Biotech Daily

Monday November 24, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: OPTISCAN UP 20%, CLINUVEL DOWN 12%**

*** VICTORIA STATE ELECTION AND STATE BIOTECHNOLOGY POLICIES**

*** GENETIC TECHNOLOGIES DR MERVYN JACOBSON AWAITS SENTENCE**

*** ACRUX: 'EMA FINDS NO CARDIAC RISK FROM TESTOSTERONE THERAPY'**

*** ADMEDUS TAKES HPV VACCINE TO PHASE I TRIAL**

*** PHARMAUST TREATS 2nd PPL-1 CANCER PATIENT**

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*** REGENEUS STREAMLINES, REDUCES COSTS, HEADCOUNT**

*** ANALYTICA PERICOACH AVAILABLE**

*** JONATHAN LIM PARTLY UNDERWRITES AVEXA SHARE PLAN TO $250k**

*** ONCOSIL CEO DANIEL KENNY TAKES DR NEIL FRAZER'S 12m SHARES**

*** BANK OF AMERICA, MERRILL LYNCH REDUCE TO 5% OF SUDA**

MARKET REPORT

The Australian stock market climbed 1.08 percent on Monday November 24, 2014 with the S&P ASX 200 up 57.5 points to 5,361.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and five were untraded. All Big Caps rose.

Optiscan was the best, up 1.3 cents or 20 percent to 7.8 cents with 6.8 million shares traded. Analytica climbed 7.4 percent; Acrux was up 5.1 percent; Admedus and Mesoblast were up more than four percent; Cellmid and IDT were up more than three percent; Sirtex rose 2.1 percent; CSL, Impedimed, Living Cell, Phosphagenics and Tissue Therapies were up more than one percent; with Benitec, Cochlear and Resmed up by less than one percent.

Clinuvel led the falls, down 55 cents or 11.7 percent to $4.15 with 33,379 shares traded. Circadian fell 8.6 percent; Atcor lost six percent; Oncosil and Patrys shed five percent or more; Antisense, Medical Developments, Neuren and Starpharma fell more than four percent; Ellex, Osprey and Viralytics were down more than three percent; Alchemia, Bionomics and Prana shed more than two percent; with Nanosonics down 1.4 percent.

BIOTECH DAILY VICTORIA STATE ELECTION EDITORIAL

Biotech Daily does not have a clear view on which of Victoria's major parties vying for votes at the election next Saturday, November 29, 2014, is best for biotechnology.

Over the past two weeks we have been swamped with media releases from the Liberal Party promising that if re-elected for the next four years, it will fund projects that should have been funded in the past four years.

An $85 million package for "seniors" includes $13.5 million for research into dementia; the $9 million for John Monash and Rupert Hamer Scholarship could fund some medical research; $127 million for obesity and chronic illness includes $20 million for an assessment program, along with anti-smoking and preventative health campaigns; $11 million for hearing loss and eye health is primarily for services; $177 million for the Monash Children's Hospital is welcome and includes, as a lower priority, research space.

A Victoria Liberal Party media release said that "a re-elected Coalition Government has also committed to building Australia's first dedicated $120 million Heart Hospital at Monash Health, Clayton".

Last month, Victoria launched a superannuation-backed $200 million Biotechnology Translation Fund managed by Brandon Capital with the promise of $5.7 million over seven years from the State, to offset fund management costs, described as "of critical importance to superannuation fund investments".

In the four years that the Liberal and National Party have governed Victoria, biotechnology and another sunrise industry, information and communication technology (ICT) have fared reasonably well, particularly compared to other State Government priorities.

Funding has continued for the Victoria Prizes and the Minister responsible Gordon Rich-Phillips has taken a keen interest in both biotechnology and ICT. It is a great shame that the third sunrise sister, environmental technologies, has been set back by poor decisions, for purely ideological reasons.

The Baillieu and Napthine Governments inherited from the previous Bracks and Brumby Labor Governments, biotechnology projects they could not stop even if they wanted. It has been pleasing to see that after a little encouragement, they did not want to stop them.

In Biotech Daily's view the Victoria Liberal National Government has not been bad for biotechnology. But it has not done anything on the scale of the previous Labor Governments and has not shown any vision for either our sector or the State.

That said, with one week to go to the election, the Daniel Andrews Labor Opposition has not enunciated a single policy for our sector. One solitary media release says that Monash Medical Centre will get a $16.2 million boost of medical imaging equipment and facilities for parents needing specialist appointments.

Biotech Daily has repeatedly asked the office of the Shadow Minister for Innovation Fiona Richardson for Labor's medical research polices and has been told that nothing can be disclosed until the formal launch.

Biotech Daily has always taken a dim view of “small target” politicians, their subterfuge and hidden agendas. “There will be no cuts to the ABC or SBS” leaps to mind.

A Labor Party officer directed Biotech Daily to the Party website and its ‘Back to work … plan for 100,000 jobs’, which included: “The Future Industries Fund - a $200 million grant program to support job-creating projects in six identified high-growth areas, including pharmaceuticals, new energy, food and fibre, and international education.”

One week to a State election and no published policy is not good enough.

While the biotechnology sector may be encouraged that there is continuity with former Health Minister Gavin Jennings as the Shadow Minister for Health, Mr Jennings has not returned any calls from Biotech Daily to discuss policy. He supports the Essendon Football Club, so he is probably up to speed on Calzada and AOD9604.

At least the Greens were upfront: “We don’t have a State biotechnology policy,” an official said, instead referring this writer to the Federal policy, which to be fair, has been championed by Adam Bandt and other Greens Federal Parliamentarians.

If we were to vote in State elections, based on Federal party policies, we would praise the R&D Tax Credit, decry the loss of Commercial Ready Grants and the Innovation Investment Funds and wonder when we will see anything from the alleged $20 billion Medical Research Future Fund which is increasingly looking like a straw man to wedge scientists on the road to privatizing our Medicare national health service.

Which raises the issue of State (and potentially Territory) contributions to our sector.

In Victoria the Steve Bracks and John Brumby Labor Governments were the best thing that ever happened for biotechnology, providing funding and political support in many different ways. The same was the case for the Peter Beattie and Anna Bligh Labor Governments in Queensland. Honestly, we couldn’t have wanted better.

The departure of Labor from New South Wales has led to the appointment of Liberal Health Minister Jillian Skinner who has allocated significant funds to medical technologies and specific areas of interest. Queensland Liberal National Party Science Minister Ian Walker appears totally engaged with our sector and on one occasion won praise from former Premier Peter Beattie for his efforts.

Currently missing from these three States, however, is an overarching philosophical and political statement about where it sees the future of the three sunrise sisters, and consequently, the future of those States. It beggars belief that despite the quantum of medical research and commercialization undertaken in South Australia and Western Australia, it is despite their Governments and certainly not because of them.

In corporate affairs, past performance is not indicative of future results. In politics, present performance is not indicative of present results.

David Langsam
Editor

GENETIC TECHNOLOGIES

Genetic Technologies founder Dr Mervyn Jacobson has been remanded for sentencing for market manipulation and was led from the Victoria Supreme Court in handcuffs.

Justice Stephen Kaye heard character evidence for Dr Jacobson from Bayside City councillor and Melbourne City Opera director James Long, Vienna-based Immunaid director Dr Andrea Tobisch and pleadings from prosecution and defence legal teams.

Mr Long said that Dr Jacobson had been passionate and enthusiastic for the Opera which was formed following the defunding of the Victoria State Opera, had donated a lot of finance and brought stability to the organization through his “good chairmanship”.

Mr Long said that Dr Jacobson had worked to save endangered animals including Ethiopian Wolves and American Wolves.

“People speak very highly of him,” Mr Long said. “The comments are unsolicited and sympathetic despite knowing of his conviction.”

Dr Tobisch said that she owned a flim company in Vienna and met Dr Jacobson in 1998 and had filmed work on cross-fostering, supported by Dr Jacobson, to save the endangered Brush-Tailed Wallaby at Healesville Sanctuary in Victoria.

In describing Immunaid, Dr Tobisch said: “We believe it could turn-off cancer.”

Dr Tobisch said that using the Immunaid system physicians could be told when to treat patients and make treatment more effective for patients and provide savings to insurers.

Dr Tobisch said that Dr Jacobson was responsible for the science, the patents and the finances of the company and his incarceration would leave a big hole in the company.

Defence barrister for Dr Jacobson, Tony Burns, told the court that it was “difficult to imagine a greater fall from grace than from medical entrepreneur to a convicted felon”.

Mr Burns said that apart from any sentence, Dr Jacobson would receive an automatic banning order from running any company of at least five years and that was a punishment in itself for a person who had been on the boards of numerous biotechnology companies.

Mr Burns referred several times to Dr Jacobson’s age of 72 years and that his physical and mental health were suffering, including having been diagnosed with a “persistent depressive disorder [and was] psychologically crushed” which was likely to be exacerbated by any incarceration and more burdensome than for a younger man.

Mr Burns said that Dr Jacobson was not the architect of the scheme, but took an opportunity presented by his son-in-law Geoffrey Newing and that no one suffered an actual loss from the market manipulation.

Justice Kaye said that the offending “undermines public confidence in the stock market”.

Prosecutor Jeremy Rapke QC said that although Dr Jacobson was not a young man none of his medical conditions were serious or life-threatening, all could be treated and acknowledged “the psychological impact of a jury verdict on the prisoner is a natural reaction to a finding of guilt”.

Mr Rapke said the argument that Dr Jacobson was not the architect of the offences ignored a large body of evidence, the offending was not out of character, “he could have stopped at any time”, greed was the primary motivation and the impact on his family was Dr Jacobson’s own doing.

Mr Rapke said that from 2007 to 2014, Dr Jacobson has been on bail and allowed to continue his business, travel and live overseas and attend high level meetings.

Mr Rapke said this was the first offence of its type to go to trial, other defendants pleaded guilty and received sentences of about two years, with all but one serving time in gaol.

Justice Kaye remanded Dr Jacobson for sentencing on a date to be fixed.

After saying an emotional goodbye to friends and family, Dr Jacobson was led from the court in handcuffs by Department of Corrections officers.

Genetic Technologies was unchanged at 1.4 cents.

ACRUX

Acrux says that the European Medicines Agency has released a statement, entitled 'No consistent evidence of an increased risk of heart problems with testosterone medicines'. Acrux republished the EMA statement, released on November 21, 2014.

The statement from the London office of the European regulator said that the Coordination Group for Mutual Recognition and Decentralised Procedures – Human, a regulatory body representing EU Member States, agreed by consensus that there was "no consistent evidence of an increased risk of heart problems with testosterone medicines in men who lack the hormone", a condition known as hypogonadism.

The EMA said that the product information was to be updated in line with the most current available evidence on safety and with warnings that the lack of testosterone should be confirmed by signs and symptoms and laboratory tests before treating men with these medicines.

The EMA said that the Coordination Group position followed a review by the EMA's Pharmaco-vigilance Risk Assessment Committee which looked at the risk of serious problems affecting the heart and circulation, particularly heart attacks, in men treated with these medicines.

The EMA said that the review was started because of some recent studies suggesting an increase in heart problems in men using testosterone, compared with men not using it.

Earlier this year, Acrux share price tumbled following news that the US Food and Drug Administration was investigating cardio-vascular risks in men taking approved testosterone products (BD: Feb 4, 2014).

The FDA said at that time that it had "decided to reassess this safety issue based on the recent publication of two separate studies that each suggested an increased risk of cardiovascular events among groups of men prescribed testosterone therapy".

The FDA said in February that it had not concluded that FDA-approved testosterone treatment increased the risk of stroke, heart attack, or death.

Today, the EMA said that the Pharmaco-vigilance Risk Assessment Committee considered these studies along with available data from other studies and analyses, and information on safety collected since marketing, and found that the evidence regarding the risk of heart problems was inconsistent: some studies suggested increased risk, while others did not, and some of the studies had problems with the design that limited the conclusions that could be drawn from them.

The Committee said that the lack of testosterone itself could increase the risk of heart problems.

The EMA said that the Committee recommended updating the product information in line with the latest evidence and to provide warnings about those who might be at increased risk of heart problems.

The EMA said that the product information should make it clear that testosterone should only be used when an abnormally low level of the hormone has been confirmed by signs and symptoms and appropriate laboratory tests.

The European regulator said that testosterone levels naturally fall somewhat with age, but restoration of these levels in healthy older men was not an authorized use of the medicine.

The EMA said that the Committee further considered that the risks of effects on the heart and circulation and any potential mechanisms for such effects should continue to be monitored and information from ongoing studies should be provided as part of the next regular safety review, to which these medicines, like all medicines in the EU were subject.

The EMA said that the Coordination Group had endorsed the recommendations and they would be implemented by the Member States where the medicines were authorized.

Acrux was up 6.5 cents or 5.1 percent to $1.345 with 3.5 million shares traded.

ADMEDUS

Admedus says its human papillomavirus therapeutic vaccine has progressed well in preclinical studies and will advance to a phase Ib study.

Admedus said that the human papillomavirus vaccine was designed to target and clear human papillomavirus-positive tumor cells and had shown “exceptional preclinical activity in a series of preclinical models”.

The company said that the therapeutic vaccine prevented disease progression, cleared the tumor and inhibited tumor formation.

Admedus chief executive officer Lee Rodne said that the latest preclinical data was “extremely exciting and clearly shows the potential of the technology”.

The company said that a TC-1 tumor mouse model, treatment with the human papillomavirus vaccine achieved 100 percent survival and seven of eight (87.5%) mice had no detectable tumors after 50 days.

Admedus said that the vaccine provided 100 percent protection against human papillomavirus-positive tumor cell formation.

The company said that in a similar study in 2013 with a competitor candidate ADXS-HPV vaccine, none survived beyond day 45.

Admedus said that with the addition of the anti-PD-1 antibody, an overall survival rate of 20 percent after 50 days was achieved.

Admedus’ 66 percent subsidiary Admedus Vaccines chairman Prof Ian Frazer said the human papillomavirus program had “progressed well and shown some very positive data”.

Admedus was up half a cent or 4.35 percent to 12 cents with 10.1 million shares traded.

PHARMAUST

Pharmaust says it has begun treatment of the second patient in its first-in-man trial of PPL-1 for cancer, with the drug appearing safe and no adverse events observed.

Pharmaust said that the patient, who had lung cancer with metastases to other organs, would receive PPL-1 daily for 28 days.

Last month, Pharmaust said that the first patient had died “due to reasons unrelated to the study drug and this has understandably resulted in a standard process of investigations resulting in delays in the treatment of the second patient” and it needed to resubmit the ethics application to the Royal Adelaide Hospital (BD: Oct 21, 2014).

Pharmaust executive chairman Dr Roger Aston said at that time that an inclusion criterion of the trial was that patients had failed all other standards-of-care and some of the patients entering the trial might have significant progressive disease.

Two weeks ago Pharmaust said the Royal Adelaide Hospital research ethics committee has approved the continuation of the trial (BD: Nov 10, 2014).

Today, Pharmaust executive chairman Dr Roger Aston said that in addition to the second patient, a further two patients had entered screening and, subject to their suitability, would begin treatment on December 2 and 9, 2014, respectively.

“Initiation of treatment of these additional two patients will mean that recruitment for the lowest treatment dose will have been completed by Christmas,” Dr Aston said.

Dr Aston said that each treatment group had three patients.

“Pharmaust will look to raising the dosage of the next cohort by five-fold in accordance with the protocol and approvals received,” Dr Aston said.

Pharmaust said that PPL-1 would be potentially administered to patients suffering from diverse cancers including lung, pancreas, oesophageal, gastric, colorectal, ovarian, breast, prostate, liver, sarcoma, lymphoma, and melanoma.

Pharmaust was up 0.1 cents or 12.5 percent to 0.9 cents with 1.2 million shares traded.

CLINICAL GENOMICS

Clinical Genomics says it will be looking for research partners for its two-gene DNA test for bowel cancer at the World Cancer Congress in Melbourne December 3 to 6, 2014.
Clinical Genomics said it would present preliminary data on the blood test for early detection of bowel cancer.
Clinical Genomics chief executive officer Dr Larry LaPointe said that there were “logistical questions about how to integrate the blood test into screening and technical questions about how to make the test more sensitive”.
“We are now starting to explore the broader range of possibilities for how a blood test for circulating tumor DNA fits in the continuum of patient care,” Dr LaPointe said.
“There is a whole raft of exciting research possibilities,” Dr LaPointe said.
“We’ve developed the blood test to this stage via our collaborations with groups like the Flinders Centre for Innovation in Cancer and the [the Commonwealth Scientific and Industrial Research Organisation],” Dr LaPointe said.
“We’re working with private health funds on implementation pilots and individual researchers on other projects,” Dr LaPointe said.
“Bowel cancer screening is an emerging global public health priority and clinicians are looking for better tests aimed at detecting cancers earlier using simple, patient accepted tests,” Dr LaPointe said.
“We need to foster ongoing research to underpin this next generation of colorectal cancer screening and molecular diagnostics in general,” Dr LaPointe said.
Clinical Genomics is a private company.

REGENEUS

Regeneus says it has completed a strategic review and it will streamline its management structure, operations and reduce costs.
Regeneus said that completion of the early stage research and development phases for a number of products allowed a greater focus on partnering and commercialization.
Regeneus chief executive officer John Martin said the review identified opportunities for streamlining management and operations without having any significant impact on business and product development milestones for the next 18 months.
“We have increased our focus on licensing commercialization partners for the co-development and distribution of products,” Mr Martin said. “Hiqcell, Kvax and our stem cell secretions cream are all at the stage where they can be commercialized and we are currently engaged with a number of parties about the distribution of these products.”
“We are also in discussions with potential partners about the licensing, development and distribution of our allogeneic stem cell products Cryoshot and Progenza,” Mr Martin said.
“The cost reductions are a result of the completion of various product development and manufacturing costs and a reduction in headcount,” Mr Martin said.
Mr Martin said the company had completed an expensive phase in the development of its products, with the Kvax vaccine manufacturing process completed and transferred to US manufacturing partner Hennessey and the manufacture process for canine Cryoshot transferred to US Manufacturing partner Lonza and undergoing final scale-up.
“Product manufacture and pre-clinical safety studies are near completion for Progenza in readiness for the first-in-man safety trial,” Mr Martin said.
Regeneus said that the measures and cost reductions meant that the company was on-track to meet its reduced quarterly cash burn target of $1.7 million, giving the company an expected two year cash runway.
Regeneus was up half a cent or 3.45 percent to 15 cents.

ANALYTICA

Analytica says its Pericoach intra-vaginal pelvic floor muscle diagnostic is available for direct purchase from its website.
Analytica said the device evaluated activity in pelvic floor muscles, transmitted to a smart-phone and uploaded and accessed by physicians through an internet 'cloud' based portal.
The company said that the Pericoach was designed to help women regularly follow doctor-recommended treatment for urinary incontinence, a problem facing up to three million women in Australia, particularly after childbirth or menopause.
Analytica said that the Pericoach would be available directly to women, clinicians and physiotherapists through its website: www.pericoach.com.
Analytica chief executive officer Geoff Daly said the launch was the culmination of four and a half years of development, testing and consultation with the clinical advisory board that includes specialists in urogynaecology, gynaecology and pelvic physiotherapy.
The company said the Pericoach would be available initially in Australia and New Zealand, with units shipped to accredited pelvic floor exercise specialists allowing women to purchase a device and subscription directly at the clinic following a consultation.
Analytica said that a Federal Government program was available to reimburse the cost of associated health professionals treating urinary incontinence through the team care plan.
The company said it expected to launch Pericoach in the US in 2015, where sales of incontinence pads were more than $5 billion annually.
Analytica said that Pericoach had been granted the CE-mark in the EU, with plans for a launch by April 2015.
Analytica was up 0.2 cents or 7.4 percent to 2.9 cents with 1.2 million shares traded.

AVEXA

Avexa says it has a partly underwritten share plan to raise funds to progress its Apricitabine or ATC for HIV and other programs and for working capital.
Avexa said that major shareholder Jonathan Lim had underwritten the share plan to $250,000, should there be a shortfall in applications below $500,000.
The company said that the new shares would cost the lower of 1.5 cents or the five-day volume weighted average price to the date the offer closed.
Avexa said that the record date was November 21, the offer would open on December 1 and close on December 23, 2014.
Avexa fell 0.3 cents or 16.7 percent to 1.5 cents with 1.7 million shares traded.

ONCOSIL MEDICAL

Oncosil says that incoming chief executive officer Daniel Kenny, will receive 12,000,000 employee loan shares vesting over three years, subject to performance hurdles.
Oncosil said that 12,000,000 employee loan shares issued to Dr Neil Frazer would be cancelled.
Earlier this month, Oncosil said that Mr Kenny would replace Dr Frazer as chief executive officer, effective from January 5, 2015 and Dr Frazer would step down from his position on the company's board, effective from November 28, 2014 and remain in a senior scientific and/or senior medical role (BD: Nov 11, 2014).
The company said the tranches of Mr Kenny's loan shares would vest on total shareholder returns of 175 percent; total shareholder returns of 250 percent; US approval for the Oncosil device; and attainment of three years of service.
Oncosil fell half a cent or five percent to 9.5 cents.

SUDA

The Bank of America Corp and related bodies have reduced their substantial shareholding in Suda from 77,806,856 shares (7.95%) to 50,859,856 shares (5.17%).

The Bank of America said it had “returned” the shares.

In July, the Charlotte, North Carolina-based Bank of America substantial shareholder notice said that the Sydney-based Merrill Lynch (Australia) Futures and London-based Merrill Lynch International were the holders of the shares as beneficial owner and as the borrower of securities in a prime brokerage agreement, respectively (BD: Jul 22, 2014).

Suda was unchanged at 6.7 cents with 1.1 million shares traded.