# Biotech Daily

Thursday October 21, 2010

*Daily news on ASX-listed biotechnology companies*

*** ASX FLAT, BIOTECH UP: BENITEC UP 18%; PATRYS DOWN 11%**

*** COMMERCIALISATION AUSTRALIA WON'T DECLARE INTERESTS, AGAIN**

*** GSK, MERCK, PFIZER, ROCHE SCOUTS PACK AUSBIOTECH MEETING**

*** ROCHE: HAVE VENTURE FUND, WILL LICENCE**

*** PROF NADIA ROSENTHAL: 'MACROPHAGES COULD CHEAT EVOLUTION'**

*** MESOBLAST PHASE II SPINAL FUSION TRIAL SAFE, WITH EFFICACY**

*** 10% OPPOSE PHARMAXIS REMUNERATION, CEO SHARES**

*** PHYLOGICA COMPLETES FIRST STAGE OF ROCHE PHYLOMER DEAL**

MARKET REPORT

The Australian stock market slipped 0.04 percent on Thursday October 21, 2010 with the S&P ASX 200 down two points to 4622.9 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, four traded unchanged and five were untraded.

Benitec was best, up 0.6 cents or 17.7 percent to four cents with 3.1 million shares traded, followed by Tissue Therapies up 14.5 percent to 39.5 cents with 702,968 shares traded and Cellmid up 10 percent to 2.2 cents with 1.1 million shares traded.

Starpharma climbed 8.1 percent; Circadian was up 6.8 percent; Acrux was up 5.7 percent; Genera, Phylogica and Universal Biosensors were up more than four percent; Prima was up 3.45 percent; Clinuvel, Nanosonics, Optiscan and Sirtex rose more than two percent; with Bionomics, Chemgenex, Pharmaxis and QRX up more than one percent.

Patrys led the falls, down one cent or 11.1 percent to eight cents with 257,671 shares traded, followed by Living Cell down 10.8 percent to 16.5 cents with 708,837 shares traded.

Prana lost 7.1 percent; Genetic Technologies was down 6.9 percent; Compumedics and Phosphagenics fell four percent or more; Viralytics and Virax were down more than three percent; Cellestis and Impedimed shed more than two percent; with Biota down 1.6 percent.

## COMMERCIALISATION AUSTRALIA

Last week Biotech Daily reported that five biotechnology companies received $3.2 million of the $8 million granted by Commercialisation Australia in July and August 2010.

The companies were Biosceptre International; Pod Orthotic; Dimerix Bioscience; Madeleine Pharmaceuticals; and Sonomedical (BD: Oct 15, 2010).

Biotech Daily discovered in the first funding round that the chairman of Commercialization Australia Dr Laurie Hammond was also a director of Athlomics, which received a grant of $250,000 (BD: Jul 14, 2010).

Biotech Daily discovered today that another winner in that round was Kord Defence, another Dr Hammond-related company.

At that time, Biotech Daily asked the Department of Innovation and Commercialisation Australia for a full list of declarations of potential conflicts of interest and was repeatedly refused.

Biotech Daily then paid the $30 fee and requested the documents under a Freedom of Information Act inquiry and published that information last month along with an editorial explaining why transparency was important and how a one-line declaration could save a lot of bother (BD: Sep 10, 2010).

Following that experience, Biotech Daily again asked the Department and Commercialisation Australia for a full list of potential conflict of interest declarations by the board deciding the July and August grants and was told that such information could "mislead" our readers.

The Federal Department of Innovation said: "It is not appropriate to publicly disclose the details of potential conflicts of interest in relation to particular applications.

"Conflicts are varied and to report them simply can be misleading.

"The public interest is best served by an understanding that a robust process exists for managing potential conflicts and that this process stands up to external scrutiny."

The process clearly does not stand up to external scrutiny because it is not being externally scrutinized.

One Federal Government department, the highly respected Australian National Audit Office, is scrutinizing another. But it's not really external.

This is just one of many reasons why the Biotech and Related Industries Leadership Group called for the funding body to be independent and arm's length from Government.

To infer that either Biotech Daily would write a misleading summary of the conflict of interest statements is bad enough, but the implication is that the readership is not sufficiently well-educated or intellectually capable to understand what potential conflict of interest statements mean.

Unfortunately, this led to Biotech Daily going back to the September declarations, only to discover that the Commercialisation Australia board has potential conflicts of interest in at least two of the companies involving at least three of the board members.

Until Biotech Daily hears back on the next $30 Freedom of Information Act inquiry, we won't know the full extent of these conflicts of interest.

Winners in the most recent round included Quinessence Labs which was granted $1,220,000 for a quantum key distribution system for secure communications and QS Semiconductors which received $462,000 for a stored charge random access memory system.

While these both appear to be most interesting technologies it should have been said that board members Dr Hammond and Dr Susan Pond were both related to Qunitessence Labs and that Commercialisation Australia chief executive officer Doron Ben-Meir has cited a potential conflict of interest for QS Semiconductors.

When a funding body has such meager funds and so many applicants, the least it can do is be transparent about its spending of tax-payer money, let alone the poor image it gives the industry – in stark contrast to the efforts of the Victoria State Labor Government, which keeps increasing its funding to biotechnology.

Anecdotal evidence suggests there have been many very negative private conversations about Commercialisation Australia at this year's Ausbiotech conference and not many, if any, that support the Department's invention.

**David Langsam**
**Editor**

AUSBIOTECH, MERCK INC, ROCHE, GLAXOSMITHKLINE, PFIZER

Representatives for four of the world's largest pharmaceutical companies told a packed Ausbiotech session what they wanted from biotechnology companies.

Chaired by Ausbiotech's Glenn Cross, Dr Phil Kearney (Merck), Dr Stella Xu (Roche), Dr Ashley Bates (Glaxosmithkline) and Dr Dan Grant (Pfizer) told the standing-room-only meeting that they wanted to see the world's best innovation and the earlier, the better.

Encouraging biotechnology companies to come to them with early stage development the panel said they needed to know what was on offer and they needed greater openness.

Dr Grant said he was not interested in signing confidentiality agreements without knowing what the product was.

"The science [in Australia] is good but the speed to market is critical," Dr Grant said.

"We need to make sure that assets don't get hung up in early stage spin-out companies," Dr Grant said.

Dr Bates said as a generalist he would do a little due diligence and then hand the project on for further evaluation.

"The biggest let-down is to find others doing the same or similar work elsewhere," Dr Bates said.

Dr Kearney said there were 'must do' areas for Merck, such as HIV, but the interest was across the board.

“All of us are looking for good science,” Dr Grant said. “You have to be the best in the world. We are not worried about time zones or travel. It’s really the things that are most advanced that attracts our attention. The easiest way to get our attention is to present at the best international conferences.”
Dr Xu said differentiation was important and companies needed to know the market landscape and see how the product made a difference for the patient.
“Talk to us early, so we know what you are researching,” Dr Xu said. The panel agreed that delay could lead to months of lost revenue.
Dr Bates said Glaxosmithkline had internal assets that were problematic in developing.
“We welcome approaches on how to take our own assets forward,” Dr Bates said.
Dr Grant said Pfizer wanted to out-licence products that it was not able to develop.
Dr Xu said changes in medicine and research meant that Roche was looking at the targets as well as the genome and needed to focus on innovation and in particular personalized medicine.
“How can we combine the right diagnostic and biomarkers for the right patient?”
Dr Xu said Roche had a venture fund and would look at a range of different deals (see separate article on Roche, below).
“If you have cutting edge science, commercial success will follow,” Dr Xu said.

## ROCHE

Roche’s Shanghai office is actively looking to partner with Australian companies.
The executive director of Roche partnering Shanghai, Dr Frank Grams told Biotech Daily that he was increasingly aware of Australian companies and Roche was not only interested in a range of indications, but had a $500 million fund to underpin its partners.
Dr Grams said that although Roche did not have permanent representation in Australia, Shanghai was a similar time zone and the distance was not a barrier.
Dr Grams said the five key therapeutic areas of interest to Roche were oncology, inflammation, virology, metabolic diseases and central nervous system disorders.
He said that both he and Dr Stell Xu were the contacts for Australian biotechnology companies and that the 90 partnering staff reported to their director Dr Dan Zabrowski who reported directly to Roche chief executive officer Dr Severin Schwan.
“We have one of the largest research and development budgets of any company in the world,” Dr Grams said. “About half our products are in-licenced.”
He said that in the past new medical entities mostly came from pharmaceutical companies but that had changed and the majority were coming form smaller biotechnology companies.
Dr Grams said Roche had about 110 to 120 internal research and development programs.
“We are interested in innovation, wherever it comes from,” Dr Grams said. “We get 2000 approaches or opportunities a year.”
“It is an iterative approach. We might say a piece is missing and if you get this we are interested. It can take two years working together to reach an agreement,” Dr Grams said.
He said the Shanghai group had signed 11 deals since inception in May 2008.
“Many are feasibility studies to see if it works in our hands and then we will do the deal.”
Dr Grams said the Roche venture fund (www.venturefund.roche.com) typically tried to be the minority investor and worked closely with licencing, so that deals also included an equity investment.
Dr Grams said the contact at the venture fund was Carole Nuechterlein and that each major indication had its own contact person.
For more information go to: www.roche.com/partnering.

## AUSBIOTECH, MILLIS ORATION: PROF NADIA ROSENTHAL

The director of the Australian Regenerative Medicine Institute Prof Nadia Rosenthal says that macrophages rather than insulin-like growth factor 1 (IGF-1) could be the key to tissue regeneration.

Prof Rosenthal delivered the Ausbiotech Millis Oration, named after University of Melbourne microbiologist Prof Nancy Millis.

Prof Rosenthal said that young humans heal easily, had robust organs and had less inflammation, but as humans aged these attributes deteriorated.

With an ageing population it became a key issue and she was investigating the balance between inflammation and degeneration, among a range of subjects.

Prof Rosenthal said her interest in the subject began as a child observing that starfish regenerated limbs and asked why it was the case that vertebrates such as zebra fish, axolotls and sharks also regenerated limbs, but close relatives, humans do not.

“Perhaps we just lost out in the evolution lottery,” Prof Rosenthal said.

She said a good inflammatory response was needed to combat disease, but the question was how to tip the balance from scarring to healing. The human liver can regenerate as can the intestine, but where there was major muscle loss there was no regeneration, she said.

Prof Rosenthal discussed the issues around insulin-like growth factor-1, stem cells, progenitor cells and a series of mouse experiments beginning with mature IGF-1 creating a ‘Schwarzenegger mouse’ which had increased disease resistance, increased muscle mass, had less fat, lived longer, had less inflammation and no greater incidence of cancer.

She said fish and amphibians could regenerate heart muscle, but we had lost that ability as a species.

Prof Rosenthal said cardiac tissue could be repaired with IGF-1 and in fish it was not the stem cells, but surface cardiomyocytes that replaced themselves for heart regeneration.

She said that macrophages were more than the ‘garbage collectors’ they first appeared to be and by polarizing macrophages with IGF-1 the M2 macrophages appeared to create their own IGF-1.

“If they are there, why does the heart not heal better?” Prof Rosenthal asked.

She said that macrophages acted as chaperones drawing cells together, like crocheting. Prof Rosenthal said macrophages were further downstream and more prolific than induced pluripotent stem cells.

Prof Rosenthal concluded the talk with the question and answer: “Can we engineer our own macrophages to cheat evolution? … In theory, we could.
Prof Rosenthal co-authored ‘Heart Development and Regeneration’ with Prof Richard Harvey which is available at www.elsevierdirect.com.

## MESOBLAST

Mesoblast says interim results from a phase II trial for minimally invasive posterior lumbar spinal fusion shows its adult stem cell product Neofuse is safe and effective.

Mesoblast said the interim trial results were presented to the ASX Small to Mid Caps Conference in Hong Kong.

The company said it was evaluating the effectiveness and safety of Neofuse for minimally invasive spinal fusion surgery of the cervical and lumbar spine in 60 patients randomized to receive either Neofuse or standard therapy across two international phase II trials cleared by the US Food and Drug Administration.

Mesoblast said the interim results from the first 17 patients enrolled in the posterior lumbar interbody fusion trial were reviewed by the data safety monitoring board and no cell-related safety issues were seen.

Mesoblast said that there was no evidence of ectopic bone formation or nerve root compression as have been reported to occur with alternative biologic therapies.

The company said that at three months of follow-up, computed tomography (CT) scans showed that about 90 percent of patients implanted with Neofuse achieved successful bone bridging.

Mesoblast said that mean pain reduction scores of more than 20 percent compared with baseline were achieved by both treatment groups.

The company said that the results extended earlier results from a pilot trial for postero-lateral lumbar fusion at New York's Hospital for Special Surgery, where 60 percent of sites implanted with Neofuse demonstrated fusion at six months compared with only 14 percent of sites implanted with hip autograft bone.

Mesoblast chief executive Prof Silviu Itescu said the company was “very encouraged by these positive interim results”.

“If the end-points of pain reduction and successful fusion are maintained throughout this trial, we would proceed with plans for our phase III pivotal trial since these are the outcome improvements expected by a regulatory body for registration of a minimally invasive lumbar fusion product,” Prof Itescu said.

“The superior safety profile of Neofuse could enable our product to be the only biologic therapy to be approved by the FDA for minimally invasive posterior lumbar interbody fusion, the preferred surgical procedure for chronic low back pain,” Prof Itescu said.

Mesoblast said that more than 500,000 spinal fusion procedures for chronic low back and neck pain are performed each year in the US, with the standard therapy being hip bone autograft obtained from a second surgical procedure.

Mesoblast said its method would eliminate the need for a second procedure, with its associated risk of infection and chronic hip pain.

Mesoblast fell one cent or 0.4 percent to $2.33.

## PHARMAXIS

The Pharmaxis annual general meeting saw more than 10 million of 120 million votes cast against the remuneration report and 50,000 free ‘performance right’ shares to chief executive officer Dr Alan Robertson

A total of 12,157,110 proxy votes (10.8%) opposed the issue of rights to Dr Robertson with 100,080,811 proxy votes (89.2%) in favor.

A similar margin of 10,883,123 proxy votes (9.7%) opposed the remuneration report with 101,319,310 (90.3%) proxy votes in favor

Pharmaxis climbed three cents or 1.1 percent to $2.84.

Biotech Daily editor David Langsam holds Pharmaxis shares and did not vote.

## PHYLOGICA

Phylogica says it has completed the first stage of its partnership with Roche to identify cell-penetrating peptides using its Phylomer drug discovery platform.

Phylogica said it met key objectives of the first stage and identified several potential candidate peptides from its Phylomer libraries.

The company said that Roche would review the data and, pending the outcome of the review, a milestone payment would be made and the next stage of the collaboration would be determined.

Phylogica said Roche provided funding to screen its libraries to identify cell-penetrating peptides that met defined criteria and the company said its report described several unique peptides that had the potential to deliver therapeutic payloads into diseased cells.

If confirmed, these peptides could be used to develop novel intracellular-targeted therapies for many types of disease, Phylogica said.

Phylogica's chief executive officer Dr Paul Watt said that Roche was "the first major pharmaceutical company to partner with us since we focused our strategy on fee-for-service drug discovery alliances".

"We have completed the first phase of the deal to a high standard and, more importantly, we have identified candidate peptides that have the potential to address the challenges of targeting intracellular disease pathways with biologics."

Phylogica was up 0.2 cents or 4.35 percent to 4.8 cents with 1.1 million shares traded.