Biotech Daily

Wednesday April 20, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ADVANCED SURGICAL UP 28%; CIRCADIAN DOWN 4%**

*** PRANA PLANS ALZHEIMER'S, ORPHAN HUNTINGTON'S PHASE II TRIALS**

*** GENETIC TECHNOLOGIES COLLABORATES ON CHEMOTHERAPY TEST**

*** IMMURON MEETS FDA FOR PHASE IIb NASH TRIAL**

*** CLINUVEL TO MEET EMEA FOR PRE-SUBMISSION MEETING**

*** PHOSPHAGENICS SIGNS NY HAIR-CARE LICENCE DEAL**

*** CBIO LOSES DIRECTOR STEPHEN STREETER**

*** CELLESTIS SHAREHOLDERS CLAIM 34% BLOCKING SUPPORT**

*** IM MEDICAL RAISES $750k; WANTS $1.85m; 1-FOR-15 CONSOLIDATION**

MARKET REPORT

The Australian stock market climbed 1.4 percent on Wednesday April 20, 2011 with the S&P ASX 200 up 65.7 points to 4859.0 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, five traded unchanged and six were untraded.

Advanced Surgical was best, up five cents or 27.8 percent to 23 cents with 28,311 shares traded, followed by Patrys up 14.3 percent to 16 cents with 1.4 million shares traded, Sunshine Heart up 13.5 percent to 5.9 cents with 1.6 million shares traded and QRX up 10.6 percent to $1.98 with 483,929 shares traded.

Prana climbed 9.5 percent; LBT was up 7.1 percent; Genetic Technologies was up 4.3 percent; Acrux, Pharmaxis and Phosphagenics were up more than three percent; Impedimed, Optiscan and Prima rose two percent or more; with Chemgenex, CSL, Mesoblast and Viralytics up more than one percent.

Circadian led the falls, down three cents or four percent to 72.5 cents with 8,567 shares traded, followed by Heartware down 3.3 percent to $1.91 with 41,975 shares traded.

Psivida lost 2.3 percent; with Bionomics, Biota, Phylogica, Sirtex and Tissue Therapies down more than one percent.

PRANA BIOTECHNOLOGY

Prana says it will ”accelerate development of its lead asset PBT2” with phase II trials for Alzheimer’s and Huntington’s disease planned to begin this year.

Prana said that orphan drug designation for the “relatively uncommon disease” Huntington’s meant that market approval for PBT2 could be “several years sooner than previously planned and at considerably less cost”.

Prana said it would conduct a phase II, placebo-controlled, double-blind study in 100 mild Huntington’s disease patients, in Australia and the US, with treatment over six months.

The company said the trial would be conducted in parallel to the previously announced 12 month phase II brain imaging study in 40 mild Alzheimer’s disease patients, in Australia, supported by the US based Alzheimer’s Drug Discovery Foundation.

The company said that recruitment for both trials was planned to begin after June 2010.

Prana’s executive chairman Geoffrey Kempler said that from a commercial perspective the diseases were very complimentary.

“From our earlier Alzheimer’s trial we showed that PBT2 significantly improves cognitive executive function,” Mr Kempler said.

“This is very relevant to Huntington’s disease given that these patients also suffer cognitive decline, for which there is no marketed treatment available,” Mr Kempler said.

“Success in the trial that we have announced today will position PBT2 as a frontrunner in the treatment of Huntington’s disease,” he said.

“We believe that PBT2 can bring the same cognitive benefits to Huntington’s disease patients that it did to Alzheimer’s disease patients,” Mr Kempler said.

“Because Huntington’s disease is a relatively uncommon disease, it is classed as an orphan indication by regulators, a status that typically confers accelerated regulatory review by authorities and faster approval to market,” he said.

“That also means the cost will be considerably less,” Mr Kempler said.

Prana said the Huntington’s disease was a genetically inherited neurodegenerative disease resulting in severe motor dysfunction and cognitive decline affecting 30,000 people in the US and about 70,000 worldwide.

The company said the only approved treatment was tetrabenazine which “only targets some of the motor loss symptoms” and was worth about $250 million a year and no drugs in development had established clinical evidence for treating cognitive decline.

Prana said the PBT2 trial intended to demonstrate the same cognitive benefits for Huntington’s disease patients that it had demonstrated in Alzheimer’s disease patients.

The company said that a treatment for Huntington’s that addressed the underlying progression of the disease could generate sales of up to $1 billion a year.

Prana said a phase IIa trial of PBT2 in mild Alzheimer’s disease patients showed that cognitive executive function was significantly improved; that PBT2 was able to restore neurons critical to cognition in mouse models; and PBT2 increased the number of spines on the dendrites of neurons, a means of permitting more neurons to interconnect thereby increasing the brain’s capacity to carry out learning and memory functions.

Prana said the findings pointed to the ability of PBT2 to restore cognition in degenerative conditions, together with positive data achieved with PBT2 in mouse models of Huntington’s disease provided confidence that PBT2 would be able to confer cognitive benefit to patients with Huntington’s disease and Alzheimer’s disease.

Prana said that copper was critical in the formation of toxic oligomers of the Huntington’s disease protein, huntingtin, that caused the brain degeneration.

Prana said that PBT2 was a metal protein attenuating compound which could redress metal imbalances in the brain and intercede in toxic oligomer formation.

Prana was up two cents or 9.5 percent to 23 cents with one million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it will collaborate with an unnamed pharmaceutical company to develop a cancer profiling product.

Genetic Technologies chief executive officer Dr Paul MacLeman told Biotech Daily that he was unable to disclose details of the pilot program collaboration, but said that if it was successful the two companies would share revenue.

In its media release Genetic Technologies said it would use “certain expertise and intellectual property to work with this world-leading pharmaceutical company to develop specific and novel genetic oncology profiling systems for the targeting of chemotherapy in late stage cancer patients”.

The company said it would collaborate in a clinical oncology study and provide the results to its unnamed partner.

Genetic Technologies said that stage of the project was expected to last “some months after which time the parties will assess progress and discuss moving to further investigations”.

Dr MacLeman said Genetic Technologies’ expertise in genetic profiling was widely respected and the collaboration was “a validation of GTG’s capabilities in the area of very low signal to noise nucleic acid analysis”.

“This research collaboration is expected to further embed GTG’s franchise in oncology testing and we expect ultimately to lead to better patient outcomes,” Dr MacLeman said.

“The need for companion diagnostics to determine effective treatments for cancer patients is well established,” Dr MacLeman said. “We are very excited by this collaboration as we continue to expand our presence in the field of personalized medicine”.

Genetic Technologies was up 0.4 cents or 4.3 percent to 9.7 cents.

IMMURON

Immuron says it will meet US Food and Drug Administration experts for its phase IIb clinical trial of IMM-124E for non-alcoholic steatohepatitis (NASH).

Immuron chief executive officer Joe Baini said the pre-investigational new drug application meeting was “designed to assist sponsor companies to progress with clinical trials that meet FDA requirements”.

“We welcome this opportunity to meet with the FDA as it will help our phase IIb clinical trial program progress as seamlessly as we can manage,” Mr Baini said.

“The pre-IND process should assist in the design of our proposed trial and decrease the possibility of future delays in the development of IMM-124E in the treatment of NASH,” Mr Baini said.

Immuron said non-alcoholic steatohepatis, or fatty liver disease, was increasingly prevalent in developed nations and was linked to increases in obesity rates and type II diabetes, with an estimated 25 million Americans expected to have the disease by 2025.

Immuron said that if untreated, the illness could lead to life threatening diseases such as cirrhosis and liver failure.

The company said IMM-124E was an oral drug candidate developed from hyper-immune bovine colostrum.

Immuron said phase I/II clinical trials demonstrated IMM-124E’s safety and efficacy against non-alcoholic steatohepatitis, as measured by liver enzyme markers and type 2 diabetes markers.

The company said the early results also showed IMM-124E was able to decrease blood triglyceride levels and improve key metabolic hormones linked to chronic inflammation.

Immuron fell 0.4 cents or 5.4 percent to seven cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will meet with the European Medicines Agency (EMEA) on May 5, 2011 to discuss its marketing application for Scenesse or afamelanotide.
Clinuvel said the meeting would review and discuss the scientific dossier and was “a vital step in the process of obtaining marketing authorization for Scenesse in Europe for the orphan designated disease erythropoietic protoporphyria under the centralized procedure”.
The company said approval would allow Clinuvel to market Scenesse in all 27 European Union member states as well as Norway, Iceland and Lichtenstein, with up to 4,000 patients in these countries.
Clinuvel said the meeting would discuss technical sections of the dossier as well as post-marketing surveillance of patients and plans for paediatric use of Scenesse.
Clinuvel said that it would have the final results of its two confirmatory trials of Scenesse in erythropoietic protoporphyria; a US phase II clinical study and a European phase III clinical study in the coming months.
The company said the trials had been conducted during 2010-2011 and data was being collected and analyzed.
Clinuvel’s vice-president of scientific affairs Dr Dennis Wright said the meeting was “a definite highlight for the company’s regulatory and clinical program as we look to secure a filing date in late 2011”.
“The Agency has proven most responsive to our intentions and progress in the treatment of EPP,” Dr Wright said.
Clinuvel was up half a cent or 0.3 percent to $1.955.

PHOSPHAGENICS

Phosphagenics says it has signed a non-exclusive licence agreement with New York hair care company operated by Rodney Cutler.
Phosphagenics said Mr Cutler operated a chain of US hair salons across New York and Miami and was affiliated with hair care brands.
The company said Cutler Salons would be licenced to use its tocopheryl phosphate mixture or TPM technology to develop a range of hair care products for the US, UK and Australian markets.
Phosphagenics said it would collaborate with Cutler to develop new formulations using its platform technology to target the delivery of active ingredients into the scalp.
The company said Cutler would be responsible for manufacturing, selling and distributing the products and would pay Phosphagenics royalties on all sales.
Phosphagenics joint chief executive officer Dr Esra Ogru said the deal was “another example of the versatility of the biotechnology company’s platform technology which has been used to develop pharmaceutical, dermatology and cosmetic lines”.
“We have established that our TPM technology enables superior topical penetration of active ingredients,” Dr Ogru said.
“This deal is our first into the lucrative hair care market,” Dr Ogru said.
Phosphagenics rose 0.5 cents or 3.45 percent to 15 cents with 2.8 million shares traded.

CBIO

CBio says non-executive director Stephen Streeter has resigned.
The company gave no further details.
CBio was up one cent or 1.8 percent to 57 cents.

CELLESTIS

The Cellestis Shareholders Action Group says investors with 32,853,318 shares or 34.2 percent of the company oppose the proposed takeover by Qiagen NV (BD: Apr 4, 2010).
The Group said that “given that a no vote of 25 percent assures that the takeover will not proceed, we can now reject this scheme”.
“We caution, however, that to ensure our victory we need every single vote that we can muster,” the Group said.
“In addition to defeating this scheme, it is important that we send the message that we are loyal, long term investors in our company and we will not be pushed out of our chosen investment for a pittance,” the Group said.
The Group said there were “still many shareholders out there that we have not yet been able to reach” but it intended to do so.
Earlier this week Cellestis chairman Ron Pitcher wrote to shareholders calling for support for the takeover (BD: Apr 18, 2011).
Cellestis fell two cents or 0.6 percent to $3.40.

IM MEDICAL

IM Medical says it has raised $750,000 in convertible loans, intends to raise a further $1.85 million and undertake a share consolidation of one share for 15 shares.
IM Medical said it would sell its radiology business to Capitol Health for 45.56 Capitol shares and up to $600,000 in cash.
The company said that with the measures it expected “to be in a stronger position to explore new opportunities to create shareholder value”.
IM Medical was originally created to market cardiac tests, was subject of a backdoor takeover by the Mark Scott Group radiology imaging businesses and has subsequently had extensive changes to its board and management.
IM Medical was untraded at 0.1 cents.