Biotech Daily

Wednesday September 29, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: SUNSHINE HEART UP 20%, PRANA DOWN 10%**

*** PRANA SELECTS PBT434 FOR PARKINSON'S DISEASE**

*** BIOTA, DAIICHI SANKYO INFLUENZA DRUG'S OCTOBER JAPAN LAUNCH**

*** SUNSHINE HEART'S NEXT GENERATION C-PULSE CONTROLLER**

*** CHINA PAYS AGENIX FURTHER $420k**

*** HEALTHLINX LICENCES AGR2 BIOMARKER TO MILLIPORE**

*** MACQUARIE'S APAF, AGILENT IN $100k GLYCOPROTEOMICS RESEARCH**

*** IM MEDICAL LOSES DIRECTOR DR ROSS WALKER**

*** US GRANTS BENITEC FURTHER HEPATITIS C RNAi PATENT**

*** QRX PLACEMENTS TO RAISE $10m; SHARE PLAN; TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.53 percent on Wednesday September 29, 2010, with the ASX200 down 24.8 points to 4645.0 points.

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

Sunshine Heart was best, up half a cent or 20 percent to three cents with 56,935 shares traded, followed by Benitec up 12.5 percent to 2.7 cents with 826,997 shares traded and Cathrx up 12 percent to 28 cents with 154,500 shares traded.

Living Cell climbed 5.6 percent; Optiscan was up 4.8 percent; Bionomics, Genetic Technologies, Nanosonics and Viralytics were up more than three percent; Clinuvel, Psivida, Starpharma and Tissue Therapies rose more than two percent; with Acrux and Sirtex up more than one percent.

Prana led the falls, down 1.5 cents or 10.3 percent to 13 cents with 37,768 shares traded.

Novogen lost 7.4 percent; Immuron fell 4.4 percent; Chemgenex was down 3.75 percent; Genera and Resmed shed more than two percent; with Alchemia, Cellestis and Prima down more than one percent.

PRANA BIOTECHNOLOGY

Prana says it has selected novel lead drug candidate PBT434 to be developed as a disease modifying treatment for Parkinson's disease.

Prana said Parkinson's disease was associated primarily with a loss of motor function, including tremors, loss of coordination and control and was the second most prevalent neurodegenerative disease after Alzheimer's disease.

The company said the loss of motor function in Parkinson's disease resulted from the loss of dopamine-producing cells in the brain's substantia nigra.

Prana said dopamine was the critical chemical messenger between neurons that enabled muscle coordination and function and Parkinson's disease was also associated with abnormally high levels of iron and the accumulation of the protein alpha synuclein.

Prana said the most effective treatments aimed to replace the lost source of dopamine, but these therapies did not slow the course of the disease and did not protect the substantia nigra.

Prana said that its scientists hypothesized that elevated iron and alpha synuclein in the presence of dopamine could lead to cell death in the substantia nigra, leading to the loss of motor function.

The company said PBT434 could prevent the ongoing loss of substantia nigra cells, prevent the elevation of iron and prevent the accumulation of alpha synuclein, so the drug had potential as a disease modifying treatment for Parkinson's disease.

Prana said PBT434 demonstrated strong efficacy in three different Parkinson's disease mouse models.

The company said the three mouse models included: a transgenic mouse model, designed to produce a form of alpha synuclein (A53T) which caused inherited Parkinson's disease; the 6-hydoxy dopamine model (6-OHDA) in which a toxin was injected directly into the substantia nigra; and the 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP) model, in which a toxin was injected into the body that entered the brain and selectively killed substantia nigra cells.

Prana executive chairman Geoffrey Kempler said PBT434 was "saving the cells that produce the chemicals needed to have normal motor function".

"Not many drugs have the evidence to claim that," Mr Kempler said.

"If the drug performs well in development, it could have a dramatic effect on the lives of Parkinson's disease sufferers," Mr Kempler said.

"It is very pleasing to see another drug candidate emerge from our extensive library of over 600 [metal protein attenuating compounds], that we have developed to bring disease modifying benefits to neurological disorders," Mr Kempler said.

Prana said the data would be presented by research director, Prof Robert Cherny, at the World Parkinson's Congress in Glasgow, Scotland from September 28 to October 1, 2010.

The company said the pre-clinical results would be available at: www.pranabio.com.

Prana fell 1.5 cents or 10.3 percent to 13 cents.

BIOTA

Biota says Daiichi Sankyo will formally launch their Inavir dry powder inhaler for influenza in Japan on 19 October 2010.

Biota said the long acting neuraminidase inhibitor (LANI) formerly known as CS-8958 or laninamivir octanoate hydrate would be marketed as a single use 20mg dry powder inhaler for adults and children.

Biota was unchanged at 94.5 cents.

SUNSHINE HEART

Sunshine Heart has engaged two industrial design and software firms to develop the next generation power and software driver for its C-Pulse heart assist system.

Sunshine Heart said that by miniaturizing the separately-housed controller and driver and combining them into one compact unit, it was broadening clinical and commercialization opportunities for the C-Pulse aorta cuff pump.

The company said it had joint development programs with two Australia-based companies, Hydrix Services and Design and Industry, to develop a smaller, quieter and lighter single-control system for use in the US pivotal clinical trial, expected to begin once the US Food and Drug Administration-approved investigational device exemption feasibility study was completed.

Sunshine Heart said the new C-Pulse design would integrate the power driver and battery pack into one unit, significantly reducing the size and the weight of external components.

The company said the external design changes would greatly improve mobility and comfort for the patient without altering C-Pulse implantable components or the way in which the device functioned inside the body.

Sunshine Heart said the new single unit would feature software enhancements intended to allow medical professionals to collect additional data to improve patient management.

Sunshine Heart chief executive officer Dave Rosa said that due to its small internal components, “the C-Pulse can ideally be implanted through minimally invasive procedures as opposed to a full sternotomy procedure”.

“Now, with the redesign of C-Pulse external components, the system will be more ergonomically appealing and comfortable for patients,” Mr Rosa said.

“Our ultimate goal is to make the C-Pulse a fully-implantable system which, much like a pacemaker, can be easily implanted and effortlessly managed by patients,” Mr Rosa said.

The feasibility study’s co-principal medical investigator, the Ohio State University Heart Center’s Dr Bill Abraham said that “reducing the size and bulk of the external system combined with a less-invasive surgical procedure will dramatically expand the use of the C-Pulse among physicians”.

“This treatment has the potential to transform the way in which heart failure is treated and I am eager to see this treatment reach more patients,” Dr Abraham said.

Sunshine Heart was up half a cent or 20 percent to three cents.

AGENIX

Agenix says it has received a further $420,000 from its attempted acquisition of Chinese bio-pharmaceutical interests.

Agenix began a process to acquire two Shanghai pharmaceutical companies in February 2007 but it stalled when a four percent shareholding Chinese landlord failed to provide a waiver for the completion of the share transaction (BD: Feb 14, Jun 6, 2007; Jul 24, 2008).

Today, Agenix said the Agenix Wholly Foreign Owned Enterprise received the September installment from Shanghai Rui Guang Bio-Pharma Development Co of RMB2,700,000 ($A420,000).

Agenix said that, to date, SHRG had strictly followed the payment terms of the March, 26, 2010 deed of variation and made all required settlement payments on time.

The company said the total amount received was RMB25 million ($A4.2 million) with further payments of RMB19 million ($A3.0 million) remaining.

Agenix was unchanged at 3.5 cents.

HEALTHLINX

Healthlinx says it has signed an agreement with Millipore Corp to licence its AGR2 monoclonal antibody.

Healthlinx said Millipore was “one of the world’s largest research reagent companies” and the worldwide non-exclusive licence allowed Millipore to market and sell the monoclonal antibody for research purposes only, with upfront fees and royalties to Healthlinx.

Healthlinx managing director Nick Gatsios said the agreement was “positive for the company for many reasons”.

“Not only do we have two streams of income from the agreement but the use of AGR2 by research institutions globally will only further validate its utility for other applications,” Mr Gatsios said. “Considering we only recently published our data regarding AGR2, this agreement suggests that there is clear interest in and potential for AGR2.”.

Healthlinx said the second, multi-centre, trial of the Ovplex ovarian cancer diagnostic blood test included the testing of two additional biomarkers, one of which was AGR2.

Healthlinx was up half a cent or 6.4 percent to 8.3 cents.

MACQUARIE UNIVERSITY

Macquarie University’s Australian Proteome Analysis Facility and Agilent Technologies will undertake a $100,000 collaboration on glycoproteomics.

A media release from Macquarie University said the collaboration would be led by Prof Nicolle Packer and would use liquid chromatography and mass spectrometry (LC/MS) to generate fragmentation data of glycoprotein glycans.

The University said the data would be used to enhance the Glycosuite database, a publicly accessible repository of glycan structures (www.glycosuitedb.expasy.org).

The media release said both the Australian Proteome Analysis Facility (APAF) and Agilent recognized the functional importance of the glycan or carbohydrate structures attached to proteins and the collaboration would extend the knowledge base for probing the role of glycans in fields such as infectious diseases, cancer and metabolic disorders.

The University said that characterizing glycans was an important step in biomedical science following genome sequencing and proteome characterization projects.

APAF director Prof Mark Molloy said the collaboration with Agilent would “enhance APAF’s capabilities to offer glycan analytical services to the biotech industry for the characterization of recombinant glycoproteins”.

Agilent life science business manager David Tunks said Glycan research was “a key in expanding our understanding of a wide range of diseases”.

Agilent was described as “the world’s premier measurement company and a technology leader in chemical analysis, life sciences, electronics and communications” operating in more than 100 countries.

IM MEDICAL

IM Medical says director Dr Ross Walker has resigned “due to medical practice and media commitments” effective from today.

IM Medical said Dr Walker was appointed a director on June 12, 2008 and would, subject to commitments, be available to consult for the company on medical matters.

IM Medical said managing director Sergio Del Vecchio had been appointed as company secretary and Mark Reynolds was appointed as chief financial officer, effective from October 1, 2010.

IM Medical was untraded at 0.1 cents.

BENITEC

Benitec says the United States Patent and Trademark Office has granted a patent entitled 'RNAi Expression Constructs'.

Benitec said the grant covered an RNAi construct solely owned by Benitec with a single promoter for targeting hepatitis C virus to inhibit the level of hepatitis C virus in cells, tissues and organs.

The company said the US Patent and Trademark Office also granted an additional 925 days patent term in recognition of the delays in examining the patent application.

Benitec chief executive officer Dr Peter French said the granting of the US patent complemented one of Benitec's other US patents ('Multiple promoter expression cassettes for simultaneous delivery of RNAi agents targeted to hepatitis C virus') which was granted in June 2010 for the use of a construct with multiple promoters, also for inhibiting the level of hepatitis C virus in cells, tissues and organs.

Benitec said it had licenced the rights to use both of these patents for hepatitis C exclusively to Tacere Therapeutics which was working with Pfizer to develop and commercialize Tacere's hepatitis C compounds.

"This patent grant also provides further validation of Benitec's RNAi technology and is a key addition to our already strong patent portfolio," Dr French said.

"Our focus continues to be the creation of opportunities to further develop and commercialize this technology," Dr French said.

Benitec was up 0.3 cents or 12.5 percent to 2.7 cents.

QRX PHARMA

QRX hopes to raise up to $10 million through the placement of 11.8 million shares at 85 cents a share, followed by a share purchase plan.

QRX said the funds would be used for a phase III adverse events study comparing high-dose Moxduo immediate release (IR) against morphine and oxycodone alone to expand label indication in US and Europe; complete a new drug application for Moxduo IR to the US Food and Drug Administration; and for working capital.

The company said there would be two placements, the first to raise $3.3 million followed by a second placement for $6.7 million and then a share purchase plan.

QRX said the record date for the share plan was September 30, 2010.

QRX said the first placement would be settled on October 7, 2010 and the second placement would be settled on November 9, 2010.

The company said the share plan would open on October 18 and close on November 12, 2010.

QRX chief executive officer Dr John Holaday told Biotech Daily that the details of the share plan would be announced following the first placement.

Dr Holaday said QRX had about 1,200 shareholders and under share plan rules shareholders were permitted to subscribe for up to $15,000 in shares.

Dr Holaday said he did not expect all shareholders to take up their entire entitlements.

QRX was in a trading halt, will resume trading on October 1, 2010 or on an earlier announcement relating to the capital raising.

QRX last traded at $1.00.