Biotech Daily

Tuesday August 12, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS UP: VENTRACOR UP 17%, AGENIX DOWN 10%**

*** PHARMAXIS BRONCHITOL IMPROVES CYSTIC FIBROSIS LUNG FUNCTION**

*** ACRUX EXPANDS KV DEAL: WINS DATA RIGHTS, MORE US PRODUCTS**

*** BIOGUIDE BRIEF: ACRUX; PHARMAXIS**

*** FDA ACCEPTS VENTRACOR TRIAL CHANGES; TGA APPROVES DEVICE**

*** MESOBLAST GROWS KNEE CARTILAGE IN SHEEP**

*** COCHLEAR PROFIT UP 15% TO $115m ON REVENUE UP 8%**

*** COGSTATE SIGNS $2.3m SALES IN 6 WEEKS**

*** AGENIX LOSES TWO MORE DIRECTORS**

*** SIRTEX SEEKS TO RESTRAIN FOUNDER DR BRUCE GRAY**

*** OPTISCAN EGM BACKS SHARE ISSUE; DIRECTORS' SHARES, FEES**

*** NEUREN CALLS PLACEMENT, SHARE PLAN EGM; ACORN TAKES 9%**

*** STEM CELL ASX CASH FLOW QUERY: COSTLY RESTRUCTURE OVER**

MARKET REPORT

The Australian stock market climbed 0.4 percent on Tuesday August 12, 2008 with the All Ordinaries up 21.0 points to 5,090.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and eight were untraded.

Ventracor was best, up 3.5 cents or 16.67 percent to 24.5 cents on moderate volumes, followed by Novogen and Polartechnics up more than 13 percent, Phosphagenics up 12.5 percent and Genetic Technologies up 11.11 percent. Mesoblast climbed 9.91 percent; Circadian, Psivida and Resmed were up more than three percent; Bionomics rose 2.94 percent; with Clinuvel, CSL, Optiscan and Pharmaxis up more than one percent.

Agenix led the falls, down 0.2 cent or 10.0 percent to 1.8 cents on modest volumes. Chemgenex, Neuren and Proteome fell five percent or more; Universal Biosensors lost 4.11 percent; Alchemia and Starpharma fell more than three percent; Acrux and Biota shed more than two percent; with Avexa and Heartware down more than one percent.

PHARMAXIS

Pharmaxis says its phase II Bronchitol trial in subjects with cystic fibrosis achieved its primary end point of demonstrating a dose dependent improvement in lung function.

Pharmaxis says the two measurements of forced vital capacity (FVC) and the amount of air that can be forcibly exhaled in one second (FEV1) showed significant changes in lung function at the end of the two-week Bronchitol treatment period.

In the 400mg treatment group FEV1 increased by 8.6% (139mls, p=0.0006 v 40mg).

In the 240mg treatment group FEV1 increased by 4.6% (87mls).

In the 120mg treatment group FEV1 increased by 3.7% (42mls).

In the 40 mg treatment group FEV1 decreased by -1.6% (-33mls).

FVC improved by 7.9% in the 400mg group (p=0.0004 vs 40mg), by 3.9% in the 240mg group, by 1.5% in the 120mg group and decreased by 0.6% in the 40mg group.

Pharmaxis chief executive officer Dr Alan Robertson said the results from the trial "reaffirms that the 400mg Bronchitol dose being used in the phase III trials is optimal for its clinical effectiveness".

"We look forward to the results from the ongoing phase III studies and to bringing Bronchitol to the market as rapidly as possible," Dr Robertson said.

The study was an open, randomized comparison of 400mg, 240mg, 120mg and 40mg of Bronchitol in 48 patients with cystic fibrosis at 12 centres in Canada and Argentina.

Bronchitol was administered twice a day for 14 days in a crossover design.

Dr Robertson told Biotech Daily that there were practical limits to using higher doses than the 400mg dose.

"We believe we are at the top of the dose-response curve," Dr Robertson said.

He said that the 40mg baseline comparison resulted from the need to measure effective doses against an ineffective dose and it was "impossible to have placebo to a dry powder".

In its media release to the ASX Pharmaxis said the secondary endpoints of the study included other spirometry and quality of life measures.

These measures also showed a positive effect for 400 mg Bronchitol on maximum mid-expiratory flow and the respiratory domain of the cystic fibrosis quality of life questionnaire, Pharmaxis said.

Additionally, no serious adverse events emerged during the 400 mg treatment period and the adverse event profile was similar across all doses.

People affected by cystic fibrosis typically experience a decline in lung function of one to two percent per year during their life, as measured by FEV1.

Pharmaxis has orphan drug designation and fast track status from the US Food and Drug Administration for Bronchitol in cystic fibrosis.

Bronchitol is designed to hydrate the airway surface, improve lung hygiene and promote normal lung clearance.

Additional data from this trial will be presented at a forthcoming scientific congress, Pharmaxis said.

A Pharmaxis-sponsored European regulatory phase III clinical trial, designed to lead to a marketing application for Bronchitol in adults and children with cystic fibrosis is due to report preliminary data early in 2009.

About 75,000 people in the major pharmaceutical markets are affected with cystic fibrosis and no products have been approved to improve lung hydration.

Pharmaxis was up two cents or 1.05 percent to $1.93.

ACRUX

Acrux has expanded its partnership with KV Pharmaceutical Company for the Evamist hormone spray and new products using Acrux's transdermal spray drug delivery system.
Acrux said Evamist was launched by KV in the US as the first estradiol transdermal spray, "targeting one of the largest markets in women's health".
The company said Evamist prescription trends were increasing in the US since the April 2008 launch and has become the second ranked transdermal hormone therapy as measured by new to brand prescriptions.
Acrux said the agreement gave it the right to use the data contained in KV's US Food and Drug Administration filing for Evamist in regulatory filings in all territories outside the US.
Acrux said it would file a marketing application in Europe, under the brand name Ellavie.
Acrux has received commercial interest for Ellavie from potential marketing partners in the non-US pharmaceutical markets.
Evamist was originally licensed by Acrux to Vivus Inc, which subsequently sub-licensed rights to KV. With Acrux's consent, Vivus has assigned the licence to KV and KV is now Acrux's licensee.
Under the new agreement, KV has licenced Acrux's transdermal spray technology for application in six additional products, with the potential to add further products.
Three pre-clinical products, including a combination hormone therapy Duomist, have been licenced for the US market only, Acrux said.
Acrux chief financial officer Jon Pilcher told Biotech Daily that the other three products were product concepts that KV suggested to Acrux but have not yet been selected.
The company said KV would fund all clinical development costs for each product and Acrux would receive royalties on US sales plus milestone payments.
Acrux would have access to the data contained in KV's FDA filings for regulatory filings in all other territories.
In return, Acrux will pay to KV a share of its licencing revenues from those territories.
The technology has further been licenced to KV to develop three new products for global markets.
Acrux said KV would fund all clinical development costs for each product and Acrux would receive royalties on global sales plus milestone payments.
Acrux chief executive officer Dr Richard Treagus said the collaboration with KV allowed the company "to proceed immediately with the commercialization of our estradiol product in the major markets outside the US, but just as importantly it aligns us strongly with a very capable and committed marketing partner".
"I am delighted that, following the launch of Evamist, KV has seen the value and potential in our unique spray technology," Dr Treagus said.
ABN Amro Morgans today valued Acrux at $2.09.
Acrux fell three cents or 2.42 percent to $1.21.

MARC SINATRA'S BIOGUIDE: ACRUX, PHARMAXIS

After covering three events with negative implications, it is nice to be back to analyzing positive news.
Acrux's announcement that it has expanded its association with KV pharmaceuticals is positive on two fronts.
Firstly, by gaining the right to use KV's Evamist data, Acrux can rapidly accelerate commercialization of the product in non-US markets, commencing with the filing of a European marketing application.

Obviously, this will bring revenues from those markets forward and, consequently, should increase the value of Acrux's shares.
Secondly, by licencing its transdermal spray technology to KV for a further six existing projects, Acrux has broadened its potential revenue streams, while reducing the risk of others given KV's deep pockets and expertise.
Although the terms of the deal are largely confidential, making it difficult to accurately value, what is available is put together nicely and augurs well for the development of these products.
The biggest signal from this announcement, however, relates back to the big question I had over Acrux when I reviewed it in August of last year (See Biotech Daily; August 15, 2007). That question was would Acrux's products sell?
Many products gain marketing approval only to find that consumers are not all that interested for one reason or another, the use of Biota's Relenza for the routine treatment of influenza being one of the best Australian examples.
We know from KV's end-of-year review, that this is not the case with Evamist, with sales being described as "on track with company expectations" and prescriptions trending toward 2,000 a month.
So, are Acrux's other products in development likely to sell?
KV through its experience with Evamist is in the best position by far to know whether the market will accept other products based on Acrux's technology and by licencing the technology for a further six indications they seem to think the answer is a resounding: "Yes".
Based on this announcement and its implications, I am raising my price target on Acrux from $2.12 to $2.25 largely on increased certainty of future sales.
Pharmaxis announced some very nice results regarding dose response to Bronchitol in cystic fibrosis patients. While these results were to be somewhat expected, for those of us who like to see good clean data behind a product, they are reassuring.
Marc Sinatra owns shares in Acrux.

VENTRACOR

Ventracor says the US Food and Drug Administration has approved "several enhancements" to its destination therapy trial of its left ventricular assist device.
Ventracor said the changes included the addition of "an alternative body habitus cohort" which allows up to 20 additional patients to be implanted with the Ventrassist left ventricular assist device as part of the trial who are not randomized to the control arm.
The company said this would allow inclusion of smaller patients especially women who would otherwise be excluded from the trial.
The company said the FDA had provided clarification of certain inclusion and exclusion criteria which was expected to simplify the enrollment procedure.
Ventracor said the Australian Therapeutic Goods Administration had approved the Ventrassist LVA4 left ventricular assist device as an approved medical device.
"It will no longer be necessary for a special access scheme application for Australian implants," Ventracor said.
The company said there were 320 patients worldwide implanted with the Ventrassist left ventricular assist device (LVAD) and 42 hospitals trained to perform an implant.
There were 26 implants of the Ventrassist LVAD in July.
There have been 96 enrolments in the US bridge-to-transplant trial and 45 enrolments in the destination therapy trial.
Ventracor was up 3.5 cents or 16.67 percent to 24.5 cents.

MESOBLAST

Mesoblast says its proprietary adult stem cells regenerated and re-grew damaged knee cartilage in post-menopausal osteoarthritis in sheep.

Mesoblast's vice president for cartilage regenerative programs Prof Peter Ghosh said the “outstanding results” indicated that Mesoblast's cells were able to support sustained regeneration of knee cartilage in post-menopausal osteoarthritis, an effect not seen with any competitor therapies currently on the market.

Mesoblast executive director Prof Silviu Itescu said the cartilage regenerative results meant the company would target product commercialization for both post-menopausal and post-traumatic knee osteoarthritis markets.

“We are sufficiently funded to commence phase II trials of our therapy in patients with osteoarthritis of the knee,” Prof Itescu said.

Mesoblast said a single injection of its allogeneic or off-the-shelf adult stem cells into arthritic knees of post-menopausal ewes with well established osteoarthritis three months after initial joint damage resulted in sustained, progressive regeneration and re-growth of knee cartilage for at least six months.

In 18 post-menopausal ewes, osteoarthritis developed following bilateral removal of the knee meniscus cartilage.

Three months later, one group of six was examined to document the extent of osteoarthritis prior to treatment.

The other two groups received hyaluronic acid alone in one knee and hyaluronic acid plus Mesoblast's allogeneic cells in the other knee.

One of these groups was then followed out for three months and the other group for six months.

Prior to receiving any treatment, three months after removal of the knee meniscus the knee joints showed extensive osteoarthritis as evidenced by severe erosions and loss of cartilage.

Mesoblast said that six months after a single injection, osteoarthritic knees that received its allogeneic cells had as much as 20 percent to 25 percent thicker and greater area of cartilage lining the damaged joint than knees that received an injection of hyaluronic acid alone (both parameters $p<0.05$).

The company said that “more important was the progressive, sustained and significant regeneration of cartilage measured at three and six months in cell-injected knees relative to baseline”.

During the six months of follow-up, osteoarthritic knees that received Mesoblast's allogeneic cells demonstrated as much as 20 percent to 25 percent thicker and greater area of cartilage lining the damaged joint compared with baseline measurements of joints before treatment (both parameters $p<0.001$).

Mesoblast said this cartilage was rich in proteoglycan, the natural constituent of joint-lining cartilage, indicating the process had induced normal, functional knee cartilage.

In contrast, no significant improvement over baseline was seen with a single injection of hyaluronic acid at either three or six months, the company said.

“As we progress in our clinical program, we will be actively seeking strategic partners with whom to commercialize our product for the broader osteoarthritic markets, including post-menopausal women,” Prof Itescu added.

Mesoblast said 40 percent of ageing women suffered from post-menopausal knee osteoarthritis.

The company said the degenerative condition of cartilage loss was the leading cause of joint pain and disability among the elderly, affecting more than 10 million people in the US.

Mesoblast climbed 11.5 cents or 9.91 percent to $1.275.

COCHLEAR

Cochlear has reported net profit after tax for the 12 months to June 30, 2008 up 15 percent to $115.2 million on total revenue up eight percent to $601.7 million.
The company reported core basic earnings per share up 14 percent to 223.4 cents.
A final dividend of 80 will be payable on September 25, 2008 with a full-year, fully-franked dividend of 150 cents a share.
In a telephone conference, Cochlear's chief executive officer Dr Chris Roberts said that the six percent revenue growth in the Americas was affected by a range of factors, including an early uptake of the Freedom Nucleus 24 upgrade and currency fluctuations.
The Mexican market was flat following the death of the surgeon performing the implants.
Dr Roberts rebutted industry comments that the implant market had become saturated thereby limiting expansion. "I don't think the US market is maturing," Dr Roberts said.
"More people are born deaf or go deaf every year than have implants," Dr Roberts said.
He said the implant operation took about one to one and a half hours, but the day surgery was only part of the implant process, which requires an infrastructure including audiologists and speech pathologists. Dr Roberts said that part of the implant process was a challenge for developing countries. He said the implant itself cost about $20,000 a unit and the cost of the operation varied widely but was in the order of $50,000 to $150,000.
Dr Roberts said the company would change its US business model to drive demand by using implant recipients to advocate their use.
He said industrial relations concerns with the manufacturing work force had been settled with individual contracts settled and membership of the Australian Manufacturing Workers Union comprising less than half the Cochlear production staff.
Cochlear climbed 32 cents or 0.68 percent to $47.14.

COGSTATE

Cogstate says a contract with to provide its computerized cognitive testing and services for a phase III schizophrenia study takes sales to $2.3 million since July 1, 2008.
Cogstate said the unnamed pharmaceutical company's phase III study had cognition as a co-primary endpoint.
The company said the study would be conducted in more than 70 sites and the Cogstate technology would be provided in seven languages.
The phase III study will generate more than $1 million in revenue over the life of the contract, with more than 50 percent recognized in the year ending June 30, 2009.
Cogstate said an additional eight contracts had been signed since July 1, 2008, taking the total to nine contracts signed with a combined value of approximately $2.3 million.
Cogstate was untraded at 10.5 cents.

AGENIX

Agenix directors James Liu and Gordon Crosbie-Walsh have resigned.
The company announced the resignation of its chairman Ravindran Govindan on August 7, 2008 and has replaced two key executives following the failure to complete the share transaction related to its acquisition of two Shanghai-based pharmaceutical companies (see Biotech Daily July 24, 28 and 31, 2008).
Agenix said Mr Liu "resigned due to other responsibilities which are incompatible with his ongoing role as a director of the company".
"Mr Crosbie-Walsh resigned for personal reasons," Agenix said.
Agenix fell 0.2 cents or 10 percent to 1.8 cents.

SIRTEX

Sirtex said it was exploring legal options to restrain founder and major shareholder Dr Brue Gray from acting in breach of his contractual obligations not to compete with Sirtex.
The action is part of a larger legal dispute involving Sirtex, Dr Gray and the University of Western Australia (see Biotech Daily; August 8, May 9, 2008).
In an announcement to the ASX after the market closed yesterday Sirtex said Dr Gray intended to revoke an undertaking not to compete with the company.
Sirtex said that on February 14, 2007, it announced that it was seeking leave to further amend its cross claim against Dr Gray in the University of Western Australia proceedings to include a claim restraining Dr Gray from breaching contractual obligations not to compete with the business of Sirtex whilst he remains a shareholder and for a period of up to three years after he ceases to hold any shares.
Sirtex said these contractual obligations were contained in the Subscription and Shareholders Agreement signed by Dr Gray when the company was established.
The company said that on February 27, 2007 it announced that the proposed amendment to the cross claim would not be necessary as Dr Gray had provided an undertaking to Sirtex in the following terms: " … Dr Gray undertakes to refrain from directly or indirectly carrying on (whether alone or in partnership or in joint venture with anyone else) or otherwise be concerned with or interested in (whether as trustee, principal, agent, shareholder, unit holder or in any other capacity) any business which is similar to or competitive with any part of present business of Sirtex.
"This undertaking is not capable of being revoked otherwise than upon 30 days prior written notice to Sirtex..."
Sirtex said Dr Gray had provided it with notice of his intention to revoke this undertaking.
Sirtex was unchanged at $2.50.

OPTISCAN

Optiscan shareholders overwhelmingly supported the issue of 11 million shares at 23 cents as well as shares for directors and an increase in the remuneration pool.
The vote to increase the directors' remuneration pool from $250,000 to $400,000 a year was the most divisive resolution with 34,253,355 proxy votes cast in favor and 4,693,714 proxy votes against.
Optiscan was up half a cent or 1.96 percent to 26 cents.

NEUREN

Neuren has called a special general meeting to ratify a proposed placement and share plan to raise $3 million.
The meeting will be asked to ratify five resolutions relating to the placement and share plan (see Biotech Daily August 6, 2008).
The meeting will be held at the company's offices Level 2, 57 Wellington Street, Freeman's Bay, Auckland on August 28, 2008 at 12.30pm.
In a separate announcement, Acorn Capital increased its holding in Neuren from 14,371,996 shares (6.53%) to 20,621,996 shares (8.89%).
Neuren fell 0.4 cents or five percent to 7.6 cents.

STEM CELL SCIENCES

Stem Cell Sciences has told the ASX that it expects to have sufficient funds from deals and cost cutting to continue operations.

The ASX noted a cash burn of $3,094,000 for the quarter ending June 30, 2008 with cash of $3,725,000 at the end of the quarter and total receipts of $41,000.

Stem Cell said it had undertaken a restructure which itself incurred costs but has been completed and reduced ongoing costs.

The company said it intended disposing of assets, had income from sales and was considering further capital raising.

Stem Cell Sciences was untraded at 32 cents.