Biotech Daily

Monday April 20, 2015

Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH DOWN: GENETIC TECH UP 22%, GI DYNAMICS DOWN 12.5%**

*** BRANDON CAPITAL RAISES $200m FOR MRCF**

*** VICTORIA JOINS NSW MEDICINAL CANNABIS TRIALS**

*** BIONOMICS BEGINS PHASE II BNC210 ANXIETY TRIAL**

*** IMMURON CLAIMS 1st US TRAVELAN SALES**

*** IMUGENE IMPROVED HER-VAXX RAISES ANTIBODIES 10-FOLD IN MICE**

*** GENETIC TECHNOLOGIES ADDS TWO US BREVAGEN TEST CENTRES**

*** SIMAVITA INCONTINENCE SYSTEM REDUCES INFECTIONS, FALLS, COSTS**

*** DIRECTORS DR LIPSCOMBE, DR PARKER TAKE 44% OF PROTEOMICS**

MARKET REPORT

The Australian stock market fell 0.76 percent on Monday April 20, 2015 with the S&P ASX 200 down 44.8 points to 5,833.1 points. Twelve of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and three were untraded. All three Big Caps fell.

Genetic Technologies was best, up 0.8 cents or 21.6 percent to 4.5 cents with 25 million shares traded, followed by Pharmaxis up 14.3 percent to 20 cents with 5.5 million shares traded and Atcor up 13.3 percent to 25.5 cents with 1.3 million shares traded.

Analytica climbed 10 percent; Actinogen, Antisense, Avita and Osprey were up four percent or more; Ellex was up 3.1 percent; Impedimed rose 2.7 percent; with Bionomics and Viralytics up more than one percent.

Friday's best, GI Dynamics, led the falls, down two cents or 12.5 percent to 14 cents with 1.3 million shares traded.

Oncosil lost 6.3 percent; Medical Developments, Mesoblast and Universal Biosensors were down more than five percent; Anteo and Prima fell four percent or more; Admedus, Cellmid and Clinuvel were down more than three percent; Sirtex shed 2.65 percent; Benitec, Cochlear, CSL, IDT and Nanosonics were down more than one percent; with Acrux and Resmed down by less than one percent.

BRANDON CAPITAL PARTNERS, MEDICAL RESEARCH COMMERCIALISATION FUND

Brandon Capital says that at $200 million it has raised “Australia’s largest ever life science focused venture fund”.

Brandon Capital said it had closed a $200 million life science venture capital fund for the Medical Research Commercialisation Fund to be known as the MRCF 3 fund, supported by existing MRCF investors Australian Super and Statewide Super, with Health Employees Superannuation Trust Australia (HESTA), an existing investor in Brandon funds, and the industry superannuation fund for the hospitality, tourism, recreation and sport industries Hostplus joining the new fund.

Last year, the Victoria Government launched the $200 million Biotechnology Translation Fund supported by all other mainland States (BD: Oct 31, 2014).

Then Victoria Minister for Technology Gordon Rich-Phillips said at that time the fund would receive $5.7 million over seven years from the State Government.

Brandon Capital managing director Dr Chris Nave told Biotech Daily at that launch that the State Government funds would offset fund management costs which were of critical importance to superannuation fund investments.

“The leading superannuation funds are happier to invest earlier if they don’t have to pay those fees and they can afford to invest and wait the typically five to seven years required before seeing a return,” Dr Nave said.

Today, Brandon Capital said that the MRCF had more than 50 Australian medical research institutes and research hospitals as members, providing investors with access to medical discoveries and the expertise and infrastructure to help develop them.

Brandon said that about $50 million of the MRCF3 fund would be reserved for 20 to 30 very early seed-stage investments in promising biotechnology or medical device technologies and the remaining $150 million would be reserved for supporting the most successful of the projects, as well as existing MRCF projects to take these opportunities to mid-stage clinical trials in patients.

Brandon Capital said that under the new fund structure, each of the superannuation investors had the opportunity to invest much larger amounts of capital in the tens of millions of dollars into the most promising assets as they matured.

“We believe that there is significant potential in Australian life sciences, which has always outperformed in terms of research innovation, but has fallen short when it comes to commercializing those discoveries,” Dr Nave said.

“This failing has been largely attributed to the lack of sufficient early stage investment capital and access to hands-on investment expertise to guide the development and commercialization of these medical technologies,” Dr Nave said.

“The performance of the MRCF funds over the past seven years demonstrates that its unique investment model has overcome these deficiencies,” Dr Nave said.

MRCF chairman and former Victoria Liberal Treasurer Alan Stockdale said that the MRCF model was “proving to be highly successful [with] last year’s acquisition of Fibrotech Therapeutics, one of the MRCF’s earliest investments, by Shire Plc ... a landmark deal for the Australian biotechnology sector”.

“This eye-catching acquisition was a validation of our approach to effectively support medical innovation in this country, leading to benefits for patients, for the Australian economy and returns for our investors,” Mr Stockdale said.

Brandon said that with the new fund, the total MRCF funds raised was $251 million.

Brandon said the first MRCF fund was raised in 2007, with the 2011 MRCF 2 a $40 million supported by the Innovation Investment Fund scheme, as well as $50million raised for the Brandon Biosciences Fund 1 in 2008, supporting Fibrotech, Global Kinetics, Osprey Medical, Polyactiva, Spinifex Pharmaceuticals and Vaxxas.

VICTORIA GOVERNMENT, NEW SOUTH WALES GOVERNMENT

The Victoria Government says it will join three New South Wales Government-run medical cannabis clinical trials.

The Victoria Government said that “many Victorians with terminal illnesses or life-threatening conditions want to use medicinal cannabis to relieve their pain and treat their conditions, including children whose parents have successfully treated them when other medicines have failed”.

A Victoria Government media release said that prior to the election, “Labor committed to legalizing the use of medicinal cannabis in exceptional circumstances because families shouldn't have to choose between breaking the law and watching their child suffer” and in Government asked the Victorian Law Reform Commission to advise how the law could be changed to legalize and regulate the use of medicinal cannabis, with the report due by the end of August, 2015.

The Victoria Government said that the three trials, being conducted by the New South Wales Government, were exploring the use of cannabis and cannabis-derived products in providing relief for patients suffering from a range of illnesses.

The Victoria Government said that the first trial of up to 200 children with severe, drug-resistant epilepsy was scheduled to start enrolling eligible patients in mid-2016, with results expected to be available within two to five years, and it hoped that at least a quarter of the participants would be from Victoria.

The media release said that New South Wales Health was working with the research community to assess interest in proceeding with a 200 patient trials for adults with terminal illness, focusing on improving quality of life and symptoms such as pain, nausea and vomiting, along with a 200-patient trial of adults with chemotherapy-induced nausea and vomiting, where standard treatment was ineffective.

The Victoria Government said it hoped that at least 25 percent of those participants for the two adult trials would be from Victoria.

Victoria Premier Daniel Andrews said that he had seen “first-hand the relief medicinal cannabis can give children with life-threatening illnesses”.

“We've asked the Law Reform Commission for its advice on how the law can be changed so that families don't have to make this difficult choice,” Mr Andrews said.

“Victorians will now be able to participate in important clinical trials that could change their lives and the lives of families everywhere,” Mr Andrews said.

Victoria Minister for Health Jill Hennessy said that by supporting and participating in the New South Wales trials “Victorians will be helping to enhance the evidence around medicinal cannabis”.

“We will support Victorians who are interested in becoming a participant in these trials to find out if they are eligible and, if so, provide funding for their participation in the trial,” Ms Hennessy said.

“We know the difference medicinal cannabis can make to people's lives,” Ms Hennessy said.

“That's why it's so important we do everything we can to help families access the treatment securely and safely,” Ms Hennessy said.

The New South Wales Department of Health website said that the State Government would invest up to $9 million over the next five years to support the three trials.

The New South Wales Government said that it would lead the trials, with the Federal and other State Governments indicating support for the initiative.

The Department of health website said that the trials would “seek to enhance available evidence to better understand the appropriate use of cannabis and cannabis derived products for medical purposes”.

BIONOMICS

Bionomics says it has begun a 24-patient phase II trial of BNC210 using functional magnetic resonance imaging to assess its effect on brain activity in patients with anxiety.
Bionomics said that the double-blinded, controlled, four-way crossover single-centre phase II study would be conducted in patients with untreated generalized anxiety disorder, randomized to receive BNC210 300mg or 2000mg, placebo or 1.5mg lorazepam.
The company said the study would evaluate the capacity of BNC210 to engage brain systems relevant to anxiety, with endpoints including significant changes in cerebral perfusion and in task-related brain activity with functional magnetic resonance imaging.
Bionomics said the study was being conducted by King's College London's Prof Allan Young as principal investigator and was expected to be completed by July 2016 with results due by October 2016.
In February, Bionomics said it had begun a dose-ascending phase Ib trial of BNC210 for anxiety and depression in more than 50 healthy volunteers, investigating the safety, tolerability, pharmacokinetics and pharmaco-dynamics of BNC210 (BD: Feb 2, 2015).
At that time, Bionomics chief executive officer Dr Deborah Rathjen said the company was "eager to get back to the clinic with BNC210 and unlock the potential of this compound."
In 2011, Bionomics said that two phase Ib trials of BNC210 demonstrated efficacy with reduced sedation and intellectual impairment, in evaluations for panic attacks compared to placebo and against the benzodiazepine lorazepam for side effects such as attention, memory, co-ordination and sedation (BD: Mar 30, 2011).
In 2012, Bionomics licenced BNC210 to the US Ironwood Pharmaceuticals, which started a phase I trial, but there were no further announcements and last year Bionomics took back BNC210 from Ironwood (BD: Jan 22, Dec 21, 2012; Nov 11, 2014).
Today, Dr Rathjen said that BNC210 had "the potential to significantly improve the lives of anxiety sufferers and we believe that with effective management of anxiety there is the potential to reduce the huge impact of the disease on societal and healthcare resources".
"Currently, there is a large unmet medical need for fast-acting anxiolytic agents that lack the side effects observed with existing treatments, which include sedation and addiction, as well as negative side effects on memory and body movement," Dr Rathjen said.
Bionomics was up half a cent or 1.25 percent to 40.5 cents.

IMMURON

Immuron says it has secured the first US orders for its over-the-counter Travelan for travellers' diarrhoea.
Immuron said the orders were from a US "travel medicine chain" with more than 240 clinics providing travel medicine services nationwide.
Immuron chief executive officer Dr Leearne Hinch said that launching Travelan in the US was "an important commercial milestone for the company, as we focus on growing Travelan revenues globally".
Immuron said that Travelan was available in Australia, Canada and the US, and was undergoing regulatory approval in China.
The company said that Travelan was marketed as a dietary supplement in the US, and could be sold through pharmacists, drug stores and general stores and it had a direct sales model through retail and online channels to take advantage of higher product margins and it was also engaging with potential non-exclusive distribution partners for the large volume pharmacies and drug stores.
Immuron said it had appointed Travis Robins as director of US sales.
Immuron was up eight cents or 42.1 percent to 27 cents.

IMUGENE

Imugene says its reformulated HER-Vaxx has demonstrated an “up to 10 times” increase in the production of cancer fighting antibodies in mice.
Imugene said the reformulation shortened in the time for the immune system to respond to HER-Vaxx a potential immunotherapy for HER-2 positive gastric and breast cancer.
The company said that pre-clinical immunologic results were expected by July 2015 and a phase Ib/II trial in HER-2 positive gastric cancer was due to begin by the end of this year.
Imugene said the work was being undertaken at the Medical University of Vienna under Prof Ursula Wiedermann, the principal investigator for the pre-clinical development of HER-Vaxx and member of its scientific advisory board.
The company said the enhanced formulation of HER-Vaxx incorporated an existing, clinically and commercially validated vaccine carrier protein, CRM197, together with an adjuvant, replacing the virosomes used in previous formulations and the pre-clinical work indicated a potentially lower dose and a fewer number of immunizations could be required for a better clinical outcome than with the previous virosome-based formulation.
The company said that based on the immunogenicity results against extracellular HER-2/neu, there was a clear difference in the kinetics of antibody responses in the course of immunizations, showing that the reformulated HER-Vaxx led to earlier antibody increases, which were significant after two immunizations, with a peak response observed after three immunizations, compared with the earlier virosome formulation.
Imugene said that HER-Vaxx stimulated a polyclonal antibody response to HER-2/neu, the oncogene which was targeted by the currently used monoclonal antibody Herceptin.
The company said it had filed patent applications around the new formulation for major jurisdictions and when granted, the patents would reset its intellectual property ownership to 2036 from the current expiry of 2030 and extend geographical coverage.
Imugene managing director Charles Walker said the reformulation was “not only the achievement of another milestone, but also a very significant technical improvement given the greatly improved cancer-fighting antibody production and, as important, the significantly improved response time based on animal model testing”.
“The kinetics, or speed of response, has been a reason why some vaccines have failed in the past and it is greatly encouraging to see this element addressed,” Mr Walker said.
Imugene was up 0.1 cents or 10 percent to 1.1 cents with 46.2 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says that two more US breast health centres will offer Brevagenplus to their at-risk breast cancer patients.
Genetic Technologies said the six centres announced in January had all provided samples in the three months to March 31, 2015 (BD: Jan 29, 2015) and with additional centres expected to follow, it expected sales growth to accelerate in the second half of 2015.
The company said that the large breast health centres were more complex with longer sales cycles, but offered higher, more stable long-term revenue potential and it was working with them and referring practitioners to create a personalized comprehensive breast cancer risk assessment approach with Brevagenplus playing an integral role.
Genetic Technologies said it had developed a protocol in which women who might be at significant risk and had little or no family history of breast cancer were being screened and the company’s chief executive officer Eutillio Buccilli said the “paradigm shifts from detection and intervention to risk assessment, prevention and even earlier detection”.
Genetic Technologies was up 0.8 cents or 21.6 percent to 4.5 cents with 25 million shares traded.

SIMAVITA

Simavita says a Danish evaluation of its smart incontinence management (SIM) system shows it reduces urinary tract infections, patient falls and lowers costs of consumables.
Simavita said that the trial was conducted in late 2014 in collaboration with the Copenhagen Municipality and distributor Abena A/S, assessing both the benefits of using an evidence based, instrumented, 72-hour assessment and the resulting outcomes of continence care plans generated by the SIM system.
The company said the objective was to determine whether the use of SIM assessments would result in an accurate, systematic approach to incontinence assessment, and deliver an optimized and person-centred consumption of incontinence pads.
Simavita said that the trial focused on residents, nursing staff and the information technology system.
The company said that customers reported the SIM system was easy to work with, 60 percent of residents assessed were subsequently wearing a smaller sized pad during the day, more than 25 percent of residents assessed were using smaller pads during the night and that post-assessment there was a reduction in urinary tract infection and a reduction in the number of falls.
Simavita said the observations should result in a lower total cost of consumables used, as well as the potential to improve clinical outcomes and reduce key risks in respect of falls and urinary tract infections which were common triggers for entry into acute care hospitals, which in turn meant higher costs to the healthcare sector, and created serious clinical and personal complexities for the elderly.
Simavita chief executive officer Philippa Lewis said the trial observations were “consistent with our experience in other markets and we are absolutely delighted that such positive clinical and commercial outcomes were identified”.
“These results now provide an excellent platform for a broader Danish roll out, as well as an important reference point for other European countries,” Ms Lewis said.
Simavita said that as a result of the trial, momentum is building in Denmark with further municipalities positioned to begin trials of the SIM system.
Simavita was up 3.5 cents or 6.9 percent to 54 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Managing director Dr Richard Lipscombe and the Parker Family’s Xylo Pty Ltd have become substantial in Proteomics with a total of 44.32 percent of the company.
In a substantial shareholder notice the Perth Western Australia- based Dr Lipscomble said he held 16,141,281 shares (31.91%) directly and indirectly through The Luk AC.
The West Perth-based Xylo Pty Ltd, for the Parker Family account, said in a notice signed by director Dr William Parker that it indirectly held 6,277,594 shares (12.41%).
Proteomics fell three cents or 13.6 percent to 19 cents.