



# Biotech Daily

Wednesday March 31, 2010

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH EVEN: USCOM UP 5%; GENETIC TECH DOWN 12.5%**
- \* **INDIA, THAI TRIALS SHOW BIODIEM FLU VACCINE SAFE**
- \* **YM BIOSCIENCES: GOOD DATA EXPANDS (CYTOPIA'S) CYT387 TRIAL**
- \* **HUNTER TO RAISE \$10m; APPOINTS JEREMY CURNOCK COOK DIRECTOR**
- \* **TAIWAN APPROVES AVITA'S RECELL WOUND TREATMENT**
- \* **PHOSPHAGENICS, NOVARTIS TRANSDERMAL INSULIN FOR FAT PETS**
- \* **IMPEDIMED REQUESTS CAPITAL RAISING TRADING HALT**

## MARKET REPORT

The Australian stock market fell 0.84 percent, on Wednesday March 31, 2010 with the S&P ASX 200 down 41.3 points to 4875.5 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and four were untraded.

Uscom was best, up three cents or 5.1 percent to 62 cents with 25,750 shares traded.

Acruz, Alchemia and Tissue Therapies climbed more than four percent; Avexa, Bone, Nanosonics, Novogen, Pharmaxis and Prana were up more than three percent; Living Cell rose two percent; with Bionomics, Heartware, Resmed and Universal Biosensors up more than one percent.

Genetic Technologies led the falls, down half a cent or 12.5 percent to 3.5 cents with 283,512 shares traded.

Antisense, Phosphagenics, Psivida and QRX lost more than four percent; Patrys, Prima and Viralytics were down more than three percent; Chemgenex shed 2.25 percent; with Cellestis, Clinuvel, Mesoblast and Sirtex down more than one percent.

## BIODIEM

Biodiem says its live attenuated influenza vaccine has shown phase I safety in trials in India and Thailand and is moving to phase II trials.

Biodiem said the trials were part of the Pandemic Influenza Vaccine Program with the World Health Organisation which has sub-licensed the drug from Biodiem's licensee Nobilon.

Biodiem said that Thailand's Government Pharmaceutical Organization, the Serum Institute of India and China's Zhejiang Tianyuan Bio-Pharmaceutical Co were authorized for egg-based manufacturing and distribution of influenza vaccines using Biodiem's live attenuated influenza vaccine (LAIV) technology, in the public sector of these countries.

The company said Thailand's Government Pharmaceutical Organization completed a phase I trial in healthy adults of its candidate vaccine and it was shown to be safe.

The Thai organization was expected to begin a phase II clinical trial in April 2010.

The Serum Institute of India demonstrated safety in its phase I trial and a phase II/III trial was in progress.

Biodiem said that subject to results, the vaccine was expected to be ready for public use in April or May this year, under the World Health Organisation program.

But Biodiem said there was potential for use of the vaccine in private markets as well as the public health system, which would require the establishment of new royalty agreements.

Biodiem was untraded at 18.3 cents.

## YM BIOSCIENCES. (CYTOPIA)

YM Biosciences says it has ethical approval to expand enrolment in its Mayo Clinic phase I/II clinical trial of Cytopia's CYT387 in patients with myelofibrosis.

Canada's YM Biosciences acquired Cytopia earlier this year (BD: Feb 1, 2010).

YM said myelofibrosis was a chronic debilitating condition, where bone marrow was replaced by scar tissue.

Mayo Clinic head of haematology Prof Ayalew Tefferi said favorable safety and biological activity data "gave us the confidence to seek approval for cohort expansion earlier than originally contemplated".

YM said that enrolment expansion would help the collection of more safety, tolerability and preliminary efficacy data and might assist with planning for subsequent registration-enabling clinical studies for patients with myelofibrosis and other myeloproliferative neoplasms.

YM chief executive officer David Allan said the preliminary findings also advanced the prospect for more rapid initiation of subsequent clinical programs.

"The JAK2 inhibitors, including CYT387, are of great interest to the global pharmaceutical industry," Mr Allan said.

"They hold therapeutic promise in numerous indications. Myelofibrosis alone is a disease that affects approximately 20,000 patients in North America with market estimates in excess of \$750 million," he said.

YM said that the phase I/II study began in November 2009 with efficacy data originally expected in the second half of 2011.

"However the evident safety and preliminary efficacy observed to date support early expansion and should allow conclusion of the study three to six months earlier," YM said.

The acceleration of the program could enable more rapid selection of doses for registration-enabling phase III studies in myelofibrosis, the company said.

YM Biosciences is listed on the Nasdaq as YMI.

## HUNTER IMMUNOLOGY

Hunter Immunology hopes to raise up to \$10 million to fund a phase IIb clinical trial of lead product HI-1640V for chronic obstructive pulmonary obstructive disease.

Hunter Immunology said Intersuisse Biosciences Australian Bioscience Fund had invested \$4 million and Indonesia's Soho Pharmaceuticals had invested \$1 million.

Hunter managing director Dr Kevin Healey said in a media release the Intersuisse and Soho funds would be supplemented with a placement of a further \$3-5 million to institutional and sophisticated investors and there would also be a rights issue to allow shareholders to participate in the raising.

The company said that HI-1640V was an immunotherapeutic to alleviate the severity of chronic obstructive pulmonary disease and three clinical trials had shown HI-1640V to be safe and effective in patients with the.

Hunter said the oral drug stimulated the immune system to fight the incidence and severity of acute bronchitis in patients with chronic obstructive pulmonary disease.

The company said chronic obstructive pulmonary disease was expected to be the world's third largest cause of death by 2020.

The company said its primary goal was a multi-centre trial of the drug on 350 patients with moderate to severe disease.

Hunter has appointed Intersuisse Biosciences Fund managing director Jeremy Curnock Cook as a non-executive director.

Mr Curnock Cook established the Rothschild Bioscience Unit in the UK and was responsible for its life science funds including Biotechnology Investments and the International Biotechnology Trust plc, which together had more than \$1 billion in net asset value (2000).

Hunter said Mr Curnock Cook was responsible for Rothschild establishing Australia's first dedicated biotechnology fund, now known as GBS Ventures.

Hunter Immunology is a public unlisted company.

## AVITA MEDICAL

Avita says Taiwan's Ministry of Health has approved its Recell autologous spray-on skin device for wound treatment.

Avita said Taiwan was a significant market for the company's products and that in addition to treating burns and other wounds, Recell would target the growing demand for aesthetic surgery, scar revision and dermal treatments for the aging population.

The company said its product focus was on Taiwan's "burgeoning middle class, an affluent and rapidly growing segment of the country's 23 million people".

Avita said Recell would be distributed through Shaw Han, a provider of medical equipment and disposable products for surgical and aesthetic applications in Taiwan.

Avita said Shaw Han was instrumental in "completing the highly complex Taiwanese approval and registration process".

Avita chief executive officer Dr William Dolphin said the Recell technology had "strong sales potential in Taiwan where the cosmetics and plastics markets are growing exponentially".

Avita said it had held meetings with key surgeons from the Taiwan military and expected to begin training in the next few months.

Avita was up 1.5 cents or 11.5 percent to 14.5 cents with 1.7 million shares traded.

## PHOSPHAGENICS

Phosphagenics says it will develop its tocopheryl phosphate mixture or TPM insulin delivery system for diabetes in pets with Novartis Animal Health.

Phosphagenics said the Novartis deal opened “new opportunities ... in the veterinary market”.

The company said Novartis would pay the costs of developing the insulin product and if it proceeded, Phosphagenics would receive an initial payment, milestone payments and royalties.

The company said diabetes affected one in 50 pets worldwide and in Australia about 40 percent of dogs and a third of the nation's cats were overweight, resulting in an increase in the incidence of diabetes in cats and dogs.

Phosphagenics said the incidence rate and contributing factors are similar in many developed countries.

The company said there were insulin products on the market for veterinary use, but they were only administered by injection, which Phosphagenics said was “painful for animals and makes ongoing treatment emotionally difficult for their owners”.

Phosphagenics said a transdermal delivered insulin “would be user friendly, would increase the appeal of insulin, reduce non-compliance and potentially result in an increase in the size of the companion animal insulin market”.

In a media release Phosphagenics chief operating officer Dr Esra Ogru said the system could gain appeal in the veterinary sector.

Biotech Daily contacted the company for comment on the application of the transdermal process compared to sub-cutaneous injection.

An email from Dr Ogru said that the transdermal insulin would be “similar to apply [to] the worming gels to dogs and cats”.

“This is the type of formulation we have – it is thick and applies like a worming/flea gel - plus Novartis will also assess sites such as under the leg or around [the] belly area - these areas have much less hair,” Dr Ogru said.

Phosphagenics was down half a cent or 4.2 percent to 11.5 cents with 5.2 million shares traded.

## IMPEDIMED

Impedimed has requested a trading halt pending an announcement on a proposed capital raising.

Trading will resume on April 6, 2010 or on an earlier announcement.

Impedimed last traded at 75 cents.