Biotech Daily

Wednesday February 11, 2015

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: GENETIC TECHNO UP 14%, PATRYS DOWN 17%**

*** FEDERAL GOVERNMENT CAPS R&D TAX INCENTIVE AT $100m**

*** AUSBIOTECH CONCERN OVER R&D TAX CHANGES**

*** CSL RECORD H1 REVENUE UP 6% TO $3.5b, PROFIT UP 7% TO $891m**

*** NOVOGEN LODGES FIRST SUPER-BENZOPYRAN PATENT**

*** CORRECTION: OTIFEX**

*** OPTISCAN PLEADS SCHULTZ TO ASX 31% QUERY**

*** SPINIFEX APPOINTS DR PETER SPARGO, DR CHRIS RICHARDSON**

*** SAFETY MEDICAL: MATTHEW MORGAN, FRANK PERTILE DIRECTORS**

MARKET REPORT

The Australian stock market fell 0.54 percent on Wednesday February 11, 2015 with the S&P ASX 200 down 31.5 points to 5,769.1 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and four were untraded.

Genetic Technologies was the best, up 0.4 cents or 13.8 percent to 3.3 cents with 31.7 million shares traded.

Medical Developments climbed 8.9 percent; Prana rose 7.5 percent; Cellmid was up 5.9 percent; Admedus, Compumedics and Nanosonics were up more than four percent; Biotron, IDT, Neuren and Osprey were up three percent or more; GI Dynamics, Oncosil and Tissue Therapies rose more than two percent; Impedimed was up 1.1 percent; with Benitec, Resmed and Sirtex up by less than one percent.

Patrys led the falls, down 0.2 cents or 16.7 percent to one cent with 11.7 million shares traded.

CSL lost 7.8 percent; Antisense fell 4.55 percent; Atcor, Optiscan and Starpharma were down more than three percent; Acrux and Mesoblast shed more than two percent; Anteo, Ellex and Pharmaxis lost one percent or more; with Cochlear and Psivida down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says the Tax Laws Amendment (Research and Development) Bill 2013, limits to $100 million the amount that can be claimed as a tax incentive.

A Federal Government media release said the Bill was passed by the Senate yesterday and will affect “fewer than 25 companies”.

The media release said the measure was initiated by former Treasurer Wayne Swan and the previous Labor government in the 2013-’14 Budget, but was not legislated.

The Government said that the research and development expenditure cap of $100 million “secures an improvement to the budget bottom line broadly equivalent to that of the original Labor measure contained in the Bill, which would have instead removed access to the research and development tax incentive for companies with aggregated assessable income of $20 billion or more”.

The Government said that the changes were “a fair and sensible outcome, providing a concession for small and medium sized companies which are typically more responsive to tax incentives for innovation while at the same time ensuring that important savings in the Budget are realized”.

A Federal Treasury official told Biotech Daily that companies spending more than $100 million a year on research and development would be eligible for the Federal Research and Development Tax Incentive up to the $100 million threshold, and money spent above that level could be claimed as a tax deduction at the corporate tax rate.

The Government media release said that the amendment would take effect from income years beginning on or after July 1, 2014.

AUSBIOTECH

Ausbiotech says that the Federal Government, Palmer United Party and Senator Nick Xenophon changes to the R&D Tax Incentive will “stifle biotech innovation”.

The industry organization said that limiting the Tax Incentive was”a further blow to Australia’s innovation ecosystem and will impact large and small biotech companies”.

Ausbiotech chief executive officer Dr Anna Lavelle said that the Tax Incentive was “the shining beacon of hope and support to the biotech industry and we have consistently praised its success and urged the Government not to limit or remove it, and to provide consistency and certainty to the sector to allow its development”.

Dr Lavelle said that the legislation as it stands, if passed by the House of Representatives, would “disadvantage local companies with the aggregation requirements”.

“This potential targeting of small companies who partner with large companies will destroy the policy intent of the R&D Tax Incentive,” Dr Lavelle said.

“The aggregation [of total partnered spending] could be a problem if it is not clarified by the Government,” Dr Lavelle told Biotech Daily.

“The backdating of this latest amendment by seven months will cause havoc with planning, create even greater uncertainty and discourage the industry from investing,” Dr Lavelle said.

Ausbiotech said it “fully supported the Australian Greens’ moving of an amendment in the Senate that would revive the much-needed quarterly payments for small and medium size businesses eligible for a R&D Tax Incentive refund – a feature that was passed with the original legislation and then overturned at the 11th after the Coalition won Government”.

Ausbiotech said that the Government should abandon plans to cut the R&D tax Incentive by a further 1.5 percent and consider the Australian Innovation and Manufacturing Incentive, which would provide a lower tax rate for profit derived from home grown intellectual property and keep its flow-on benefits in Australia.

CSL

CSL says its net profit after tax for the six months to December 31, 2014 was up 7.2 percent to a record $US692.2 million ($A890.8 million) on revenue up 5.6 percent to $US2,744.1 million ($A3,531.4 million).

Research and development expenditure increased 1.8 percent from $US229.3 million in the six months to December 31, 2013 to $US233.4 million for the six months to December 31, 2014 or as a percentage of total revenue, research and development expenditure fell from 8.9 percent for the half year to December 31, 2013 to 8.5 percent for the six months to December 31, 2014.

CSL said that diluted earnings per share was up 9.7 percent to $US1.455.

The company said that the interim unfranked dividend of 58 US cents, compared to the previous corresponding period's 53 US cents, would be paid on April 10, 2015, with a record date of March 18, 2014.

CSL said it had cash and cash equivalents of $US1,060.6 million at December 31, 2014.

In a media release and teleconference, CSL chief executive officer Paul Perreault said the company had delivered "a solid first half result and continued to invest in future growth as part of our strategy".

Mr Perreault said he expected to close the Novartis acquisition by the end of 2015 and CSL continued to increase its investment in research and development.

Mr Perreault said that sales revenue rose with "double digit growth in albumin and specialty products with a 24 percent increase in influenza vaccines following a severe Northern Hemisphere influenza season".

Mr Perreault said that with the Novartis acquisition the company would become the "number two in the global influenza vaccine industry".

He said that although the global market for plasma products was expected to continue to grow, so too would competitors.

Mr Perreault revised the full-year growth forecast for CSL down from 12 percent to 10 percent.

Mr Perreault said that sales of albumin for burns, trauma and infection were up 16 percent with increasing demand from China.

He said that immunoglobulin product sales were up five percent to $US1,122 million underpinned by sales of Privigen with expanded indications but "the average immunoglobulin sales price was negatively impacted as a greater proportion of sales were made into lower priced markets".

Mr Perreault said that demand for self-administered subcutaneous Hizentra and was strong in both the US and Europe.

He said that haemophilia product sales were up three percent to $US558 million and specialty products increased 13 percent to $US443 million, "driven largely by sales of Kcentra and Berinert".

Mr Perreault said that Bio-CSL were up 15 percent to $A276 million with influenza vaccine sales comprising $A116 million.

Mr Perreault said that the US Food and Drug Administration application for Prolong 9 was on-track for a 2016 launch and that if the phase II trial of the reconstituted high density lipoprotein CSL112 for plaque removal following cardiac arrest was successful and was followed by a successful 12,000 patient phase III trial, it had "the potential to be a game changer" at little cost as it was derived from the existing plasma donations.

"If successful this will be a blockbuster," Mr Perreault said.

He said that CSL had 117 plasma collection centres in the US and Germany.

CSL fell $7.05 or 7.8 percent to $82.95 with 5.3 million shares traded.

NOVOGEN

Novogen says it has lodged the final specifications of a patent covering its first family of super-benzopyran compounds with the US Patent and Trademark Office.

Novogen said that super-benzopyrans were a new chemical structure of increasing complexity and diversity and the platform had produced the three drug candidates of TRXE-002 for ovarian cancer, TRXE-009 for glioblastoma and other cancers as well as TRXE-0025 for prostate cancer.

The company said that its chemists had identified six patent families of related compounds and the final patent specifications it had lodged was for the first of those families, with some hundreds of molecules designed and manufactured over the past 12 months, focused on the ability to kill cancer stem cells.

Novogen said that the underlying pharmacophore, or the composition of the molecule responsible for its action, had been identified and formed a key aspect of the patent.

The company said that work was progressing on the remaining five potential patent families to determine the underlying pharmacophores, and when completed, the appropriate patents would be lodged.

Novogen's head of drug discovery and manufacture Dr Andrew Heaton said that the last 12 months had been productive in "reducing our super-benzopyran drug discovery program to practice, allowing the final specification to be lodged".

"Happily we also are seeing these drugs successfully come through their large-scale manufacturing process ahead of a number of clinical trials over the next 12 months," Dr Heaton said.

Novogen chief executive officer Dr Graham Kelly said the families of not previously seen compounds were proving "an extraordinary rich source of potential new therapeutics".

"It is remarkable that the same underlying molecular structure can yield compounds of such diverse biological activity," Dr Kelly said.

Dr Kelly said that the pleiotropy, or one gene being responsible fo more than one characteristic, was "what makes this family of compounds so valuable".

"The lodgement of this patent also opens the way for our collaborators to present data for conference presentations and publications where disclosure of molecular structure is required," Dr Kelly said.

Novogen was unchanged at 13.5 cents with one million shares traded.

OTIFEX THERAPEUTICS

Last night's edition reported on the Otifex phase Ia trial of betahistine nasal spray for otitis media with effusion, or glue ear, incorrectly spelling the company name as "Otifix".

Biotech Daily's Prime Fact-Checker again apologies unreservedly and says he has listened to his colleagues and is moving forward, but in any case it was his predecessor's fault and good spelling begins today.

Otifex is a private company backed by Uniseed and the Brandon Capital-managed Medical Research Commercialisation Fund.

OPTISCAN

Optiscan has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 30.9 percent from 6.8 cents on February 6 to 8.9 cents on February 10, 2015, and noted an increase in trading volume.

Optiscan fell 0.3 cents or 3.85 percent to 7.5 cents with 5.05 million shares traded.

SPINIFEX PHARMACEUTICALS

Spinifex says it has appointed Dr Peter Spargo and Dr Christine Richardson for its chemistry, manufacturing and controls to drive development of EMA401 for chronic pain.
Spinifex said that Dr Spargo had been appointed as the head of chemistry, manufacturing and controls.
The company said Dr Spargo had worked in pharmaceutical research and development for more than 25 years and previously acted as an industry consultant, including to Spinifex and held executive roles at the Italy-based Creabilis and France's Novexel.
Spinifex said that Dr Spargo began his industry career at Pfizer UK rising to head of chemical research and development in Europe and led Pfizer development teams.
The company said that Dr Spargo held a Doctorate of Philosophy from Cambridge University, completed post-doctoral research at Columbia University and was a fellow of the Royal Society of Chemistry and authored numerous scientific papers and patents.
Spinifex said that Dr Richardson had been appointed director and non-clinical project manager of chemistry, manufacturing and controls.
The company said that Dr Richardson was most recently Novartis Pharmaceuticals program operations manager and had previously been an executive with the company in the US and in Europe.
Spinifex said that Dr Richardson held a Doctorate of Philosophy from New York University and completed a Masters Certificate in applied project management at Villanova University.
Spinifex chief executive officer Dr Tom McCarthy said the company was making "excellent progress in preparing further phase II clinical trials of EMA401 in post-herpetic neuralgia, painful diabetic neuropathy and pain due to osteoarthritis and intend to initiate these studies in the middle of this year".
"In Pete and Chris we have added two exceptionally capable and experienced individuals to our senior management and created a strong [chemistry, manufacturing and controls] capability to complement our clinical development team," Dr McCarthy said.
Spinifex is a private company.

SAFETY MEDICAL PRODUCTS

Safety Medical says it has appointed Matthew Morgan and Frank Pertile as directors replacing Peter Christie and Simon Jenkins.
Safety Medical is in the process of becoming 3D Medical for three dimensional printing and holographic projection for medical imaging (BD: Nov 25, 2014; Feb 9, 2015).
The company said that Mr Morgan was "an experienced advisor and non-executive director and was currently the principal of advisory firm Millers Point Company and was previously a venture capitalist at Queensland Investment Corporation.
Safety Medical said that Mr Morgan had previously worked for DB Capital, Todd Capital and Merlin Ventures and was currently a non-executive director of Bluechiip, Diversa and Leaf Resources.
The company said that Mr Pertile was a director and owner of a privately held investment company with interests in property as well as listed and unlisted companies and he previously held positions with wealth management companies.
Safety Medical was untraded at five cents.