Biotech Daily

Thursday August 19, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH FLAT: CATHRX UP 13%; OPTISCAN DOWN 8%**

*** FEDERAL ELECTION 2010 EDITORIAL: NEPOTISM OUR BEST HOPE**

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MARKET REPORT

The Australian stock market edged up 0.09 percent on Thursday August 19, 2010 with the S&P ASX 200 up 4.1 points to 4479.0 points.

Twelve of the Biotech Daily Top 40 stocks were up, 10 fell, 14 traded unchanged and four were untraded.

Cathrx was best, up two cents or 13.3 percent to 17 cents with 53,000 shares traded, followed by Virax up 10.7 percent to 3.1 cents with 769,667 shares traded. Sunshine Heart climbed 9.7 percent; Pharmaxis was up four percent; Bionomics was up 3.3 percent; Clinuvel, Psivida and Tissue Therapies rose more than two percent; with Acrux, Impedimed and Sirtex up one percent or more.

Optiscan led the falls, down 0.4 cents or 8.2 percent to 4.5 cents with 557,126 shares traded. Biota, Novogen, Patrys and Viralytics lost more than three percent; Phylogica and QRX shed more than two percent; with Prima and Universal Biosensors down more than one percent.

FEDERAL ELECTION 2010 EDITORIAL

There is much at stake for biotechnology in this Federal Election and it is with some reluctance that Biotech Daily casts aside regrets over past decisions and “moves forward” to evaluate which major political parties are good or bad for this industry.

The baggage of Lindsay Tanner and Kim Carr’s savage cuts to our sector has to be weighed as a negative for Labor.

The Howard Government’s building on the Hawke/Keating Commercial Ready initiative is a plus for the Coalition.

But that is not what is at stake on Saturday.

As truly pathetic as Commercialisation Australia’s $80 million a year compares to world best practice (Israel’s $US350 million a year for one third the population), it exists; and is said to be complementary to the 45 percent research and development tax credit - which the industry applauds overwhelmingly – primarily because it is quite literally better than nothing, but also because it is better than the existing 125 percent tax rebate.

Labor’s few promises for our sector are common to all industries and include pushing the tax credit Bill through the Senate, effective from July 1, 2010, along with providing a $5000 tax break on equipment and creating a National Register of Business Names.

The Coalition has promised to retain the existing tax rebate system and delay any research and development tax credit system, indefinitely.

This Liberal Party has retreated from John Howard’s vote-buying economic policies – tax cuts for families to have more children and vote Liberal – and is promising smaller Government with little spending and plenty of savings.

Labor claims it has increased research and science spending by 34 percent and while biotechnology hasn’t seen any of that, we will eventually reap the benefit of better funding for science education at high schools and universities. The Government may be exaggerating, but there has been significant new spending on science under Labor.

Unsurprisingly, the Greens policies focus on environmental issues, but the party has long supported key innovation technologies from alternative energy generation to waste disposal and information technology.

Last week we published the Greens proposals on increased spending on research and science, but it is directed at public institutions and there is nothing specific on commercialization.

The Greens are believed to be supportive of the R&D Tax Credit, but have been unable to commit to it.

The Coalition policies were released very late in the campaign and contain just one clear positive and a series of negatives for biotechnology.

The positive is the reinstatement of an international science linkage program worth $23 million over four years, but the negatives include a commitment to abolish the R&D tax credit scheme and of significant concern is the initiative to “stop Labor’s ‘advocacy science’”.

There is serious disquiet that the Coalition is again questioning the science of climate change and laying the ground for further vetoes over particular research such as reproductive and stem cell technologies.

Money sensibly saved by a Coalition Government axing commercialization funds to the clothing, textiles, footwear and the automotive industries, unfortunately will not go to innovation, but directly into general revenue “to reduce debt”.

Finally, the question of the National Broadband Network is most relevant to biotechnology.

Our sector is hugely exposed to the vagaries of the internet, with state-of-the-art, web-based, clinical trials and intelligent heart monitoring systems to name but two technologies to gain from faster speed and increased bandwidth.

Tony Abbott’s claimed savings by going band-aid rather than suture is what financiers would call “under-capitalization”. “We’ll buy the cheap unusable one first and see how we go” is a guarantee to go nowhere.

Biotech Daily believes the 45 percent research and development tax credit is a clear decision-maker for this election and the clever knitting of rural and regional tele-health with the National Broadband Network is a strong second argument.

The Coalition has opened a can of worms with its proposals on ‘Advocacy Science’. It has a very poor record in this regard.

The choice comes down to a Labor Party that claims it supports the funding and advancement of science and technology, but has instead cut grants to our sector; against a Coalition that has made much of its desire to curtail public expenditure and is uncomfortable with many aspects of science, from opposition to some reproductive technologies and stem cell research, to denial of climate change and a desire to unwind the National Broadband Network.

Finally, Prime Minister Julia Gillard said in her election campaign speech this week, that her niece Dr Jenna Malone has a PhD in biotechnology.

Given Prime Minister Julia Gillard’s stated desire to create jobs for workers, biotechnology’s best hope is for a little traditional Labor Party nepotism and a few more jobs for the girls (and boys).

David Langsam
Editor

LIBERAL NATIONAL COALITION

The Liberal National Coalition policies for innovation, industry, science and research were announced yesterday afternoon, offering little new money to biotechnology.

The "Coalition's Plan for Real Action" policies are critical of Labor's spending on the textile footwear and clothing industry and its support for the motor vehicle industry.

The Coalition says it would scrap the 45 percent research and development tax credit scheme and retain the existing tax rebate system.

The Coalition policy says it will "stop Labor's 'advocacy science'".

An adviser to Coalition innovation spokeswoman Sophie Mirabella told Biotech Daily that the Coalition was "not seeking to politicize science whatsoever".

"We want scientists to be free to speak on their areas of expertise free from government interference," the adviser said.

He said there was concern that Innovation Minister Senator Kim Carr required all science documents to be approved by his office and that the Chief Scientist had rejected the concept of peer-reviewed articles questioning the science of climate change.

The Coalition said it would adopt a charter in consultation with the science community to ensure that scientific activities funded by the public purse were objective, independent and apolitical.

Much of the document is critical of the Labor Government saying it had commissioned multiple reviews, but failed to take action in response to their recommendations.

"Labor said it wanted to stop big claims on Australian R&D tax incentives by successful companies and railed against anyone who disagreed - and then immediately handed a cheque of $30 million to the biopharmaceutical giant CSL for such activity without even batting an eyelid," the Coalition said.

"In government, Labor has even attempted to muzzle and vilify scientists who have dared to criticize its policies," the document said.

Many policies relate to cost-cutting and further reviews. The Coalition said lowering the Corporate Tax rate to 28.5 percent, opposing a carbon tax and abolishing Labor's mining tax would deliver major benefits to Australian businesses.

The Coalition will cut $278 million from the Green Car Innovation Fund.

The policy document said the Department of Innovation, Industry, Science and Research had three divisions working on small business and under the Coalition the bodies and programs would be administered by 'Business Assist' in a fee-for-service basis.

The Coalition said it would "retain the existing R&D Tax Concession system … until at least July 1, 2011, but would consider future improvements such as the possible transition to tax credits".

The Coalition said it would review the effectiveness of Commercialisation Australia to provide better support for commercialization but there was no increase in grant allocation.

The document said a Coalition Government would "enhance Australia's venture capital market … [and] review the Innovation Investment Fund to assess its effectiveness".

The Coalition would support increased public awareness of Australian science, extending the Science Connections Program and provide $16.7 million over three years.

A Coalition Government would provide $23 million for a new International Science Initiative to support Australia's bilateral and multilateral science relationships.

The Coalition would consider changing the structure of the Office of the Chief Scientist to a statutory authority.

The Coalitions said it would spend $11.4 million over three years on a Research Training Scheme to avoid "a significant decline in the number of high-quality research graduates".

The final Coalition policy was to work with the Australian Bureau of Statistics to better measure the impacts of innovation-related policies.

CHEMEQ TECHNOLOGIES

In the first announcement to the ASX regarding Chemeq since July 2009, the company's administrators said it had a collaboration with Eli Lilly's animal health division, Elanco.
The administrators Ferrier Hodgson published a media release from the Perth-based Chemeq saying the research and commercialization agreement was a collaboration using Chemeq's polymeric antimicrobial technology.
Chemeq said it would receive research fees, milestone payments and revenues on any product developed.
Chemeq commercial vice-president Bill McHenry said the technology was developed "around 10 years ago [and] it has taken some time to find the right partner to deliver the technology to the world".
The company said the collaboration was "further demonstration of Chemeq Technologies' strong and successful partnership model".
The company said it also had a partnership with France's Arkema to manufacture the technology.
Chemeq tumbled from $8.00 a share in June 2003 to 8.3 cents by May 2007.
In May 2007 the convertible note holders who had injected about $60 million into the company demanded a return on their investments and the company was suspended from the ASX following the appointment of administrators (BD: May 30; Jun 1, 2007).
A history of the company is included in a Biotech Daily interview with then chief executive officer David Williams at: http://www.biotechdaily.com.au/pages/ceo-interviews.php.
Mr McHenry told Biotech Daily today that the convertible note holders had provided "a lot of support" to Chemeq.
"They've stuck with the business all the way," Mr McHenry said.
He said that although the first deal was with Elanco for animal health products, Chemeq "wanted to broaden the target for the anti-microbial market".
He said the company was investigating potential uses in cosmetics and industrial uses as well as in human pharmaceuticals.
"That really does change the mix," Mr McHenry said.
Chemeq remains in a suspension at 8.3 cents.

CSL

CSL says that its Fluvax influenza vaccine has been restricted in Europe and the US for paediatric use.
Fluvax has been the focus of concern over paediatric febrile convulsions and the Australian chief medical officer Prof Jim Bishop said CSL's seasonal influenza vaccine should not be used on children under that age of five years (BD: Jun 30, 2010).
CSL's head of communication Sharon McHale told Biotech Daily at that time that there was a nine in 1,000 incidence of febrile convulsions associated with Fluvax, compared to the more usual one in 1,000 rate.
Today Ms McHale told Biotech Daily that the European Medicines Agency had restricted the vaccine to children aged five years and older, while the US regulator had advised it not be used in children under the age of nine years.
Ms McHale said the vaccine was intended for children aged six months and older.
Ms McHale said that paediatric febrile convulsions were a serious concern to CSL, but the reduction in potential market size was not material.
CSL fell 10 cents or 0.3 percent to $31.80 with 5.2 million shares traded.

SIRTEX MEDICAL

Sirtex says two European studies have reconfirmed previous studies that SIR-Spheres microspheres were an effective option for patients with inoperable liver cancer.

Sirtex said the results of a randomized, controlled, 46-patient Belgian trial published in the Journal of Clinical Oncology showed that in patients with liver metastases from colorectal cancer who had failed all available standard-of-care chemotherapy, SIR-Spheres microspheres more than doubled the time to the progression of colorectal liver metastases (the primary endpoint of the study) from a median of 2.1 months in patients receiving chemotherapy alone to 5.5 months in patients receiving SIR-Spheres microspheres plus chemotherapy (hazard ratio 0.38; p=0.003).

The company said the Belgian study led by Brussels' Institut Jules Bordet's Dr Alain Hendlisz showed SIR-Spheres significantly extended the time to progression of disease anywhere in the body, from 2.1 months in the chemotherapy control arm to 4.5 months in patients in the combination arm (hazard ratio 0.51; p=0.03), as well as significantly increasing disease control, from 35 percent to 85 percent respectively (p=0.001).

Sirtex said the trial included a cross-over design for patients in the control arm following failure of chemotherapy alone. All patients in the control arm were reassessed for suitability for SIR-Spheres, with 43 percent of patients receiving selective internal radiation therapy (SIRT).

Median survival was increased from 7.3 months in the chemotherapy control arm to 10 months in the SIR-Spheres plus chemotherapy arm.

The investigators said that SIR-Spheres should be considered as a valid therapeutic option for patients with chemotherapy-refractory liver-limited metastatic colorectal cancer.

Sirtex said that at the same time, the results of a 50-patient, independent, multi-centre, Italian study published in the British Journal of Cancer showed SIR-Spheres microspheres produced a significant and meaningful response in patients with advanced inoperable liver tumors who had failed all available chemotherapy treatments.

Sirtex said the Italian study led by Rome's Regina Elena National Cancer Institute's Prof Maurizio Cosimelli was the first single-arm, prospective clinical trial of SIR-Spheres in the salvage therapy of patients with metastatic colorectal cancer and who had been heavily pre-treated with chemotherapy.

Sirtex said the results showed an overall response rate of 24 percent, which met the trial's pre-determined criteria for significance, plus stable disease reported in a further 24 percent of patients.

In two patients, the tumors shrank sufficiently to permit surgeons to plan potentially curative surgery. The median overall survival for the trial was 12.6 months.

Patients who responded to SIR-Spheres or had stable disease experienced a significantly longer median survival compared to non-responders (16 months versus 8 months; p=0.0006), with 40 percent of responders remaining alive at two years compared to none of the non-responders.

The investigators concluded that patients with liver-only or liver-dominant colorectal cancer metastases who had failed chemotherapy and who remained fit should be considered for radio-embolization, which highlights the potential for SIR-Spheres to be used to treat a greater number of patients than at present.

Sirtex chief executive officer Gilman Wong said the two studies provided "further clear evidence that SIR-Spheres microspheres afford improved clinical benefits in a patient population with limited treatment options available".

"The Belgian study is now the third independent, randomized, controlled trial using SIR-Spheres microspheres to meet its primary end point," Mr Wong said.

Sirtex was up five cents or one percent to $5.05.

CELLMID

Cellmid says that a mouse model trial of its monoclonal antibodies, CDY91 and CDY92, for multiple sclerosis has shown a decrease in disease severity.

Cellmid chief executive officer Maria Halasz told Biotech Daily the two antibodies were also being trialed for rheumatoid arthritis but results were not expected for at least six months.

The company said that the testing was conducted independently by the Swiss-based Preclin contract research organization, which had specialist expertise in autoimmune diseases.

Cellmid said that both CDY91 and CDY92 antibodies decreased disease severity in the multiple sclerosis model.

The company said that treatment with the CDY91 antibody significantly reduced inflammatory cell infiltration of the spinal cord indicating a disease modulating effect, demonstrating potential application in other inflammatory conditions.

Cellmid said that in addition to its anti-inflammatory effect, CDY91 has also significantly increased the number of regulatory T cells in the periphery.

The company said that regulatory T cells were key immune cells responsible for controlling autoimmunity.

The greater the regulatory T cells numbers, the less likely that autoimmunity could develop, the company said.

Cellmid said that cell-based assays have been completed to further elucidate the antibodies' effect on the development of inflammatory and autoimmune diseases with the view to identify the best disease indication for their use.

Cellmid's head of product development Darren Jones said the findings were encouraging.

"Previous studies using mice without the ability to produce midkine clearly demonstrated that midkine can drive multiple sclerosis like disease by increasing inflammation and suppressing [regulatory T cells]," Mr Jones said.

Cellmid said the studies confirmed midkine's dual role in inflammatory and autoimmune disease modulation and showed that antibodies targeting midkine might be important in reducing severity of the symptoms through these mechanisms.

"Cellmid deliberately sought out an independent party to rigorously test the two antibody candidates, rather than conduct these studies in-house," Ms Halasz said.

"This approach ensures total objectivity, and we can now confidently progress our programs based on these results," Ms Halasz said.

Cellmid said it would continue pre-clinical studies on CDY91 and CDY92 and conduct further testing on a number of its other proprietary anti-midkine antibodies.

Cellmid said it had more than 100 monoclonal antibodies to midkine and a large portfolio of patents for their application in the treatment of inflammation, autoimmunity, vascular plaque formation and adhesion related diseases such as endometriosis.

Cellmid was unchanged at 2.2 cents with 2.5 million shares traded.

ITL

ITL has requested a trading halt pending an announcement relating to "a restructure of the board of directors and senior management".

Trading will resume on August 23, 2010 or on an earlier announcement.

ITL traded at six cents.

AUSTRALIAN MUSEUM EUREKA PRIZES

Biotechnology and medical research have shared part of the $190,000 Australian Museum Eureka prizes for 2010 with individual prizes each worth $10,000.

National Health and Medical Research Council biomedical fellow and principal investigator at the Australian National University's Research School of Biology Dr Rowena Martin has won the inaugural Macquarie University Eureka prize for early career research for her work on chloroquine-resistant malaria parasites.

In a media release, the director of the Australian Museum Frank Howarth said that malaria infected up to 500 million people a year, killing up to three million people, mostly children younger than five years of age living in the poorest nations on earth.

"Dr Rowena Martin has offered a way forward in malaria treatment through her excellent research and breadth of technical skills, rare in such a young scientist just 35 years of age," Mr Howarth said.

The Australian Museum said chloroquine killed malaria parasites by interfering with the digestion of their human host's red blood cells with the drug accumulating in a digestive compartment of the parasite until it reaches toxic concentrations.

In chloroquine-resistant parasites, the drug is unable to accumulate due to mutations in a protein called the chloroquine-resistance transporter and so never reaches the level of concentration required to kill the parasite.

Dr Martin has shown how the mutant protein protects the parasite from the drug's toxic effects, the Museum said.

Dr Martin has shown that the compound verapamil, blocks the mutant protein from transporting chloroquine from the digestive compartment, allowing the drug to reach the toxic levels it does in non-resistant parasites.

Her work has opened up two possible paths to future malaria treatment: the development of compounds, such as verapamil, to be used in combination with chloroquine to render the parasite once again susceptible to the drug; or the development of new drugs that act like chloroquine but bypass the resistance mechanism, the Museum said.

The Museum said the director of the Lowy Cancer Research Centre at the University of New South Wales Prof Philip Hogg had won the 2010 Industry & Investment New South Wales Eureka Prize for Medical Research Translation.

The Museum said the award recognized Prof Hogg's work in monitoring real-time cell death during chemotherapy.

"The anti-cancer drugs developed as a result of Prof Hogg's research have the advantage of being effective against every type of tumor because all solid tumors rely on blood vessels to thrive," Mr Howarth said.

"There are also potential applications of this research in treating other diseases where abnormal formation of new blood vessels plays a central role, such as macular degeneration that causes blindness," Mr Howarth said.

The Museum said that a first-generation molecule which targeted the cells that make new blood vessels in tumors was in trials involving 21 adults with solid tumors and there was preliminary evidence that it has inhibited the cancer without causing toxic side-effects.

A second-generation compound which targets both the tumor blood vessels and the tumor cells will go into trial on patients with advanced solid tumors at the Prince of Wales Hospital in Sydney later this year.

Prof Hogg and his team are also developing third and fourth-generation compounds that can be taken as a pill and the University of New South Wales owned Cystemix had been formed to manage the commercial development of the compounds.

PRIMA BIOMED

Prima has appointed Dr Sharron Gargosky as senior vice-president for the CVac clinical programs.

Prima said Dr Gargosky had 18 years experience in the biotechnology and pharmaceutical industries and had worked in senior positions for three different companies which have successfully received US Food and Drug Administration approval for orphan drugs.

The company said Dr Gargosky would be based in the US and would be a senior member of the executive team.

Prior to joining Prima, Dr Gargosky was a member of ILMU Consulting providing project management and operational expertise for pharmaceutical drug and biologic development.

Prima said Dr Gargosky was formerly chief scientific officer at Pulse Health in Portland and prior to that chief scientific officer at Hyperion Therapeutics in San Francisco.

Dr Gargosky has a postdoctoral fellowship in paediatric endocrinology from Stanford University in California, a Ph D in biochemistry from University of Adelaide and a Bachelor of Science from the University of Adelaide.

Prima fell 0.1 cents or 1.1 percent to nine cents with 1.4 million shares traded.

STIRLING PRODUCTS

Stirling has appointed Alan Payne as group chief executive officer and business development manager responsible for sales and development of its Telemedcare products.

Stirling said Mr Payne was an accountant with extensive business development experience that included more than 20 years in healthcare, technology and capital markets.

Stirling was unchanged at 1.3 cents with 6.9 million shares traded.