Medicus shed more than two percent; Admedus, Impedimed, Medical Developments, Nanosonics, Neuren and Resmed were down more than one percent; with Acrux down 0.75 percent.

SIENNA CANCER DIAGNOSTICS

Sienna said that the US Food and Drug Administration has approved its telomerase-based adjunct in-vitro diagnostic, initially for bladder cancer.
Sienna has previously said that 90 percent of cancers up-regulated telomerase and the detection of telomerase in cytology samples would be an important adjunct test for the diagnosis of cancer (BD: October 6, 14, 2016).
Today, Sienna said that the FDA approval was “the final regulatory step in the commercialisation of a clinical test for the cancer biomarker telomerase”.
The company said that the diagnostic would be made available to US pathology laboratories by distribution partner Statlab Medical Products, enabling laboratories to detect the presence of telomerase in cells found in cytological samples.
The company said the test used immune-cyto-chemistry, allowing pathologists to visualise exactly which cells stained positive for the presence of telomerase.
Sienna said that an important initial application would be as an adjunct to routine urine cytology testing and would provide additional information for pathologists to use as part of their diagnostic assessment of bladder cancer.
Sienna said about 1.5 million urine cytology tests were performed every year in the US.
Sienna is a public unlisted company.

SIMAVITA

Simavita says it has launched its Assessplus automated incontinence assessment product for carers of disabled and elderly citizens in Australia, Europe and North America.
Simavita said that it was an approved provider under Australia’s National Disability Insurance Scheme (NDIS) and the Assessplus would be eligible for Federal Government assistance through its Home Care Packages scheme designed to deliver greater assistance to seniors to keep them living at home.
Simavita chief commercial officer Peta Jurd told Biotech Daily that the disability and home care providers would buy the $750 kits which included the computer tablet and data-pod, which was attached to the sensor in the incontinence pad.
Ms Jurd said that customers would then pay the provider “a one-off fee of about $200 to $250 per assessment for the correct pad capacity and toileting and change times”.
“The customer’s fee is reimbursable under the NDIS and the Federal Government Home Care Packages,” Ms Jurd said.
Simavita said that approval as an NDIS provider would “greatly assist … in delivering product to carers and directly to NDIS participants via the NDIS portal”.
Simavita said that Assessplus was an easy-to-use product developed to help people and their carers who live at home and struggle with the management of incontinence and did not require training to use.
The company said it was “highly cost effective and designed to reduce the on-going cost of managing incontinence [delivering] fast and automated care plans and …real improvements in quality of life expectations including complications associated with dehydration, falls and injuries, skin ulcers and urinary infections”.
Simavita said that Governments and insurers were moving to service programs designed to assist people in need, to stay in their family homes longer.
The company said that Assessplus was its first product for smart, wearable and disposable sensors for the health care industry, following on from its first generation smart incontinence management (SIM) systems for elderly care operators, hospitals and rehabilitation centres.
Simavita was unchanged at 8.3 cents.

JOHNSON & JOHNSON INNOVATION, JANSSEN RESEARCH & DEVELOPMENT

Johnson & Johnson says Melbourne's RMIT Micro-Nanomedical Research Center, led by Dr Leslie Yeo, has won one of three $US500,000 ($A662,721) prizes.

Johnson & Johnson said that the Royal Melbourne Institute of Technology group won the grant and offers of residency at Johnson & Johnson Innovation in its World Without Disease Quickfire Challenge for a core technology consisting of a portable hand-held personalized nebulization platform enabling the aerosolization of drugs for their delivery through inhalation to the lungs.

Johnson & Johnson said the needle-free technology provided systemic delivery of small and large molecule therapeutics, as well as local targeting directly to the lungs, which made it attractive for targeting lung diseases, including lung cancer, the specific area with a critical unmet medical need.

Johnson & Johnson said that along with the Maryland-based Glyscend Inc and California's Neurotrack, RMIT University were selected from more than 470 applicants.

PHARMAXIS, WOOLCOCK INSTITUTE OF MEDICAL RESEARCH

Pharmaxis says it has a research collaboration with Sydney's Woolcock Institute of Medical Research to develop an inhalation therapy for cystic fibrosis.

Pharmaxis said that the National Health and Medical Research Council has awarded a research grant of $421,545 for development and testing of its Orbital inhaler with a dry powder formulation of the antibiotic tobramycin.

The company said it developed that Orbital inhaler "to deliver high-doses of dry powder drugs to the lungs in a more effective and convenient manner than existing technology".

Pharmaxis said the collaboration would be led by Woolcock deputy director and head of respiratory technology Prof Paul Young, with Prof Daniela Traini and Prof Scott Bell.

Pharmaxis chief executive officer Gary Phillips said the research had the "potential to see Australian innovation translated into a commercial product ready for late stage clinical trials and partnering".

Prof Bell said Australia had about 3,200 people with cystic fibrosis who needed regular antibiotic treatment for lung infection, due to thick mucosal secretion build-up in the lung.

"The ability to deliver antibiotics locally, using the Orbital device overcomes a number of challenges that we are facing in the clinic and this clinical trial is likely to pave the way to better health outcomes and quality of life," Prof Bell said.

Prof Young said that patients had to load multiple drug-containing capsules into their devices when taking their daily dose of antibiotics.

"With a lack of flexibility in this model, patients may encounter tolerability and cough issues along with logistical issues relating to loading, emptying and cleaning of their inhaler," Prof Young said.

"The Orbital circumvents these problems by providing a press-button, single use device containing the whole antibiotic dose that the patient can inhale over a number of breaths that are suitable to them," Prof Young said.

Prof young said that the approach would improve the quality of life for cystic fibrosis patients "mark a revolutionary way in which we deliver antibiotics for cystic fibrosis".

"The Orbital is capable of delivering a high payload of antibiotics for the treatment of infection in cystic fibrosis patients," Prof Young said.

Pharmaxis said that a phase I trial showed the Orbital could administer large amounts of dry powder to healthy subjects in one inhalation without compromising safety or tolerability and was capable of housing up to 400mg of powder.

Pharmaxis was unchanged at 26 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has signed a partnership with Linear Clinical Research to offer a combined analytical testing and clinical trials from January 2017.

Proteomics said that the deal with the Perth, Western Australia-based Linear had the "potential to double [its] analytical services revenue and break new ground in companion diagnostics" and would target the bio-pharmaceuticals and oncology markets.

The company said it would conduct advanced bio-analytical testing for Linear's clinical trials, including testing patient responses to drugs during clinical trials and analyzing blood samples to determine how long a drug stays in a person's system and would be one of three companies providing pharmaco-kinetic testing in Australia.

Proteomics said that Linear would be able to offer advanced pre-trial sample analysis and biomarker discovery through its Promarker technology.

Proteomics managing director Dr Richard Lipscombe said that services income was averaging $100,000 a month and the deal had "the potential to double that".

"We're delighted to enter into this exciting agreement with Linear, which will be strongly beneficial to our respective businesses," Dr Lipscombe said.

The company said that the partnership would target companion diagnostics to help drug developers bring drugs to market more efficiently and would allow Proteomics to use its Promarker biomarker discovery platform to analyse clinical trial samples to search for biomarkers for drug response.

Proteomics said that the companies would draw on their complementary strengths in Linear's North American, Chinese and Japanese markets and Proteomics Middle East and Indian markets.

Proteomics said that both companies were headquartered at the Queen Elizabeth II Medical Campus in Western Australia "allowing for seamless operation of analytical services and trial activities at the same site".

Proteomics was up 3.5 cents or 13.5 percent to 29.5 cents.

TBG DIAGNOSTICS

TBG says it will be the exclusive distributor of Omixon's Holotype human leukocyte antigen typing products for bone marrow matching in the Asia-Pacific.

TBG said that the distribution and support contract with the Cambridge, Massachusetts-based Omixon included China, Hong Kong, Taiwan and Australia.

The company said that Omixon supplied high-resolution human leukocyte antigen (HLA) genotyping products to more than 20 hospitals worldwide.

TBG said that the Holotype HLA was a combination assay and software product that used next generation sequencing and provided one of the most accurate high-resolution genotyping available.

The company said that it had added Omixon's Holotype HLA protocols to a list of HLA typing products that could be automated by its DX-ATM automated pipetting system.

Omixon chief executive officer Tim Hague said his company was "delighted to be working with such a highly skilled and motivated sales and technical support partner as TBG Diagnostics".

TBG chief operating officer Eugene Cheng said the partnership was "a significant opportunity for our company to continue our supply of innovative HLA solutions to the growing Asia-Pacific market".

TBG fell half a cent or 3.1 percent to 15.5 cents.

CYNATA THERAPEUTICS

Cynata says it has received $1,748,874 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Cynata said that Federal R&D Tax Incentive refund related to expenditure in the year to June 30, 2016.
Cynata was unchanged at 68 cents.

ANTISENSE

Antisense says it has received $395,598 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Antisense said the rebate related to research and development expenditure for the year to June 30, 2016.
Antisense was up 0.3 cents or 7.5 percent to 4.3 cents.

ANTEO DIAGNOSTICS

Anteo's annual general meeting narrowly avoided a remuneration report first strike but faced up to 33.7 percent opposition to the 10 percent placement capacity.
Yesterday, the company said that chairman Mark Bouris had resigned to spend more time with his other companies and today's announcement omitted the number of proxy votes received relating to his re-election (BD: Nov 14, 2016).
The remuneration report was passed with 248,024,387 votes (72.4%) in favor but with 79,096,799 votes (23.1%) against.
Anteo said that the greatest dissent was against the approval of the 10 percent placement capacity with 134,358,400 votes (33.7%) against and 246,197,574 votes (61.8%) in favor.
The company said that the ratification of a prior share issue was passed with a wider margin as were resolutions on the re-election of directors Dr John Hurrell, Dr Geoff Cumming and Rolf Sickman.
The company's most recent Appendix 3B new issue announcement said that Anteo had 1,133,929,581 shares on issue meaning that the opposition to the placement facility amounted to 11.8 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.
Anteo was unchanged at 5.2 cents.

ANATARA LIFE SCIENCES

Anatara's annual general meeting passed all resolutions, with 24.85 percent opposition to the 10 percent placement facility and director options.
Anatara said that the placement capacity faced 2,848,859 votes (24.85%) opposition with 7,496,229 votes (65.36%) in favor and with 1,122,505 votes (9.79%) left open.
The remuneration report and the re-election of director Dr Jar Hetzel were passed overwhelmingly.
The company's most recent Appendix 3B new issue announcement said that Anatara had 49,413,236 shares on issue meaning that the opposition to the placement facility amounted to 5.8 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.
Anatara was up one cent or 0.9 percent to $1.11.

SIRTEX MEDICAL

Perpetual and its subsidiaries have increased their substantial shareholding in Sirtex from 4,732,962 shares (8.21%) to 5,314,335 shares (9.21%).
Perpetual said that it bought and sold the shares from August 25 to November 4, 2016 at prices ranging from $26.95 to $33.77.
Sirtex was up 14 cents or 0.5 percent to $28.14 with 136,938 shares traded.

NOXOPHARM

DRH Superannuation and David Hannon say they have reduced their holding in Noxopharm from 8,391,429 shares (11.16%) to 7,526,273 shares (10.01%).
The Sydney-based DRH Superannuation substantial shareholder notice said that the registered shareholders included its DRH Superfund No2, RAH (STC) Pty Ltd and Mr Hannon.
DRH said that Mr Hannon and RAH bought and sold shares between August 25 and November 11, 2016.
Noxopharm fell half a cent or 1.4 percent to 35 cents.

NUHEARA

Stephen Coupe says he and his superannuation fund have become a substantial shareholder in Nuheara with 35,000,000 shares or 5.5 percent of the company.
The substantial shareholder notice said that Mr Coupe, care of accountants Oxley Parners of Bong Bong Street, Bowral, New South Wales, acquired the shares which were held by the Coupe Super Fund and S A Coupe Pty Ltd.
The notice said that the shares were bought between May 13 and October 20, 2016, on-market, but did not disclose the cost of the shares as required under the Corporations Act 2001.
Nuheara was unchanged at 6.1 cents with 1.3 million shares traded.

ADALTA

Adalta says it has appointed the San Diego, California-based Dr Robert Peach as a non-executive director effective from November 14, 2016.
Adalta said that Dr Peach was Receptos Inc co-founder and chief scientific officer and the company was developing drugs for relapsing multiple sclerosis, inflammatory bowel disease and other autoimmune diseases.
The company said that Dr Peach had experience in research and drug development, and held executive and scientific positions at Apoptos Inc, Biogen Idec, Idec Pharmaceuticals Corp and Bristol-Myers Squibb Pharmaceutical Research Institute.
Adalta said that Dr Peach held a Bachelor of Science and a Masters of Science from the New Zealand's University of Canterbury and a Doctorate Philosophy from the University of Otago.
Adalta fell 4.5 cents or 20 percent to 18 cents.