Biotech Daily

Wednesday August 19, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: OPTISCAN UP 15%, CYTOPIA DOWN 5%**

*** BIOTA BACK IN $38m PROFIT, REVENUE UP 85% TO $83m**

*** HUNTER HALL INCREASES TO 13% OF BIOTA**

*** CSL PROFIT UP 63% TO RECORD $1.1bn; REVENUE UP 32% TO $5bn**

*** FDA GO AHEAD FOR BONE PHASE III CAPSITONIN OSTEOPOROSIS TRIAL**

*** MESOBLAST'S ANGIOBLAST RAISES $7-10m**

*** PEPLIN COMPLETES 2nd PHASE III AK TRIAL ENROLMENT**

*** IMMURON'S BIOGUARD IN HIV G-I INFLAMMATION TRIAL**

*** IMUGENE PLEADS SCHULTZ TO ASX 49% PRICE JUMP QUERY**

*** AGENIX LOSES CEO DR STEPHEN PHUA**

MARKET REPORT

The Australian stock market slipped a further 0.18 percent on Wednesday August 19, 2009 with the S&P ASX 200 down 7.8 points to 4373.8 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and three were untraded. All three Big Caps were down.

Optiscan was best, up 0.9 cents or 14.75 percent to seven cents with 65,000 shares traded, followed by Benitec up 0.4 cents or 13.8 percent to 3.3 cents.

Novogen climbed 9.1 percent; Compumedics and Starpharma were up five percent or more; Bionomics was up 4.4 percent; Alchemia, Antisense and Cellestis rose more than two percent; Cathrx, Genetic Technologies, Heartware and Nanosonics were up more than one percent; with Circadian and Pharmaxis up by less than one percent.

Cytopia led the falls, down 0.4 cents or five percent to 7.6 cents with 109,234 shares traded, followed by Avexa down 4.8 percent to 10 cents with 2.2 million shares traded and Phosphagenics down 4.2 percent to 11.5 cents.

Acrux, Chemgenex, Cochlear, Living Cell and Viralytics lost more than three percent; Biota, Mesoblast, Peplin, Prana and Progen shed more than two percent; CSL and Impedimed were down more than one percent; with Resmed down by 0.55 percent.

BIOTA

Biota has returned to profitability with net profit after tax for the 12 months to June 30, 2009 of $38,181,000 on revenue up 85 percent to $83,334,000.

In 2007-'08 Biota had a net loss of $6.5 million and in 2006-'07 a net profit after tax of $20.2 million.

Biota said total revenue included $45 million of Relenza royalties compared to $20.5 million in 2007-'08, $12.6 million of collaboration income from licencing agreements with Astrazeneca and Boehringer Ingelheim compared to the previous year's $15.2 million, $20 million from the litigation settlement with Glaxosmithkline and grant income of $2.8 million from the US National Institutes of Health for the development of long acting neuraminidase inhibitor (LANI) programs.

The company said costs decreased to $41.5 million from the previous year's $54.3 million with litigation costs of $7.2 million down from the $21.8 million in 2007-'08, following conclusion of the litigation.

Biota said cash at June 30, 2009 was $86.7 million up from $60.2 million the previous year.

The company reported diluted earnings per share of 21.6 cents compared to the previous year's loss of 3.5 cents.

Biota's net tangible assets per share was up from 35 cents to 55 cents.

The company said it would return $20 million to shareholders or about 11 cents a share.

The record date is November 19, 2009 with payment on December 3, 2009.

Biota fell 4.5 cents or 2.3 percent to $1.895 with 994,666 shares traded.

BIOTA

Hunter Hall Investment Management increased its substantial shareholding in Biota from 21,119,010 shares (12.1%) to 22,969,593 shares (13.13%).

CSL

CSL's net profit after tax for the 12 months to June 30, 2009 was up 63 percent to $1,145.9 million on revenue up 32 percent to $5,039.4 million.

CSL said that a final unfranked dividend of 40 cents a share with a record date of September 18, 2009 would be paid on October 9, 2009, taking total dividends to 70 cents compared to 46.0 cents on 2007-'08.

Diluted earnings per share was 191.74 cents up from 126.85 cents the previous year.

CSL's chief executive officer Dr Brian McNamee said that for the 2009-'10 year the company expected net profit after tax between $1,160 million and $1,260 million, at 2008-'09 exchange rates.

"This represents 14 to 24 percent growth on the underlying operational profit for fiscal year 2008-'09," Dr McNamee said.

"Given the volatile foreign exchange environment we have provided with our results materials a foreign currency sensitivity analysis to assist investors in determining the impact of movement in key currency pairs," Dr McNamee said.

CSL fell 44 cents or 1.31 percent to $33.12 with 6.6 million shares traded.

BONE MEDICAL

Bone says it the US Food and Drug Administration has approved an open investigational new drug fast-track phase III trial of oral Capsitonin for osteoporosis.
Bone director Leon Ivory said the company was planning the 12-month trial.
In its media release Bone said the primary endpoint would be change in bone mineral density, thus avoiding the need to focus on collecting bone fracture data in multi-year studies, as is required with new drugs for the chronic condition.
Bone said the FDA response indicated a requirement for modest non-clinical data regarding pharmacokinetics and toxicology which was expected due to the nature of the oral formulation that specifically avoids any new chemical entities.
Bone's chairman Leif Jensen said the FDA response was "consistent with our earlier communications with the Agency and provides clarity not only for the company but also for potential pharmaceutical partners and investors".
Bone said it intended to undertake further work on the scaling-up of the Capsitonin and to generate further data identifying the appropriate dose levels to be used in the study.
Bone said it would also continue with the filing of an additional investigational new drug application for Capsitonin for osteoarthritis, which was "a substantial market where there is a great need for a safe product which alleviates bone pain".
Bone was untraded at 16 cents.

MESOBLAST

Mesoblast says primarily Australian investors have committed a minimum of $7 million and up to $10 million in its US sister company Angioblast Systems.
Mesoblast said Lodge Corporate assisted with the capital raising from Australian investors.
Mesoblast's directors welcomed Angioblast's successful funding by new investors as further third-party validation of its "underlying value proposition, underscoring the inherent value of Mesoblast's significant equity stake in the company".
The founder and executive director of both companies Prof Silviu Itescu told Biotech Daily that following the capital raising he would own "about 40 percent" of Angioblast, less than 30 percent of Mesoblast and Mesoblast would hold its 38 percent of Angioblast.
Prof Itescu said most of the funds had been raised from Australian investors.
Prof Itescu said he was "comfortable being diluted through the company's maturation" but it was not the primary objective of the capital raising which was to raise the required funds for the company to mature.
"It indicates confidence from new investors in the future of the companies," Prof Itescu said.
"The more capital that comes in, the more the founding investors are diluted and the investor base is broadened," Prof Itescu said.
Mesoblast's media release said that Angioblast would use the funds to significantly advance its cardiovascular and other clinical programs towards phase III trials".
"On the basis of continued positive results from its lead indications, Angioblast will seek to obtain additional funding for phase III trials and product commercialization needs via either an initial public offering or alternative commercial transactions," the company said.
Together with Mesoblast's cash reserves, the two companies have up to $26.5 million in funds for clinical development of the shared adult stem cell platform technology.
Mesoblast said the funding "underpinned the nature of potential strategic corporate partnerships for both companies".
Mesoblast fell three cents or 2.5 percent to $1.16 with 925,659 shares traded.

PEPLIN

Peplin says it has completed enrolment in its second phase III clinical trial of PEP005 (ingenol mebutate) Gel for actinic (solar) keratoses on non-head areas.

Peplin said it was the final of four pivotal trials planned for the submission of the new drug application for actinic keratosis.

The company said this second pivotal phase III trial for non-head locations, known as Region-Ib, enrolled about 200 patients.

Peplin said it was designed to replicate the recently completed Region-I trial and confirm the results of that trial in which PEP005 Gel (0.05%), demonstrated a total clearance rate across all anatomical non-head locations of 27.4 percent ($p<0.0001$), a median lesion reduction of 66.7 percent ($p<0.0001$) and statistical significance when compared to vehicle for clearance of actinic keratoses on the chest and the especially difficult-to-treat locations, the arm and back of hand.

Peplin said it planned to complete the Region-Ib results by the end of 2009.

Peplin's chief executive officer Tom Wiggans said the four week enrolment period for the trial "further demonstrates the enthusiasm by physicians and their patients for new AK treatment options, validating the existence of an unsatisfied medical need that PEP005 Gel could fulfill".

The Region-Ib trial is a randomized, double-blind, vehicle-controlled clinical trial conducted at multiple sites in the US.

Peplin fell 1.5 cents or 2.6 percent to 57 cents.

IMMURON

Immuron says it expects to close recruitment soon of a trial of its bovine colostrum Bioguard product to control abnormal gastrointestinal inflammation associated with HIV.

Immuron said the trial being run by the University of New South Wales' National Centre for HIV Epidemiology and Clinical Research has recruited 69 of the 71 required patients.

This company said the study was being conducted in 21 centres with results expected by mid-2010.

Immuron said the trial would investigate Bioguard's efficacy in helping control the abnormal gastrointestinal inflammation associated with HIV infections.

Immuron said it expected Bioguard would slow the progress of the HIV disease either alone or in combination with an anti-retroviral drug.

The study examines patients with well-controlled HIV infections, but poor immune recovery and will measure the efficacy of immune recovery of adding either Bioguard or raltegravir, a new class of anti-HIV drug or combinations of both Bioguard and raltegravir to an optimized HIV therapy.

Immuron was up 0.4 cents or 6.15 percent to 6.9 cents with 1.7 million shares traded.

IMUGENE

Imugen has told the ASX that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 8.4 cents on August 10, 2009 to 12.5 cents, a 48.8 percent increase, today and noted an increase in trading volume.

In its response Imugene did not refer to its recent announcement on development of a swine influenza vaccine for pigs (BD: Jul 27, 2009) or reports that a Victorian pig farm has reported its animals suffering swine 'flu.

Imugene was up 2.5 cents or 26.3 percent to 12 cents with 1.6 million shares traded.

AGENIX

Agenix says chief executive officer Dr Stephen Phua's contract will not be renewed when it expires in January 2010.

The company said the contract was "not congruent with the board's direction for the company's organization architecture and financial goals".

The company thanked Dr Phua for his efforts and ongoing cooperation.

Agenix is in a voluntary suspension and last traded at 1.7 cents.