Biotech Daily

Friday January 30, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: LABTECH UP 20%, BIONOMICS DOWN 14%**

*** FEDERAL REPORT: 'DRUGS 2nd LARGEST MANUFACTURING EXPORTER' - INDUSTRY ENDANGERED BY INERTIA**

*** EDITORIAL: A ONCE IN AN ECONOMIC LIFETIME OPPORTUNITY**

*** BIOTA EARNS UP TO $18m FROM UK RELENZA STOCKPILE ORDER**

*** CE MARK FOR HEARTWARE'S PUMP; EUROPEAN SALES BEGIN**

*** AVITA H1 INCOME UP 672% TO $1.3m**

*** STARPHARMA EARNS $3m, HAS $6m CASH**

*** SECOND TISSUE THERAPIES' SOUTH AFRICAN PATENT GRANTED**

*** TYRIAN CUTS STAFF; APPOINTS HEAD OF DEVELOPMENT, REGULATION**

*** MEDICAL THERAPIES HAS $183k CASH; JUGGLING FUNDING OPTIONS**

*** COMPANIES WITH LESS THAN TWO QUARTERS CASH**

*** ANTEO APPOINTS DR GEOFFREY CUMMING CEO; STARTS ON $250k**

*** INCITIVE APPOINTS CYGNET CAPITAL'S ERIC DE MORI DIRECTOR**

MARKET REPORT

The Australian stock market climbed 0.41 percent on Friday January 30, 2009 with the S&P ASX 200 up 14.5 points to 3,540.7 points. Eight of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and 12 were untraded.

Labtech was best, up two cents or 20.0 percent to 12 cents, followed by Heartware up eight cents or 13.33 percent to 68 cents, both on small volumes and Biota up 4.5 cents or 10.23 percent to 48.5 cents with 1.5 million shares traded. Impedimed and Sunshine Heart climbed more than nine percent; Novogen was up 5.63 percent; CSL was up 3.96 percent; Clinuvel and Sirtex rose more than two percent; with Cochlear up 1.92 percent.

Bionomics led the falls, down three cents or 13.64 percent to 19 cents with 560,000 shares traded, followed by Tyrian down 12.5 percent to 3.5 cents with Chemgenex and Psivida both down 11.5 percent to 35.5 cents and $1.065, respectively. Ventracor fell 8.42 percent; Pharmaxis shed 6.57 percent; Acrux and Phosphagenics were down five percent or more; Polartechnics fell four percent; Arana, Mesoblast and Viralytics shed more than two percent; with Avexa down 1.43 percent.

FEDERAL GOVERNMENT

The Federal Minister for Innovation Senator Kim Carr released the Pharmaceuticals Industry Strategy Group report saying the pharmaceuticals industry is “Australia's second largest exporter of manufactured goods”.

“The pharmaceuticals industry is important to Australia,” Senator Carr said.

“Not only does it provide high-wage, high-skill jobs for 40,000 people, it is Australia's second largest exporter of manufactured goods and spends $860 million annually on research and development," Senator Carr said.

A Federal Government media release said the Group's recommendations aim to help secure the Australian pharmaceuticals industry's future through attracting investment in high value research and development, clinical trials and specialized manufacturing activity.

“The Government is committed to setting the right conditions to boost the growth of knowledge-intensive, globally integrated industries, like pharmaceuticals, that deliver economic and social benefits to the community,” Senator Carr said.

“In these challenging economic times the Government is addressing immediate priorities as well as focusing on longer term plans to secure productivity and jobs for the future,” Senator Carr said.

The media release said the report recommended: implementation of measures proposed by the Review of the National Innovation System; streamlining the regulatory and operating environment for clinical trials; and a co-investment scheme for strategic projects.

A copy of the report is available at www.innovation.gov.au/pisg.

The Pharmaceuticals Industry Strategy Group was co-chaired by CSL’s chief executive officer Dr Brian McNamee.

The report said in its executive summary that “Australia can have globally competitive and sustainable research and development, clinical trials and manufacturing sectors that make a positive and increasing economic and social contribution to Australia”.

The report said a viable and sustainable pharmaceuticals industry requires:

- predictable, timely and transparent regulatory and reimbursement systems that provide companies with a clear and streamlined path to market;
- an appropriate and balanced intellectual property regime;
- strong and effective capital markets that will fund high risk projects that have sufficient potential commercial returns;
- taxation arrangements that do not deter companies from investing in relatively high risk activities like research and development or complex, value adding pharmaceuticals manufacturing;
- an appropriately resourced tertiary education sector capable of producing high quality, job ready, science and medical research graduates; and
- a strong and effective collaboration between industry and academic research.

The Pharmaceuticals Industry Strategy Group said “many of these outcomes are best considered as part of, or in response to, other reviews that have been commissioned by the Australian Government”.

The Review of the National Innovation System (NIS Review), the Review of Australian Higher Education and the Review of Australia’s Tax System can all have a positive influence on the Australian pharmaceuticals industry, the group said.

“In the absence of any Government intervention, the Australian pharmaceuticals industry is likely to decline as global rationalization trends continue,” the report said.

“This is likely to undermine the ongoing viability of most pharmaceuticals manufacturing operations in Australia and threaten to reduce Australia’s pharmaceuticals manufacturing capacity,” the Pharmaceuticals Industry Strategy Group said.

BIOTECH DAILY EDITORIAL

There is no point subsidizing the dying industries of the 18th and 19th centuries whose boards and management failed to retain any of their past obscene profits for a rainy – or drought-ravaged – day.

This recession and the world-wide public commitment to Keynesian pump-priming is a once in a lifetime opportunity to reshape the Australian economy into the world leader it should be, comparable to Sweden, Denmark and Israel.

The two obvious places to put our taxes, tax-breaks and incentives are the pro-environment industries and biotechnology. We are the globally acknowledged way of the future, so it is time the Federal Government and to a lesser extent the State Governments got used to the inevitable and helped rather than hindered.

On January 27, 2009, the promising Perth-based Biopharmica announced that Diagnostic Array Systems had completed its Bactrak project - a diagnostic genetic microarray for the identification of microbial pathogens causing a range of lung diseases.

Biopharmica is the majority owner of the Melbourne-based Diagnostic Array Systems, a joint venture with RMIT University.

The company also announced that partly due to the Federal Labor Government's axing of the Commercial Ready Grant scheme without a replacement, it had been forced to make its chief executive officer Dr Peter King redundant and directors would be taking their pay in shares rather than cash – not necessarily a bad thing.

What is necessarily a bad thing is the Labor Party mind-set that subsidies only go to the biggest industries with the greatest political clout, including the welfare industry.

It is shockingly short-sighted that in its first 12 months in office – the only time when it can effect change – the Rudd Labor Government has done nothing to change the economy and underpin industries, not of the future but of the here and now.

The Federal Government needs to rethink its policies on energy, transport and industry and make decisions for the 21st and 22nd centuries not the Satanic Mills of the 18th century nor the Dickensian 19th century.

Israel, with 7 million people, has a technology sector way in advance of our own. Why? How? It is not a difference in population or demographics; we are both clever, well-educated countries – except Australia is not constantly at war – it is because the Israeli Government has used massive subsidies to attract the best and brightest, despite the neighborhood conflict. And we can't do the same, despite our beaches, tennis and football. And English is our first, not second language. Israel provides grants that don't need to be repaid until the company is in profit. It fosters innovation and commercialization.

On January 26, 2009, Norway provided $640 million for biotechnology as part of a $4.3 billion stimulus package. It was reported the measure would prevent half of the company's biotechnology groups from going bankrupt.

The Federal Government is rearranging the deck chairs as the automotive industry's Titanic sinks slowly into the depths, instead of providing just a couple of oars to the survivors to create the new future.

Biotechnology is roughly the same size as the automotive sector, possibly bigger when all the biotechnology salaries in all the universities and institutions are compared to all the salaries in all the mechanical workshops.

The value in export sales is comparable and although more appears to be spent on cars than drugs, devices and diagnostics, that figure has proved elusive. Ford and GMH don't have to tell us their income, profit or staffing levels because they are private subsidiaries of foreign-owned corporations.

They are equivalent to the Australian operations of Glaxosmithkline, Merck Sharp and Dome and Pfizer, but the car manufacturers, along with the mining companies, have squandered decades of enormous profits.

Where are the Australian automotive equivalents of CSL, Cochlear, Resmed, Pharmaxis, Biota, Sirtex, Cellestis and Ventracor and the other 60 or so leading listed biotechs? Apart from Repco, are there any?

I'll leave the pro-environment industries to fight their own case, but it should be noted that when I wrote to the then head of BHP Paul Anderson to ask why it was that we could import wind turbines with their 30m prefabricated steel towers more cheaply from Denmark rather than build them in Australia, he investigated the steel division and sold it. I'm not sure the two events were that directly connected, but they may as well have been.

Selling coal and iron to countries who no longer want them, encouraging uranium mining for a powerful lobby, subsidizing ancient and dying industries like the infernal combustion engine which loses 90% of its power before it hits the wheels is a disgrace. Moreso when the path to the future is clear and ignored.

It is time for Labor to dump its dinosaurs, lemmings and dodos and realign the Australian economy for the future.

It appears that the Federal Labor Government has contributed to rising unemployment in the two sectors that should be creating wealth for the next two centuries; the biotechnology and pro-environment industries.

Sitting in Melbourne's 43°C heat with my coal-fired, so-called 'base-load' electricity shut down and unable to publish Biotech Daily because of it, I wish I had solar panels on my roof to give the miniscule power required for the modem to send this edition on time.

Prime Minister Kevin Rudd, Senator Carr, Finance Minister Lindsay Tanner and Federal Treasurer Wayne Swan need to go no further than their Labor colleagues Victoria's Premier John Brumby and former Queensland Premier Peter Beattie to reevaluate their policies.

David Langsam
Editor

BIOTA

Biota says the UK Department of Health has ordered 10.6 million treatment courses of Relenza (zanamivir) from its Relenza partner Glaxosmithkline.

Biota said the UK was the second European country with France to hold a treatment stockpile sufficient to treat 50 percent of their population.

The company said the UK Government decision to buy zanamivir was consistent with recommendations published by the European Medicines Agency and the UK's Royal Society and Academy of Medical Sciences, which separately recommended the diversification of antiviral stockpiles to include zanamivir in addition to Tamiflu (oseltamivir), especially with the emerging evidence of resistance.

Biota said financial terms had not been disclosed, but it estimated that the completed contract might represent a royalty income of up to $18 million.

In its media release Glaxosmithkline said the UK Department of Health had doubled its stockpile to cover approximately half the British population; enough to treat all of those who fall ill with pandemic influenza should the clinical attack rate reach the UK Government's worst case planning scenario of 50 percent.

Zanamivir constitutes approximately a third of the UK's current antiviral stockpile.

Glaxosmithkline said the World Health Organization considered a new influenza pandemic "inevitable" but nobody can predict when and where it will emerge, who it will affect or how severe it will be.

Glaxosmithkline said it had invested significantly in expanding its global manufacturing and research capabilities in both vaccines and anti-virals and in planning for the continuity of critical business operations and processes in the event of a flu pandemic, in order to safeguard the continued supply of critical medicines.

Biota was up 4.5 cents or 10.23 percent at 48.5 cents with 1.5 million shares traded.

HEARTWARE

Heartware says it has Conformitée Européenne (CE) Mark approval for its Heartware Ventricular Assist System.

Receipt of the CE Mark enables Heartware to initiate commercial sales of the system throughout the European Union.

Heartware's submission for CE Mark was based on data from the first 25 patients to have been implanted in its international clinical trial.

Of the 25 patients, 23 (92 percent) survived to 180 days or to heart transplantation, the primary endpoint of the trial.

A total of 50 patients were enrolled in the trial and within this broader group, the survival rate has remained above 90 percent.

The clinical trial's principal investigator at the Medical University of Vienna, Dr Georg Wieselthaler, said his team "was the first to implant the Heartware device and our enthusiasm for this pump has grown during the trial".

Dr Wieselthaler said he expected the Heartware system "to play an important role in the future management of heart failure."

The principal investigator at Hannover Medical School, Dr Martin Strueber, said his team had implanted the Heartware device in 19 patients who had been supported by the system for an average of over 300 days each.

Heartware said it would focus on its existing trial sites and expand to targeted hospitals.

Heartware's left ventricular assist device is in a 150-patient US clinical trial for the bridge-to-transplant indication.

Heartware climbed eight cents or 13.33 percent to 68 cents.

AVITA MEDICAL

Avita says it received $529,488 from customers for the three months to December 31, 2008, up 639 percent over the $82,825 received in the same period of 2007.
Avita said receipts from customers for the six months to December 31, 2008 were $1,313,766, up 672 percent over receipts of $195,593 for the previous corresponding period.
The company said the revenue increase was due to the addition of the respiratory product line acquired in the merger with Visiomed Group and increased sales of Recell from the Clinical Cell Cultures part of the merger.
Avita said losses increased by $298,600 or 26 percent over the previous period due to one off costs associated with exit payments to former senior managers of Clinical Cell made redundant during the period; major revisions to the manufacturing processes, to be reflected in significantly improved margins in the future; the restructure of the company's quality system resulting in achievement of ISO certification; and increased expenses directed to focused sales and marketing efforts.
In its Appendix 4C quarterly statement Avita said its total operating and investing cash burn for the three months to December 31, 2008 was $1,721,436 with cash at the end of the quarter of $6,344,888.
Avita was up 1.2 cents or 19.05 percent to 7.5 cents.

STARPHARMA

Starpharma's revenue for the three months to December 31, 2008 was $3,048,000, described as royalty and licence income from development partners.
Starpharma said the funds included payments from SSL International and grant and contract payments from the US National Institutes of Health for Vivagel development costs.
In its Appendix 4c quarterly report Starpharma said its total operating and investing cash burn for the three months to December 31, 2008 was $792,000 and the company had $6,057,000 in cash.
Starpharma was unchanged at 17 cents.

TISSUE THERAPIES

South Africa has granted Tissue Therapies a patent entitled 'Skin Regeneration System'.
Tissue Therapies said the patent followed the earlier granting of the patent 'Growth Factor Complexes and Modulation of Cell Migration and Growth' by the Republic of South Africa Patent office in early 2007 and by the Intellectual Property Office of New Zealand in 2006.
The Vitrogro patent 'Growth Factor Complex' was granted in both Australia and New Zealand during 2005.
All claims in the Vitrogro patent 'Growth Factor Complex' have been granted by the US States Patent and Trademark Office (BD Jan 16, 2009).
Tissue Therapies chief executive officer Dr Steven Mercer said that applications to protect the family of Vitrogro patents had been lodged in the US, Canada, EU, Japan, China (including Hong Kong), South Korea, India, Australia, New Zealand and South Africa.
Trademark protection of Vitrogro has been sought in the same jurisdictions.
Tissue Therapies was up half a cent or 2.63 percent to 19.5 cents.

TYRIAN DIAGNOSTICS

Tyrian says it has completed “initiatives to align its assets and organizational structure with its business objectives”.

Tyrian said it had been “streamlining and refining its operations over the past 18 months” and this week the number of staff in the research and development and technology development areas had been reduced, in line with continued refocusing on diagnostics activities.

The company said Michelle Gow had been appointed head of product development and regulatory affairs to assist in bringing new products to marketable stage.

Ms Gow has worked in Australia, the US and South Africa and previously was director of corporate quality and regulatory affairs with Unilife.

At Tyrian, she will be responsible for transferring products onto the company’s Diagnostiq platform and co-ordinate the preparation of products for the market.

Tyrian said it reduced staff by 17 since June 2008, from 42 to 25, including the closure of its therapeutics business in Boston.

The company said this was “the end step in a process which began with the divestiture of the former technology business and non-core research programs to focus on developing and commercializing diagnostic products”.

The restructure, with other cost management initiatives, will reduce Tyrian’s ongoing gross operating expenditure by $250,000 a month from April 2009.

Tyrian chief executive officer Dr Jenny Harry said the company’s effort was “focused on completing our existing partnered products for commercialization and building our product pipeline to leverage our intellectual property position in point-of-need diagnostics”.

Tyrian fell half a cent or 12.5 percent to 3.5 cents.

MEDICAL THERAPIES

In its Appendix 4C quarterly report Medical Therapies said it that it had a total operating and investing cash burn of $309,000 for the three months to December 31, 2008 and cash at the end of the quarter of $183,000.

Medical Therapies said that following the balance date of December 31, 2008 the company received a research and development tax offset refund of $133,900 from the Australia Taxation Office.

The company said its operating cash outflow of $309,000 was a 29 percent drop compared with the previous quarter.

The reduction in spending meant that most research and development activities had been halted, but includes patent costs and has allowed the company to preserve the value of its Midkine related assets.

Medical Therapies said it was pursuing mergers and acquisitions to provide development capital.

Medical Therapies chief executive officer Maria Halasz said a $2m funding commitment from NS Capital was being pursued and there had been further confirmation of the intention to invest but the delay in funding was due to current market conditions.

Ms Halasz said the company had many balls in the air and was constantly in discussions to raise funds.

Medical Therapies has convertible notes on issue to the value of $1.1 million which matured on December 31, 2008.

The company said it was negotiating with note-holders to amend the terms of the notes to provide additional time to meet its obligations.

Medical Therapies was untraded at 2.5 cents.

COMPANIES WITH LESS THAN TWO QUARTERS CASH

Several biotechnology companies reported late today that they had less than two quarters cash as at December 31, 2008.

Some of the companies had explanations including fund-raising after the December 31, 2008 cut-off date but others provided no explanation.

Due to the number of companies reporting their Appendix 4c quarterly reports late in the afternoon or after the market closed, Biotech Daily urges readers to go the companies' documents before drawing any conclusions.

The companies posting Appendix 4C quarterly reports late toady which appear to have less than two quarters cash include IM Medical, Karmelsonix, Neuren, Norwood Abbey, Solagran, and Unilife.

ANTEO DIAGNOSTICS

Anteo Diagnostics (formerly Biolayer)has appointed Dr Geoffrey Cumming as chief executive officer replacing interim CEO Dr Joe Maeji.

with Dr Maeji resumes his role as Anteo's chief scientific officer.

Dr Cumming has more than 30 years experience in the biotechnology, medical and healthcare related markets in technical, commercialization, product development, merger and acquisition activities.

Dr Cumming has worked Roche Diagnostic Systems, Sienna Cancer Diagnostics and ICI Australia. He is a non-executive director of BMDi Tuta and Sienna Cancer Diagnostics.

He has a Bachelor of Applied Science, Bachelor of Science (Hons), a doctorate in Philosophy and a Masters of Business Administration.

Anteo said Dr Cumming would receive a salary package of $250,000 a year including statutory superannuation; annual leave of four weeks; a 12 month cash bonus incentive program linked to and payable on the achievement of value accretive key performance indicators; and a long term incentive component to be determined.

Anteo was untraded at one cent.

INCITIVE

Incitive has appointed Eric de Mori as a director.

Mr de Mori is the associate director of corporate finance for corporate advisory and stock broking firm Cygnet Capital and has more than five years investment banking and analyst experience covering both biotechnology and the resources sector.

Incitive said Mr de Mori had significant experience in the small capitalization sector of the ASX, specifically in project identification and review, deal structuring and capital raising.

Incitive was untraded at three cents.