Biotech Daily

Wednesday August 13, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: PEPLIN UP 10%, LIVING CELL DOWN 7%**

*** CSL TO PAY $3.1bn FOR TALECRIS PLASMA BUSINESS**

*** CSL PROFIT UP 30% TO $702m ON REVENUE UP 15%**

*** STARPHARMA TRIALS VIVAGEL'S ANTIVIRAL RETENTION**

*** ANTISENSE LOSS DOWN 50% ON REVENUE UP 1300%**

*** CIRCADIAN'S VEGENICS WINS US ANGIOGENESIS INHIBITOR PATENT**

*** SUNSHINE HEART RESPONDS TO FDA QUERIES**

*** ARANA EGM FINALLY BACKS PERFORMANCE PLAN**

*** PROF IAN CHUBB APPOINTED TO CSIRO BOARD**

*** PROF PETER COLMAN WINS $50k VICTORIA, $100k SMORGON PRIZE**

MARKET REPORT

The Australian stock market retreated 1.9 percent on Wednesday August 13, 2008 with the All Ordinaries down 94.4 points to 4,995.9 points. Eight of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and eight were untraded.

Peplin was best, up 3.5 cents or 10.29 percent to 37.5 cents on small volumes, followed by Heartware up 8.77 percent to 62 cents and Cochlear up 8.51 percent to $51.15.

Neuren climbed 5.26 percent; Ventracor was up 4.08 percent with 1.9 million shares traded; with Antisense and Pharmaxis up more than one percent.

Living Cell led the falls, down two cents or 7.41 percent to 25 cents on very small volumes followed by Cathrx down 6.25 percent to 75 cents.

Agenix and Phosphagenics were both down 5.56 percent; Biota and Clinuvel fell more than four percent; Cytopia and Viralytics lost more than three percent; Cellestis and Novogen were down more than two percent; with Alchemia, Arana, Avexa, Genetic Technologies, Mesoblast, Optiscan and Sirtex down more than one percent.

CSL

CSL will acquire Talecris Biotherapeutics for $US3.1 billion ($A3.5 billion) from Cerberus Partners and Ampersand Ventures.

CSL told the ASX that Talecris was “one of the world’s leading manufacturers and marketers of plasma-derived protein therapies”.

CSL’s managing director Dr Brian McNamee said Talecris was “highly complementary to CSL’s existing business”.

“The acquisition will …provide CSL with the additional scale, breadth of products, geographical presence, low cost base and capacity to increase output to enhance our position in the $US15 billion global plasma products market,” Dr McNamee said.

The purchase price comprises a cash payment of US3.1 billion less any net debt that may be assumed by CSL, payable on completion of the acquisition.

CSL said the acquisition, subject to regulatory approvals, would combine Talecris’ products and manufacturing capabilities with its own plasma collection business, commercial platform, production capabilities and product portfolio.

CSL said the acquisition was expected to deliver additional, scale-efficient manufacturing facilities; integration between all the manufacturing sites to maximize the number and yield of plasma products; an enhanced portfolio of plasma and recombinant products, with a strong market presence and broad geographical registrations, achieved by adding Talecris’ liquid intravenous immunoglobulin (IVIG) Gamunex and Alpha1-PI therapy Prolastin, to CSL’s product range; enhanced positions in key geographies, including the US, providing a platform to increase diversity and volume of product sales; a more flexible, higher capacity and efficient plasma collection business, integrated with the manufacturing spine, operating a common automated system and capable of meeting plasma needs across a range of geographical markets; and a highly optimized supply chain to ensure timely, adequate, secure and reliable supply at lowest cost.

CSL said Talecris had 56 US plasma collection centres and two manufacturing facilities.

For the year to June 30, 2008, Talecris generated sales of $US1.2 billion and adjusted earnings before interest taxation depreciation and amortization of $US258 million.

Talecris is headquartered in Research Triangle Park, North Carolina.

If CSL does not receive anti-trust approval to complete the acquisition within twelve months, the acquisition may be terminated, resulting, under certain circumstances, in CSL incurring a $US75 million break fee to be paid to the vendors.

The acquisition is being funded through equity and debt. The equity funding comprises an underwritten placement to raise $US1,500 million and a share purchase plan for shareholders to buy up to $5,000 in shares. The record date is August 22, 2008.

The balance of the cash and transaction costs will be funded through cash balances, undrawn bank facilities and a bridge facility from Merrill Lynch International (Australia), expected to be replaced with longer term debt financing within 12 months.

CSL is being advised by Merrill Lynch, Simpson Thacher & Bartlett LLP and Allens Arthur Robinson.

The business to be acquired includes manufacturing facilities at Clayton, North Carolina which fractionates 2.5 million plasma equivalent litres a year and Melville, New York which has a front-end fractionation capacity of approximately 1.0 million plasma equivalent litres a year and specialty products.

Talecris has invested $US563 million in acquiring its plasma collection centres and upgrading facilities. CSL also acquires all of Talecris’ inventory and other working capital as well as regional offices in Canada and Germany.

CSL was in a trading halt for the placement and last traded at $39.00

CSL

CSL has reported net profit after tax for the 12 months to June 30, 2008 up 30 percent to $701.8 million on total revenue up 15 percent to $3,794.3 million.
The company reported basic earnings per share up 29.5 percent to 127.6 cents.
A fully franked final dividend of 23.0 cents will be paid with a record date of September 22, 2008.
In an outlook statement chief executive officer Dr Brian McNamee said the company expected “stable market conditions for our plasma therapies business and growing contribution from royalties associated with the international sales of Gardasil”.
He said the contribution from CSL’s influenza vaccine was expected to increase over the medium term as new northern hemisphere markets developed.
Dr McNamee said research and development investment would increase to $265 million to $275 million.
“For the 2008-‘09 fiscal year we expect net profit after tax of between $810 million and $850 million at constant currency,” Dr McNamee said.

STARPHARMA

Starpharma has begun a clinical trial of Vivagel in 12 women to measure the level of antiviral activity retained after vaginal administration.
Assessment will be by laboratory assay of vaginal samples collected up to 24 hours after Vivagel application.
The cervico-vaginal samples will be taken at five time points post application, straight after application and at one, three, 12 and 24 hours.
The samples will then be tested in vitro against HIV and herpes simplex virus 2 (HSV-2 or genital herpes).
The study in 12 women will determine the timescale over which Vivagel retains activity against HIV and HSV-2.
Starpharma chief executive officer Dr Jackie Fairley said the short trial would provide “a potential surrogate for antiviral efficacy of Vivagel in humans ahead of phase III studies”.
“It will also give an indication of just how long before sex you could apply Vivagel to prevent infection,” Dr Fairley said.
The study is being conducted at the Centre for Clinical Studies in Melbourne and is funded by the US National Institutes of Health.
Starpharma said Vivagel was being developed as a vaginal microbicide for the prevention of HIV and HSV-2.
Other applications are being assessed, including prevention of human papillomavirus (HPV), contraception and treatment of bacterial vaginosis.
Starpharma was unchanged at 25 cents.

ANTISENSE

Milestone payments from Israel’s Teva Pharmaceuticals for Antisense’s ATL1102 multiple sclerosis drug have had a dramatic impact on the company’s preliminary final report.
Antisense has reported a decreased loss by 55.8 percent from $4,835,963 for the year to June 30, 2007 to $2,136,886 for the year to June 30, 2008.
Revenue increased by 1299.97 percent to $6,815,492, of which $US6 million related to payments from Teva.
Antisense climbed 0.1 cents or 1.49 percent to 6.8 cents.

CIRCADIAN

Circadian's subsidiary Vegenics has been granted a US patent covering all therapeutic and diagnostic uses for antibodies to VEGF-D, a target for cancer and other diseases.
Circadian said that vascular endothelial growth factor D (VEGF-D) was closely related to VEGF-A, the target of Genentech's Avastin cancer therapy.
The patent grants exclusive rights to VEGF-D antibodies and to the use of VEGF-D antibodies in all therapeutic indications and diagnostic applications.
Circadian said the patent provided "a major commercial advantage to Vegenics".
It ensures that only Vegenics can commercialize VEGF-D antibodies for therapeutic applications in the US. The patent extends until mid-2019.
Vegenics is developing its VGX-200 series of humanized VEGF-D antibodies as anticancer agents.
Circadian chief executive officer Robert Klupacs said that "stemming from the enormous success of Avastin, the development of antibody drugs targeting angiogenic molecules such as VEGF-D is widely considered one of the most promising strategies in the pharmaceutical industry".
"It is an important protection for our internal therapeutics development programs and represents a major asset for commercial partnerships with other companies seeking to pursue this approach," Mr Klupacs said.
Vegenics owns worldwide rights to an extensive intellectual property portfolio covering angiogenesis targets VEGF-D, VEGF-C and the receptor protein VEGFR-3.
Circadian was unchanged at 83 cents.

SUNSHINE HEART

Sunshine Heart has lodged additional information with the US Food and Drug Administration supporting its C-Pulse heart cuff application.
Sunshine Heart said that over the past 12 months, there had been a dialogue with the FDA over the investigational new device application initially submitted in June 2007.
The additional information responds to specific clinical and technical questions raised by the FDA in correspondence and meetings over the last six months.
Sunshine Heart expects to receive a further response from the FDA within 30 days and believes the information addresses all the issues raised by the FDA but may cause the FDA to invite the company to provide further additional information.
Sunshine Heart's chief executive officer Don Rohrbaugh said the further filing was a substantial effort from the company's regulatory and technical teams.
Mr Rohrbaugh said that subject to approval the company planned to begin enrolling up to 20 patients for a US clinical trial at six leading medical institutions, by the end of 2008.
Sunshine Heart said C-Pulse sought to relieve and in some cases reverse the symptoms of moderate heart failure by using counter-pulsation technology to increase cardiac output, increase coronary blood flow and reduce the heart's pumping workload.
Sunshine Heart said that following successful completion of the initial US clinical trial, the company would seek FDA approval for a larger clinical study of more than 100 patients as a precursor to marketing C-Pulse in the US.
The company will also seek Conformitée Européenne (CE) Mark approval for C-Pulse based on the initial US clinical trial data.
The company said that in June it completed a $5.4 million underwritten rights issue and at June 30, 2008 had cash reserves of $9.8 million, targeted for the US clinical trial.
Sunshine Heart expects US health insurance reimbursement for part of the clinical trial.
Sunshine Heart was untraded at seven cents.

ARANA

Arana's troubled performance share plan has finally been approved by shareholders.
At the extraordinary general meeting in Melbourne, Arana chairman Robin Beaumont told shareholders that variations on the plan had previously been defeated (see Biotech Daily; July 14, 2008) or withdrawn and the company had revisited the proposal.
"I think what we've ended up with is a good system," Mr Beaumont said.
He said executives would only be rewarded if shareholders benefit.
Mr Beaumont confirmed that 10 senior executives including chief executive officer Dr John Chiplin would benefit from the scheme and said the plan might be extended to other employees but ruled out the idea that it might apply to all employees.
A second resolution asked shareholders to approve the grant of performance shares to Dr Chiplin.
Arana's notes to the meeting said the share plan required the average closing share price for the three months to December 31, 2010 to exceed a 10 percent compound annual growth rate of the base share price of $1.17, the three month average closing price to December 31, 2007, that is at least $1.56.
In the case of Dr Chiplin, the number of shares offered would be 50 percent of his total remuneration package or 213,675 shares. There is no cost to Dr Chiplin for the shares.
There was division in the meeting with a group of four shareholders opposing both the share plan and the award of shares to Dr Chiplin.
The vote was won on a show-of-hands and it appeared that both votes were won by a majority of seven to four.
Biotech Daily approached the group of four shareholders but they refused to identify themselves or comment on their opposition.
Arana's chief financial officer Neill Henderson later told Biotech Daily the four shareholders voting against the resolutions were Melbourne-based Arana employees.
Arana said a total of 57,580,740 proxy votes were cast in favor of the share plan with 6,119,048 proxy votes against the proposal.
A total of 56,949,757 proxy votes were cast in favor of the grant of shares to Dr Chiplin with 6,501,226 proxy votes against.
Arana fell 1.5 cents or 1.31 percent to $1.13.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Australian Government has appointed Prof Ian Chubb as a part-time member of the Commonwealth Scientific and Research Organization (CSIRO) board.
The Minister for Innovation, Industry, Science and Research Senator Kim Carr said Prof Chubb's "experience and expertise in the higher education and research sectors will be of great value to the CSIRO".
"Prof Chubb's proficiency as a policy advisor to the Australian Government and his broad experience on a variety of peak bodies and committees will complement the existing skills and expertise of the CSIRO board," Senator Carr said.
Senator Carr said collaborative initiatives with the university sector were "an important factor in enabling CSIRO to make the most effective contribution to the Australian innovation system".
Prof Chubb is the vice-chancellor of the Australian National University and the chair of the International Alliance of Research Universities. Previously he was vice-chancellor of Flinders University and served as a senior executive at Monash University and the University of Wollongong.

VICTORIA PRIZE, FELLOWSHIPS; SMORGON PRIZE

Bio-molecular scientist Prof Peter Colman has won the $50,000 Victoria Prize and a further $100,000 for the Walter and Eliza Hall Institute.

Victoria's Innovation Minister Gavin Jennings said Prof Colman was pivotal in the development of Biota's Relenza influenza drug and would be presented with the Victoria Prize tonight by the Governor of Victoria, Prof David de Kretser.

Mr Jennings said Prof Colman won the $50,000 prize for his groundbreaking research and for discovering a new class of anti-influenza drugs.

The Victoria Prize is complemented by the $100,000 Anne and Eric Smorgon Memorial Award from the Jack and Robert Smorgon Families Foundation which is granted to the Victoria Prize winner's research institute, in this case the Walter and Eliza Hall Institute of Medical Research.

Mr Jennings said Prof Colman's breakthrough was in 1989 when he led the Commonwealth Scientific and Industrial Research Organisation team that discovered the drug zanamivir, having crystallized and solved the three-dimensional structure of neuraminidase.

"As a result of his work, two neuraminidase inhibitors, Relenza and Tamiflu, are registered for the treatment and prevention of influenza, an illness that strikes 500 million people worldwide every year and is the 12th highest cause of death for Australians," Mr Jennings said.

"Prof Colman's discovery ranks with that of [Dr] John Cade, who discovered lithium as a treatment of bipolar disorder," Mr Jennings said.

"In 2001 Prof Colman moved to the Walter and Eliza Hall Institute of Medical Research to head up research in structural biology and drug discovery," he said.

A former chief of the CSIRO division of bio-molecular engineering, Prof Coleman was also director of the bio-molecular research institute and a founding member of the board of directors of Biota.

Prof Colman has had more than 90 original scientific papers published, 20 of which have been referenced more than 6,000 times.

Mr Jennings also announced the winners of the Victoria Fellowships, which assist emerging leaders in science, engineering and technology.

"The scientists and engineers honored today are to be congratulated for their creative, innovative approach to scientific research," Mr Jennings said.

Fellows receive an $18,000 travel grant to undertake a short-term international study mission, to receive specialist training, or to develop commercial ideas.

A Victorian Government media release said that among the winners of the 2008 Victoria Fellowships are Dr Ian Majewski to investigate next generation gene sequencing to enable easier identification of people at high risk of developing disease and Dr Steven Pas to develop novel image technology that can detect subtle changes in the nanostructure of tissues and industrial materials earlier than current technology.