# Biotech Daily

Thursday June 11, 2015

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH EVEN: ADMEDUS UP 8%, CLINUVEL DOWN 7%**

*** ACTINOGEN READY FOR LAST STAGE OF PHASE I XANAMEM TRIAL**

*** PRIMA RECEIVES $320k FRENCH TAX CREDIT**

*** PATRYS PAT-SM6 MANUFACTURE FURTHER DELAYS CANCER TRIAL**

*** ASIA UNION DECREASES TO 6% OF TISSUE THERAPIES**

*** IMMURON APPOINTS DR DAN RUBEN PERES INNOVATION HEAD**

## MARKET REPORT

The Australian stock market climbed 1.43 percent on Thursday June 11, 2015 with the S&P ASX 200 up 78.1 points to 5,556.7 points.

Twelve of the Biotech Daily Top 40 stocks were up, 11 fell, 14 traded unchanged and three were untraded. All three Big Caps fell.

Admedus was the best, up half a cent or 8.3 percent to 6.5 cents with 11.6 million shares traded.

Actinogen and Atcor climbed five percent or more; Cellmid, IDT and Oncosil rose more than four percent; Anteo and Compumedics were up more than three percent; Impedimed and Medical Developments rose more than two percent; with Bionomics and Starpharma up more than one percent.

Clinuvel led the falls, down 22 cents or 7.2 percent to $2.83 with 113,437 shares traded.

Biotron and GI Dynamics lost more than three percent; Avita and Tissue Therapies shed more than two percent; Benitec, Cochlear and Prima were down more than one percent; with Acrux, CSL, Nanosonics, Osprey, Resmed and Sirtex down less than one percent.

## ACTINOGEN MEDICAL

Actinogen says it has ethics approval for the third and final stage of the second phase I trial of Xanamem for Alzheimer's disease.

Actinogen chief executive officer Bill Ketelbey previously told Biotech Daily that the phase I trial was in three stages with 24 volunteers in the dose escalation section; 12 volunteers in the fed-versus-fasting section; and four patients in the final section undergoing lumbar puncture to confirm central nervous system pharmaco-kinetics as well as plasma and cerebro-spinal fluid levels (BD: Mar 31, Apr 14, 2015).

In a media release today, Actinogen said that the primary endpoint was "to demonstrate that Xanamem [was] efficiently delivered to the brain, its primary site of action in Alzheimer's disease".

The company said that the trial was being conducted at Linear Clinical Research, a world-class clinical trial facility that is part of the Queen Elizabeth II Medical Centre in Perth, Western Australia.

Actinogen said that the fed-fasted dosing of 12 participants on 35mg of Xanamem had been completed with results expected in August 2015, but both the first and second stages "demonstrated the safety and tolerability of Xanamem, even at the highest dose of 35mg twice daily".

The company said that dosing in the final pre-clinical rodent toxicology study was "well underway with the results expected before the end of the year".

Actinogen said that it was significant that all the studies remain on-track, with results to be incorporated into the research documentation supporting an investigational new drug application to the US Food and Drug Administration later this year for the phase II trial to be run in the US, as well as Australia, New Zealand and the UK.

"The ongoing excellent progress of this Xanamem study sets us up well to start the phase II trial of Xanamem in patients with Alzheimer's disease in the first half of 2016," Dr Ketelbey said.

"It is particularly pleasing to continue on-track with our development plans for this promising new treatment for Alzheimer's disease," Dr Ketelbey said.

Actinogen was up 0.4 cents or 5.3 percent to 7.9 cents with 3.3 million shares traded.

## PRIMA BIOMED

Prima says it has received EUR226,055 ($A320,000) in a cash rebate from the French state under the Crédit d'Impôt Recherche, or Research Tax Credit, scheme.

Prima said that the cash rebate was for expenditure by its wholly-owned subsidiary, Immutep on LAG-3 research and development activities at its Châtenay-Malabry, Paris

The company said that Crédit d'Impôt Recherche French Government tax incentive was introduced in 1983 providing a 30 percent reimbursement of eligible expenditure for French companies doing research and development in Europe.

Prima said it inherited the laboratory with its December 2014 acquisition of the French company Immutep SA and was working on new products in addition to development of the existing pipeline, including lead compound IMP321 for metastatic breast cancer patients receiving first-line chemotherapy (BD: Dec 17, 2014).

Prima fell 0.1 cents or 1.1 percent to 8.9 cents with 5.0 million shares traded.

## PATRYS

Patrys says the production run of PAT-SM6 immunoglobulin M (IgM) has not produced an adequate mass of antibody meeting release specifications, delaying a planned trial.

Patrys said that “as the variability in the yield and consistency of the end product is unresolved, the initiation of the proposed combination trial of PATSM6 in refractory multiple myeloma patients remains on hold”.

In November 2014, the company announced complications in manufacturing involved purification yields which would delay the commencement of its planned clinical trial and these complications were overcome by changing the protein separation system used and in February 2015, the company said that the bulk finished antibody product had not met release specifications (BD: Nov 7, 2014).

Patrys said that the variations in product quality were likely the result of this change in the protein separation system, with individual batches not meeting specifications of acceptable product and batch-to-batch variation, meaning that individual batches cannot be pooled as a single stock of IgM for clinical trials.

The company said that independent advice was that the release specifications were too rigid for a product at this stage of development given the batch-to-batch variability, but the manufacturer will not release the batches for human use.

Patrys said it would approach the scientific advisory board of the German regulator, the Paul Ehrlich Institut with data collected over the past months to obtain its advice, but believes this approach “will have a low probability of success in getting approval to use the material in a clinical trial”.

Patrys chief executive officer Dr James Campbell said: “We understand the frustration felt by shareholders of Patrys with this latest setback.”

“The production and development of antibodies is a complex, costly and lengthy process, and whilst these types of issues are not unusual it is nevertheless disappointing,” Dr Campbell said.

“Given the therapeutic responses observed in patients treated with PAT-SM6 and PAT-SC1 in the clinic, Patrys remains committed to realising the potential of IgMs,” Dr Campbell said.

Dr Campbell said the company would review its strategy in regard to IgMs including the potential for process improvements and continue to evaluate strategic collaborations and other complementary assets.

Patrys was unchanged at 1.1 cents.

## TISSUE THERAPIES

Asia Union Investments says it has reduced its substantial shareholding in Tissue Therapies from 21,115,983 shares (6.98%) to 18,034,018 shares (5.96%).

The Sydney-based Asia Union said that between June 1 and 5, 2015 it sold 3,081,965 shares for $136,583 or an average price of 4.4 cents a share.

In March Asia Union said it had bought 1,319,749 shares for $277,147 on March 6, 2015 in the placement at 21 cents a share (BD: Mar 5, 2015)

Tissue Therapies fell 0.1 cents or 2.9 percent to 3.4 cents.

## IMMURON

Immuron says it has appointed Dr Dan Ruben Peres as innovation senior vice-president.

Immuron said that Dr Peres would be responsible for leading and managing its phase II clinical trial program currently underway for non-alcoholic steatohepatitis and to support a US National Institute of Health-funded phase II clinical trial program for alcoholic steatohepatitis.

The company said that Dr Peres previously worked in clinical and medical managerial roles in pharmaceutical and medical device companies such as Exalenz Biosciences, Carbofix Orthopedics, NMB Medical Applications, Bypass Makafim, Ioptima and Novonordisk Israel.

Immuron said that Dr Peres had been responsible for operational, marketing and business-development activities throughout his career, which began as a physician and medical director in various roles in the Israeli Army.

The company said that Dr Peres qualified as a physician in 2002 when he graduated from the Sackler School of Medicine at Tel-Aviv University.

Immuron was up four cents or 18.2 percent to 26 cents.