Biotech Daily

Tuesday March 30, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHOSPHAGENICS UP 14%; BONE DOWN 10%**

*** GLAXOSMITHKLINE'S DEBORAH WATERHOUSE – NO ORDINARY BOSS**

*** FDA APPROVES CLINUVEL 'ORPHAN' PHASE II EPP TRIAL**

*** US GENE PATENT RULING 'NO IMPACT' ON GENETIC TECHNOLOGIES**

*** LIVING CELL APPROVED FOR INCREASED NZ DIABECELL TRIAL DOSE**

*** QRX BEGINS PHARMACOKINETIC CONTROLLED RELEASE STUDY**

*** ATCOR SIGNS $1m PHARMACEUTICAL COMPANY CONTRACT**

MARKET REPORT

The Australian stock market was up 0.4 percent, on Tuesday March 30, 2010 with the S&P ASX 200 up 19.5 points to 4916.8 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and three were untraded.

Phosphagenics was best, up 1.5 cents or 14.3 percent to 12 cents with 1.0 million shares traded, followed by Clinuvel up eight percent to 27 cents with 1.1 million shares traded.

Patrys climbed 7.1 percent; Optiscan was up 6.45 percent; LBT was up 5.6 percent; Chemgenex and Pharmaxis climbed more than four percent; Sunshine Heart and Uscom were up more than three percent; Benitec, Living Cell, Psivida and QRX rose more than two percent; with Biota up 1.3 percent.

Bone led the falls, down 1.5 cents or 10 percent to 13.5 cents with 22,288 shares traded, followed by Cathrx down 9.1 percent to 15 cents and Antisense down eight percent to 2.3 cents with 8.6 million shares traded.

Novogen lost 7.5 percent; Genetic Technologies and Prana were down more than six percent; Nanosonics fell 4.1 percent; Cellmid was down 3.45 percent; Cellestis shed 2.3 percent; with Alchemia, Bionomics, Starpharma and Viralytics down more than one percent.

GLAXOSMITHKLINE

Directed to Portable 13 on the outskirts of the Glaxosmithkline plant in Boronia, on the outskirts of Melbourne, I'm puzzled by the location of the boss's office.

I soon discover that GSK's vice president and general manager for Australia and New Zealand, Deborah Waterhouse, is no ordinary boss.

Ms Waterhouse made a conscious decision to leave the corporate office where ordinary workers fear to tread and created her own space among the working staff so she could be part of the Glaxosmithkline process and hear directly about complaints, innovations and bright ideas.

"In the main block, nobody came spontaneously to see me. Here, I've turned my office into a meeting room," Ms Waterhouse said.

Deborah Waterhouse – no known relation to the Australian horse racing family – must have the best 'girl who made good' story I've heard.

The daughter of a Birmingham butcher, she grew up on the Chelmsley Wood council estate and went to school in the 1970s in the seriously working class Handsworth where she says she developed her "passion for equality".

Escaping from her hometown, as many English teenagers do, she enrolled in an Arts degree at Liverpool University and majored in English and Economic History.

Her first job was in the boys' world of the UK car industry working in marketing at Land Rover. She says it made her tougher.

A postgraduate degree in marketing at London University was completed just in time to be headhunted by Glaxo Wellcome in 1996, where Deborah was a junior in the marketing team with the title "respiratory brand manager marketing".

But she quickly rose to area manager responsible for South West England based in the picturesque Roman town of Bath, where she met her husband to be, Dr Lloyd Bender, a South African paediatric eye surgeon in 1998.

Deborah says that she realized that research and development was the other wing to sales and marketing for a major pharmaceutical company and began studying all the science she missed in secondary school and university.

"If you want to be successful in a pharmaceutical company you need to understand the sales force and the other life blood is research and development. Big pharma is a very complicated machine."

"I read and learnt and learnt," she says, effectively teaching herself a basic science degree.

One of the many lessons along the way was the need to integrate and democratize bureaucracies.

Deborah has led the planned move from outer Boronia, where the land was very cheap when Glaxo first bought it, to inner city Abbotsford.

She says it will be an open plan office and all staff, herself included, will have the same size desks and the same equipment.

“It will be a non-hierarchical structure, more organic and cross-functional to share and spread thinking and ideas.”

“Some of the most acute observations come from unexpected sources,” she says.

“I’m trying to build something that is big pharma, but there are many ways to partner with people, not like an army, but flexible, a more fluid approach to running a company – a real cross-functional connectivity in a clear framework.”

Ms Waterhouse underlines that she is not interested in chaos, but a definite structure that allows all parts of the process to be in constant communication and be fertile ground for ideas.

Her progressive approach sounds radical, except that it once was standard text book organizational behavior, thrown out by the corporate macho management of the 1980s.

Ms Waterhouse says the company’s collaborations are with scientists, biotechnology companies, universities and institutions and she believes that her approach will bring Glaxosmithkline the greatest long term rewards.

She was chosen to head the Australia and New Zealand operation following her period as the head of HIV for Europe and later as the head of human resources for Europe.

She worked with one of the then candidates for the role of Glaxosmithkline Plc’s chief executive officer, Andrew Witty, developing a 10-year strategy to evolve the global organizational model.

Mr Witty was successful and Deborah says his patronage was helpful in her August 2008 appointment as the head of the company’s Australian and New Zealand operations, reporting to the head of Glaxosmithkline Asia Pacific, Christophe Weber.

Aware that there are still career opportunities ahead, Deborah Waterhouse says she loves Australia and is here for the medium term, well beyond the move to the Abbotsford headquarters planned for July this year.

Her children Georgia and James are at school in Brighton and husband has finally been given approval to practice medicine working at Melbourne’s Royal Children’s Hospital and the Royal Victorian Eye and Ear Hospital.

Deborah Waterhouse has come an awfully long way from Chelmsley Wood.

David Langsam
Editor

CLINUVEL

Clinuvel says the US Food and Drug Administration has approved a 60-patient phase II study of afamelanotide for erythropoietic protoporphyria.

Clinuvel spokesman Lachlan Hay told Biotech Daily the FDA also approved orphan drug status for afamelanotide.

In a media release the company said the six month study, would be conducted in Alabama, California, New York, North Carolina, Texas and Utah and was the first US therapeutic trial of afamelanotide.

Clinuvel said that about 3,000 Americans were known to have erythropoietic protoporphyria (EPP), a disease characterized by "intolerable pain" in which the skin blisters and burns when exposed to normal levels of light and sunlight.

Clinuvel said erythropoietic protoporphyria was incurable and affected patients for life and as a result, patients spent most of their lives indoors, leading a secluded life.

The company said that sunscreens were of no use in the disease as they don't block out visible light in the blue spectrum, which is the cause of toxic reactions.

Clinuvel said it had spent more than $70 million during the past 10 years developing afamelanotide as the world's first photo-protective drug, which worked to activate a barrier of pigmentation, or melanin, between light and a person's skin.

The company said the implantable drug was the size of a rice grain and was able to stimulate and increase skin pigmentation in fair-skin patients who are less protected from ultra-violet light damage.

Clinuvel said afamelanotide had been administered to more than 500 patients to date in clinical trials in Europe and Australia, with preliminary phase III results "showing good safety and first signs that EPP symptoms can be prevented".

Clinuvel chief executive officer Dr Philippe Wolgen said the US trial was "a major step event [in] the company's existence".

"In afamelanotide we are developing a unique drug to serve patients whose skin is most affected by ambient light," Dr Wolgen said.

"Our principle goal is to develop a safe preventative therapeutic option for EPP patients, who are most severely affected by light and UV," Dr Wolgen said.

Clinuvel was up two cents or eight percent to 27 cents with 1.1 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies chief executive officer Dr Paul MacLeman says a US court case on BRCA1 and BRCA2 gene patents have no impact on his company.

Dr MacLeman told Biotech Daily that his company licenced the patents for gene testing for breast and ovarian cancer from the US-based Myriad Genetics which was sued in the US District Court in New York by the American Civil Liberties Union over the patents.

The widely reported finding said genes were not patentable as they were part of nature and not inventions.

Dr MacLeman said his company performs numerous tests each year and they are "complex and difficult tests to run" but provided useful information.

Dr MacLeman's predecessor as chief executive officer at Genetic Technologies Michael Ohanessian wanted to recover costs from institutions performing the tests, but the company's founder and major shareholder Dr Mervyn Jacobson stepped in to reverse the decision (BD: Jun 11, Dec 2, 2008).

Not charging public institutions for performing the tests remains the company's policy, Dr MacLeman said.

Genetic Technologies fell 0.3 cents or 6.98 percent to four cents.

LIVING CELL

Living Cell says it has approval for the next stage of its New Zealand phase II human clinical trial of Diabecell porcine islet of Langerhans cells for type 1 diabetes.

Living Cell chief executive officer Dr Paul Tan said the New Zealand Data Safety and Monitoring Board approval followed the board's positive assessment of the first four patients.

Living Cell's medical director Prof Bob Elliott said that with the smaller dose of Diabecell, two patients had "eliminated or reduced life-threatening episodes of hypoglycaemic unawareness, a serious complication without warning symptoms and which can lead to accidents and coma".

Dr Tan said the Russian eight-patient phase I/IIa trial were "supported by the responses we see in New Zealand patients who have much more unstable diabetes".

"In the next stage of this New Zealand trial we will be looking to ascertain additional benefits Diabecell could deliver with a higher dose," Dr Tan said.

Living Cell said the first four New Zealand patients were given a single implant of 10,000 islet equivalents/kg body weight, similar to the dose given to some of the Russian patients.

In the first New Zealand patient, who has been followed for 24 weeks after implant, daily insulin dose has been reduced by 25 percent and hypoglycaemic unawareness has been eliminated, giving an early indication of success, the company said.

Living Cell said that in the next phase of the trial, four new patients would be given a higher dose of 15,000 IEQ/kg by July 2010, with interim results due in October 2010 and final unblinding and reporting of results after one year follow up.

Living Cell said it was investigating additional trials in other jurisdictions.

Living Cell was up half a cent or 2.1 percent to 24.5 cents with 1.2 million shares traded.

QRX PHARMA

QRX has begun its first pharmacokinetic phase I trial to evaluate the profiles of experimental controlled-release morphine and oxycodone formulations for Moxduo CR.

QRX said Moxduo CR contained a fixed three to two morphine to oxycodone combination and was intended to be dosed twice daily in patients experiencing chronic pain, which the company said was a $US7 billion dollar market worldwide.

The company said the two-part US Food and Drug Administration-approved pilot study would compare the rate at which key components of the controlled-release formulation were absorbed, distributed, metabolized and eliminated by the body to the pharmacokinetic profiles of co-administered MS Contin 30mg (sustained release morphine) and Oxycontin 20mg (sustained release oxycodone).

QRX said the study would determine which of the various experimental formulations provided the optimum duration of drug levels in the blood for incorporation into Moxduo CR tablets.

QRX chief executive officer Dr John Holaday said with the initiation of the trial, "all three Moxduo product presentations are now in the clinic and progressing toward commercialization". Moxduo comes as both immediate and controlled release as well as intravenous formulations.

"Our goal is to provide physicians and patients with a variety of complementary dual-opioids for managing moderate to severe pain from hospital to home," Dr Holaday said.

"Our vision for the Moxduo CR tablet is to provide 12 hours of relief in patients with moderate to severe chronic pain including cancer, lower back, osteoarthritis, and neuropathic pain," Dr Holaday said.

QRX was up 2.5 cents or 2.7 percent to 96.5 cents.

ATCOR MEDICAL

Atcor says it has signed a $US955,000 ($A1,038,000) agreement with an unnamed “major international pharmaceutical company” to supply Sphygmocor systems and trial services.
Atcor is the developer and marketer of the Sphygmocor system which measures central blood pressures and arterial stiffness noninvasively.
The company said the contract was a new agreement with an existing customer and “a large portion of the contract value will be recognized in the current financial year”.
Atcor was up one cent or 7.1 percent to 15 cents.