Biotech Daily

Wednesday December 8, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: MESOBLAST UP 22%; HEARTWARE DOWN 5%**

*** CEPHALON, MESOBLAST $1.7bn STEM CELL DEAL**

*** BIOGUIDE BRIEF: CEPHALON SWOOPS ON MESOBLAST - GOOD FOR ALL**

*** ASX TELLS CBIO DIRECTORS TO SELL SHORTFALL SHARES**

*** CELLMID LAUNCHES HAIR LOSS PRODUCTS**

*** US PATENT GRANTED FOR ANTISENSE'S ATL1103**

*** EAST HILL, LANDON T CLAY, PROMIC TAKE 5% OF BIOTA**

*** GBS VENTURES INCREASES, DILUTED TO 24% OF SUNSHINE HEART**

MARKET REPORT

The Australian stock market fell 0.57 percent on Wednesday December 8, 2010 with the S&P ASX 200 down 26.9 points to 4699.9 points.

Ten of the Biotech Daily Top 40 stocks were up, 10 fell, 13 traded unchanged and seven were untraded.

Mesoblast was best, up as much as 36.6 percent to $4.45, before closing up 72 cents or 21.6 percent to $4.05 with 1.5 million shares traded, followed by Antisense up 11.1 percent to one cent with 12.6 million shares traded.

Clinuvel climbed 9.8 percent; Circadian was up 5.7 percent; Phosphagenics was up 4.35 percent; Optiscan and Sunshine Heart were up more than three percent; with Biota and Sirtex up more than one percent.

Heartware led the falls, down 15 cents or 5.45 percent to $2.60 with 5,000 shares traded.

Cellmid, Tissue Therapies and Uscom lost more than four percent; Nanosonics was down 3.5 percent; Psivida shed 2.1 percent; with Bionomics and Starpharma down more than one percent.

MESOBLAST

In a deal worth up to $1.7 billion, Cephalon will pay at least $US100 million in upfront fees and take a 19.99 percent stake in Mesoblast to partner on its adult stem cell technology.

In the biggest deal in Australian biotechnology, Cephalon says it will buy its stake in Mesoblast at $4.35 a share and should shareholders approve the 19.99 percent stake, Cephalon will pay a further $US30 million in upfront fees.

Mesoblast chief executive officer Prof Silviu Itescu told Biotech Daily that his company was guaranteed an upfront fee of $US100 million with the further $US30 million pending shareholder approval for Cephalon taking a 19.99 percent stake in Mesoblast at $4.35 a share a 45 percent premium to the 30-day volume weighted average price (VWAP) market price prior to the announcement, worth about $US220 million.

Prof Itescu said the deal was standard for a serious US deal and there was no reason it should be any different for a serious Australian deal.

Prof Itescu said Cephalon would partner with Mesoblast for the cardiac, neurological and cord expansion uses of the adult mesenchymal precursor stem cells, while Mesoblast would have cash for other indications including diabetes, autoimmune and inflammatory diseases, ophthalmic indications as well as orthopedic bone and cartilage conditions

“They were interested in our most advanced indications,” Prof Itescu said.

“This de-risks the costs of the phase III clinical trials and in cardiac they are very expensive,” Prof Itescu said.

“We retain the manufacturing rights. We will make the product and sell the product and we can control the roll out of products that remain ours,” Prof Itescu said.

Prof Itescu said the manufacturing plant would “probably be outside the US” and he was looking for a low cost and tax efficient “first world” country.

Prof Itescu said that Ireland, Switzerland and Singapore were possible locations but Australia had a corporate tax rate of 30 percent the US rate was 35 percent.

In a media release Mesoblast said it would have a cash balance of $250 million for its retained indications.

In a teleconference Prof Itescu said there was no royalty component for the deal, but Mesoblast would earn income from the transfer prices and sales of manufactured product.

Prof Itescu said the first Cephalon-Mesoblast cardiac trial would be the on-going congestive heart failure indication.

He said phase III cardiac trials cost upwards of $100 million and the US Food and Drug Administration could require more than one trial.

Prof Itescu said milestone payments included up to $100 million for indication approvals.

In its media release the Frazer, Pennsylvania-based Cephalon said it would partner with Mesoblast for congestive heart failure, acute myocardial infarction, Parkinson's disease, and Alzheimer's disease as well as products for augmenting haematopoietic stem cell transplantation in cancer patients.

Under the agreement Mesoblast is responsible for the conduct and expenses of certain phase IIa clinical trials and commercial supply of the products, while Cephalon will be responsible for the conduct and expenses of all phase IIb and phase III clinical trials and subsequent commercialization of the products.

Cephalon will limit its investment to 19.99 percent for 12 months and chief operating officer J Kevin Buchi will be appointed a Mesoblast director, effective immediately.

“This global licencing agreement positions Cephalon as a leader in regenerative medicine while further strengthening our late stage pipeline with another innovative biologic platform,” Mr Buchi said.

Mesoblast climbed as much as $1.22 or 36.6 percent to $4.45, closing up 72 cents or 21.6 percent to $4.05 with 1.5 million shares traded.

MARC SINATRA'S BIOGUIDE BRIEF: MESOBLAST

First Acrux and now Mesoblast - publicly listed Australian biotechnology companies are finally beginning to shine brightly.

The deal which grants Cephalon exclusive rights to Mesoblast's congestive heart failure, acute myocardial infarction and bone marrow transplant products, as well as for the early stage indications of Parkinson's and Alzheimer's diseases is the biggest deal I can remember beyond the Big Three – CSL, Cochlear and Resmed.

Importantly, it will put lots of cash in the Mesoblast bank account: $US350 million in total ($US30 million pending shareholder approval) when the proceeds of the 19.99 percent placement to Cephalon at $4.35 a share are taken into account ($US130 million up-front payment plus $US220 million from the placement).

This becomes $384 million if you add Mesoblast's cash in the bank as of the last Appendix 4C quarterly report, assuming Australian-US parity. Potential milestones of up to $US1.7 billion could see this bank balance swell even further.

Besides the obvious positive signal this deal sends regarding Mesoblast's technology, the cash they now hold gives them much greater flexibility in terms of developing the numerous products that remain in their portfolio.

Essentially, they can choose if they wish, to take these products much further down the commercialization path, which, in turn, may well mean better deals to come.

I am sure that this thought will warm the cockles of every Mesoblast shareholders' heart.

Investors can also start to pencil-in a takeover offer by Cephalon, who has found Australia a happy hunting ground, having bought Arana last year and looks very likely to take Chemgenex next year.

In fact, a takeover offer is probably only one or two good phase 2b trial results away and could make Mesoblast the next billion dollar biotech.

Yeah, I know, it was supposed to be Chemgenex – I'll have to wear that.

Marc Sinatra
Analyst

* Marc Sinatra has recently written research notes on Mesoblast for Lodge Partners.

* Neither Marc Sinatra nor Biotech Daily editor David Langsam hold Mesoblast shares and are kicking themselves for it.

CBIO

CBio says directors have sold rights issue shortfall shares acquired without knowing they required shareholder approval to do so.

In a notice to the ASX, CBio said a substantial shareholder notice from director Dr Michael Monsour related to the disposal of shares acquired under the rights issue shortfall at the direction of the ASX, due to an unintentional breach of ASX Listing Rule 10.11.

CBio said that on November 22, 2010, the company lodged Appendix 3Y director interest statements in relation to shares acquired by entities associated with Prof John Funder and Dr Monsour as part of the shortfall to the rights issue.

The company said it was told by the ASX that the issue of shares to directors under the shortfall required prior shareholder approval and the issue was therefore in breach of Listing Rule 10.11 and the shortfall shares should be disposed.

CBio said the shares were sold at a price equivalent to the issue price, no profit was made on the unintentional breach and it had taken steps to ensure such a breach was not repeated.

The company said that both Dr Monsour and Prof Funder remained shareholders and were fully supportive of the company.

Dr Monsour had an interest in 9.7 million CBio shares or 8.14 percent of the company as well as 3.1 million options and acquired 3.8 million shares under the rights Issue.

Prof Funder has an interest in 100,000 shares and one million options.

CBio fell one cent or 4.8 percent to 20 cents.

CELLMID

Cellmid says it has launched its first hair loss or alopecia related products through its wholly owned subsidiary Advangen International.

Cellmid said Advangen had exclusive Australasian distribution rights to a novel, scientifically-validated range of hair loss products and an option to extend exclusivity to the US and Europe.

The company said the hair loss products would be sold on Advangen's website, www.advangen.com.au or through selected hairdressing salons from February 2011.

Cellmid said the product range contained "active ingredients of natural origin that have been shown to inhibit FGF-5, a protein responsible for the transition of the hair follicles from growth to rest phase".

Cellmid said that animal and human studies demonstrated that using FGF- 5 inhibitors extended the growth phase of each hair follicle and decreased the amount of hair lost, which over time should result in a fuller head of hair, with increased thickness and length.

The company said the products had been developed by Japan's National Institute of Advanced Industrial Science and Technology and further developed by the Skin Research and Technology Group in Yokohama, the Department of Dermatological Science at the University of Tokushima and by Advangen Inc of Japan.

Cellmid said that findings of the in-vitro, pre-clinical and human clinical studies in relation to the active ingredients were detailed in the 2007 publication 'Sanguisorba officinalis root extract has FGF-5 inhibitory activity and reduces hair loss by causing prolongation of the anagen period' available at the Advangen website.

Cellmid said that Advangen would apply to the Australian Therapeutic Goods Administration for approval to market its range of products with therapeutic claims.

Advangen's products have been on sale in Japan since 2008, with more than half a million units sold to date.

Cellmid fell 0.2 cents or 4.55 percent to 4.2 cents with 16.3 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says the US Patent Office has granted a further patent covering ATL1103 as a potential treatment for growth and sight disorders.

Antisense said that the patent entitled 'Modulation of growth hormone receptor expression and insulin-like growth factor expression' added to the extensive patent position on ATL1103 and broader applications of antisense technology targeting the human growth hormone receptor.

The company said an Australian patent had also been allowed and would proceed to grant on December 16, 2010 with related patents under examination in other major markets.

Antisense was up 0.1 cent 11.1 percent to one cent.

BIOTA

East Hill Holding Co, Landon T Clay and Promic have become substantial shareholders in Biota with the acquisition of 9,150,481 shares or 5.06 percent of the company.

The initial substantial shareholder notice said several East Hill related companies acquired the shares along with Landon T Clay as the sole manager and member of East Hill Holding Co.

The notice gave an Oxford, UK address from Promic (formerly Prolysis Ltd) and addresses in Providence, Rhode Island and Delaware for the East Hill entities which included East Hill University Spinouts Funds.

Biota chief financial officer Damian Lismore said that East Hill was the major investor in Prolysis, which Biota acquired last year.

Mr Lismore said Promic was effectively a shell company controlled by East Hill and East Hill had continued to invest in Biota.

In November 2009 Biota said it had acquired the pre-clinical antibacterial assets of Oxford's Prolysis Ltd for $10.8 million as Biota shares, along with up to a 15 percent share in all milestone and royalties earned on commercialization with Biota retaining all upfront payments on licenced programs (BD: Nov 12, 2010).

Biota was up one cent or one percent to 97.5 cents.

SUNSHINE HEART

Two GBS Venture Partners funds have increased their substantial holding in Sunshine Heart and have been diluted through the recent capital raisings.

GBS as trustees of the GBS Bioventures III fund increased and was diluted from 95,102,505 shares (17.71%) to 163,032,865 shares (16.1%).

GBS as trustees of the GBS Bioventures II fund increased and was diluted from 44,286,140 shares (8.25%) to 75,919,097 shares (7.5%).

Sunshine Heart was up 0.1 cents or 3.7 percent to 2.8 cents with 2.1 million shares traded.