

# Biotech Daily

Wednesday August 18, 2010

## Daily news on ASX-listed biotechnology companies

- \* ASX EVEN, BIOTECH DOWN: SUNSHINE UP 23%; CATHRX DOWN 21%
- \* PHYLOGICA CONFIRMS \$110m+ MEDIMMUNE PHYLOMER DEAL
- \* BIOGUIDE BRIEF: PHYLOGICA IS DEAL, IS GOOD
- \* BIOTA PROFIT DOWN 57% TO \$16.2m; REVENUE UP 12% TO \$67.6m
- \* CSL BLAMES EXCHANGE RATES FOR PROFIT DOWN 8.1% TO \$1,053m
- \* ELLEX GIVES PROFIT UPGRADE GUIDANCE
- \* RUSSIAN PROTECTION FOR STARPHARMA'S VIVAGEL-COATED CONDOM
- \* CSL TO BUY-BACK UP TO \$900m IN SHARES
- \* LUDWIG INSTITUTE TAKES 7% OF CIRCADIAN
- \* QRX WINS FROST & SULLIVAN GONG
- \* MONASH'S PROF CHARLES MACKAY WINS \$60k GSK GONG

#### MARKET REPORT

The Australian stock market slipped 0.05 percent on Wednesday August 18, 2010 with the S&P ASX 200 down 2.1 points to 4474.9 points. Eleven of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and three were untraded.

Sunshine Heart was best, up 0.6 cents or 23.1 percent to 3.2 cents with 45,355 shares traded, followed by Cellmid up 10 percent to 2.2 cents with 200,000 shares traded.

LBT climbed 6.25 percent; Heartware was up 3.54 percent; Resmed and Tissue Therapies rose more than two percent; with Cochlear, Starpharma and Universal Biosensors up more than one percent.

Cathrx led the falls, down four cents or 21.05 percent to 15 cents with 121,492 shares traded, followed by Antisense down 11.8 percent to 1.5 cents with 662,000 shares traded.

Virax lost 9.7 percent; Genetic Technologies was down 8.8 percent; Bone fell 7.1 percent; Phylogica lost 5.95 percent; Clinuvel and Phosphagenics fell more than four percent; Pharmaxis and Prima were down more than three percent; CSL, Living Cell, Optiscan and Patrys shed two percent or more; with Chemgenex and Circadian down more than one percent.

### **PHYLOGICA**

Phylogica has confirmed its potentially more than \$US99.5 million (\$A110.2 million) deal with Medimmune to evaluate its Phylomer library for novel antimicrobial peptides.

Phylogica requested a trading halt on August 3, 2010, which was extended to a voluntary suspension to finalize the formal documentation relating to the research partnership, but a media lunch led to the early release of the details (BD: Aug 3, 4, 5, 2010).

Exchange rate fluctuations have slightly increased the Australian dollar value of the deal. Phylogica chief executive officer Dr Paul Watt told Biotech Daily that Medimmune was interested in the Phylomers because his company "had already demonstrated the efficacy of Phylomer peptides in multi-resistant clinical strains of Pseudomonas aeruginosa". Prof Watt said Pseudomonas aeruginosa was involved in multi-resistant, hospital-acquired, gram-negative infections such as catheter infections, pneumonia and

complications with cystic fibrosis.

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Phylogica said Astrazeneca's Medimmune would evaluate Phylogica's Phylomer peptide library for novel antimicrobial peptides.

In particular, the Phylomer library would be screened "to identify drug candidates with potent activity against the gram-negative bacterium, Pseudomonas aeruginosa.

Phylogica's Phylomers are fragments of proteins suitable for being used as antibodies. Phylogica said it would receive \$US750,000 (\$A830,516) as an upfront payment and an additional \$US750,000 in committed research funding for an initial 12-month period.

Phylogica said in the media release that it was eligible to receive milestones payments of up to \$US98 million "in addition to royalties on potential worldwide sales".

Dr Watt said Medimmune was "a world leader in the successful development of novel biological drugs to treat infectious diseases".

"This alliance underscores the versatility and substantial opportunity of Phylomer peptides, which have potent activity on challenging targets such as found in multi-drug resistant bacteria," Dr Watt,

The company said it retained the existing rights to its internal program of anti-microbial Phylomer peptides directed against multi-resistant bacteria.

Phylogica fell half a percent or 5.95 percent to 7.9 cents with 1.2 million shares traded.

## MARC SINATRA'S BIOGUIDE BRIEF: PHYLOGICA

It's good to be able to write on a truly positive occurrence for an Australian biotechnology company, even if the finally confirmed deal is well and truly old news.

In fact, so well known is the news that some investors seemed to sense it was coming even before Phylogica requested a trading halt, with the price going from 6.8 cents on open to 8.4 cents when the halt was put in place.

The volume of Phylogica shares traded was also the highest it had been in three months. But enough about the sieve-like properties of the cone-of-silence surrounding Phylogica's offices.

Phylogica's deal with Medimmune is a good deal for Australian biotechnology, no two ways about it, and it is the sort of story the industry needs after what has been a fairly negative period in its history.

The program, which aims to develop a drug to treat Pseudomonas aeruginosa, will use Phylogica's Phylomer peptide libraries and their high throughput screening capabilities.

The deal gives Phylogica \$US750,000, the possibility of development, regulatory and commercial milestone payments of up to \$US98 million and an undisclosed sales royalty.

When this deal is compared to Acrux's \$US50 million upfront and \$US285 million milestones and Chemgenex's \$18 million up front and \$120 million milestones for Europe alone, the upfront looks low, while the milestones look pretty good.

The deals done by Acrux and Chemgenex, however, were done for products that have been substantially de-risked, such that Acrux and Chemgenex are much more likely to make substantial amounts of money from the achievement of milestones than Phylogica.

The royalty rates payable to Acrux and Chemgenex are probably in the very solid double digit range, while Phylogica's are almost certain to be in the mid single digit range.

A better comparator is probably the former Cytopia's deal with Novartis for compounds targeting the kinase, JAK3, which was at only a slightly later stage of development than Phylogica's deal.

That deal involved \$13 million in up-front and funding payments over the first three years and up to \$274 million in milestone payments.

A little care is required in interpreting this deal because funding agreements are generally not considered part of a deal's upfront or headline value and Cytopia also owned the rights to the JAK3 target as opposed to Phylogica which only owns the compounds covered by the deal. Compared to Cytopia's deal, Phylogica's isn't a world beater.

Having said that, any deal with a big pharma is still a very good deal.

Marc Sinatra, Analyst marc@biotechdailv.com.au

#### **BIOTA**

Biota says its net profit after tax was down 57 percent to \$16,235,000 for the 12 months to June 30, 2010 on revenue up 12 percent to \$67,590,000.

Biota said the revenue figures did not include grant income or the previous year's \$20 million litigation settlement with Glaxosmithkline.

The company said its Relenza royalties from Glaxosmithkline were a record \$63.7 million Biota said that is net tangible assets per share was 54 cents at June 30, 2010, a 10.2 percent increase above the 49 cents at June 30, 2009.

The company said that diluted earnings per share was 9.1 cents compared to the previous year's 21.6 cents.

Biota said it spent \$21,749,000 on research and development an increase of 62.9 percent on the previous year and equivalent to 32.2 percent of total revenue.

Biota said that no dividend would be paid.

Biota was unchanged at 98 cents.

## **CSL**

CSL says its net profit after tax was down 8.1 percent to \$1,053 million for the 12 months to June 30, 2010 on revenue down 8.2 percent to \$4,627 million.

In a media release, CSL said its profit was up 22 percent "at constant currency" meaning that if exchange rates were the same as the previous year, it would have posted \$1,240 million net profit after tax and total revenue could have been \$5,270 million.

Biotech Daily's reporting policy is to use actual funds received, rather than hypothetical accountancy calculations.

CSL said that is net tangible assets per share was \$5.93 at June 30, 2010, compared to \$7.43 at June 30, 2009, a fall of 20.2 percent.

The company said that diluted earnings per share was 185.19 cents compared to the previous year's 191.74 cents.

CSL said it spent \$316,722,000 on research and development an increase of 1.6 percent on the previous year and equivalent to 6.8 percent of total revenue.

CSL said it had paid an unfranked interim dividend of 35 cents a share on April 9, 2010 and would pay a partially franked final dividend of 45 cents a share with a record date of September 17, 2010.

CSL managing director Dr Brian McNamee said the company had "a strong operational result in a period of currency headwinds, rigorous competition and significant healthcare reform around the world".

"Whilst certain markets have been subdued in line with the broader economic environment, underlying medical demand for CSL's plasma therapies reflects the importance of these life saving products," Dr McNamee said.

"Following the World Health Organisation announcements regarding the 2009 influenza pandemic, CSL's global sales of H1N1 influenza or 'Swine Flu' vaccine, together with related fill and finish activities, provided a significant contribution," Dr McNamee said. In his outlook statement Dr McNamee said the World Health Organisation recently announced that the world is no longer in phase six of an influenza pandemic alert and has moved into the post-pandemic period.

"For the 2010-'11 financial year we anticipate net profit after tax of between \$980 million and \$1,030 million, at fiscal 2009-'10 exchange rates," Dr McNamee said.

"Although slightly less than 2009-'10, this represents a growth of up to 10 percent on the underlying operational profit, largely reflecting CSL's global plasma therapeutics business which is expected to deliver this growth," Dr McNamee said.

"Foreign exchange rate movements may impact this forecast and to assist investors we have provided a foreign currency sensitivity analysis with our results materials," he said. CSL fell 88 cents or 2.7 percent to \$31.90 with 5.3 million shares traded.

## **ELLEX MEDICAL LASERS**

Ellex says its full year net profit before tax for 2010 is expected to be about \$3.5 million, a 13 percent improvement compared to \$3.1 million in the previous year.

Ellex said the figure was subject to final audit and followed a better than expected first half of the financial year, in which net profit before tax was \$1.735 million.

Ellex chief executive officer Simon Luscombe said the company's "continued efforts to exercise tight cost control, reduce debt and improve operating efficiencies have contributed positively to our bottom line, despite a challenging global economic environment."

Ellex said it expected to release its results next week.

Ellex was up two cents or 12.1 percent to 18.5 cents.

### **STARPHARMA**

Starpharma says the Russian patent office will grant the first patent specifically for the Vivagel-coated condom on August 20, 2010.

Starpharma said it had filed the patent in major markets including the US, Canada, Europe, China, India and Japan.

The company said that both Vivagel and the Vivagel-coated condom were "already protected by a portfolio of granted Vivagel patents in major markets" but the new patent family provided additional protection for the condom product and extended the duration of coverage in each market for which it is granted.

Starpharma said the Russian grant provided coverage for the coated condom until at least 2026.

Starpharma chief executive officer Dr Jackie Fairley said the grant was "an important milestone in the commercialization of the Vivagel-coated condom".

"Although each patent office works according to slightly different criteria, we consider this successful grant to be a very encouraging sign more widely," Dr Fairley said.

Starpharma said that protection in Russia was "very valuable in its own right as Starpharma's commercial partner SSL has the leading position in the Russian condom market". SSL International has about 40 percent of the global branded condom market and was the owner of Durex, the number one global condom brand, Starpharma said. Starpharma was up one cent or two percent to 52 cents.

## CSL

CSL will buy back up to \$900 million worth of its shares on issue.

The company said it had a total issue of 549,698,043 shares and the buy-back was for "on-going capital management".

CSL said that "for illustration purposes only, if that maximum number is ultimately acquired, and the average price per share paid is \$33.00, that maximum number of shares would be approximately 27.272.000.

CSL said the buy-back would begin on September 1, 2010 and continue for up to 12 months.

### **CIRCADIAN TECHNOLOGIES**

The Ludwig Institute for Cancer Research has increased its substantial shareholding in Circadian from 2,589,635 shares (5.72%) to 3,122,090 shares (6.73%).

The Switzerland-based was a co-creator of the original vascular endothelial growth factor (VEGF) technology acquired by Circadian.

Circadian fell one cent or 1.5 percent to 65 cents.

#### **QRX PHARMA**

QRX has won the 2010 North American Frost & Sullivan Award for new product innovation of the year for its Moxduo immediate-release dual opioid for pain.

QRX said pain was the leading cause of disability in the US, costing more than \$US100 billion (\$A110 billion) a year.

Frost & Sullivan research analyst Katheryn Symank said that Moxduo's formulation allowed morphine and oxycodone to work synergistically resulting in a more potent pain reliever and a 25 to 75 percent decrease in moderate-severe adverse side effects. QRX was unchanged at 96 cents.

## **GLAXOSMITHKLINE**

Monash University's professor of immunology Prof Charles Mackay has won the \$60,000 Glaxosmithkline Australia Award for Research Excellence for 2010.

In a media release Glaxosmithkline said the award recognized "outstanding achievement contributing to the improvement of human health".

Glaxosmithkline said Prof Mackay received the award for his work in immunology and inflammation, which includes his discovery of GPR43 as a major regulator of innate and inflammatory response.

Glaxosmithkline Australia medical director Dr Camilla Chong said Prof Mackay was chosen for his "outstanding publication record and his involvement in three research programs that have gone into clinical testing".

"We hope this award will draw attention to Prof Mackay's excellent work... and that it can translate into something with actual clinical benefits," Dr Chong said.

"GSK is committed to fostering scientific skills and nurturing Australian ideas in the quest for new and improved medicines," Dr Chong said.

Glaxosmithkline said Prof Mackay's research had showed that products of bacterial metabolism, short chain fatty acids, stimulate immune cells through GPR43, and that this might be a molecular mechanism linking diet, gut microbiota, and inflammation.

"The impact of this work means it's just possible that the way we think about treating inflammatory diseases in the future will be completely altered," Prof Mackay said. "It won't be just taking a pill," he said.

"One consideration will be the make up of our microbiota, and whether we can manipulate this with dietary supplements," Prof Mackay said.

"It is highly conceivable that we will use these alternative approaches to preventing or treating inflammatory diseases," Prof Mackay said.

Professor Mackay's research was conducted at the Garvan Institute in Sydney where he was director of the immunology and inflammation research program for 10 years and the work was done as part of the Cooperative Research Centre (CRC) for asthma and with participation of Glaxosmithkline in the UK.