Biotech Daily

Tuesday April 6, 2010

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: LIVING CELL UP 16%; AVEXA DOWN 7%**

*** US BIOSIMILARS LAW 'GOOD FOR BIOTECH' - MESOBLAST, PRIMA**

*** SLOW SALES FORCE FLUOROTECHNICS FUNDRAISING**

*** CANADA APPROVES USCOM SALES**

*** AUSTRALIAN ETHICAL QUITS GENERA, ACQUIRES IMPEDIMED STAKE**

*** IDT PLEADS SCHULTZ, H1 LOSS TO ASX 21% PRICE FALL QUERY**

*** RESONANCE COMPLETES FIBROSCAN TRIAL RECRUITMENT**

*** INCITIVE EGM TO DIVEST BIOTECH ASSETS**

MARKET REPORT

The Australian stock market climbed 0.94 percent on Tuesday April 6, 2010 with the S&P ASX 200 up 46.0 points to 4953.7 points.

Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and five were untraded.

Living Cell was best, up four cents or 16.0 percent to 29 cents with 3.1 million shares traded, followed by Prima up 1.5 cents or 10.7 percent to 15.5 cents with 6.9 million shares traded and Clinuvel up six percent to 26.5 cents.

Optiscan, Phylogica, Starpharma and Tissue Therapies climbed more than two percent; with Acrux, Biota, Chemgenex and Mesoblast up more than one percent.

Avexa led the falls, down one cent or 6.7 percent to 14 cents with 2.3 million shares traded.

Genera, Impedimed, Novogen and Viralytics lost five percent or more; Benitec, Phosphagenics and Universal Biosensors fell more than four percent; Alchemia and Uscom were down more than three percent; with QRX down 2.2 percent.

MESOBLAST, PRIMA BIOMED

Mesoblast and Prima have welcomed the US 'biosimilars' legislation saying it provides protection and financial encouragement for invention.

The main provision of the legislation appears to be a 12 year period of exclusivity in the US for biologic inventions (see Mesoblast statement below).

Biotech Daily expects to publish analyses of the legislation in tomorrow's edition.

Last week Prima chief executive officer Martin Rogers told Biotech Daily that the legislation would provide protection above and beyond existing patent protection.

"It is similar to the orphan drug legislation of 1983," Mr Rogers said.

"Pharmaceutical companies said 'ho hum' but it makes a difference for biotech companies," Mr Rogers said.

"For biotech companies on the cutting edge it provides the financial incentive to make new discoveries," Mr Rogers said.

Today Mesoblast added its weight to the debate saying the US Patient Protection and Affordable Care Act (HB 3590), which was signed into law March 23, 2010 was "expected to have a positive impact on the commercial prospects" for both Mesoblast and its US-sister company, Angioblast Systems.

Mesoblast said the Act would "facilitate a material increase in the long-term revenue projections for [Angioblast and Mesoblast] for their biologic products in the US, the world's largest market for regenerative medicines".

Mesoblast said a key provision in the Act provided "a biologic innovator with long-term exclusive market protection of its approved product against abbreviated approval of biosimilar biologic products by the US Food and Drug Administration".

Mesoblast said a biosimilar product was deemed to be interchangeable with an already approved reference biologic based upon highly similar analytical studies and clinical trials that demonstrated safety, purity and potency for the same indication.

Mesoblast said the Act explicitly prohibited FDA approval of a biosimilar until 12 years after the date on which the reference biologic product was first approved.

The company said the Act further stipulated an additional six months of exclusivity for the use of reference biologic products in the paediatric population.

Mesoblast said that under the Act, the innovator might receive a further 12 years of exclusivity from the date of approval of any subsequent biologic product which had a structure that has been modified to result in a change in safety, purity, or potency of the reference biologic.

Mesoblast said that maintaining commercial exclusivity for its biologic products through a robust international patent portfolio was fundamental to its commercial strategies.

The company said the US Patent and Trademark Office had granted Mesoblast and Angioblast key composition-of-matter and manufacturing patents for their cell therapy products and the patents provided protection for the companies' reference biologic products in the US to at least 2019, with potential for significant patent life extension.

Additional patents have been filed covering specific uses of the companies' biologic products that considerably extend the duration of patent protection.

The new provisions for biosimilar biological products within the Act, provided Mesoblast and Angioblast with the potential to significantly extend commercial exclusivity for their cell therapy products in the US well beyond initial patent expiration dates.

Mesoblast said the extra protection would significantly increase the long-term revenue projections for both companies.

Mesoblast was up four cents or 1.98 percent to $2.06.

Prima was up 1.5 cents or 10.7 percent to 15.5 cents with 6.9 million shares traded.

FLUOROTECHNICS

Fluorotechnics will have to raise funds as slow sales of its new electrophoresis Flattop system has led to a revenue shortfall for the year to June 30, 2010.

Fluorotechnics said it had forecast revenue of $7 million to $10 million but that was more likely to be about $5 million compared to the $3.2 million for 2008-'09.

The company said that the level of interest from customers in its high performance electrophoresis (HPE) Flattop system was strong but it was taking longer than expected to complete the sales process of the system.

"In many cases, this stems from a greater than envisaged time for the customers to obtain approval for this type of capital expenditure," Fluorotechnics said.

"To a lesser extent sales have also been negatively impacted by unfavorable exchange rates," the company said.

Fluorotechnics said it was confident of the sales potential of its products, especially the HPE Flattop system.

Fluorotechnics chief executive officer James Walker told Biotech Daily that electrophoresis was the electrical dispersion of particles and was of particular use in proteomics with applications including separation, detection and analysis and protein matching.

The company said that since the launch of the HPE Flattop system, customers had been "almost universally impressed by the superior and attractive performance of the system … evidenced by the growing number of opinion leaders who have become customers".

Fluorotechnics said that due to the reduced sales expectations, the company would want to raise additional working capital.

Fluorotechnics was unchanged at 33 cents.

USCOM

Health Canada's Medical Devices Bureau has approved a medical device licence for Uscom's ultra-sonic cardiac output monitor.

Uscom said the licence was a requirement for sales in Canada and completed the company's worldwide regulatory approval program.

The company said that its marketing partner Spacelabs was responsible for the Canadian market and could begin Canadian sales activities.

The monitor has been used in research activities in Canada and was evaluated by Canadian physicians at international meetings, the company said.

Uscom chairman Rob Phillips said Canada was "a sophisticated and significant medical device market which has shown considerable interest in our technology".

Uscom fell two cents or 3.2 percent to 60 cents.

GENERA BIOSYSTEMS, IMPEDIMED

Australian Ethical Trusts has sold its holding in Genera Biosystems and taken a stake in Impedimed.

Australian Ethical also has investments in Cochlear, Pharmaxis, QRX, Resmed, Tissue Therapies.

The organization's portfolio manager Andy Gracey told Biotech Daily that Australian Ethical had acquired about 4.15 million shares in Impedimed at 65 cents a share.

Biotech Daily editor David Langsam holds Australian Ethical Trust units.

Genera fell four cents or 5.4 percent to 70 cents.

Impedimed fell four cents or five percent to 76 cents.

IDT

IDT says it is not aware of any information that has not been announced which, if known, could be an explanation for recent trading in its securities.
The ASX said the company's share price fell 19 cents or 20.9 percent from 91 cents on March 26, 2010 to 72 cents on April 1, 2010, along with an increase in trading volumes.
IDT said it had previously announced an after tax loss of $639,000 for the half year to December 31, 2009 compared to an after tax profit of $3,071,000 reported for the half year to December 31, 2008.
The company said it the half year financial reports expected the underlying business would "remain flat in the short term until the international economic outlook improved".
IDT said it had not completed a transfer of assets from Pfizer and negotiations were ongoing.
IDT was up two cents or 2.6 percent to 80 cents.

RESONANCE HEALTH

Resonance Health says it has finished patient recruitment and magnetic resonance imaging scanning for its Fibroscan test for the measurement of liver fibrosis.
The company said it was analyzing the data and would provide an update by the end of April, 2010.
Resonance was up 0.1 cents or four percent to 2.6 cents.

INCITIVE

Incitive shareholders will vote on the demerger of its biotechnology assets and distribute 510,188,014 Sarantis shares to holders registered on the record date of May 14, 2010.
Incitive's company secretary Winton Willesee told Biotech Daily that Sarantis was a wholly-owned subsidiary of Incitive holding the company's biotechnology assets and would continue after the demerger as a public unlisted company.
Two further resolutions propose the issue of 12,625,000 Sarantis options to chairman Mel Bridges and 12,500,000 Sarantis options to director Eric de Mori.
The meeting will be held at Level 1, 2 Ross Place, South Melbourne on May 6, 2010 at 9.30am.
Incitive will become an oil and gas exploration company (BD: Mar 12, 2010).
Incitive was unchanged at 0.7 cents.