Biotech Daily

Wednesday June 15, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTISCAN UP 4%, LIVING CELL DOWN 12%**

*** PSIVIDA'S NEW $158m PFIZER BIO-ERODIBLE EYE TREATMENT DEAL**

*** FURTHER DELAY FOR FEDERAL R&D TAX CREDIT**

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*** MAYNE REVIEW SAVES $3m A YEAR; SUBACAP ON-TRACK**

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*** OCH-ZIFF TAKES 21% OF BRAIN RESOURCE**

*** NEUREN 1-FOR-1 RIGHTS ISSUE TO RAISE UP TO $8m**

*** LANDON CLAY, EAST HILL TAKE 7% OF BIOTA**

*** CELL CARE TAKES 19.9% OF CRYOSITE**

*** STIRLING CLAIMS DEAL FOR DELTARAN FOR BRAIN DISEASES**

MARKET REPORT

The Australian stock market fell 0.4 percent on Wednesday June 15, 2011 with the S&P ASX 200 down 18.2 points to 4,566.8 points. Five of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and eight were untraded.

Optiscan was the best of the few, up 0.2 cents or four percent to 5.2 cents with 82,180 shares traded; followed by Phosphagenics up 3.7 percent; Mesoblast up 2.6 percent; Resmed up 1.05 percent; with Cellestis and Heartware up by less than one percent.

Living Cell led the falls, down one cent or 12.2 percent to 7.2 cents with 880,100 shares traded, followed by Antisense down 10 percent to 0.9 cents with 29.1 million shares traded. QRX lost 8.5 percent; Bioniche and Bionomics fell more than four percent; Genetic Technologies and Starpharma were down more than three percent; Phylogica and Viralytics shed more than two percent; with Alchemia, Biota, Clinuvel, Cochlear, CSL, Impedimed, Nanosonics, Prima and Tissue Therapies down one percent or more.

PSIVIDA

Psivida has signed a potential $157.8 million deal with Pfizer to develop its bio-erodible drug delivery implant for the treatment of glaucoma and ocular hypertension.

Psivida said it had amended and restated its April 2007 research and development agreement with Pfizer to focus solely on the development of a long-term, sustained-release implant to deliver latanoprost for patients with ocular hypertension and glaucoma.

In 2007, Psivida and Pfizer signed a potential $203 million collaborative research and licence agreement for Psivida's drug delivery technologies, including Medidur in ophthalmic applications (BD: Apr 4, 2007).

Psivida communications vice president Brian Leedman told Biotech Daily that his company separately licenced the Medidur technology to Alimera Sciences of Alpharetta, Georgia to carry the generic corticosteroid fluocinolone acetonide, which was then named Iluvien, specifically for diabetic macula oedema.

Today, Psivida said the implant to be developed under the new agreement with Pfizer was a bioerodible version of its Durasert technology system and was designed to be injected into the subconjunctival space of the eye.

Psivida said Pfizer would pay an upfront fee of $US2.3 million and, with technical assistance from Pfizer, Psivida would develop the glaucoma product candidate through phase II clinical trials.

Psivida said that at that point, Pfizer could exercise its option for an exclusive, worldwide license to develop and commercialize the product candidate in return for a $US20 million payment, double-digit royalty payments on any sales of the product and additional development, regulatory and sales performance milestone payments of up to $US146.5 million.

The company said that if Pfizer did not exercise its option, it would retain the right to develop and commercialize the glaucoma product on its own or with a partner.

As part of the amended agreement, Psivida regains all rights to its intellectual property in ophthalmic applications previously included in the original agreement other than that required for the latanoprost implant.

Psivida chief executive officer Dr Paul Ashton said the $US2.3 million payment was above the $US7.0 million in research and development support received from Pfizer under the 2007 partnership.

Pfizer senior vice-president Dr Yvonne Greenstreet said that latanoprost was the most commonly prescribed drug for reduction of intraocular pressure in the treatment of ocular hypertension and glaucoma.

"If successfully developed and approved by regulatory authorities, using Psivida's unique drug delivery technology to deliver latanoprost could play a significant role in addressing compliance issues associated with a daily eye drop regimen for the treatment of glaucoma," Dr Greenstreet said.

Separately, Psivida announced the start of a phase I/II dose-escalating study designed to assess the safety and efficacy of the latanoprost implant in patients with elevated intraocular pressure.

Mr Leedman said the device was based on the Durasert technology system, providing long-term, sustained release of latanoprost and broke down as a bio-erodible polymer.

The implant is designed to be administered by an eye care professional in a minimally invasive, outpatient procedure.

If successful, Psivida said it would proceed to a multi-center phase II trial and that trial would determine whether Pfizer would take over the development program.

Psivida was untraded at $3.90.

FEDERAL GOVERNMENT R&D TAX CREDIT

The Federal Government says its $1.8 billion research and development tax credit will not start as promised on July 1, 2010, but has been delayed by a further year.

A media release from Treasurer Wayne Swan and Innovation Minister Senator Kim Carr said the start date for the research and development tax credit would be July 1, 2011, compared to the original date of July 1, 2010 in the 2009 Budget (BD: May 13, 2009).

The Tax Laws Amendment (Research and Development) Bill 2010 and the Income Tax Rates Amendment (Research and Development) Bill 2010 were passed by the House of Representatives prior to the August 21, 2010 Federal Election, lapsed when because Parliament was prorogued, were passed again by the House after Parliament resumed and were expected to be introduced into the Senate in November last year, but the Government did not make time to debate the Bills (BD: Nov 23, 25, 26, 2010).

There has been speculation that rather than face defeat of the Bills with Senator Steve Fielding believed to oppose the tax credit proposals, the Government chose to wait until July 1, 2011 when the Greens would hold the balance of power in the Senate.

In today's media release the Government said it would introduce quarterly payments for small and medium businesses from January 1, 2014, and claimed the companies would "get their credit sooner, significantly improving their cash flow and incentive to invest".

It was not clear whether there would be annual payments before that date and a Government spokesperson did not respond to questions by the time of publication.

The Federal Government said the deferral of the start date had a negative impact of $310 million in 2011-'12 and a positive impact in 2012-'13 of $270 million.

The Government said the reintroduction "builds on Labor's policy reform agenda of the past four years and will be a major benefit for businesses that innovate and use [research and development] as a platform for future growth".

The Government said it welcomed "crossbench Senators announcing their support which means the parliamentary road-block put in place by the Coalition will finally be removed".

"The new and improved credit will target more funds to genuine [research and development] deserving of public support [which was] good news for industry and better value for taxpayers," the Government said.

The media release said the Bills would deliver a 45 percent refundable tax credit to companies with an aggregated turnover of less than $20 million and a 40 percent non-refundable offset to all others.

The Government said an advisory group would be established through the Innovation Australia Board to monitor the implementation and operation of the credit.

The Government said that through Ausindustry it would run an extensive education program to ensure firms are kept up to date.

AUSBIOTECH

Ausbiotech said it welcomes the announcement saying "the biotechnology community is today celebrating news that the much-needed research and development tax credit will be delivered imminently, providing a major boost for innovative biotechnology companies and spill-over benefits for the community from biotechnologies".

The industry body said start-up innovation companies would be "the big winners from the tax credit's 45 percent refundable component" and the legislation would also benefit large companies by reducing the cost of conducting eligible activities in Australia.

Ausbiotech chief executive officer Dr Anna Lavelle said the announcement was "the result of more than two years of advocating, consultation and working toward a good policy for innovation, however the work is not done yet".

Dr Lavelle said quarterly payments were preferable to the original annual payments.

BIOTECH DAILY EDITORIAL

While we join Ausbiotech in being grateful that the Bills will finally be reintroduced into the Senate and passed with the support of the Greens, the delays have robbed biotechnology companies of several years of funds.

The research and development tax credit Bills were part of a program with Commercialisation Australia to replace the Commercial Ready program and other Federal programs axed by Treasurer Wayne Swan and then Finance Minister Lindsay Tanner in the 2008 Budget (BD: May 14, 2008).

When introduced the tax credit Bills included a start date of July 1, 2010.

Having taken so much from the sector, there would be no harm in maintaining that start date with tax credit payments from the finalization of 2010-'11 tax accounts.

Instead, we must be grateful the Government has bothered to pursue the Bills, at all.

What is particularly chaffing, though, is that at the same time that biotechnology wins a small share of Commercialisation Australia's $80 million a year, Innovation Minister Senator Kim Carr gave General Motors Holden – a company that historically repatriated vast profits to its offshore owners - $40 million to develop a so-called 'greener Commodore'.

As Cochlear chief executive officer Dr Chris Roberts put it so well: "How many $30,000 Cochlear ear implants can you fit into a Boeing 747, compared to $30,000 Monaros?"

Let alone coal trucks.

MAYNE PHARMA GROUP

Mayne Pharma says it has found significant redundancies at its Salisbury South Australia production site and its European registration application for Subacap is on track.

Mayne said the Salisbury review identified "a number of redundant roles as well as other cost savings that will eliminate non-value added activity and refocus the business".

The company said the cost of the redundancies was expected to be about $1.1 million in 2010-'11 with on-going savings of about $2.9 million a year.

Mayne said it was in the review cycle of its European marketing application for Subacap, formerly known as Suba-itraconazole, an improved version of the existing drug itraconazole used to treat fungal infections.

The company said it would meet with the UK's Medicines and Healthcare products Regulatory Agency later this month to discuss any outstanding regulatory issues.

Mayne Pharma's chief executive officer Dr Roger Aston said the company was pleased with the feedback on the dossier provided to the Agency and believe it was in a position to provide responses to the outstanding issues and remained on track with previous expectations for the approval of Subacap by the end of 2011.

"In addition, we will also be meeting with the [US Food and Drug Administration] in August 2011 to receive guidance on further requirements for the US registration of Subacap," Dr Aston said.

Mayne said that sales of Doryx broad-spectrum tetracycline antibiotic tablets had been impacted by the repositioning of the Doryx portfolio in preparation for the introduction of new dosage forms and the continued and unprecedented strength of the Australian dollar.

The company said that FDA approval for new Doryx formulations had been deferred to give the FDA further time to complete their evaluation.

Mayne said it was confident that approval for the new Doryx tablets would be received in the near term and possibly prior to June 30, 2011.

Mayne fell 2.5 cents or 4.7 percent to 51 cents.

ANTISENSE THERAPEUTICS

Antisense says it has ethics approval for its phase I trial of the growth hormone receptor targeting drug ATL1103 for potential use in a range of disorders.
Antisense said the Nucleus Network would conduct a randomized, placebo-controlled, double-blind study of single ascending doses and multiple doses of ATL1103 to assess its safety, tolerability, pharmacokinetics and pharmacodynamics in healthy subjects at its unit co-located at the Austin Hospital, Heidelberg, Victoria.
Antisense said it was important for the study to obtain key data on the level of effect of ATL1103 on insulin-like growth factor 1 (IGF-I) levels in the blood.
The company said that reducing elevated levels of serum IGF-I to normal was the therapeutic endpoint in the treatment of the growth disorder acromegaly and reducing the effects of IGF-I has a potential role in the treatment of diabetic retinopathy, nephropathy and certain forms of cancer.
Antisense said that dosing was expected to commence on schedule by October 2011 once the Australian Therapeutic Goods Administration acknowledged receipt of the requisite documentation and subjects had been screened for eligibility.
The company said that both the single ascending dose and multiple dose stages of the trial were expected to be completed with the database lock by April, 2012.
Antisense fell 0.1 cents or 10 percent to 0.9 cents with 29.1 million shares traded.

BPH ENERGY, CORTICAL DYNAMICS

BPH Energy says Japan has granted investee company Cortical Dynamics “a key patent relating to its Brain Anaesthesia Response (BAR) monitoring unit”.
BPH said the patent was entitled ‘Method of Monitoring Brain Function’ and provided protection until January 14, 2024.
The company said Cortical had patents awarded in Australia, New Zealand and the US and had developed an extensive patent portfolio encapsulating the BAR monitor, providing patent protection across a number of key brain monitoring markets.
Cortical director David Breeze said, the grant of the Japanese patent was “a milestone for Cortical Dynamics and we are also very pleased to have the patent awarded within one of the largest [electroencephalogram] brain function monitoring markets in the world”.
Cortical Dynamics has an initial public offer underway for 10 million shares at 20 cents a share with attaching options and expects to listing on the ASX under the code CDZ on July 29, 2011 (BD: Jun 3, 2011).
BPH was unchanged at 3.5 cents.

CELLESTIS

Cellestis says the Supreme Court of Victoria has ordered the company to convene a shareholder meeting to consider the Qiagen scheme of arrangement (BD: Apr 4, 2011).
Cellestis said the scheme meeting would be held at the RACV Club, Level 17, 501 Bourke Street, Melbourne on July 20, 2011 at 1.30pm (AEST).
The company said a scheme booklet was expected to be sent to shareholders on June 20, 2011, following registration with the Australian Securities and Investments Commission.
Cellestis was up one cent or 0.3 percent to $3.35.

BRAIN RESOURCE

Brain Resource says the New York-based Och-Ziff Capital Management Group will take a 21 percent strategic position through $10,000,000 in convertible notes.
Brain Resource said Och-Ziff's Oz Management would be the investment manager of the subscribers Sculptor Finance Ireland and related parties.
Brain Resource chairman Dr Evian Gordon said the external validation and scale of the brain health market opportunities marked a significant milestone.
"Having an investor of this caliber has significant operational benefits for Brain Resource as it extends new large market opportunities," Dr Gordon said.
"Most importantly, we have found in Och-Ziff a partner that has aligned interests in capitalizing on the timeliness of the brain sector becoming mainstream," Dr Gordon said.
"This capital base provides us with the resources to significantly drive sales of our current scalable web products," Dr Gordon said.
"It also allows us to extend our web brain training platform direct to consumers," Dr Gordon said.
Brain Resource said that the bonds converted into shares at 40.5 cents per share, with a five year term and no coupon payable.
The company said that
Conversion equates to the issue would be in two tranches of $5,000,000 each with the second tranche subject to conditions precedent including approval by the subscribers of the appointment of a chief executive officer to lead the US subsidiary and business plan, along with Brain Resource shareholder approval.
The company said Dr Gordon and executive director Dan Segal together held 18 percent of the company and intended to vote the shares they hold or control in favor of the issue, in the absence of a superior proposal.
Brain Resource said that Spinite Pty Ltd was a 17 percent shareholder and would also vote in favor of the second tranche of convertible bonds.
Brain Resource was unchanged at 30 cents.

NEUREN PHARMACEUTICALS

Neuren hopes to raise up to $8 million through a renounceable one-for-one share rights issue at 1.3 cents a share.
Neuren said it had placed $2 million in May and June and the rights issue was to "to give eligible shareholders the opportunity to acquire new shares at the same price as the shares issued in those recent placements" (BD: May 4, Jun 6, 2011).
The company said the placements and rights issue would fund corporate overheads and operating costs for 2012 when it expected to complete its phase II trials of its neuro-protective compounds, NNZ-2566 and Motiva.
Neuren said the record date for the rights issue was June 27, 2011, the offer opened on June 29 and closed on July 14, 2011.
Neuren was unchanged at 1.7 cents with 6.6 million shares traded.

BIOTA HOLDINGS

Landon Clay, East Hill Holding Co and associates have increased their substantial shareholding in Biota from 11,138,837 shares (6.14%) to 12,874,055 shares (7.15%).
East Hill said the shares were bought at prices between $US1.17 and $US1.43 ($A1.095 to $A1.34) between April 14 and June 7, 2011.
Biota fell 1.5 cents or 1.4 percent to $1.055.

CRYOSITE

Cell Care Australia and related parties have become substantial shareholders in Cryosite with the acquisition of 9,297,381 shares or 19.93 percent.
The initial substantial shareholder notice said the shares were acquired for $929,251 or 10 cents a share.
The related parties include Cell care directors James Stuart Craig, Alastair Lucas and their related companies Bellwether Pty Ltd and Matsaroll Pty Ltd.
Cryosite and Cell Care are both involved at cord blood storage.
Cryosite was untraded at 9.5 cents.

STIRLING PRODUCTS

Stirling says that with Zodiac Capital it has a conditional agreement with the St Petersburg-based Cice Group to use a high density aerosol for the pulmonary delivery of deltaran.
Stirling said deltaran, which was also known as a delta sleep-inducing peptide, had been approved in Russia to treat brain damage, dementia and Alzheimer's disease.
The company said it would launch its Kidneyvital product at Pharmacy Expo 2011, at the Sydney Convention and Exhibition Centre at Darling Harbour, this weekend.
looks forward to a major increase in revenue through the coming financial year.
Stirling said it continued to search for a chief executive officer and hoped to raise GBP2 million to list on London's Alternative Investment Market.
Stirling was up 0.1 cents or 33.33 percent to 0.4 cents with 53. 7 million shares traded.