Biotech Daily

Wednesday August 24, 2011

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: VIRAX UP 29%, PATRYS DOWN 6%**

*** LONG-AWAITED FEDERAL 45% R&D TAX CREDIT ON THE WAY**

*** SPINIFEX RAISES FURTHER $6.5m FOR PAIN DRUG TRIALS**

*** VIRALYTICS PREPARES FOR FDA-APPROVED PHASE II MELANOMA TRIAL**

*** BAYER TO CANCEL TYRIAN AGREEMENTS; REVIEW, REDUNDANCIES**

*** MESOBLAST REVENUE UP 15,708% TO $121m, PROFIT UP 713% TO $91m**

*** COGSTATE REVENUE DOWN 15% TO $8m, PROFIT TURNS TO $846k LOSS**

*** QUIXOTE INVESTMENT TAKES 17% OF COGSTATE**

*** SPARTAN TAKES 6% OF ACUVAX**

MARKET REPORT

The Australian stock market slipped 0.14 percent on Wednesday August 24, 2011 with the S&P ASX 200 down 5.8 points to 4167.6 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and eight were untraded.

Virax was the best, up half a cent or 29.4 percent to 2.2 cents with 275,000 shares traded.

Mesoblast and Tissue Therapies climbed more than five percent; Benitec and Viralytics were up more than four percent; Anteo and Heartware were up more than three percent; Alchemia, Cochlear and Pharmaxis rose two percent or more; with Bionomics, Circadian, Living Cell, Nanosonics and Resmed up one percent or more.

Patrys Cell led the falls, down half a cent or 6.25 percent to 7.5 cents with 140,531 shares traded, followed by LBT down 5.4 percent to 5.3 cents with 245,000 shares traded.

Cellmid, Impedimed and Phylogica fell more than four percent; Genetic Technologies and Sirtex were down more than three percent; Prima shed 2.8 percent; with Acrux, CSL and Optiscan down more than one percent.

FEDERAL GOVERNMENT, AUSBIOTECH, AUSTRALIAN GREENS

The first of two Federal Government Bills providing for a 45 percent tax credit on research and development expenditure has been passed by Parliament.

The Tax Laws Amendment (Research and Development) Bill 2010 as amended by the Senate was passed by the House of Representatives and will be sent to the Governor-General for Royal Assent, the last step before becoming an Act of Parliament.

Last year Innovation Minister Senator Kim Carr said the tax credit was “the most important reform to business innovation support in a generation” worth $1.6 billion a year to business (BD: Aug 11, 2010). Senator Carr said at that time the tax credit would provide a 45 percent refundable tax credit for companies turning over less than $20 million a year and a 40 percent nonrefundable tax credit to all other companies.

An officer of the Australian Parliament told Biotech Daily that the companion Bill, the Income Tax Rates Amendment (Research and Development) Bill 2010 would be returned to the Senate for a further reading and if approved would then come back to the House of Representatives and if approved would then be sent to the Governor-General for Royal Assent, a process likely to take up to a week. Senator Carr’s office said this Bill related to Australian Taxation Office payment provisions.

In a media release, industry organization Ausbiotech said the biotechnology community welcomed the news that the tax credit would become a reality.

Ausbiotech chief executive officer Dr Anna Lavelle said it was “the most significant positive news that the industry has had for a number of years”.

“The new tax incentive will deliver a major boost for innovative biotechnology companies and spill-over benefits for the community from biotechnologies,” Dr Lavelle said.

“For small biotech companies it’s going to mean significant difference to their R&D programs and inject substantial new funds into the industry and that will stimulate new investment,” Dr Lavelle said.

Ausbiotech said the legislation would be effective from July 1, 2011 with quarterly payments of cash refunds, instead of annual payments, from January 1, 2014

Ausbiotech said that start-up innovation companies, especially biotechnology companies trading in loss, would be the biggest beneficiaries from the 45 percent refundable component and also benefit large companies by reducing the cost of conducting eligible activities in Australia by up to 10 percent, making Australia more competitive for biomedical and pharmaceutical research and development and clinical trials.

The Australian Greens deputy leader Senator Christine Milne said that the Bills “increased support for small and medium sized businesses, particularly after the Greens secured amendments to help the cash-flow of these companies which are the engine room of innovation in Australia”.

Senator Milne said the agreement to make quarterly cash payments was reached “as a result of an innovative political process initiated by the Greens which featured a round table representing stakeholders from different perspectives and representatives of Treasury and several departments and the Minister's office”.

The Member of the House of Representatives for Melbourne and Greens’ Science, Research, Industry and Innovation spokesman Adam Bandt said “the new R&D tax regime will dovetail with new investments in the clean economy that the Greens were able to secure in the carbon price negotiations”.

Mr Bandt said that a key to driving investment would be the Government setting a goal of three percent of gross domestic product to be invested in research and development across the economy, taking Australia above the average for the Organisation for Economic Co-operation and Development “and bring us into line with Germany and Japan”.

SPINIFEX PHARMACEUTICALS

Spinifex says it has secured a further $6.25 million of venture capital investment to fund the development of its pain management drug, EMA401.

Spinifex said GBS Venture Partners, Brandon Capital Partners, Uniseed Management and Uniquest provided the expanded series B funding, adding to their previous $12 million investment.

The company said the funds would be used to expand the EMA401 phase II clinical trial program to the treatment of pain and hypersensitivity in peripheral nerve injury patients and the treatment of pain and hypersensitivity in cancer chemotherapy patients.

Spinifex said the new trials followed its ongoing collaboration with Imperial College London's Prof Praveen Anand at Hammersmith Hospital and would run parallel with a phase II trial of EMA401 in post-herpetic neuralgia, which was expected to begin in September.

Spinifex said that in post-herpetic neuralgia was a painful condition that developed in some patients following herpes zoster, or shingles, and where existing therapies did not relieve pain in all individuals.

The company said EMA401 was an angiotensin II type 2 (AT2) receptor antagonist and the discovery that this class of molecules offered an innovative approach to the treatment of neuropathic and inflammatory pain was made by the University of Queensland's Prof Maree Smith.

Spinifex said it had licenced the technology and conducted a pre-clinical and early clinical development program, with EMA401 showing efficacy in a number of relevant mouse and rat models and with positive phase I trial results for human safety and pharmacokinetics.

Spinifex chief executive officer Dr Tom McCarthy said that the further investment "allows us to expand the EMA401 phase II clinical program and also gives us additional flexibility as we plan the further development of this asset".

Prof Anand said that based on human tissue laboratory data, the AT2 receptor was "a very promising novel target in pain research and EMA401 has demonstrated excellent results in our studies".

Prof Anand said the study designs incorporated "new functional pain biomarkers and correlative histological assessments".

"In addition, the selection of the clinical indications was informed by a broad assessment of AT2 receptor localization in somatic and visceral pain pathways and functional studies in isolated human neurones to better define clinical doses, Prof Anand said.

Spinifex said its clinical program for EMA401 was initially focused on neuropathic pain, an area of high unmet medical need.

The company said that the market for neuropathic pain treatments was expected to continue to increase and reach $US6.2 billion by 2017.

Spinifex said that despite that growth, available therapies needed to be improved as a significant proportion of neuropathic pain patients don't respond and these treatments have dose-limiting side-effects.

The company said EMA401 was being developed as a potential first-in-class oral treatment for neuropathic pain and related symptoms without central nervous system side effects.

Spinifex is a private company.

VIRALYTICS

Viralytics management is preparing for its phase II trial of Cavatak Coxsackie A21 virotherapy for melanoma, hoping to enroll the first patient before the end of 2011.

In June, Viralytics said the US Food and Drug Administration had approved the US-based multi-centre trial of Cavatak for late stage melanoma (BD: Jun 27, 2011).

The company said at that time that the trial would have up to 63 patients of which 54 would be evaluable and was a single arm intra-tumoral trial injecting Cavatak to multiple tumors on up to 10 separate occasions over an 18-week period.

Viralytics managing director Bryan Dulhunty told Biotech Daily that along with meeting shareholders, in Melbourne, with inventor and chief scientific officer Prof Darren Shafren, they were building the team that would take them through the clinical trials and meeting potential strategic consultants.

Comparing the method of action to B-Raff inhibitors and antibodies, Prof Shafren said that Cavatak would bind to ICAM1 receptors which were in vast numbers on the surface of cancer cells, while being in far lower numbers on healthy cells.

“Normal cells have innate immunity to the virus, which the cancer cells have given up for immortality,” Prof Shafren said.

Prof Shafren said that Cavatak had been shown to be safe and well-tolerated and the company was hoping to demonstrate that it could be used either as an adjunct to other cancer treatments or as a monotherapy.

“It is intended for metastatic cancers and melanoma is our proof-of-concept,” he said.

Prof Shafren said Cavatak could be suitable for pancreatic and lung cancers which expressed high levels of ICAM1.

He said Cavatak could be injected directly into the tumor, but many were inaccessible, which was why it had been also trialed as an intravenous infusion.

Prof Shafren said that if Cavatak was give as a combination therapy “the combination could reduce the doses of chemotherapy but still get the same efficacy”.

“There is clinical interest in combination therapy of our virus with immune enhancing antibody-based treatments for cancer,” Prof Shafren said.

Mr Dulhunty said that Amgen recently acquired Biovex for $1 billion in March 2011 and the Cavatak technology was similar to the Biovex technology.

Viralytics was up two cents or 4.8 percent to 44 cents.

TYRIAN DIAGNOSTICS

Tyrian says that some or all of its agreements with Bayer Cropscience AG to commercialize agriculture diagnostic products are likely to be terminated.

Tyrian said it would review its options, but to reduce costs and conserve cash, material contracts would be terminated and employees would be made redundant by the end of November 2011.

The company said there were several agreements around its proprietary Diagnostiq platform with Bayer, including a licence agreement, development, evaluation and supply agreements relating to the Diagnostiq tests and readers for defined agricultural fields.

Tyrian said it had intended to use the revenues from agriculture diagnostics to fund the longer term development of point-of-care medical diagnostics.

The company said that despite the Readrite wheat test showing precision and accuracy, extensive marketing efforts would be needed to unseat the entrenched gold standard test.

Tyrian chairman Roger Amos said the outcome of the partnership with Bayer was “most disappointing”.

Tyrian fell 0.2 cents or 50 percent to 0.2 cents with 26.85 million shares traded.

MESOBLAST

Mesoblast says revenue for the 12 months to June 30, 2011 was up 15,708 percent to $120,921,285 with net profit after tax up 713 percent to $90,606,590.
Mesoblast said that revenue from ordinary activities includes revenue from continuing operations of $19,257,822 and other income of $101,663,463, which included a gain made of $86,737,561 on the revaluation of the previously held investment in Angioblast Systems when the remaining shares of Angioblast were purchased and it became a wholly owned subsidiary.
Mesoblast chief financial officer Jenni Pilcher told Biotech Daily that the revenue figure includes $14,609,186 of the $US130 million received from Cepahlon (BD: Dec 8, 2010), with the remainder on the balance sheet as deferred revenue to be spread over the next two to three years.
The company said research and development expenditure was up 102.4 percent to $15,314,548.
Mesoblast said asset net backing per share was up 324.4 percent to 102.7 cents.
The company said diluted earnings per share was 39.78 cents for the year to June 30, 2011compared to previous corresponding period loss of 10.51 cents.
Mesoblast said it had $263,227,585 in cash at June 30, 2011, up 721.3 percent compared to $32,049,327 at the end of the previous financial year.
The company said no dividend would be paid.
Mesoblast was up 38 cents or 5.3 percent to $7.55 with 1.6 million shares traded .

COGSTATE

Cogstate says its revenue fell 15 percent to $8,248,060 in the 12 months to June 30, 2011, taking last year's net profit after tax of $1,637,615 to a loss of $846,206.
Cogstate said its earnings per share fell from 2.5 cents for the previous year to a loss per share of 1.3 cents.
Cogstate it had $3,306,563 in cash and equivalents at June 30, 2011 compared to $3,092,437 for the previous corresponding period.
Cogstate was unchanged at 17 cents.

COGSTATE

Quixote Investment of Portland Oregon has become a substantial shareholder in Cogstate with the acquisition of 12,961,831 shares or 17.37 percent of the company.
The initial substantial shareholder notice said Quixote acquired the shares for cash of $938,000 and non-cash valued at $1,268,511 or an average price of 17.1 cents a share.

ACUVAX

Spartan Nominees of Bicton, Western Australia has become a substantial shareholder in Acuvax with the acquisition of 141,500,000 shares or 6.17 percent of the company.
The initial substantial shareholder notice said Spartan acquired the shares for $153,000 or 0.11 cents a share.
Acuvax was untraded at 0.2 cents.