Biotech Daily

Tuesday November 29, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: COMPUMEDICS UP 5%, ADMEDUS DOWN 8%**

*** GENETIC TECHNOLOGIES, MELBOURNE UNI COLORECTAL CANCER TEST**

*** MEDICAL DEVELOPMENTS 22 COUNTRY PENTHROX APPLICATION**

*** CYNATA LODGES 'IPSC ASSAY' PATENT APPLICATION**

*** MEDADVISOR, ASTHMA AUSTRALIA PARTNERSHIP**

*** ANTISENSE 1-FOR-5 BONUS, NEW OPTION OFFER**

*** IMMURON RECEIVES $1.6m FEDERAL R&D TAX INCENTIVE**

*** CELLMID RECEIVES $831k FEDERAL R&D TAX INCENTIVE**

*** HYPERION TAKES 6% OF COCHLEAR**

*** UP TO 45% OF PROBIOTEC OPPOSE DIRECTOR GRAHAM MORTON**

*** WAYNE STRINGER GROUP DOWN TO 19% OF PROBIOTEC**

*** AVEXA LOSES SINGAPORE DIRECTOR ALLAN TAN**

MARKET REPORT

The Australian stock market fell 0.13 percent on Tuesday November 29, 2016 with the ASX200 down 6.9 points to 5,457.5 points. Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and four were untraded. All three Big Caps rose.

Compumedics was the best, up 3.5 cents or 4.8 percent to 76.5 cents with 420,337 shares traded. Avita, Cellmid and Medical Developments climbed more than three percent; Actinogen, Ellex and Resmed rose more than two percent; Clinuvel, Osprey, Universal Biosensors and Viralytics were up more than one percent; with Cochlear, CSL, Nanosonics and Opthea up by less than one percent.

Admedus led the falls, down three cents or 7.7 percent to 36 cents with 950,614 shares traded. Uscom lost 6.7 percent; Airxpanders, IDT, Mesoblast, Polynovo and Prana fell more than five percent; Impedimed retreated 4.15 percent; Neuren was down 3.1 percent; Genetic Signatures and Prima shed more than two percent; Bionomics and Orthocell were down more than one percent; with Pro Medicus, Sirtex and Starpharma down by less than one percent.

GENETIC TECHNOLOGIES, THE UNIVERSITY OF MELBOURNE

Genetic Technologies says it has licenced a novel saliva-based colorectal cancer risk assessment test from the University of Melbourne.

Genetic Technologies said that under the licence agreement it would develop and commercialize the risk assessment test developed by Prof Mark Jenkins and his research team at the University's Centre for Epidemiology and Biostatistics.

The company said that preliminary modelling studies were first published in Future Oncology on February 1, 2016, in a paper entitled 'Quantifying the utility of single nucleotide polymorphisms to guide colorectal cancer screening', with a summary at: http://www.futuremedicine.com/doi/abs/10.2217/fon.15.303?journalCode=fon.

Genetic Technologies said the "simulated case-control study of one million patients indicated that a panel of 45 known susceptibility [single nucleotide polymorphisms] can stratify the population into clinically useful [colorectal cancer] risk categories".

The company said that the technology could be used to identify people at high risk for colorectal cancer who should be subjected to intensive screening which could reduce the risk of occurrence and death from the disease.

Genetic Technologies said that those identified as low risk could be spared expensive and invasive screening, preventing unjustified adverse events and saving money.

The company said that a validation study supporting the work was nearing completion and was expected to be published within the next six months.

Genetic Technologies said that the technology was similar to its Brevagenplus test for breast cancer and the licence of the colorectal cancer test was "a significant milestone for the company as it seeks to diversify its product pipeline and become a key player in the single nucleotide polymorphisms-based cancer risk assessment landscape".

Genetic Technologies said that the terms and conditions of the agreement were confidential, but it would be responsible for the commercial development of the test and with the University it would conduct "a robust, on-going research collaboration enabling the company to leverage the University's renowned world-class expertise in [single nucleotide polymorphism-based] risk assessment and risk model development.

Genetic Technologies chief executive officer Eutillio Buccilli said the relationship with the University was "comprehensive and highlights our overall corporate mission to become a leader in the genomics-focused oncology diagnostics industry".

The company said that excluding skin cancers, colorectal cancer was the third most common cancer diagnosed in men and women in the US, with a lifetime risk of five percent and it was the third leading cause of cancer-related deaths in the US and early diagnosis was key to survival and the majority of cases were preventable by early detection and removal of pre-cancerous polyps.

Genetic Technologies said the main challenge with current screening was compliance and one large randomized controlled trial had a compliance rate of 47 percent.

The company said that the most common screening tool was a faecal occult blood test or visual inspection of the bowel by endoscopy, and while the faecal occult blood test had a high sensitivity it had a low positive predictive value, meaning a patient with a positive blood test would then require colonoscopy.

The company said that colonoscopy could be used as a primary screening tool, but it was expensive and the infrastructure as a primary tool prohibitive.

Genetic Technologies said that as with breast cancer, the more the physician could tailor a screening program to the patient's level of risk, the greater the impact of screening would have on the disease.

Genetic Technologies was up 0.3 cents or 30 percent to 1.3 cents with 4.6 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says Western Europe distributor Mundipharma has submitted an application to have Penthrox approved for sale in 22 European countries.

In January, Medical Developments launched the Penthrox inhaled methoxyflurane analgesic in the UK and Ireland following approvals in the UK and the Republic of Ireland (BD: Oct 28, Nov 9, 2015; Jan 27, 2016).

In September 2015, the company said that the Cambridge UK-based Mundipharma International Corp would pay up to $US54.5 million for the exclusive rights to Penthrox in 39 European countries (BD: Sep 14, 2014).

Today, Medical Developments said that Mundipharma filed the application with the UK Medicines & Healthcare Products Regulatory Agency under the European decentralized procedure for approvals in Austria, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Germany, Iceland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

The company said that the proposed indication was for the “Emergency Relief of moderate to severe pain in conscious adult patients with trauma and associated pain”.

Medical Developments said that the UK Agency would be the reference member state and would lead, manage and evaluate the regulatory application on behalf of the 22 countries.

The company said that during the decentralized procedure each country would have an opportunity to ask questions, make comment and seek clarification and the procedure took up to 210 days, followed by a 30 day individual country national phase, which was “largely an administrative phase dealing with translations and packaging”.

Medical Developments said that Penthrox was already approved in France and Belgium and the 22 marketing authorizations and sales were expected by July 2018.

Medical Developments chief executive officer John Sharman said the submission was “one of [the company’s] largest achievements to date”.

“The regulatory process being undertaken is identical to our successful registration of Penthrox in the UK, France, Belgium and Ireland,” Mr Sharman said.

Medical Developments said that national regulatory applications were expected to be filed with agencies in the Netherlands, Greece, Macedonia, Serbia, Albania, Liechtenstein, Montenegro, Kosovo, San Marino, Vatican City, Bosnia and Herzegovina, Andorra and Monaco.

“We have already delivered substantial orders into the French, UK, Irish and Belgium markets and this is a significant step forward in the globalization of Penthrox,” Mr Sharman said.

Medical Developments was up 17 cents or 3.95 percent to $4.47.

CYNATA THERAPEUTICS

Cynata says it has filed a patent application relating to its Cymerus mesenchymal stem cell technology to IP [intellectual property] Australia.

Cynata said the patent application, entitled ‘IPSC Assay’ described induced pluripotent stem cells and “certain novel aspects of [its] … Cymerus therapeutic mesenchymal stem cell technology” and if granted would provide coverage until November 2036.

The company said the patent application added to its “growing intellectual property portfolio, and further strengthens Cynata’s position as a leader in the economical production of single donor-derived, clinical grade [mesenchymal stem cells]”.

Cynata said that if the unnamed application was granted, it would “provide valuable commercial exclusivity in key markets around the world”.

Cynata was up 2.5 cents or 3.5 percent to 73.5 cents.

MEDADVISOR

Medadvisor says it has entered into a partnership with the not-for-profit health association Asthma Australia for an initial period of 12 months.
Medadvisor said that Asthma Australia was “a valuable source of information and guidance to its community of Australians living with asthma, their carers and health professionals”.
The company said that an estimated 2.4 million people in Australia had asthma, “driving an estimated $28 billion in hidden costs” each year of which $1.1 billion were directly related to the loss of productivity as a result of the condition.
Medadvisor said it had more than 45,000 users with asthma using its mobile telephone internet-based platform to manage their regular prescriptions of asthma medications.
The company said that its data showed that asthmatics using its platform were up to 30 percent more adherent to their preventer medication than those not using the platform.
Medadvisor said that an Australian study showed that nine of 10 Australians with asthma were using their inhalers incorrectly, increasing their risk of hospitalisation by 50 percent.
Medadvisor was up 0.1 cents or 2.8 percent to 3.7 cents.

ANTISENSE

Antisense says it will provide one free option for every five shares held at the December 5, 2016 record date and offer new options at 0.2 cents each.
In October, Antisense said that investors would vote at the annual general meeting to cancel Strongbridge Biopharma’s 8.5 percent holding, approve an option issue to shareholders and offer an unmarketable parcel facility (BD: Oct 11,2016).
In November, the annual general meeting defeated the remuneration report but passed all other resolutions (BD: Nov 10, 2016).
The company said in October that the proposed bonus and new option issues recognized that ATL1103 partnering plans had not progressed as expected and the existing listed loyalty options were due to expire in January 2017.
Antisense said it intended to issue free bonus options to all ordinary shareholders on a pro-rata basis.
Today, Antisense said that it would offer one bonus option to eligible shareholders for every five shares held on the record date of December 5, for no consideration and exercisable at eight cents per option by December 19, 2019.
The offer of new options at 0.2 cents each would have the same record date of December 5, the offer would open on December 6 and close on December 15, 2016 also exercisable at eight cents per option by December 19, 2019.
Antisense said that investors could apply for an equal number of new options as their holding of their existing ANPO options.
Antisense was untraded at 4.1 cents.

IMMURON

Immuron says it has received $1,590,043 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Immuron said that the tax incentive was for research and development programs for the year to June 30, 2016.
Immuron was up 3.5 cents or 11.7 percent to 33.5 cents.

CELLMID
Cellmid says it has received $831,409 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Cellmid said the rebate related to expenditure on its midkine and FGF5 inhibitor programs for the year to June 30, 2016.
Cellmid was up 0.1 cents or 3.45 percent to three cents.

COCHLEAR
The Brisbane-based Hyperion Asset Management says it has increased its substantial shareholding in Cochlear from 2,874,928 shares (5.03%) to 3,472,955 shares (6.05%).
Hyperion said the registered holders included JP Morgan Chase Nominees, BNP Paribas, Citibank Nominees, National Nominees, RBC Investor Services and individually managed accounts with relevant interests held by 20 superannuation funds, trusts and entities.
The company said it bought the 598,027 shares between May 14 and November 23, 2016, for $77,928,533 or an average price of $130.31 a share.
Cochlear was up 40 cents or 0.3 percent to $118.50 with 277,987 shares traded.

PROBIOTEC
Up to 44.5 percent of Probiotec's annual general meeting voted against the election of director Graham Morton.
Yesterday, Probiotec said that following a call by founder and former executive director Charles Wayne Stringer to remove directors Robert Maxwell Johnston and Richard David Kuo and discussions ahead of the annual general meeting, directors Mr Johnston, Mr Kuo and Graham Buckeridge had resigned and Geoffrey Ronald Pearce had been appointed as an independent, non-executive director and chairman (BD: Nov 28, 2016).
The company said yesterday that if Mr Pearce and Mr Morton were re-elected as directors at the meeting, they would join Wesley Stringer on the board.
Probiotec said that 15,113,799 proxy votes (44.5%) opposed the re-election of Mr Morton, with 17,811,982 votes (52.5%) in favor and 1,010,848 votes were at the proxy's discretion.
The company said that 6,298,949 votes (18.1%) opposed the re-election of Mr Pearce with 27,475,331 votes (70.0%) in favor and 983,182 votes at the proxy's discretion.
Probiotec said the remuneration report was passed with 29,191,890 votes in favor, 1,191,151 votes against and 982,348 at the proxy's discretion.
The company's 2016 annual report said that Probiotec had 52,929,356 shares on issue, meaning that the largest opposition vote against Mr Morton amounted to 28.6 percent of the company, sufficient to requisition extraordinary general meetings.
Probiotec was untraded at 51.5 cents.

PROBIOTEC
Probiotec founder and former executive director Charles Wayne Stringer has reduced his holding from 12,460,845 shares (23.54%) to 9,998,405 shares (18.9%).
The substantial shareholder said that the shares were held by Mr Stringer and Jane Stringer, as well as Mr Stringer's Inston Pty Ltd.
Earlier this month, Mr Stringer increased his holding from 9,637,690 shares (18.2%) to 12,460,845 shares (23.54%) in an association with the Balwyn North, Melbourne-based Ganter Corp and Rudi Ganter and said that the association would cease following the company's annual general meeting (BD: Nov 8, 2016).

AVEXA

Avexa says that Singapore-based director Allan Tan has retired following today's annual general meeting, which passed all resolutions.

Avexa was up 0.2 cents or eight percent to 2.7 cents