Biotech Daily

Wednesday May 10, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NANOSONICS UP 6%, IDT DOWN 7%**

*** BUDGET 2017: 1st MRFF $66m TRICKLES IN, STEADY AS SHE GOES**

*** BIOTECH DAILY EDITORIAL COMMENT**

*** G MEDICAL IPO RAISES $12m FOR ELECTRONIC HEALTH**

*** MONASH LICENCES IMMUNO-ONCOLOGY PROGRAM TO CORVUS**

*** AVITA: 'FDA HAS NO QUESTIONS ON BARDA RECELL APPLICATION'**

*** IMMURON TRIAL SUPPLIES OF IMM-529 FOR CLOSTRIDIUM DIFFICILE**

*** MEDIBIO, MAYO MENTAL HEALTH DEVELOPMENT AGREEMENT**

*** IDT WINS VICTORIA MANUFACTURING GONG**

*** IM RAISES $498k TO BECOME BABYLON OPERATIONS MINING SERVICES**

MARKET REPORT

The Australian stock market climbed 0.61 percent on Wednesday May 10, 2017 with the ASX200 up 35.5 points to 5,875.4 points. Eighteen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and two were untraded.

Nanosonics was the best, up 20 cents or 6.35 percent to $3.35, with 983,496 shares traded.

Uscom climbed 5.1 percent; Cellmid, ITL and Prana were up more than three percent; Cochlear, Cyclopharm, Genetic Signatures and Universal Biosensors rose more than two percent; Acrux, Admedus, Atcor, Factor Therapeutics, Neuren, Opthea and Sirtex were up more than one percent; with Airxpanders, CSL, Medical Developments and Pro Medicus up by less than one percent.

IDT led the falls, down one cent or 7.1 percent to 13 cents with 200,955 shares traded.

Reva lost 5.7 percent; Actinogen, Polynovo and Starpharma fell more than four percent; both Impedimed and Prima were down three percent; Compumedics, Ellex, Mesoblast and Osprey shed more than two percent; Avita, Bionomics, Pharmaxis and Resmed were down more than one percent; with Viralytics down half a percent.

FEDERAL BUDGET 2017

The Federal Budget has allocated $65.9 million from the Medical Research Future Fund and made few, if any, other changes to the biotechnology and medical research sector.

The Federal Treasurer Scott Morrison did not cite any support for biotechnology or innovation in his half-hour Budget speech last night, with medical research mentioned in passing.

Mr Morrison made commitments to the Medicare universal health insurance system and the Pharmaceutical Benefit Scheme, with no change to funding for the National Health and Medical Research Council, the Australian Research Council and the Commonwealth Scientific and Industrial Research Organisation.

A Department of Industry official told Biotech Daily that the proposed $2 million cap on the Research and Development Tax Incentive was not included in the Budget.

The $20 billion Medical Research Future Fund was first announced in the 2014 Budget of then Treasurer Joe Hockey and from inception held $1 billion from the Hospitals and Charities Fund, as well as allegedly receiving the benefit of a raft of cuts to the Health budget.

Today, the Budget papers said that over the next four years the Government would "move substantially towards doubling its current medical research funding".

"This Budget starts the Government's disbursements from … [the MRFF] worth $20 billion by 2021 … [delivering] $1.4 billion over the next five years," Budget papers said.

The Budget papers said the $65.9 million would fund eight "investments" including $20 million for preventive health and research translation projects, of which $10 million was for Advanced Health Translation Centres and $10 million for the Australian Prevention Partnership Centre, as well as $33 million for clinical trials and $12.9 million for "breakthrough research investments".

The Budget said that $10.8 million would be allocated for childhood cancer research and trials, including $4.4 million for Cancer Australia, as well as $1.4 million to fast track research collaborations on paediatric brain cancer, with a further $5 million from the MRFF for young people with cancer and $68 million for the South Australian Government to establish Australia's first proton beam therapy facility for research and treatment of cancer and $2.1 million to ban cosmetic animal testing.

An NHMRC executive told Biotech Daily that the total grant budget "estimated actual" spending for 2016-'17 was $852,458,000, rising to $871,932,000 in 2017-'18, and included both the main Medical Research Endowment Account and other special funding measures.

The Australian Research Council grant budget increased from the estimated actual $744,363,000 in 2016-'17 to $758,055,000 in 2017-'18.

Medicines Australia said it had a five-year agreement with the Federal Government that would "deliver $1.8 billion in savings that will be reinvested into the supply of medicines, including more breakthrough therapies on the Pharmaceutical Benefits Scheme".

Medicines Australia said the changes would see single brand, or innovative, medicines reduced in price after being on the PBS for five, 10 and 15 years, respectively, while on entry of brand competition, there would be an increase from the current 16 percent reduction to 25 percent.

The Budget included company tax cuts, continued the $20,000 instant asset write-off for businesses below $10 million turnover for another year, but included extra payments for businesses with a turnover of more than $10 million of $5,000 upfront for each foreign employee on a permanent work visa and $1,800 for each employee on a temporary skill shortage visa, while those under $10 million would pay $3,000 for permanent work visas and $1,200 for temporary skill shortage visas.

BIOTECH DAILY EDITORIAL COMMENT

Biotech Daily welcomes the 2017 Budget, primarily for not cutting funding to the major agencies and not implementing the proposed $2 million R&D Tax Incentive cap.

When he became Prime Minister in 2015, Malcolm Turnbull promised that innovation would be at the centre of his Government. Eighteen months and three Innovation Ministers later, the word “innovation” was notably absent from the Treasurer’s speech.

The start of Medical Research Future Fund allocations is welcome, albeit curious that it has taken four Budgets to find $65.9 million from a previously invested $1 billion, along with the “savings” made in previous swingeing cuts to the Health Budget.

The support for Medicare and the Pharmaceutical Benefit Scheme is a sea-change in Liberal-National Coalition thinking, and an unstated apology for heading towards the dysfunctional, byzantine US health insurance arrangements in previous Budgets.

That said, the penny-pinching 1.5 percent cut to the Gillard-era 45 percent Tax Incentive remains, as does the Ferris, Finkel, Fraser Review proposal to cap the R&D Tax Incentive at $2 million, causing unnecessary uncertainty and likely to harm the most promising biotechnology companies. If some companies are rorting the system, tighten it up so that Bentley Continentals are not part of the R&D budget. Better still, appoint an Independent Expert Biotech Board to authorize genuine research for tax concession purposes.

Budget measures cutting funds to universities and creating education disincentives to the less well-off means the talent-pool for biotechnology, medical research and engineering will be reduced. The $2.8 billion universities’ cut, along with a lower income threshold to repay student loans does not help the diversity of next generation scientists, managers and executives. Treating New Zealand students as foreigners and making them pay the full cost of degrees – a fortnight after Anzac Day - is simply bizarre.

David Langsam
Editor

G (GEVA) MEDICAL INNOVATIONS

G Medical has raised the full $12 million in its initial public offer at 20 cents a share to list on the ASX and commercialize its mobile telephone electronic health devices.
The Perth-based G Medical, named after founder Dr Yacov Geva, opened under the ASX code of GMV down 20 percent at 16 cents at 11.30am this morning.
In February, the company said it had completed clinical trials of its technology, which included a mobile telephone cover for providing data as well as a “vital signs monitor system” which could provide electrocardiograms, respiration rate, oxygen saturation and temperature measures, with next generation models measuring blood pressure, blood glucose, uric acid, cholesterol and haemoglobin (BD: Feb 20, 2017).
G Medical said it expected Conformité Européenne (CE) mark approval by July 2017 and US Food and Drug Administration approval by the end of the year, with a memorandum of understanding with Winola Lake for US distribution and a term sheet with Guangzhou Sino-Israel Bio-Industry Investment Fund for China.
G Medical said its management team was led by executive director Dr Yacov Geva the chairman was Dr Kenneth Melani, with directors including Guangzhuo Israel Biotech Fund chairman Dr Shuki Gleitman and Otsana Capital director Dr Brendan de Kauwe.
G Medical closed down six cents or 30 percent at 14 cents with 8.9 million shares traded.

MONASH UNIVERSITY

Monash University says Corvus Pharmaceuticals, has licenced an undisclosed immuno-oncology program, including a lead candidate from the University.
Monash said the Burlingame, California-based Corvus focused on the development and commercialization of novel immuno-oncology therapies and planned to develop any product candidates resulting from the collaboration.
The University said that product candidates would be developed as mono-therapies and potentially as combination therapies with its existing product candidates that targetted the adenosine receptor pathway.
Monash University Biomedicine Discovery Institute director Prof John Carroll said that Prof Charles MacKay and Dr Remy Robert had “created a first-class asset for the treatment of cancer”.
“We look forward to collaborating with the Corvus team to help them develop improved therapies for patients,” Prof Carroll said.
The University said that Corvus lead product CPI-444 was an oral small molecule checkpoint inhibitor designed to disable a tumor’s ability to subvert attack by the immune system by inhibiting adenosine in the tumor microenvironment.

AVITA MEDICAL

Avita says that US Food and Drug Administration has reviewed a pre-emergency use authorization for Recell and had no “additional comments or questions at this time”.
Avita said the pre-emergency use authorization was filed by the Biomedical Advanced Research and Development Authority (BARDA) with which it had a $US61.9 million contract “to establish an inventory so that Recell can be deployed to help deal with a mass casualty scenario involving burn injuries” as well as to provide operational support to develop its treatment of burn injuries “secondary to detonation of a nuclear device” (BD: Sep 30, 2015; Jun 27, 2016).
The company said that BARDA made the submission to the FDA to allow the emergency deployment of Recell for a mass casualty event involving burn injuries.
Avita said that the FDA review was conducted at the pre-approval stage because, during exigent circumstances, the time available for the submission and review of an emergency use request might be severely limited.
The company said the review was a milestone and brought it closer to establishing a stockpile of the Recell spray-on autologous skin for wounds, including burns.
Avita said that the initial BARDA order had a value of about $US8 million the Authority could opt to buy in advance of market approval, which the company wa also pursuing.
The company reported that BARDA said a pre- emergency use submission was not an indication of the FDA’s views on the product’s potential, nor that the sponsor had obtained or submitted all the information necessary for the FDA to review a formal request for consideration of an emergency use application, but was a mechanism to begin early discussions with the FDA prior to an emergency.
Avita chief executive officer Adam Kelliher said that “important boxes have been ticked, and it is very positive that the information … has satisfied FDA’s initial review”.
The company said its program for a US pre-market approval was on-track, with all data collected from its pivotal clinical trial involving seven US burns centres and it expected to submit its application in mid-2017, with an FDA decision expected in mid-2018.
Avita said that the FDA had approved Recell for compassionate use for life-saving events and continued access for medical professionals who participated in the trial.
Avita fell 0.1 cents or 1.1 percent to 8.9 cents.

IMMURON

Immuron says it has manufactured trial supplies of oral immunotherapeutic drug candidate IMM-529 for the prevention of Clostridium difficile infection recurrence.

Immuron said that IMM-529 was manufactured by the Commonwealth Scientific and Industrial Research Organisation Separations Science team and Pharmaceutical Packaging Professionals, in part with a grant of $50,000 from the Food Innovation Australia enterprise solutions centre program.

Immuron chief executive officer Thomas Liquard said the company was “thrilled to have completed this very important milestone”.

“IMM-529 is the second therapeutic drug candidate the company is progressing toward clinical trials,” Mr Liquard said.

“This demonstrates that Immuron’s platform has the potential to develop multiple therapeutics which may result in several revenue opportunities for the company in the future,” Mr Liquard said.

Immuron said that a 60 patient, phase I/II study of IMM-529 would begin at Israel’s Hadassah University by July 2017 to evaluate the safety and efficacy in combination with existing standards of care for acute and chronic Clostridium difficile infection, with results in mid-2018.

The company said that Clostridium difficile was a major medical problem causing an estimated annual economic cost of more than $US10 billion globally.

Immuron said that Clostridium difficile was especially acute in hospitals and in long-term in-patient care facilities and an estimated 29,000 patients died each year from the infection in the US alone.

The company said that IMM-529 was a biological product intended to prevent and treat Clostridium difficile without destroying the microbiome, which antibiotic treatments did.

Immuron said that the IMM-529 antibodies survived transit through the stomach and remained functional in the large intestine, resulting in localized toxin B neutralisation at the site of infection before significant damage is done, binding to spores and vegetative cells in the gut and preventing toxin B translocation into the blood supply.

Immuron climbed 4.5 cents or 8.4 percent to 58 cents.

MEDIBIO

Medibio says it has a three-year development agreement with the Mayo Clinic for its assessment and management of mental illness technology.

Medibio said that under the joint agreement, it and the Rochester, Minnesota-based Mayo Clinic would develop new products to assist physicians in quantitatively addressing psychiatric conditions while improving the quality, outcomes and costs associated with patient care.

The company said that its cardiac rhythm analytic platform used a panel of circadian, sleep and autonomic system biomarkers to quantify and characterize mental illness, to “help guide healthcare providers in the diagnosis of psychiatric conditions in patients”.

Medibio director Dr Franklyn Prendergast said that the Mayo Clinic provided “precisely the clinical expertise Medibio needs to validate use of our technology as a decision-support tool in the detection and diagnosis of depression and other mental health illnesses”.

The company said mental health was “the largest clinical problem today” with about 350 million people having depression and it being the leading cause of disability in the US.

Medibio said that given the subjective nature of the clinical assessments, fewer than 10 percent of patients received optimal therapy following initial assessments.

Medibio was up one cent or 3.6 percent to 29 cents.

VICTORIA GOVERNMENT, IDT AUSTRALIA

The Victoria Department of Economic Development says that IDT has won a Victorian Manufacturing Hall of Fame medical technologies and pharmaceuticals award.

The Department said that the award recognized “individuals and companies who embrace new technologies and manufacturing techniques, are export focused and excel in business innovation”.

The Department said that IDT specialized in “high-containment, high-potency manufacturing of active pharmaceutical ingredients and finished drug products, including tablets, capsules and injectables, microbiological and analytical testing”.

“In the last 12 months, IDT has successfully undertaken many projects for international companies with products bound for the US, Europe, Japan and other global markets,” the Department said.

IDT chair Graeme Kaufman said the company was “honoured to receive this award from the Minister of Industry and Employment Wade Noonan”.

“The Victorian Government has been and continues to be a strong supporter of IDT Australia’s efforts to develop and grow our advanced pharmaceutical manufacturing business,” Mr Kaufman said.

IDT fell one cent or 7.1 percent to 13 cents.

IM MEDICAL

IM Medical says its underwritten, three-for-eight, non-renounceable entitlement offer at 0.1 cents a share has raised $498,000 to become Babylon Operations.

In April, IM said it had a six month option agreement to acquire the Perth, Western Australia-based Babylon Operations which was “a recently established provider” of equipment rental and diesel maintenance services to the resource maintenance sector (BD: Apr 5, 2017).

The company said that applications totalled about $252,000 with the balance placed by Patersons Securities.

IM said that the funds would be used to repay creditors, including outstanding converting notes and to provide working capital.

In 2015, IM said its attempt to acquire data centre service provider Syncom Australia Pty Ltd through a reverse takeover had failed (BD: Jan 18, May 22, Jul 23, 2015).

Previously, IM Medical had been attempting to commercialize cardiac testing.

IM was untraded at 0.1 cents.