Biotech Daily

Thursday June 21, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTISCAN UP 56%, ACRUX DOWN 14.5%**

*** MAYNE'S ANTI-FUNGAL SUBACAP CLOSER TO UK APPROVAL**

*** USPTO EXAMINER OBJECTS TO ACRUX APPLICATOR PATENT**

*** QUEENSLAND $14.5m GRANTS FOR UQ BIO-MEDICAL PROJECTS**

*** ZEISS ORDERS $800k OPTISCAN NEURO-MICROSCOPE PROTOTYPES**

*** FLEMING SG EXITS CALZADA**

*** CLINUVEL REQUESTS 'POTENTIAL CAPITAL RAISING' HALT**

*** TERRAPINN HOSTS 1st AUSTRALIAN BIOPHARMA CONFERENCE**

MARKET REPORT

The Australian stock market fell 1.08 percent on Thursday June 21, 2012 with the S&P ASX 200 down 44.8 points to 4,087.6 points.

Five of the Biotech Daily Top 40 stocks were up, 16 fell, 12 traded unchanged and seven were untraded. All three Big Caps fell.

Optiscan was the best, up five cents or 55.6 percent to 14 cents with 178,681 shares traded, followed by Ellex up 13.3 percent to 17 cents with 55,500 shares traded.

Prana climbed 3.2 percent; Heartware was up 2.1 percent; with Anteo up 1.4 percent.

Acrux led the falls, down 69 cents or 14.5 percent to $4.07 with 2.7 million shares traded.

Bionomics lost 9.7 percent; Allied Health, Antisense and Benitec were down more than five percent; Neuren fell 4.2 percent; Alchemia, Mesoblast and Pharmaxis were down more than three percent; Avita, Phylogica and Tissue Therapies shed more than two percent; Impedimed, QRX, Sirtex and Starpharma were down more than one percent; with Cochlear, CSL and Resmed down by less than one percent.

MAYNE PHARMA GROUP

Mayne Pharma says the UK Medicines and Healthcare products Regulatory Agency has reversed its previous decision and has advised that Subacap is approvable.

Mayne said that the Agency formally advised that it could reactivate the decentralised procedure to seek approval in Germany, Spain and Sweden and that the marketing authorization application was “approvable in the UK”.

The company said that the decision was the result of a six month process of working with the Agency to respond to the questions raised by the Commission on Human Medicines review of the Subacap dossier in December 2011.

Last year Mayne said that the UK Medicines and Healthcare products Regulatory Agency required responses to questions about Subacap, the oral capsule super-generic formerly known as Suba-itraconazole, a variation on the drug itraconazole marketed as Sporanox and those questions would delay approval beyond June 30, 2012 as further clinical work could be required (BD: Dec 15, 2011).

In 2009, the UK regulator required a further pharmacokinetic study to show that Suba-itraconazole performed as well against European Sporanox as US Sporanox and in 2010, Mayne (then Halcygen) said the UK pharmacokinetic study showed clinical bioequivalence of a half-dose of its anti-fungal drug Suba-itraconazole with Sporanox and it hoped to have marketing authority in 2011 (BD: Aug 29, 2009; Mar 2, 2010).

In December 2011, Mayne said the UK Agency said that while clinical data presented in the dossier showed Subacap superiority over placebo, no conclusions on the non-inferiority of Subacap compared to the reference drug Sporanox could be made as the reference drug did not show superiority over placebo.

Today, Mayne investor relations manager Lisa Pendlebury told Biotech Daily that the company had provided a further data package including pharmaco-kinetic and pharmaco-dynamic analyses to the Commission on Human Medicines.

Ms Pendelbury said that the next regulatory step would be to provide a dossier to the Medicines and Healthcare products Regulatory Agency, finalizing a number of particular issues including labeling, packaging and stability.

In a media release, Mayne chief executive officer Scott Richards said the formal notice of approvability was “an important step towards gaining marketing approval for Subacap in Europe which, subject to the satisfactory review of all elements of our dossier, we anticipate receiving approval by the end of calendar 2012”.

Mayne Pharma said that the proposed labeling was consistent with the reference drug itraconazole and covered superficial and systemic infections.

The company said that the UK Commission on Human Medicines’ decision confirmed that no further clinical work would be required to support the Subacap application.

Mayne said it was considering several regulatory pathways for Subacap in the US and had sought agreement from the US Food and Drug Administration through the special protocol assessment scheme for the design of a phase III clinical trial in onychomycosis.

The company said that the special protocol assessment was a declaration from the FDA that the phase III clinical study’s design, endpoints, statistical analyses and other aspects were acceptable to support regulatory approval of the product.

Mayne said that it expected to receive this agreement before the end of 2012.

The company said that Subacap provided enhancements to patients and prescribers with reduced inter and intra-patient variability and a more predictable clinical response enabling a reduction in active drug quantity to deliver therapeutic blood levels.

Mayne said that global sales of itraconazole formulations were more than $US500 million a year.

Mayne was up 2.5 cents or 7.1 percent to 37.5 cents.

ACRUX

Acrux says the US Patent and Trademark Office examiner has raised objections to its underarm administration patent application.

Acrux said the patent was granted in Australia in September 2011 and notice of allowance had been received in New Zealand, with applications under examination in a number of other countries around the world.

The company said the US examination process included a series of submissions by Acrux and responses from the USPTO.

Acrux chief financial officer Jon Pilcher told Biotech daily that there was “nothing unusual about this type of objection.

“It is not unusual to go through a process in a patent examination and you usually have a number of iterations of the application,” Mr Pilcher said.

Acrux said it was “confident in the merits of the patent claims and intends to continue the examination process”.

Acrux fell 69 cents or 14.5 percent to $4.07 with 2.7 million shares traded.

QUEENSLAND GOVERNMENT, THE UNIVERSITY OF QUEENSLAND

The Queensland Government has provided $14.5 million to University of Queensland science and bio-medical projects

In a media release, the University of Queensland said the grants were for medical imaging technologies, type 2 diabetes treatments, animal health vaccines and biomedical implants.

The University said that the Queensland Minister for Science, Information Technology, and Innovation Ros Bates announced the grants at the 2012 BIO Conference in Boston.

Ms Bates said the funding would boost Queensland's science credentials and had the capacity to markedly improve the state's economic, employment and lifestyle prospects.

The University said the Herston Imaging Research Facility and Cancer Molecular Diagnostics would receive $3.5 million for imaging technologies to observe disease processes in patients and $2 million would be proved to Prof Maree Smith for translational projects developing life science discoveries, such as vaccines, into commercial products.

The University said that $2 million would be provided to a collaboration with Pfizer to develop new treatments for diabetes and cardiovascular diseases.

The Australian Institute for Bioengineering and Nanotechnology will receive funds for several projects, including a $1.2 million partnership with private company DSM to provide a biologics scale-up facility for Brisbane; a further $485,000 for a Prof Peter Gray led project to link mammalian cell line development expertise with DSM Biologics’ expertise in production to deliver a class of therapeutics based upon the production of clinical amounts of protein; and $250,000 for a project led by Prof Lars Nielsen leveraging funds from the Commonwealth Government, allow the Metabolomics unit to continue its operation at the Institute, providing services in fields such as biology, medicine, plant and industrial biotechnology.

An Australian Institute for Bioengineering and Nanotechnology spokesman told Biotech Daily that a grant of $470,000 was awarded Stem Cells Ltd for stem cell core facilities which was separate to the Institute but housed in the same building.

Other grants included $1 million for single dose, shelf stable vaccines targeting major cattle diseases, $672,500 to profile genetic and metabolic capabilities of microbial communities in sugarcane soils; a grant of $360,000 to Dr Kate Schroder for strategies to predict type 2 diabetes risk; and $925,000 for nanotechnology plastics development and manufacture.

OPTISCAN

Optiscan says that Carl Zeiss has placed its first purchase order worth $800,000 for its endo-microscopy neurosurgery systems.
Optiscan said the pre-production prototypes of its rigid endo-microscopy system for neurosurgery would be exclusively supplied to Carl Zeiss, the world's leading supplier of neurosurgical visualization equipment and would assist the final steps in the regulatory process and were expected to be deployed in clinical trials with key opinion leaders.
Optiscan said it expected to complete the order in August 2012.
The company said that the order was "a major milestone in the development of the neurosurgery market for Optiscan's technology".
Optiscan climbed five cents or 55.6 percent to 14 cents with 178,681 shares traded.

CALZADA

Fleming SG Capital has ceased its substantial holding in Calzada, selling all 29,158,903 shares for $1,457,945 or five cents a share.
The Perth-based Fleming notice was signed by director George Cameron-Dow.
In 2010 Fleming became substantial in Calzada acquiring the 29,158,903 shares for $874,297 or three cents a share from Xceed (BD: Jun 22, 24, 2010).
At that time Mr Cameron-Dow was a director of Calzada, Xceed and Fleming.
Today, Mr Cameron-Dow told Biotech Daily he had resigned from Calzada in 2010 and Xceed in 2011 and Fleming currently had no other biotechnology investments.
Calzada fell 0.2 cents or 3.6 percent to 5.4 cents with 3.6 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel has requested a trading halt pending an announcement "regarding a potential a capital raising".
Trading will resume on June 25, 2012 or on an earlier announcement.
Clinuvel last traded at $1.60.

BIOPHARMA AUSTRALASIA CONVENTION

Events manager Terrapinn says the first Biopharma Australasia Convention will be held in Sydney August 23 and 24 2012.
Terrapinn said that the conference at the Swissotel in Sydney would be split into eight modules over the two days, including: digital pharma marketing; generics; vaccines; drug discovery and development; market access; partnering and investment; and clinical trials.
Terrapinn said that speakers at the Biopharma Convention would include Merck Sharp and Dohme director of licencing and external research Dr Phil Kearney, Boehringer Ingelheim executive Mark Peterson, CSL's head of research and development product development Dr Simon Green, Biota head of product development Dr Jane Ryan, Bionomics chief executive officer Dr Deborah Rathjen, Phylogica chief financial officer Nick Woolf and Benitec chief executive officer Dr Peter French.
For more information and to register go to www.terrapinn.com/bio.