Biotech Daily

Monday January 21, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: QRX UP 10%, OPTISCAN DOWN 9%**

*** MEDICAL DEVELOPMENTS PHASE III: PENTHROX EFFICACY, SAFETY**

*** BIOXYNE REVIEWS HI-164OV DATABASE**

*** EURO-PATENT FOR CELLMID MIDKINE VASCULAR OCCLUSIVE DISEASE**

*** AGENIX 1-FOR-1 RIGHTS ISSUE TO RAISE $1m**

*** COGSTATE H1 REVENUE DOWN TO $9m, LOSS DOWN TO $500k**

*** BONE CLAIMS EARLY BN006 SUCCESS IN RHEUMATOID ARTHRITIS**

*** DR MALCOLM MCCOLL STARTS AS VIRALYTICS CEO TODAY**

*** CORRECTION: PATRYS**

MARKET REPORT

The Australian stock market climbed 0.13 percent on Monday January 21, 2013 with the S&P ASX 200 up 6.3 points to 4,777.5 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and five were untraded.

QRX was the best, up 9.5 cents or 10.1 percent to $1.04 with 144,262 shares traded, followed by Neuren up 10 percent to 3.3 cents with four million shares traded.

Medical Developments climbed 9.1 percent; Pharmaxis and Viralytics were up five percent or more; Cellmid, Ellex, Genera and Prana were up four percent or more; Phosphagenics was up 3.3 percent; Acrux, Genetic Technologies, Heartware and Starpharma were up more than one percent; with Cochlear, Nanosonics and Resmed up by less than one percent.

Optiscan led the falls, down one cent or 8.7 percent to 10.5 cents with 135,069 shares traded. Sunshine Heart and Tissue Therapies lost more than three percent; Circadian and Patrys shed more than two percent; Alchemia, Clinuvel, Reva, Sirtex and Universal Biosensors were down more than one percent; with CSL and Mesoblast down less than one percent.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its 300-patient pivotal phase III trial of inhaled methoxyflurane for pain has shown efficacy and safety.

Medical Developments said that the randomized, double-blind, placebo-controlled, clinical study at six centres in the UK compared self-administered methoxyflurane via its Penthrox inhaler at a dose of up to 6.0ml to placebo for the treatment of acute pain in patients presenting at an emergency department with minor trauma.

The company said the trial was completed on-time and on-budget.

Medical Developments said the study was “a very significant milestone … [and] provides us with clinical evidence of the safety and efficacy of Penthrox and will become a critical component of our regulatory strategy to introduce Penthrox into new markets internationally and in particular, Western Europe”.

The company said it expected to apply for marketing authorization for selected countries in Europe by April 2013 and would update countries considering Penthrox registration.

Medical Developments said all primary and secondary endpoints were met with “a highly significant difference between the methoxyflurane and placebo group ($p < 0.0001$) in the analysis of the change of … pain intensity score from baseline”.

The company said there was “a highly significant difference ($p = 0.0002$) between the methoxyflurane and placebo groups in the use of rescue medication requested by the patient within 20 minutes of the start of treatment.

Medical Developments said that the median time to first pain relief for the methoxyflurane group was four minutes compared with the median time to onset of meaningful pain relief for intranasal fentanyl of 11 minutes and 16 minutes for oro-mucosal fentanyl.

The company said that 126 patients (84.6%) in the methoxyflurane group experienced their first pain relief with 1-10 inhalations and overall, the study demonstrated a highly significant treatment effect by all efficacy analysis.

Medical Developments said that in terms of safety both methoxyflurane and placebo were well tolerated with no deaths and only one serious treatment-emergent adverse event, which was unrelated to the study or the study drug.

The company said that the number of patients experiencing treatment emergent adverse events leading to the withdrawal of study treatments was lower in the methoxyflurane group (1.3%) compared to the placebo group (2.0%).

Medical Developments that, overall, methoxyflurane was well-tolerated with most adverse reactions being mild, transient and in line with anticipated pharmacological action.

Medical Developments was up 16 cents or 9.1 percent to $1.91.

BIOXYNE

Bioxyne says it has begun analyzing the full database of the phase II study of HI-164OV for chronic obstructive pulmonary disease.

Last year, the 320-patient trial showed that HI-164OV failed to meet its endpoints, triggering a share price fall in the newly listed Bioxyne and a consequent board and management spill (BD: Jun 28, Dec 14, 2012).

Today, the company said the analysis would allow it to compare the phase IIb study (H-005) with earlier studies (H-002 and H-004).

Bioxyne said that the patent covering HI-164 was “long dated” and the active substance HI-164OV was covered to 2029 and development could take a variety of forms and be in-house or external.

Bioxyne was up 0.2 cents or 7.7 percent to 2.8 cents.

CELLMID

Cellmid says the European Patent Office intends to grant its patent application entitled ‘Pharmaceutical composition for vascular occlusive disease’.

Cellmid said the application with claims covering the use of short interfering RNAs (siRNAs) to prevent midkine expression in blood vessel walls was filed in May 2006 and the patent was expected to expire in 2026.

The company said that animal studies showed that midkine expression in damaged blood vessels contributed significantly to vessel narrowing and obstruction and inhibiting midkine prevented or reduced narrowing.

Cellmid said that vascular occlusive disease was the biggest cause of premature death in Western nations and occurred where blood vessels were narrowed or blocked and could occur at many sites in the body, including the heart causing coronary heart disease, the brain causing a stroke, the kidneys causing reno-vascular disease and the limbs causing peripheral vascular disease such as deep vein thrombosis.

The company said that targeting midkine in vascular disease was a potential treatment of both the initial vessel narrowing, known as stenosis, and the re-occurrence of narrowing, known as restenosis, that frequently occurred after surgical interventions such as stenting.

Cellmid’s head of product development Darren Jones said that restenosis was a common and significant problem in coronary heart disease who had received stents to unblock their coronary arteries.

“Administering a treatment that stopped or slowed restenosis at the same time as stenting would be a valuable improvement to current practice,” Mr Jones said.

“Cellmid’s European patent covers claims to use [midkine] inhibitors to do this,” Mr Jones said.

Cellmid said it had 11 granted patents in the US, Europe, Japan, China and Australia for both siRNAs and antibodies to treat angiostenosis and the new patent further protected those rights and granted composition of matter claims for midkine-specific siRNAs.

Cellmid chief executive officer Maria Halasz said that the granting of protection for a further class of midkine inhibitors beyond midkine antibodies confirmed the breadth of the company’s intellectual property assets.

“RNA interference gives Cellmid another potential option by which to eliminate [midkine] in disease settings,” Ms Halasz said.

“Furthermore, it adds yet another disease area that Cellmid has exclusive rights to treat via [midkine] inhibitors,” Ms Halasz said.

Cellmid was up 0.1 cents or four percent to 2.6 cents with 36.8 million shares traded.

AGENIX

Agenix says it hopes to raise up to $1,235,000 through a one-for-one rights issue at three cents a share.

Agenix said each new share would come with a free attaching option exercisable at five cents by June 30, 2015.

The company said the record date was January 30, the offer would open on February 6 and close on February 20, 2013.

On December 27, 2012 Agenix told the ASX that Fortrend Securities had reneged on its draw-down equity facility (BD: Jan 20, 2013).

Agenix was untraded at 3.8 cents.

COGSTATE

Cogstate says that revenue for the six months to December 31, 2012 was expected to be $6.1 million with net loss after tax down from $1 million to $1.2 million to about $500,000.
Cogstate said the total value of clinical trials sales contracts signed in the six months to December 31, 2012 was $8.7 million, down 14.7 percent from the record high of $10.2 million recorded at December 31, 2011.
The company said that revenue was primarily derived from milestone payments relating to clinical trials contracts that were currently underway or completed during the quarter.
Cogstate said that at December 31, 2012 it had $10.6 million of clinical trials revenue contracted that would be recognized in future periods compared to the previous year's $9.2 million.
Cogstate said it had cash holdings of $4.26 million at December 31, 2012, compared to $3.45 million at the same time in 2011.
Cogstate was up 2.5 cents or 7.7 percent to 35 cents.

BONE MEDICAL

Bone says that initial findings from its BN006 proof-of-concept experiment for rheumatoid arthritis shows that BN006 reduces inflammation.
Bone said that BN006 was derived from its Mozaic peptide discovery technology and the trial used a collagen-antibody induced arthritis model, a commonly accepted disease model for rheumatoid arthritis.
The company said that the reduction in inflammation appeared to be dose-related and BN006 appeared to achieve a significant reduction in inflammation with only a modest reduction of tumor necrosis factor (TNF).
Bone did not disclose how many patients were in the trial.
Bone said that TNF was one of the body's inflammatory agents that played an important role in the rheumatoid arthritis disease process.
Bone's chairman, chief scientific officer and inventor of the Mozaic plaform Dr Roger New said the current standard of care for the treatment of rheumatoid arthritis were all monoclonal antibodies that worked by binding directly to TNF and blocking its activity systemically.
"This is a blunt approach that reduces TNF's ability to play its normal role in the body's immune response, which can then lead to the most common adverse events that limit the clinical role of these products," Dr New said. "In our BN006 proof of concept study, BN006 achieved its anti-inflammatory effect with only a small reduction in TNF."
"While adalimumab (Humira) completely eliminated inflammation in our study, it also almost completely blocked TNF," Dr New said. "This provides powerful experimental evidence for BN006's selective mechanism of action, which works by acting directly on macrophages to reduce their inflammatory activity."
"It reinforces the potential for BN006 to become an important advance in the treatment for [rheumatoid arthritis] and improve the lives of the millions of patients who suffer from this terrible debilitating disease," Dr New said.
Bone chief executive officer Peter Young said that the company was placing its product portfolio emphasis on BN006 and on Capthymone, its oral parathyroid hormone product, and the move also reflected regulatory uncertainty over the use of calcitonin, the basis of its Caspitonin oral calcitonin product, for the treatment of osteoporosis after a European Medicines Agency recommendation to restrict its use due to concern about a possible, previously unidentified safety risk observed in data from other calcitonin companies.
Bone was unchanged at 0.3 cents with 36.3 million shares traded.

VIRALYTICS

Viralytics says that Dr Malcolm McColl assumed the role as chief executive officer, effective from today.

Formerly Starpharma's business development executive, Dr McColl was appointed to the Viralytics position last year, but at that time the company was not able to specify a start date (BD: Nov 14, 2012).

Viralytics was up 1.5 cents or five percent to 31.5 cents.

PATRYS

Last night's Special Summer Catch-Up Edition reported that Citigroup held seven percent of Patrys, but this was an accidental inclusion from a previous edition.

Citigroup holds shares in Patrys but is below the five percent substantial shareholding threshold.

The sub-editor, and not the compiler of the edition, made the mistake and has been admonished.

Patrys fell 0.1 cents or 2.9 percent to 3.4 cents.