Biotech Daily

Tuesday October 4, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: LIVING CELL UP 9.5%, DIMERIX DOWN 20%**

*** BIOSCIENCE MANAGERS $50m 'SIGNIFICANT INVESTOR VISA' FUND**

*** DIMERIX: 'EARLY DATA BACKS DMX-200 FOR KIDNEY DISEASE'**

*** VOLPARA'S 1st SALE TO PERTH'S WOMEN'S AND BREAST IMAGING**

*** IMMURON $992k RIGHTS SHORTFALL, OVER-SUBS TAKES TOTAL TO $6m**

*** VIRALYTICS CAVATAK FOR PANCREATIC CANCER, TRIALS DATA**

*** ANATARA FILES DETACH FOR PIGLETS APPLICATION, HUMANS NEXT**

*** RESAPP AGM FOR 27m DIRECTOR, SCIENTIST, ADVISOR OPTIONS**

*** PETER HARDING-SMITH ANTEO CFO, RICHARD MARTIN DIRECTOR**

*** RACE APPOINTS PROF ROLAND WALTER CONSULTANT**

MARKET REPORT

The Australian stock market edged up 0.1 percent on Tuesday October 4, 2016 with the ASX200 up 5.5 points to 5,484.0 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and two were untraded. All three Big Caps were up.

Living Cell was best, up 0.7 cents or 9.5 percent to 8.1 cents with 270,775 shares traded, followed by Universal Biosensors up 9.3 percent to 29.5 cents with 101,444 shares traded.

Benitec, Clinuvel, Factor Therapeutics, Polynovo and Viralytics climbed more than three percent; Neuren rose two percent; Cochlear, Ellex, Impedimed and Nanosonics were up more than one percent; with Airxpanders, CSL, Pro Medicus, Resmed, Reva and Sirtex up less than one percent

Dimerix led the falls on what appeared to be good news (see below), down 0.3 cents or 20 percent to 1.2 cents with 24.5 million shares traded.

Prana lost 7.6 percent; Bionomics and Oncosil fell more than four percent; Compumedics, Osprey and Psivida were down more than three percent; Avita, Prima and Uscom shed two percent or more; Acrux, Anteo, Atcor, Medical Developments, Orthocell and Starpharma were down more than one percent; with Mesoblast down 0.9 percent.

BIOSCIENCE MANAGERS

Bioscience Managers says its $50 million Ventures I Fund is the first of a series of funds designed for Significant Investor Visa applicants.

Bioscience Managers, Chief Investment Officer Matt McNamara told Biotech Daily that the Fund would be offered as a venture capital opportunity to clients of BT (formerly Bankers Trust) Investment Management, to meet the visa requirement that at least 10 percent of the investment or $500,000 was in venture capital.

The company said that the Significant Investor Visa (SIV) or sub class 188C Business Innovation and Investment Visa required an investment of $5 million.

Bioscience Managers managing-director Jeremy Curnock Cook said the fund was “a breakthrough moment for many earlier stage, unlisted companies”.

“Access to funding is vital in turning ideas into life-saving products and I am confident we will see effective new healthcare products reach the market as a direct result of this new source of capital,” Mr Curnock Cook said.

Mr Curnock Cook said that small healthcare and biomedical companies were particularly suitable for venture capital investment because of the size of the opportunity and the high potential returns.

“You need high returns to match the higher risk but with judicious selection, there is no reason why investors should not do very well out of this sort of investment,” Mr Curnock Cook said.

BT (formerly Bankers Trust) Investment Management Group chief executive officer Emilio Gonzalez said the fund would “provide our growing number of SIV clients with the opportunity to invest in innovative earlier-stage healthcare solutions, underpinning Australia’s ability to meet the increasing healthcare needs of an aging population”.

“This provides a winning solution for both our investors and healthcare innovation in Australia,” Mr Gonzalez said.

Mr McNamara said the fund would adopt the same strategy that produced annualized net returns above 20 percent for several previous funds.

“Our approach is always to be hands on with management and to take a relatively large stake in a smaller number of investments to ensure we can contribute, to make a significant difference,” Mr McNamara said.

“The companies in this fund will be at an earlier stage than our other funds, so we will help them to meet the challenges of developing management teams, adding regulatory and clinical trial expertise and being introduced to capital and international networks,” Mr McNamara said.

Former Ausbiotech chief executive officer and Fund adviser Dr Anna Lavelle said the Fund was “a step change for earlier stage companies and sorely needed in Australia”.

“Together with later stage venture funding we now have a smooth continuum of capital access that will be of material benefit to many,” Dr Lavelle said.

Mr McNamara said Bioscience Managers would continue to comb through more than 200 investment opportunities each year, choosing those that were high quality and had significant technological or market advantages.

“We are looking forward to the challenge of identifying the right opportunities for the fund and I am confident that Australia’s impressive record in research and commercialisation will shine through,” Mr McNamara said.

“We simply don’t believe there is an alternative to thoroughly checking potential investee companies to ensure they have the right ingredients to become highly successful,” Mr McNamara said.

Bioscience Managers said it had applied to participate as a fund manager for the Federal Government’s $250 million Biomedical Translational Fund.

DIMERIX

Dimerix says that interim data from its phase II study of DMX-200 for chronic kidney disease shows the drug is well tolerated with some reduction of proteinuria.

Dimerix said that 21 of the planned 30 patients in part A of the trial had been dosed, with two completing the study and one ceased, and final results expected by the end of 2017.

Dimerix said that 11 participants had completed the 90mg dose, the mid-point of part A of the study, with three of the 11 showing a 50 percent reduction or greater in proteinuria, or blood in urine, over and above the standard-of-care and the DMX-200 described as “well tolerated with an encouraging safety profile”.

The company said that the findings were “encouraging as reductions in proteinuria are difficult to achieve in this disease setting, where participants are already on standard of care of a renin angiotensin system inhibitor, in this case irbesartan”.

Dimerix said that irbesartan had been shown in large-scale clinical trials to reduce proteinuria by about 25 percent from baseline in patients with chronic kidney disease.

The company said that the participants began the study with their proteinuria reduced as far as possible on standard of care.

Melbourne Renal Research Group clinical associate and co-principal investigator Prof David Packham said that recruitment had exceeded expectations.

“The total [67] months participant exposure to the drug to date appear to show an excellent safety and tolerability profile with treatment emergent adverse events very much in line with that expected of the study population,” Prof Packham said.

“Sufficient data has now been generated to inform dosage selection and progression to part B of the planned trial,” Prof Packham said.

Dimerix executive chairman Dr James Williams said that the interim data from part A of the study “increases our confidence in the safety of DMX-200 in this patient population and indicates that clinically significant reductions in proteinuria are possible in some patients”.

“We are now in the final stages of recruitment for part A and ready to move to next stage of the trial,” Dr Williams said.

Dr Williams said that chronic kidney disease affected more than 26 million people in the US alone and was “a large unmet medical need with progression of disease resulting in end-stage renal disease”.

Dimerix said that the two patients who completed the study continued to access treatment through the Australian Therapeutic Good Administration special access scheme, at the request of their doctor with one of the patients achieving a 66 percent reduction in proteinuria at their 90mg maximum dose(BD: Apr 19, 2016).

The company said that in the part A dose escalation study, the time on study from first dosing was up to 32 weeks and the average patient age was 62 years in a range from 36 years to 87 years.

Dimerix said that in addition to the study drugs, patients were taking between two and 20 concomitant medications, with an average of nine drugs, for management of other conditions and symptoms of kidney disease.

The company said that an 87 year old patient ceased the study due to the emergence of anaemia secondary to a gastrointestinal bleed, thought to be associated with a pre-existing polyp whilst on the blood thinning drug, warfarin, coincident with the first dose of study drug, but it considered this event “unlikely to be due to DMX-200”.

Dimerix said that part A of study would cease recruitment at the earlier of 30 participants, or the end of November 2016 and was expected to be completed by the middle of 2017, with part B planned to begin shortly after.

Dimerix fell 0.3 cents or 20 percent to 1.2 cents with 24.5 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says the Perth, Western Australia-based Women's and Breast Imaging clinic, is the first customer for its Enterprise software for the early detection of breast cancer.

Volpara said that the Enterprise software was an internet-based software product to help breast-screening clinics deliver "high-quality, personalized breast screening services to ensure women receive appropriate screening procedures with reduced discomfort" (BD: Sep 21, 2016).

The company said it would receive an annual licence fee as well as a fee for each breast screening.

Volpara chief executive officer Dr Ralph Highnam said there was "significant … interest among breast screening clinics and hospitals in Volpara Enterprise and the benefits it can bring to patient care, internal efficiencies and quality assurance, and we are very happy with the speed at which we have been able to deliver the first sale of this new product".

"The [US Food and Drug Administration] is focused on improving quality control in mammogram screening, particularly in relation to compression and positioning … and [the] Enterprise's quality control features help clinicians and screening centres overcome these issues," Dr Highnam said.

Women's and Breast Imaging's head radiologist Dr Maria Vanessa Atienza-Hipolito said that Enterprise was "an all-in-one tool that would help the clinic deliver the highest standards of breast screening and cancer detection for women".

"As a local leader in breast imaging technology, we were the first clinic in WA to adopt Volpara's products to measure breast density," Dr Atienza-Hipolito said.

"This has been an important differentiator for our clinic, given the link between breast density and risk of developing breast cancer," Dr Atienza-Hipolito said. "We can now also obtain feedback on appropriate positioning and compression for each scan, so that we have the best chance of picking up any cancers."

Volpara was up 4.5 cents or 8.7 percent to 56 cents.

IMMURON

Immuron says that shortfall subscriptions worth $677,229 and $315,000 in oversubscriptions take the total raised in its rights issue to $6,322,474.

In July, Immuron said that the three-for-10 rights issue at 25 cents a share raised $5,330,245 of a hoped-for $6 million (BD: May 31, Jul 5, 2016).

Immuron said that each new share came with an attaching option, exercisable at 55 cents each within three years from the date of issue, pending shareholder approval.

The company said the money would fund the company to interim results from the phase II non-alcoholic steato-hepatitis trial, when 30 patients had completed the trial, which was expected by end of the year, with 25 patients having completed treatment to date.

Immuron chairman Dr Roger Aston said the company was "very pleased at the oversubscription of this right issue and we are delighted to be able to accommodate additional capital".

Immuron chief executive officer Thomas Liquard said that the company had "a unique and scalable platform that can produce incredibly differentiated compounds which are capable of changing the paradigm of care for the diseases we target".

"As our portfolio of programs continue to grow and strengthen, Immuron is uniquely positioned to take advantage of key opportunities in huge markets including immune-mediated diseases, such as [non-alcoholic steato-hepatitis and infectious diseases such as [Clostridium] difficile," Mr Liquard said.

Immuron was untraded at 24.5 cents.

VIRALYTICS

Viralytics says it is investigating Cavatak as an immunotherapy for pancreatic cancer and has presented further incremental data on trials for melanoma and bladder cancer.

Viralytics said that metastatic pancreatic cancers expressed elevated levels of surface ICAM-1, the specific receptor targeted by Cavatak, or Coxsackievirus A21, and in-vitro cultures of human pancreatic cells were demonstrated to be susceptible to Cavatak-mediated oncolysis.

The company said that it had investigated Cavatak as a treatment for pancreatic cancer in an orthotopic mouse model both as a single agent and in combination with gemcitabine.

Viralytics said that palpable tumors within the pancreas were intra-tumorally injected with Cavatak twice over three weeks and gemcitabine was subsequently administered intra-peritoneally four times over 12 days in the combination treatment arm.

The company said that Cavatak as a single agent and in combination with gemcitabine was well tolerated and induced notable tumor reduction and/or stabilization as assessed by bio-luminescent imaging in a number of animals.

Viralytics said that anti-tumor activity mediated from single agent or combination Cavatak treatment regimens translated into statistically significant increases in survival rates compared to mice treated with gemcitabine alone.

The company said that the presented pre-clinical data suggested that Cavatak might have potential anti-tumor activity in human pancreatic cancer, which had a five-year survival rate of seven percent

The poster, entitled 'Pre-clinical investigation of Cavatak (Coxsackievirus A21) as a potential treatment for Pancreatic Cancer' is available on the Viralytics website at: http://www.viralytics.com/our-pipeline/scientific-presentations/.

Viralytics said that further data from its completed phase II Cavatak in late-stage melanoma (Calm) extension trial and phase I/II Cavatak in non-muscle invasive bladder cancer (Canon) trial was presented at the Replicating Oncolytic Virus Therapeutics meeting in Vancouver, British Columbia, October 1 to 4, 2016.

The company said the Calm extension trial was conducted in a 13-patient cohort of the 70-patient phase II trial, investigating the efficacy and safety of intra-lesional Cavatak in advanced melanoma, which confirmed an overall response rate of 28.1 percent and a durable response rate of 21.1 percent.

Viralytics said that in the extension study, biopsies were taken from melanoma lesions prior to and after the administration of Cavatak and tissue analysis showed that Cavatak facilitated "notable changes within the tumour micro-environment".

Viralytics managing-director Dr Malcolm McColl said the results "demonstrate the capacity of Cavatak to modify the tumour micro-environment with the potential to then drive enhanced activity of the checkpoint inhibitors".

Viralytics said that the phase I/II Canon trial was investigating the tolerance of escalating doses of Cavatak delivered directly into the bladder through a catheter in 15 first-line patients with non-muscle invasive bladder cancer.

The company said that clinical activity was demonstrated by evidence of viral replication and notable signs of tumor inflammation following either single or multiple administrations of Cavatak in multiple patients.

Viralytics said that a complete response was observed in one of the three patients in the highest-dose cohort of the monotherapy and to date the intra-vesicular administration of Cavatak was generally well-tolerated with no grade 2 or higher product-related adverse events.

Viralytics was up 3.5 cents or 3.85 percent to 94.5 cents.

ANATARA LIFESCIENCES

Anatara says it has lodged its application to register its Detach non-antibiotic for piglet diarrhoea with the Australian Pesticides and Veterinary Medicines Authority.

Anatara said that once the dossier was approved by the Authority, a marketing authorisation or registration would be issued and Detach would be commercially available to farmers for the control of diarrhoea in their piglets.

Anatara executive chairman Dr Mel Bridges said the company had “put together a very strong application which supports the use of our lead product Detach as an alternative to the mass use of antibiotics in livestock production, in this case, in pigs”.

“The importance of the submission is underscored by the United Nations’ assertion last month that antimicrobial resistance is ‘the greatest and most urgent global risk’,” Dr Bridges said.

“It is clear we need viable alternatives to antibiotics to address the growing issue of drug resistance,” Dr Bridges said.

“The Anatara team will turn its attention to further progressing our pipeline of novel products, including a product focused on the treatment of gastrointestinal disease in humans,” finished Dr Bridges.

Anatara was up 5.5 cents or 4.8 percent to $1.20.

RESAPP

The Resapp annual general meeting will vote to issue four directors 14.6 million options with a further 12,366,667 options for scientists, employees and advisors.

Resapp said that it proposed to issue chief executive officer Dr Tony Keating 3,800,000 options, with 3,600,000 options to each of chairman Dr Roger Aston, Chris Ntoumenopoulos and Brian Leedman.

The company said that the options would vest in two tranches with the first tranche exercisable at a 20 percent premium and the second tranche exercisable at a 100 percent premium to the 20-day volume-weighted average price to September 16, 2016.

Resapp said it proposed to issue 2,000,000 consultancy options each to Dr Paul Porter and Dr Udantha Abeyratne, as well as 2,000,000 employee options and 1,016,250 shares and 6,366,667 options to advisors to its $12.5 million placement (BD: Apr 20, 2016).

The company said that other resolutions included the approval of the remuneration report, the 10 percent placement capacity and the ratification of 62.5 million placement shares as well as the re-election of directors Mr Ntoumenopoulos and Mr Leedman.

The meeting will be held at the Four Seasons Hotel, 199 George Street, Sydney on November 2, 2016 at 2pm (AEDT).

Resapp was up 2.5 cents or 5.6 percent to 47 cents with 3.2 million shares traded.

ANTEO DIAGNOSTICS

Anteo says it has appointed Peter Harding-Smith as its chief financial officer replacing Richard Martin who continues as a non-executive director.

Anteo said that Mr Harding-Smith had financial, governance and company secretarial experience and had worked for more than 10 years with ASX-listed companies as chief financial officer and company secretary.

The company said that Mr Harding-Smith would be issued 2,000,000 options exercisable at 150 percent of the 10-day volume-weighted average price to the issue date within four years and vesting one year from the date of issue.

Anteo fell 0.1 cents or 1.9 percent to 5.1 cents with two million shares traded.

RACE ONCOLOGY

Race says that the Seattle, Washington-based Fred Hutchinson Cancer Research Centre's Prof Roland Walter has been appointed as a consultant.

Race said that Prof Walter was an oncologist and acute myeloid leukaemia expert, who would help develop clinical protocols for its Bisantrene and "optimising the drug's clinical positioning in the treatment of … acute myeloid leukaemia".

The company said that Prof Walter was also a University of Washington School of Medicine professor and his research focused on acute myeloid leukaemia.

Race was unchanged at 23 cents.