Biotech Daily

Monday July 26, 2010

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN:**
- GENETIC TECHNOLOGIES UP 12%; IMPEDIMED DOWN 9.5%

*** BIOTA BEGINS PHASE II BTA798 RHINOVIRUS DRUG FOR ASTHMATICS**

*** QRX US NDA DELAYED 3 MONTHS, NEW EURO TRIAL; 2012 LAUNCH**

*** EGM BACKS MAJOR CHANGES TO OCCUPATIONAL & MEDICAL**

*** SUNSHINE HEART HAS (JUST) LESS THAN TWO QUARTERS CASH**

*** RESMED JOINS S&P ASX100**

*** BPH'S DR ROBIN SCAIFE WINS $75k MELANOMA DRUG GRANT**

MARKET REPORT

The Australian stock market climbed 0.62 percent on Monday July 26, 2010 with the S&P ASX 200 up 27.7 points to 4486.1 points.

Nine of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and eight were untraded.

Genetic Technologies was best, up 0.4 cents or 11.8 percent to 3.8 cents with 70,000 shares traded, followed by Living Cell up 9.5 percent to 23 cents with 118,500 shares traded.

Compumedics climbed 7.1 percent; Alchemia was up 6.25 percent; Antisense was up 5.9 percent; Novogen was up 3.7 percent; Heartware rose 2.6 percent; with Pharmaxis up 1.9 percent.

Impedimed led the falls, down seven cents or 9.5 percent to 67 cents with 54,568 shares traded, followed by Sunshine Heart down 8.3 percent to 3.3 cents with 61,368 shares traded.

Prima, QRX and Tissue Therapies fell more than five percent; Phosphagenics and Prana lost more than three percent; Acrux, Cathrx, Chemgenex and Viralytics shed more than two percent; with Cellestis, LBT and Nanosonics down more than one percent.

BIOTA

Biota has begun a US Food and Drug Administration-cleared, 400-patient, phase II clinical trial of its antiviral drug BTA798 in patients with chronic asthma.

Biota's vice-president of research Dr Simon tucker told Biotech Daily that BTA798 was expected to reduce asthma exacerbations through treatment of the underlying viral infection, not by acting directly to treat the asthma.

"We are targeting the virus that triggers the worsening of the asthma symptoms," Dr Tucker said.

"It is not acting as a bronchodilator in any way," Dr Tucker said.

Biota said in its media release to the ASX that BTA798 was orally administered and active against human rhinovirus (HRV), which was associated with the common cold.

The company said BTA798 had been shown to reduce the incidence of HRV infection in healthy volunteers in a phase IIa viral challenge study completed last year (BD: Jun 11, 2009).

Biota said at that time that the phase IIa challenge study showed proof-of-concept in humans and reduced the incidence and severity of the infection.

Biota said last year that BTA798 was shown to reduce the incidence and severity of HRV infection when compared to placebo and these benefits were dose-proportional.

Biota said at that time that it intended to licence the global rights to the HRV program and was actively seeking commercial partners.

Today, Biota said the US phase II trial was designed to investigate the impact of BTA798 on cold and asthma symptoms when given shortly after the onset of an infection.

Biota said asthmatics often suffered a worsening of their asthma when they developed a cold and could gain considerable befit from BTA798.

The company said the safety and efficacy study would be a randomized, placebo-controlled, double-blind trial that will involve approximately 60 sites across the US and enroll up to 400 patients.

Biota said the trial was timed to coincide with the peak of the northern hemisphere human rhinovirus cold season, which typically began in late August and with favorable recruitment conditions, the results might be available as early as mid-2011.

The primary efficacy endpoint is an assessment of the severity and duration of cold symptoms and their impact on patient functioning.

Secondary endpoints include incidence and severity of asthma symptoms, changes in lung function and duration and intensity of viral shedding from the upper respiratory tract.

Biota said the trial was budgeted to cost up to $25 million over two years and "a number of major pharmaceutical companies … contributed to the study design".

Potential partnering discussions have confirmed the need for a product with the profile of BTA798 in asthmatics, Biota said.

Biota said its investment in the study, with a successful outcome, should significantly enhance the value of any future licence.

The company said that rhinoviruses could cause up to 50 percent of all adult colds, and were the predominant cold virus in children.

Biota said that in otherwise healthy individuals, rhinovirus infections were a self-limiting, minor inconvenience, but 75 percent of common colds suffered by children under five years of age in the US, were medically attended.

But they were "a major cause of hospitalization and respiratory distress in individuals with chronic underlying respiratory conditions, including asthma and chronic obstructive pulmonary disease (COPD) sufferers and rhinovirus was associated with about 70 percent of all asthma exacerbations and more than 50 percent of the hospitalized cases.

Biota was up half a cent or 0.5 percent to 97 cents.

QRX PHARMA

QRX says it expects to file its new drug application for immediate release Moxduo pain drug to the US Food and Drug Administration early next year, instead of late this year.

QRX chief executive officer Dr John Holaday told Biotech Daily the FDA filing was expected to be completed by April 2011, instead of the previous guidance of the end of 2010.

Dr Holaday said the company expected to file its European marketing authorization application by September 2011.

In a media release to the ASX QRX said it had "positive outcomes" in its European scientific advice meetings on the development and registration of Moxduo IR, its immediate release combination of 12mg morphine and 8mg oxycodone.

The company said it was completing pivotal phase III trials required for filing a new drug application for Moxduo IR with the FDA.

QRX said it intended to submit a marketing authorization application in Europe, the second largest market (about $US3.5 billion) in the world for opioid analgesics.

In support of these registration activities, the company said it held scientific advice meetings in Germany and the UK in May 2010.

Based on the positive responses in the meetings, QRX said it would select Germany as the lead agency for European marketing authorization application (MAA) review and would submit the application in 2011.

"Similar to the FDA's acceptance of our streamlined development plan for Moxduo IR, feedback and guidance from the European agencies regarding the suitability of our data package for MAA submission is also positive," Dr Holaday said.

"Our objective is to launch Moxduo IR globally in 2012 and this feedback clears a significant hurdle and facilitates our European regulatory and commercialization strategy," Dr Holaday said.

QRX said that the German Federal Institute for Drugs and Medical Devices had advised the company that the data package available from the US studies was considered acceptable for marketing authorization application submission in Europe with the addition of a phase III study in bunionectomy patients comparing the adverse event profile of Moxduo IR to equi-analgesic doses of morphine and of oxycodone with a total of 300 patients.

QRX said the study would include the proposed primary safety endpoints of the occurrence rate of moderate-severe nausea, emesis or dizziness, with an improvement for Moxduo IR compared to morphine and oxycodone treatments being defined as a clinically relevant effect.

Assuming a positive outcome of this additional study and pending review of the marketing authorization application, such differences could be cited in the product package labeling in Europe and will further augment data for label claim submission with the FDA in the US.

QRX said it completed a pivotal phase III combination rule study in April 2010 and announced that primary and secondary endpoints were achieved.

The company said Moxduo IR demonstrated both a statistically superior analgesic effect compared to morphine and oxycodone alone as well as a favorable side effect profile despite delivering twice the opioid dose of its individual components.

These findings complement earlier clinical trials demonstrating that Moxduo IR opened the therapeutic window by providing significant acute pain relief while reducing side effects.

Dr Holaday told Biotech Daily that with twice the pain relief Moxduo had the same level of side-effects as either 12mg morphine or 8mg oxycodone "which is the flip-side of the same amount of pain relief for half the side effects, giving more flexibility to the physician".

QRX fell 5.5 cents or 5.2 percent to 99.5 cents.

OCCUPATIONAL & MEDICAL INNOVATION, SUN BIOMEDICAL

Occupational & Medical chairman David Shirley has been voted off the board along with a raft of major changes subject to a deed of company arrangement.

Elected to the board were Michael Doery, Sun Biomedical directors Terry Cuthbertson and Gary Stewart.

The meeting voted to issue 480,000,000 shares at half a cent a share to raise $2.4 million as well as issue 60,000,000 shares at 0.25 cents a share and 60,000,000 attaching options exercisable at half a cent each.

The meeting voted to consolidate shares on a one-for-five basis, reducing the present 45,286,974 shares to 9,057,394 shares.

The meeting also voted to change the company's name from Occupational & Medical Innovations to OMI Holdings.

Administrators SV Partners said all resolutions were passed, with about five million proxy votes in favor with 4,713,896 votes at the proxy's discretion.

Apart from the share consolidation resolution which had 196,675 proxy votes against, all other resolutions were opposed by more than 1.6 million proxy votes against.

The closest resolution was to remove Mr Shirley from the board which was approved by 4,889,974 proxy votes in favor and 1,816,614 proxy votes against.

Sun Biomedical is expected to retain OMI in the biotechnology sector.

Occupational and Medical last traded at 14.5 cents.

Sun Biomedical was unchanged at 0.1 cents with 1,000,000 shares traded.

SUNSHINE HEART

Sunshine Heart says its net operating cash burn for the three months to June 30, 2010 was $2,191,000 with cash at the end of the quarter of $3,942,000.

Sunshine Heart said in June that it would require $US40 million ($A47 million) to complete a phase III pivotal trial of the company's C-Pulse aorta cuff pump system (BD: Jun 3, 2010).

Sunshine Heart chief executive officer David Rosa said at that time the company would raise the necessary funds in stages following the completion of the phase I trial enrollment expected about October 2010.

The company's chief financial officer Rowena Hubble told Biotech Daily that fund raising plans were in line with what was said in June and the company was in negotiations for a future capital raising.

Sunshine Heart fell 0.3 cents or 8.3 percent to 3.3 cents.

RESMED

Resmed has been promoted into the Standard & Poors ASX100 list, effective from the close of business on July 30, 2010.

There were very few changes to the S&P indices and no other biotechnology company was promoted or demoted.

Resmed fell five cents or 0.7 percent to $7.19 with 3.4 million shares traded.

BPH CORPORATE

BPH says its principal researcher Dr Robin Scaife has been awarded $75,000 from the Scott Kirkbride Melanoma Research Centre.

BPH said the funds would assist a melanoma drug discovery program at the Western Australian Institute for Medical Research.

The company said the Scott Kirkbride Melanoma Research Centre supported research for improved diagnosis and treatment of melanomas and was established in 2005 in memory of Perth golfer, Scott Kirkbride, who died from melanoma in 2004 at the age of 27 years.

BPH said that although melanomas had a reputation for being particularly refractory to therapeutic intervention, some types of melanoma had been shown to respond well to a new class of customized cancer drugs.

The company said that Dr Scaife and his collaborators at the Western Australian Institute for Medical Research and the University of Western Australia, would use the high-content imaging and analysis platform at Molecular Discovery Systems to screen an arsenal of new drug-like molecules for inhibitors of melanoma cell survival and proliferation.

BPH owns 20 percent of Molecular Discovery Systems following last year's in specie share return.

BPH fell 1.5 cents or 13.0 percent to 10 cents with 5.2 million shares traded.