Biotech Daily

Wednesday September 17, 2008

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECHS UP: CATHRX UP 25%, SUNSHINE DOWN 22%**

*** CATHRX HAILS 1st CATHETER SALES**

*** CHEMGENEX RAISES $13m; OFFERS 85c SHARE PLAN**

*** VIRAX PARTNER POSTS MORE POSITIVE CANCER TRIAL DATA**

*** RAB SPECIAL SITUATIONS TAKES 19.6% OF BIOLAYER**

*** MESOBLAST SISTER'S ORPHAN STATUS FOR MARROW TRANSPLANT**

*** NORWOOD ABBEY RESTRUCTURES EYECARE ASSETS**

*** US PATENT FOR HEALTHLINX NON-CORE TECHNOLOGY**

*** FEDERAL COURT APPROVES HEARTWARE US MOVE MEETINGS**

*** SUNSHINE HEART ON ROADSHOW**

MARKET REPORT

The Australian stock market fell 0.6 percent on Wednesday September 17, 2008 with the All Ordinaries down 30.1 points to 4,769.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and seven were untraded. All three Big Caps were up.

Cathrx was best up 15 cents or 25 percent to 75 cents with 5,000 shares traded, followed by Universal Biosensors up 11.43 percent to 78 cents.

Avexa climbed 8.11 percent; Bionomics was up 7.69 percent; Living Cell and Prana were up five percent or more; Clinuvel climbed 4.08 percent; Cellestis and CSL rose more than two percent; with Genetic Technologies, Heartware and Novogen up more than one percent.

Sunshine Heart led the falls, down 2.4 cents or 21.82 percent to 8.6 cents, followed by Antisense and Polartechnics down more than nine percent.

Alchemia lost 8.93 percent; Peplin and Phylogica fell more than six percent; Labtech and Viralytics were down more than five percent; Pharmaxis was down 3.18 percent; with Chemgenex, Neuren, Phosphagenics and Progen down one percent or more.

CATHRX

Cathrx says it has achieved the first sales of any of its products, namely its modular diagnostic catheters, to its United Kingdom-based distributor.

Cathrx chairman Denis Hanley told Biotech Daily the initial sales were for trials in several hospitals and about 200 Cathrx catheters valued at about $150 each made up the first order.

“We expect sales will build steadily,” Mr Hanley said.

“We have multiple products for multiple countries,” he said.

Cathrx chief executive officer Neil Anderson said the first sale to Europe was “a major commercial milestone for our business”.

“We look forward to building sales and growing market share in Europe in coming months,” Mr Anderson said.

“Our experienced distributor network is rolling out a carefully designed sales plan at select hospitals in the main European medical markets,” he said.

Cathrx said cardiac catheters were minimally invasive tools widely used by specialist cardiologists to diagnose and treat different types of cardiac arrhythmias.

The company said the global cardiac catheter market was estimated to be worth $US1 billion and growing at 10 percent a year.

The European market is estimated to be worth $265 million.

Cathrx manufactures and markets a range of catheters for the diagnosis and treatment of cardiac arrhythmias.

Cathrx climbed 15 cents or 25 percent to 75 cents on small volumes.

CHEMGENEX

Chemgenex has raised $12.9 million through a placement of 15,216,153 shares at 85 cents a share and will offer a share plan to stockholders.

Chemgenex said the placement was included a commitment of $6.5 million by existing major shareholders Alta Partners, GBS Venture Partners and Merck Santé, a subsidiary of Merck KGaA.

The company said Alta, GBS and Merck Santé increased or maintained their respective percentage holdings in Chemgenex and other investors with expertise in the biotechnology sector also made significant investments.

Chemgenex said the funds were for the continued clinical trial program of lead oncology drug candidate, omacetaxine.

Chemgenex chief executive officer Dr Greg Collier said the company was “delighted to have successfully completed this placement given the current financial market conditions”.

Dr Collier said Chemgenex was “on course to complete enrollments for the clinical section of our regulatory filing by the end of 2008” as well as filing the chemistry, manufacturing and controls section of the rolling new drug submission at the end of March, 2009 and to complete the submission in mid-2009.

“These are all critical milestones in the development and commercialization strategy for omacetaxine,” Dr Collier said.

Chemgenex said it would offer eligible shareholders the opportunity buy up to $5,000 of shares at 85 cents a share without brokerage or transaction costs.

The record date is today, September 17, 2008. The plan opens on September 22, 2008 and closes on October 3, 2008 with quotation expected on October 15, 2008.

ABN Amro Morgans was adviser and lead manager for the placement and will manage the share plan.

Chemgenex fell 1.5 cents or 1.85 percent to 79.5 cents.

VIRAX

Virax says Transgene has further positive phase IIb clinical trial results for TG4010 as an adjunct to first line chemotherapy in patients with advanced non-small cell lung cancer.

The Strasbourg France-based Transgene drug uses Virax's Co-X-Gene technology under a licence agreement, in which Virax benefits from milestone and royalty payments on Transgene achieving relevant development milestones and sale of product.

Transgene's public offer manager Bryan Garnier and Co estimated peak annual sales of €750 million ($A1339 million) for TG4010 in its 'Emerging Growth Research Report' of June 6, 2005, Virax said.

Virax said the new data built significantly on the previous report by Transgene (see Biotech Daily; June 3, 2008) that the phase IIb trial met its primary endpoint for progression free survival.

Transgene said the "promising new clinical data" indicated that after 17 months of follow up, the data shows that long time survival is greater for those patients who received TG4010 in combination with chemotherapy of 39 percent survival, compared to those receiving chemotherapy alone with 23 percent survival.

Quoting Transgene, Virax said TG4010 vaccination did not adversely affect the quality of life of patients.

Transgene further identified a sub-population of patients, those with a normal blood level of activated natural killer cells (a group of cytotoxic lymphoctes), for which TG4010 appears to be even more efficacious.

For these patients there was an increase in 6.7 months of median survival of 18 months compared to 11.3 months).

Virax's chief executive officer Dr Larry Ward said the clinical trial data was "extremely promising and a major step towards Transgene getting TG4010 to the market".

"The demonstration of a survival benefit for those patients receiving TG4010 is very important as survival will no doubt be a pre-requisite for any major regulatory authority to approve such a [non-small cell lung cancer] product for registration," Mr Ward said.

He said the demonstration that Transgene had a biomarker to identify patients for which TG4010 was more efficacious would help significantly in the successful design of the pivotal phase III clinical trials that will be the next stage of development.

Transgene have previously said that they plan to partner TG4010 for the later stages of clinical development.

Transgene chief executive officer of Dr Philippe Archinard said the overall results were "extremely promising".

"We will be gathering further results over the coming months whilst already preparing the next development steps towards registration of TG4010 for advanced NSCLC," Dr Archinard said. "In parallel Transgene is seeking a collaborative partnership that will ensure the product's future clinical development for this indication, as well as for other indications and settings," he said.

Virax was untraded at 3.5 cents.

BIOLAYER

RAB Special Situations Master Fund has become a substantial shareholder in Biolayer with a holding of 35,000,000 shares or 19.57 percent of the company.

RAB described itself as "a Cayman Islands registered company" and gave a London address, with HSBC Custody Nominees Australia named as the registered holder of the securities.

Biolayer was untraded at 2.5 cents.

MESOBLAST

The US Food and Drug Administration has granted orphan drug designation for Mesoblast's adult stem cell technology for bone marrow transplant patients.

Mesoblast said the FDA gave its US sister company, Angioblast Systems, "the right to use the proprietary off-the-shelf allogeneic mesenchymal precursor cells for insufficient haematopoietic stem cell production in patients with haematologic malignancies who have failed treatment with conventional chemotherapy".

Mesoblast quoted the March issue of Biology and Bone Marrow Transplantation, saying that the probability that an individual in the US would require a haematopoietic stem cell bone marrow transplant sometime during their life was 1 in 217.

The company said the FDA's orphan drug designation was reserved for new drugs or therapies being developed to treat diseases or conditions affecting fewer than 200,000 patients a year in the US.

Orphan drug designation allows for an accelerated FDA review process, seven-year US market exclusivity on obtaining authorisation, tax benefits, and exemption from user fees.

The company said haematopoietic stem cells were used to regenerate bone marrow in patients whose own bone marrow was damaged and destroyed by treatments for various cancers.

The greater the number of haematopoietic stem cells transplanted, the greater the likelihood that the bone marrow transplant will successfully engraft and regenerate a patient's damaged bone marrow, Mesoblast said.

Mesoblast said that preclinical studies showed the allogeneic mesenchymal precursor cells significantly expanded the number of haematopoietic stem cells in culture.

The results of these studies formed the basis for the successful orphan drug submission.

Mesoblast's executive director Prof Silviu Itescu said the orphan drug designation was "a significant milestone for the platform stem cell technology".

"It broadens the potential commercial applications to conditions requiring repair and regeneration of bone marrow, including various cancers and genetic diseases," Prof Itescu said.

"Significantly, orphan drug designation for our cells in these conditions may facilitate earlier revenues and market exclusivity," Prof Itescu said.

Mesoblast climbed one cent or 0.88 percent to $1.15.

NORWOOD ABBEY

Norwood Abbey says the first major step in the restructuring of its Eyecare assets has been agreed.

Norwood Abbey said the Pallikaris (Epilasik) licence agreement becomes a fully paid up licence with no licence fees, royalties or other commercialization payments of any kind required.

The company said Pallikaris' interests convert to a 30 percent direct equity in Norwood Devices, which will house the Eyecare project avoiding any further costs under the Pallikaris' agreements, Norwood Abbey said.

The University of Crete research agreement is cancelled, avoiding all future costs under that agreement.

Norwood Abbey said about $600,000 was expunged from its current liabilities.

The company said the restructure was "a major step in the Norwood strategy of being able to sell and/or out-licence its technologies, to move its projects towards cash neutral positions and to reduce its liabilities".

Norwood Abbey fell 0.1 cents or 7.69 percent to 1.2 cents.

HEALTHLINX

Healthlinx says the US Patent and Trademark Office has issued a notice of allowance for a key patent related to its vascular permeability program.

Healthlinx said the patent was the first in a series of related patents in-licenced from the University of Virginia in August 2006.

Healthlinx managing director Nick Gatsios told Biotech Daily that the vascular permeability program was an asset class "inherited" when Cryptome Pharmaceuticals was acquired by Healthlinx.

"We own the target and the compounds that inhibit that target," Mr Gatsios said.

Mr Gatsios says there was interest in the intellectual property and Healthlinx hoped to partner the program.

Healthlinx primary focus is the use of biomarkers to develop diagnostics to detect and monitor diseases and the first commercial targets are ovarian cancer and prostate cancer.

In a media release to the ASX Healthlinx said it was also exploring additional out-licencing opportunities for the vascular permeability program.

Healthlinx is in a proposed collaboration with Canada's Insymbiosis to develop the drug candidate CR014 for acute respiratory distress syndrome with a potential market of more than $US1 billion.

The company said no effective therapeutic treatments were available for the disease that kills 30 to 40 percent of diagnosed patients.

The patent covers modulation of a key pathway controlling aberrant vascular permeability critical to a number of diseases

Healthlinx said the patent was "at the core of the recent agreement with Insymbiosis".

The patent focuses on inhibition of the p21 activated kinase pathway as a method for treating aberrant vascular permeability associated disorders and potentially has widespread application for the treatment of associated diseases or disorders including acute respiratory distress syndrome, ischemia, stroke and burns.

Healthlinx said CR014 demonstrated efficacy in reducing the adverse effects of lung injury in an animal model of acute respiratory distress syndrome.

The proposed joint venture will conduct a full pre-clinical evaluation of CR014 with a view to progressing to clinical trials.

In the media release Mr Gatsios said the notice of allowance by the US Patent and Trademark Office would "reinforce the value of the in-licenced intellectual property and provides further incentive to move forward with our development plans".

Healthlinx said it was in the process of finalizing agreements and pre-clinical development plans with Insymbiosis with the view to have the program commence in the near future.

Healthlinx fell 0.4 cents or 7.27 percent to 5.1 cents.

HEARTWARE

The Australian Federal Court has approved Heartware's stockholder meetings to vote on the proposed redomiciliation from Australia to the US.

Heartware announced the move earlier this year (see Biotech Daily; May 16, 2008).

The proposed transaction will be implemented through three separate schemes of arrangement between the company and its shareholders, optionholders and performance rights holders.

The scheme meetings will be held on October 22, 2008 in the Adelaide Room, Sofitel Sydney Wentworth Hotel, 61-101 Phillip Street, Sydney beginning at 10am.

Heartware climbed one cent or 1.64 percent to 62 cents.

SUNSHINE HEART

Sunshine Heart says its senior management will conduct a series of short investor presentations in Australia and New Zealand from September 26, to October 2, 2008.

Sunshine Heart said that the investor meetings follow US Food and Drug Administration conditional approval for the first US clinical trial for the company's C-Pulse heart assist therapy for patients suffering from moderate heart failure (see Biotech Daily; September 12, 2008).

Patient enrolment is expected to begin by the end of 2008 at six US medical institutions.

The investor presentations will be held in Auckland on September 26, Brisbane on September 29, Perth on September 30, Melbourne on October 1 and Sydney on October 2, 2008.

Sunshine Heart fell 2.4 cents or 21.82 percent to 8.6 cents.