Biotech Daily

Thursday October 6, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CELLMID UP 19%; ANTISENSE DOWN 11%**

*** CELLMID HUMANIZES FIRST MIDKINE ANTIBODY HU91**

*** BENITEC US ddRNAi HEPATITIS C PATENTS GRANTED, ALLOWED**

*** CALZADA'S WOUND TREATMENT NOVOSORB PASSING PRE-CLINICAL**

*** WILSON HTM REDUCES 1% IN AVITA**

*** PETER VAUGHAN REPLACES ISONEA CO SEC BRAD SLADE**

MARKET REPORT

The Australian stock market was up 3.65 percent on Thursday October 6, 2011 with the S&P ASX 200 up 143.4 points to 4,069.9 points.

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

Cellmid was the best, climbing as much as 37.5 percent before closing up 0.3 cents or 18.75 percent at 1.9 cents with 4.4 million shares traded, followed by Genetic Technologies up 13.3 percent to 17 cents with 588,430 shares traded and Prana up 10.3 percent to 16 cents with 180,693 shares traded.

Anteo and Pharmaxis climbed more than nine percent; Allied Health rose 7.1 percent; Prima was up 6.7 percent; Benitec and Cochlear were up more than five percent; Nanosonics was up 4.2 percent; Acrux, CSL, Genera, Mesoblast and Phosphagenics were up more than three percent; Optiscan and Tissue Therapies rose more than two percent; with Bionomics, Heartware, Resmed and Sirtex up more than one percent.

Antisense led the falls, down 0.1 cents or 11.1 percent to 0.8 cents, with 25.1 million shares traded, followed by Clinuvel down seven percent to $1.45 with 6,946 shares traded.

Universal Biosensors lost 4.8 percent; Circadian and Reva were down more than three percent; Living Cell shed 2.2 percent; with Alchemia and Biota down more than one percent.

CELLMID

Cellmid says its collaboration with Antitope has completed humanization of a first-in-class anti-midkine antibody, hu91, resulting in a drug that can enter clinical development.

Cellmid chief executive officer Maria Halasz told Biotech Daily that midkine was an inflammation protein that recruited leukocytes and the antibody would inhibit its action.

Ms Halasz said that pre-clinical work had been through intravenous delivery and Cellmid was targeting inflammatory kidney diseases such as diabetic nephropathy, lung diseases, including chronic obstructive pulmonary disease and surgical adhesions.

Ms Halasz said that abdominal surgery could leave scarring that allowed organs to adhere, but a prophylactic treatment with the midkine antibody could prevent adhesion.

Cellmid said that the humanization was completed on time and within budget.

The company said that functionality and binding characteristics of the humanized antibody were “well within the range needed for a successful drug candidate and are equivalent to the precursor mouse monoclonal antibody”.

Cellmid said the humanization was “the most significant milestone to date” in its antibody program and removed a substantial risk from the clinical development path.

The company said it signed a research collaboration agreement to humanize its lead mouse monoclonal antibody candidate CDY91 using Antitope’s proprietary Composite Human Antibody technology (BD: Apr 13, 2011).

Cellmid said that a number of variants resulted from the collaboration and they were tested for biological function and binding affinity to midkine by independent contract research organizations to select the best candidate for clinical development.

The company said hu91 biological function was determined with cell migration assays, measuring the drug’s potential to inhibit cells migrating in response to midkine signaling.

Cellmid said midkine was a potent promoter of inflammatory cell migration and hu91’s main mechanism of action was to block this migration from occurring by mopping-up midkine in the blood and tissues to reduce inflammatory damage.

The company said the studies showed the humanized candidate (hu91) was slightly superior (80 percent inhibition) to the mouse precursor (78 percent inhibition) at preventing cell migration.

Cellmid said that antibody binding or affinity to midkine was also assessed using standard Biacore methods to measure the dissociation constant between hu91 and midkine compared to CDY91 and midkine, with the dissociation constant for hu91 measured at 3.00 nanomolar (nM) as compared with 3.26nM for CDY91, where a lower dissociation constant indicated stronger binding affinity.

The company said that as well as producing a human drug candidate, Antitope’s technology avoided immunogenic motifs in the antibody, meaning that hu91 was not expected to generate an immune response in patients, making it potentially safer.

Cellmid said that hu91 validation studies prior to entering human clinical trials included animal models of kidney and lung inflammatory diseases as well as surgical adhesions.

Cellmid’s head of product development Darren Jones said that successfully engineering a humanized antibody with matching performance to the mouse precursor was “a very pleasing result”.

“Importantly, fully retained functionality has been confirmed by the blinded studies conducted by independent research organizations,” Mr Jones said.

“This is a very significant achievement for our technical team as we now have a drug that is ready to enter human clinical trials subject to completion of the final preclinical validation studies,” Ms Halasz said.

Cellmid climbed as much as 37.5 percent before closing up 0.3 cents or 18.75 percent at 1.9 cents with 4.4 million shares traded.

BENITEC

Benitec says it has been granted a US patent entitled ‘RNAi expression constructs with liver-specific enhancer/promoter’.
Benitec said the patent contained claims to its DNA-directed RNA interference (ddRNAi) expression constructs specifically for RNAi in the liver and supported its hepatitis program with claims to methods of using the liver specific ddRNAi expression constructs to suppress the hepatitis virus.
Benitec said it also received a notice of allowance on a separate US patent application containing claims directly relating to hepatitis therapy using its ddRNAi technology.
The company said the patent claims were to an RNAi construct with a single promoter for targeting hepatitis C virus to inhibit the level of hepatitis C virus in cells, tissues and organs, together with methods for inhibiting hepatitis C.
Benitec chief executive officer Dr Peter French said that allowance of the US patent application complemented Benitec’s other US patents “also directed to constructs and methods for inhibiting the level of hepatitis C virus in cells, tissues and organs”.
Benitec said it expected the application to be granted in the coming months.
The company said that following the grant of the European patent ‘Multiple promoter expression cassettes for simultaneous delivery of RNAi agents’ earlier this year, the patent has been validated in France, the UK, Germany, Ireland, Switzerland, The Netherlands, Monaco, Luxembourg, Denmark, Spain, Italy and Sweden.
Benitec said the patents provided protection to 2025 and were licenced to Tacere Therapeutics for hepatitis C.
The company said that their allowance and/or granting were “an important step in confirming Benitec’s dominance in the gene silencing landscape using ddRNAi”.
Benitec was up 0.1 cents or 5.3 percent to two cents with 5.1 million shares traded

CALZADA

Calzada says its Novosorb material for wound treatment has continued to pass its pre-clinical testing program.
Calzada said Novosorb was intended to be used in its biodegradable temporising matrix (BTM) for the treatment of full thickness burns and wounds.
The company said it had received a preliminary report on the 90-day long-term implantation, combined with assessment of sub-chronic systemic toxicity in rats indicating no noticeable effect.
Calzada said that so far the Novosorb material performed successfully in all in-vivo tests performed under the ISO10993 studies.
The results of the final two in-vivo studies of 180-day long term implantation and genetic toxicity were expected to be received within the next three months.
Calzada was up 0.4 cents or 7.1 percent to six cents.

AVITA MEDICAL

Wilson HTM Investment Group has reduced its substantial holding in Avita from 19,393,000 shares (8.14%) to 16,959,950 shares (7.12%).
Wilson HTM said that between July 12, and October 4, 2011 it sold 2,871,050 shares for $295,200 or an average price of 10.28 cents a share and between August 8 and August 30, 2011 it bought 438,000 shares for $49,509 or an average price of 11.3 cents a share.
Avita was unchanged at 9.9 cents.

ISONEA

Isonea (formerly Karmelsonix) says joint company secretary Brad Slade has resigned, with immediate effect.

Isonea said Mr Slade had been joint company secretary since July 31, 2008 with Phillip Hains of the Armadale Melbourne-based CFO Solution.

The company said the CFO Solution's Peter Vaughan had been appointed joint company secretary with immediate effect.

Isonea was up 0.1 cents or 8.3 percent to 1.3 cents.