Biotech Daily

Tuesday May 3, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: GENETIC TECHNO UP 18%; ANTISENSE DOWN 9%**

*** CHEMGENEX, MESOBLAST WELCOME TEVA VALIDATION OF CEPAHLON**

*** NOVOGEN'S MARSHALL EDWARDS RAISES $US4m**

*** VICTORIAN GOVERNMENT BUDGETS $7.9m FOR INNOVATION**

*** KARMELSONIX APPOINTS OMRON DISTRIBUTOR**

*** ELLEX CLAIMS EARLY SUSTAINED AMD EFFICACY**

*** ARGENTINA APPROVES LIVING CELL DIABECELL TRIAL**

*** HEALTHLINX APPOINTS CPC TO ASSIST WITH FDA PATHWAY**

*** PRIMA APPOINTS CFO IAN BANGS JOINT COMPANY SECRETARY**

*** BIO-MELBOURNE BRIEFING: USING COMMERCIALISATION AUSTRALIA**

MARKET REPORT

The Australian stock market fell 0.84 percent on Tuesday May 3, 2011 with the S&P ASX 200 down 40.7 points to 4784.6 points.

Seven of the Biotech Daily Top 40 stocks were up, 16 fell, 11 traded unchanged and six were untraded.

Genetic Technologies was the best, again, up 3.5 cents or 17.95 percent to 23 cents with 5.9 million shares traded. Chemgenex climbed 5.3 percent; Sunshine Heart was up 3.9 percent; Starpharma rose 2.85 percent; with QRX up one percent.

Antisense led the falls, down 0.1 cents or 9.1 percent to one cent, with 30.8 million shares traded, followed by Universal Biosensors down 10 cents or 7.1 percent to $1.30 with 6,000 shares traded.

Phosphagenics lost 6.45 percent; Benitec and Impedimed fell four percent or more; Patrys and Viralytics were down more than three percent; Acrux, Heartware, Phylogica, Prana, and Psivida shed more than two percent; with Alchemia, Biota, Pharmaxis and Sirtex down one percent or more.

CHEMGENEX, MESOBLAST

The chief executive officers of Chemgenex and Mesoblast have welcomed the proposed acquisition of the Pennsylvania-based Cephalon by Israel's Teva Pharmaceuticals.
Cephalon announced overnight that it had accepted a bid of $US6.8 billion ($A6.2 billion) from Israel's Teva Pharmaceuticals, citing its pipeline as part of the value to Teva.
Cephalon previously rejected a $US5.7 billion bid from Ontario's Valeant Pharmaceuticals, in which Valeant criticized Cephalon's pipeline including the proposed acquisition of Chemgenex and Pennsylvania's Gemin X Pharmaceuticals.
The criticism of early stage acquisitions could be interpreted as indirect criticism of the $1.6 billion partnership with Mesoblast, but chief executive officer Prof Silviu Itescu told Biotech Daily that Valeant had been "silent on Mesoblast".
Prof Itescu said he was "delighted" by the proposed Teva acquisition of Cephalon and that his partnership had moved from a large biotechnology player to a much larger pharmaceutical company.
"Teva is the biggest generics company in the world and they want to transform themselves, in particular to biological drugs," Prof Itescu said.
"Teva has validated Cephalon's strategy of expansion," Prof Itescu said.
Prof Itescu said he had previously held discussions with Teva executives who he described as "very smart, very switched-on and very interested in the stem cell space".
Chemgenex chief executive officer Dr Greg Collier also welcomed the Teva offer.
"It's a great result for people who believe in the pipeline that Cephalon has been building," Dr Collier told Biotech Daily.
He said the increase in the Chemgenex share price to 69.5 cents, compared to the offer of 70 cents, indicated the market thought that risk had been removed from the bid.
Valeant was openly critical of Cephalon's strategy of broadening its pipeline and said in an April 11, 2011 media release that "the current strategy of developing untested biotech products departs dramatically from Cephalon's historical focus of marketing products other companies have primarily developed and taken through the regulatory process".
Valeant congratulated Teva and Cepahlon on the deal and withdrew its bid for Cephalon.
Cephalon has republished on its Nasdaq website, a report that the law office of Abe Shainberg was investigating the Cephalon board "for possible breaches of fiduciary duty and other violations of state law in connection with the sale of the company to Teva".
Chemgenex was up 3.5 cents or 5.3 percent to 69.5 cents with 5.2 million shares traded.
Mesoblast was up four cents or 0.5 percent to $8.19.

NOVOGEN, MARSHALL EDWARDS

Novogen says Marshall Edwards has raised $US4,000,000 through the issue of 835,217 common stock shares at $US1.33 a share and the exercise of warrants.
Novogen said the one year series B warrants for 626,413 shares of common stock in its 65 percent US subsidiary would be at the initial exercise price of $US1.33 each.
Novogen said the offer was expected to close about May 13, 2011, subject to conditions including the closing of the asset purchase agreement (BD: Apr 6, 2011).
Novogen said the proceeds would be used primarily to continue development of Marshall Edwards' two lead oncology programs, including a phase I clinical trial of its intravenous drug candidate NV-143, which had demonstrated pre-clinical activity against a broad range of tumor cell lines, as well as studies required prior to clinical trials of its lead mitochondrial inhibitor candidate NV344 later this year.
The company said Roth Capital Partners acted as the placement agent.
Novogen fell half a cent or 1.7 percent to 28.5 cents.

VICTORIA GOVERNMENT

The Victorian Government says it has provided a $7.9 million package for technology focused initiatives in the 2011-‘12 State Budget.

A Department of Business and Innovation media release said $5.3 million over four years had been committed to establish the Office of the Lead Scientist; with $1.2 million over four years for the Victorian Biotechnology Advisory Council; $1 million over two years for the Industry Sustainability Working Committee; and $400,000 over three years for collaborative networks for technology transfer.

The Minister for Innovation Louise Asher said the Office of the Lead Scientist would articulate a clear vision and strategic goals for science, technology and innovation.

“The Office has an important role that will support the development and direction of innovation and science policy,” Ms Asher said.

“The Office will provide advice on major science, technology and research infrastructure, help build links between institutions and industries across the innovation value chain and support the commercialization of Victorian research,” Ms Asher said.

The media release said the Victorian Biotechnology Advisory Council will report to the Minister for Technology Gordon Rich-Phillips and provide a direct link between industry and government in fostering Victoria’s dynamic biotechnology industry.

“The Council will support the Coalition Government’s commitment to working with Victorian businesses in the development and direction of innovation and science policy, technology and research,” Mr Rich-Phillips said.

Ms Asher said the Industry Sustainability Working Committee would liaise with industry, research and educational organizations and provide strategic advice to the Government on industry sustainability issues.

“The Committee will help to ensure that Victorian businesses and industry operate in a more sustainable way and that Victorians have the skills and opportunities to secure jobs in the emerging green economy,” Ms Asher said.

Ms Asher said the Collaborative Networks for Technology Transfer would help to bring private companies, industry organizations and different levels of government together and generate solutions to specific industry problems.

“It will establish formal commercialization networks between industry and the private sector and develop a suitable showcase to further promote the commercial technology opportunities identified through the initiative,” Ms Asher said.

KARMELSONIX

Karmelsonix has appointed the Japan-based Omron Healthcare to distribute its clinical and personal Wheezometers.

Karmelsonix Asia-Pacific managing director Paul Eisen said the contract with Omron was for large geographic areas of the world and was still under negotiation.

Karmelsonix said in its media release that Omron had signed a letter of intent to become the exclusive distributor of the Wheezometer in multiple international territories after examining the growth prospects of the device to assist asthma sufferers or those suffering from other respiratory illnesses.

The company said the pocket-sized Wheezometer measured wheeze rate over a 30 second period and documented the patient’s extent of wheeze and his or her response to treatment such as before and after the use of a bronchodilator.

Karmelsonix said the Wheezometer had been cleared for use in Europe, the United States and for patient and professional use in Australia.

Karmelsonix was up 0.2 cents or 14.3 percent to 1.6 cents with 121 million shares traded.

ELLEX MEDICAL LASERS

Ellex says most of the 24 patients treated with its retinal regeneration therapy (Ellex 2RT) for early age-related macular degeneration have had sustained visual improvement.

Ellex said 24 patients in the 50-patient trial had been assessed at 12-month post-treatment and along with sustained visual improvement in the treated eye the majority of patients also noting an improvement in the fellow, untreated eye.

The company said the treated patients also had demonstrated reduction of the extracellular deposits of drusen in the treated eye.

Ellex said nine of 14 patients described in a presentation at the meeting of the Association for Research in Vision and Ophthalmology at Fort Lauderdale, Florida, currently underway had sustained visual improvement, but was unable to provide the 24 patient data.

Ellex said that visual function improved predominately in the regions of greatest dysfunction, which were associated with the highest likelihood of progressing to the advanced stage of age-related macular degeneration (AMD).

The company said that extensive laboratory research showed no evidence of laser damage to photoreceptor cells.

Ellex chief executive officer Tom Spurling said that “unlike other treatment options for AMD which target the late-stage complications associated with the disease, Ellex 2RT offers the potential to treat AMD in its early stages”.

“For the first time, AMD can be treated before vision is lost,” Mr Spurling said.

Ellex said that age-related macular degeneration was a progressive disease affecting the central area of the retina called the macula and was the leading cause of blindness in the developed world.

The company said that the early form of the disease accounted for up to 80 percent of all cases of age-related macular degeneration in the world and no treatment existed to halt the progression to its advanced stage, which is associated with severe vision loss.

“The fact that we have been able to maintain the positive effects of Ellex 2RT over a 12-month period provides further evidence that Ellex 2RT offers significant hope for the millions of people worldwide who suffer from AMD,” Mr Spurling said.

“Our next step is to secure key regulatory approvals during the 2011 calendar year, based on the positive clinical results achieved to date, and to expand the clinical trials across a larger and more diverse patient sampling in order to validate our clinical findings,” he said.

Ellex said the interim 12-month results of 24 patients in the prospective clinical trial, conducted in collaboration with Centre for Eye Research Australia at the Royal Victorian Eye and Ear Hospital demonstrated the clinical efficacy of Ellex 2RT in partially halting or reversing the degenerative processes which cause age-related macular degeneration.

The head of macular research at the Centre for Eye Research Australia Prof Robyn Guymer said that in the six months since first reporting early results “we have observed a sustained improvement in the visual function in the majority of patients”.

“This is an extremely positive result,” Prof Guymer said.

“To date there has been no proven intervention in early AMD that significantly halts or causes regression of the disease process,” Prof Guymer said.

“Our research shows that application of 2RT treatment is safe and painless and results in both improved visual function and drusen resolution,” Prof Guymer said.

Ellex said completion of the 12-month follow-up of all 50 patients was targeted for the end of 2011 and preparations for a long-term, multi-centre randomized control trial were underway to demonstrate the ability of Ellex 2RT to reduce the progression rate to advanced age-related macular degeneration.

Ellex was up 1.5 cents or 8.3 percent to 19.5 cents.

LIVING CELL TECHNOLOGIES

Living Cell says Argentina has become the third country to approve a phase II trial of Diabecell porcine islets of Langerhans for type 1 diabetes.

Living Cell said the trial of eight adult patients, including those with unstable diabetes and severe hypoglycaemia, would begin in Buenos Aires by the end of 2011.

The company said each patient would receive two implants of Diabecell, three months apart, with a dose seeking component.

Living Cell said the trial had ethical approval from the relevant authority of the Eva Perón Hospital in San Martín, Argentina; the central ethics committee of the Minister of Health of the Buenos Aires Province; the coordinating committee for transplantation in Buenos Aires and the Minister of Health of the Buenos Aires Province, Dr Alejandro Collia.

The company said Dr Adrian Abalovich had been appointed the principal investigator with University of Colorado Health Sciences Center Prof Boris Draznin providing external supervision of the trial.

Living Cell said the Argentinean trial approval followed a positive assessment from the New Zealand data safety and monitoring board of the first 12 patients to receive Diabecell implants in its phase II New Zealand trial, as well as favorable two-year follow up data from its Russian phase I/IIa clinical trial.

The company said Diabecell had been granted registration as a medical technology in Russia and there were plans for a collaborative development of Diabecell in Asia following the strategic investments made by China's Jiangsu Aosaikang Pharmaceutical Co and Japan's Otsuka (BD: Mar 9, Apr 12, 2011).

Living Cell medical director Prof Bob Elliott said Dr Abalovich had "a published record as a researcher in the area of porcine islet implantation".

"He provides excellent leadership of a group who will expand the dose seeking trials of Diabecell," Prof Elliott said. "The healthcare infrastructure in Argentina is one of the more sophisticated in Latin America with clinical trials run to international [good clinical practice] standards."

Living Cell chief executive officer Dr Ross Macdonald said the trial was "intended to build upon encouraging clinical data to date and will provide additional robust clinical information relevant to our future pivotal clinical study program".

"Strategically, the trial creates the potential for future commercialization in a new jurisdiction," Dr Macdonald said.

Living Cell was unchanged at 11 cents.

HEALTHLINX

Healthlinx says it has appointed CPC Clinical Research to assist in its US Food and Drug Administration regulatory pathway for its Ovplex ovarian cancer test.

Healthlinx said the Colorado-based contract research organization was associated with the University of Colorado Denver and had managed trials at more than 100 international sites as well as in 42 states in the US over 20 years.

The company said that would assist in the preparation of a pre-investigational device exemption submission to the FDA and coordinate meetings with the regulator with the goal of obtaining registration for Ovplex.

Healthlinx said CPC had significant experience in working with companies seeking FDA approvals for diagnostics and medical devices.

Healthlinx chief executive officer Nick Gatsios said CPC would also identify opportunities to expand his company's business activities in the US.

Healthlinx fell 0.2 cents or 3.5 percent to 5.5 cents.

PRIMA BIOMED

Prima says that it has appointed chief financial officer Ian Bangs as joint company secretary, effective immediately.
A Prima spokesman said Phillip Hains would continue as company secretary.
Prima was unchanged at 34 cents with 7.9 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network will hold a briefing on using the Commercialisation Australia progam on May 18, 2011.
The Bio-Melbourne Network said Commercialisation Australia was announced in 2009 by the Australian Government and had funding of $278 million over the five years from 2010 to 2014, with ongoing funding of $82 million per year thereafter.
The Network said that in 2010, Commercialisation Australia supported more than 20 biotechnology-related projects (BD: Apr 16, Jul 14, Sep 10, Oct 21, 2010; Mar 4, 2011).
Bio-Melbourne Network chief executive officer Michelle Gallaher said the biotechnology industry could benefit from the Commercialisation Australia program and it was “not just for fledgling businesses in ‘hot areas’ such as green technology”.
The Network said that two of the Victorian case managers for Commercialisation Australia, Dr Elane Zelcer and Dr Rob Crombie would share their experience in the innovation and research sector and discuss building value in an innovation-driven business.
The workshop will include case studies of successful Commercialisation Australia recipients and senior people within these companies will participate in a panel discussion, including Sienna Diagnostics chief executive officer Dr Kerry Hegarty, Advent Pharmaceuticals business development director Dr Robin Coleman and Florey Neuroscience Institutes’ deputy director Dr Henry De Aizpurua.
The Bio-Briefing is hosted and sponsored by Pricewaterhousecoopers, Freshwater Place, Level 19, 2 Southbank Boulevard, Southbank on May 18, 2011 with registration from 3:45pm with presentation at 4pm.
To register go to: http://www.biomelbourne.org/events/view/184.