



Biotech Daily

Friday June 14, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: IMPEDIMED UP 15%, NEUREN DOWN 5%**
- * **US SUPREME COURT MYRIAD BRCA GENE PATENT CASE:
- GOOD FOR BENITEC, POTENTIAL FOR GENETIC TECHNOLOGIES**
- * **ANTISENSE ATL1103 BEATS CURRENT ACROMEGALY DRUGS IN MICE**
- * **BIOTECH IN FEDERAL GOVERNMENT MANUFACTURING PRECINCT**
- * **PRIMA OPTIONS RAISE \$1.5m; TOTAL \$6.5m RAISED**

MARKET REPORT

The Australian stock market bounced back 2.04 percent on Friday June 14, 2013 with the S&P ASX 200 up 96.0 points to 4,791.8 points.

Twenty-one of the Biotech Daily Top 40 stocks were up, eight fell, five traded unchanged and six were untraded.

Impedimed was the best, up one cent or 15.4 percent to 7.5 cents, with 86,987 shares traded, followed by Patrys up 14.3 percent to 3.2 cents with 1.2 million shares traded and Circadian up 11.1 percent to 30 cents with 3,000 shares traded.

Antisense climbed 9.1 percent; Allied Health, Compumedics, Genetic Technologies and Universal Biosensors were up eight percent or more; Benitec climbed 7.1 percent, Osprey and Reva were up more than six percent; Avita and Nanosonics rose five percent or more; Prima was up 3.1 percent; Heartware, Prana and Sirtex rose more than two percent; Anteo was up 1.5 percent; with Acrux, Cochlear, QRX, Resmed and Starpharma up by less than one percent.

Neuren led the falls, down 0.3 cents or five percent to 5.7 cents, with 1.6 million shares traded.

Living Cell fell 4.35 percent; Alchemia, Mesoblast and Tissue Therapies lost more than three percent; Clinuvel shed 2.6 percent; Optiscan and Psivida were down more than one percent; with CSL down 0.3 percent.

US SUPREME COURT, BENITEC BIOPHARMA, GENETIC TECHNOLOGIES

A mixed decision on gene patents by the US Supreme Court on gene patenting has been described as positive for Benitec and adding potential sales for Genetic Technologies. In the case of the Association For Molecular Pathology versus Myriad Genetics Inc, the US Supreme Court decided that human DNA could not be patented but synthetically created DNA could be patented.

The decision is different to an Australian Federal Court decision that found that extracted human DNA was an invention and patentable, whereas DNA in situ was a discovery and not patentable (BD: Feb 15, 2013).

In the US Supreme Court, Justice Clarence Thomas delivered the opinion, in which Chief Justice John Roberts, Justice Anthony Kennedy, Justice Ruth Ginsburg, Justice Stephen Breyer, Justice Samuel Alito, Justice Sonia Sotomayor and Justice Elena Kagan, joined, and in which Justice Antonin Scalia joined in part. Justice Scalia filed an opinion concurring in part and concurring in the judgment.

Justice Thomas said that the respondent Myriad Genetics Inc, discovered the precise location and sequence of two human genes, mutations of which could substantially increase the risks of breast and ovarian cancer.

Justice Thomas said that Myriad obtained a number of patents based on its discovery and the case involved claims from three of them and required the Court "to resolve whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible ...by virtue of its isolation from the rest of the human genome".

"We also address the patent eligibility of synthetically created DNA known as complementary DNA (cDNA), which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins," Justice Thomas said.

"For the reasons that follow, we hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring," Justice Thomas said.

"We, therefore, affirm in part and reverse in part the decision of the United States Court of Appeals for the Federal Circuit," Justice Thomas said.

The judgment is at: http://www.supremecourt.gov/opinions/12pdf/12-398_8njq.pdf.

Benitec said that its DNA-directed RNA interference (ddRNAi) technology used synthetic DNA constructs and the Court's "affirmation that synthetically produced pieces of DNA are patentable supports Benitec Biopharma's patents and technology".

In May following a personal account of breast cancer by actor Angelina Jolie in the New York Times, Genetic Technologies chief executive officer Alison Mew told Biotech Daily that Myriad held the patents for the BRCA genes and her company held the rights to the BRCA testing in Australia and New Zealand (BD: May 16, 2013).

"Only five to 10 percent of breast cancer is due to the BRCA gene mutations," Ms Mew said at that time.

Ms Mew said that Genetic Technologies also had the Brevagen sporadic breast cancer risk assessment test, launched in the US in 2011 and that "the vast majority of breast cancer arises sporadically, against which the Brevagen test is directed".

Today, Ms Mew was overseas not available for comment.

Lodge Partners analyst Marc Sinatra told Biotech Daily that most of the BRCA patents were close to expiring in 2014 and 2015 and the decision could allow Genetic Technologies to provide the BRCA tests alongside the Brevagen test in the US.

Benitec was up 0.1 cents or 7.1 percent to 1.5 cents with 1.3 million shares traded.

Genetic Technologies was up 0.8 cents or 8.7 percent to 10 cents.

ANTISENSE THERAPEUTICS

Antisense says that ATL1103 suppresses growth hormone receptor (GHR) expression in mice significantly better than two current treatments for acromegaly.

Antisense said the data was presented at the International Pituitary Congress in San Francisco California by the University of Queensland's Prof Mike Waters as part of his talk entitled 'GH/IGF-I and Cancer'.

The company said that in addition to ATL1103 demonstrating positive new data for acromegaly, Prof Waters said the findings were significant for ATL1103's potential application in treating cancer.

Antisense said that 11 groups of eight mice each were dosed with two separate doses of ATL1103 for three weeks alone (12mg/kg and 25mg/kg) and also in combination with two current drugs for acromegaly, pegvisomant in two doses (5mg/kg and 20mg/kg) and a single dose level of octreotide

The company said that ATL1103 suppressed GHR RNA expression and significantly reduced downstream insulin-like growth factor I (IGF-I) RNA expression in the liver to levels lower than that achieved by either pegvisomant and octreotide, when used alone at the doses employed in this study.

Antisense said that ATL1103 also lowered serum IGF-I levels consistent with its effects in reducing IGF-I RNA expression in the liver; the liver being the main source of IGF-I in the blood.

The company said that ATL1103 in combination with pegvisomant showed a more significant reduction in liver IGF-I RNA compared to either agent used alone, suggesting that the combination could be useful for both cancer and acromegaly treatment.

Antisense said that the use of ATL1103 in combination with pegvisomant was claimed in the patent application it had lodged covering the use of any antisense drug to GHR in combination with pegvisomant to enhance therapeutic effect through until 2033.

Antisense said that Prof Waters was a member of its ATL1103 scientific advisory group, had been involved in the study of growth hormone action for more than 30 years and was the first to purify and characterize the growth hormone receptor.

The company said that reviewing the data in his advisory capacity, Prof Waters was impressed with ATL1103's effects in suppressing GHR RNA expression in the liver, which led to Prof Waters incorporating the company's new data in his presentation on GH/IGF-I and cancer.

"We know patient populations without GHR, such as those with Laron syndrome, are protected from developing cancer and that those populations that have a more active form of GHR appear more susceptible to lung cancer," Prof Waters said.

"Many tumors produce their own GH independently of circulating or systemic GH, and knockdown of tumor GHR is likely to be the best therapeutic strategy for these types of tumors," Prof Waters said.

"In this study, ATL1103 was shown to potently reduce GHR expression in the liver by 99 percent at the low dose tested," Prof Waters said.

"I think if this level of GHR reduction could be achieved in the tumors of cancer patients, then ATL1103 becomes a very exciting new agent for cancer treatment," Prof Waters said.

Antisense director of drug discovery and patents Dr George Tachas said that ATL1103 consistently suppressed GHR and the key markers of GH activity in animal studies, while similarly demonstrating effects on GH activity markers in a phase I trial in normal volunteers.

The company said that ATL1103 was in a phase II trial in acromegalic patients.

Antisense was up 0.1 cents or 9.1 percent to 1.2 cents with 10.1 million shares traded.

FEDERAL GOVERNMENT

The Federal Government has appointed a board with several biotechnology representatives to establish the Manufacturing Precinct to begin operation in July 2013. A media release from the Minister for Climate Change, Industry and Innovation, Greg Combet said the Manufacturing Precinct was part of the Government's \$500 million 'Industry Innovation Precinct' initiative and the board met for the first time yesterday in Melbourne.

The former managing director and chair of Siemens' Australian and New Zealand Albert Goller will chair the Manufacturing Precinct board.

The Manufacturing Precinct board members board are:

the Commonwealth Scientific and Industrial Research Organisation's Manufacturing, Materials and Minerals group executive Dr Calum Drummond;

Universal Biosensors head of business development Dr Fred Davis;

genetically modified laboratory mouse manufacturer Ozgene's chief executive officer Dr Frank Koentgen;

Australian Nuclear Science and Technology Organisation chair Prof Paul Greenfield;

Boeing Research and Technology Australia general manager Mike Edwards;

Toyota Motor Corporation Australia corporate services executive director Mike Rausa;

Australian Manufacturing Workers' Union national secretary Paul Bastian;

B&R Enclosures general manager and director Christine Bridges Taylor, Codan's former chief executive officer Codan Michael Heard;

Silk Logistics Group managing director John Dixon; and

Morson Engineering general manager Rhett Morson.

Mr Combet said the industry-led Manufacturing Precinct board would help build a culture of innovation and collaboration across manufacturing in Australia.

"The board includes a strong mix of major manufacturers and [small to medium sized enterprises], along with representatives from unions, the research sector and the manufacturing value chain," Mr Combet said.

"We know that collaboration and innovation are vital to improving the productivity of our industries and these experienced business and research leaders will work with our manufacturing sector to improve knowledge and skills, deploy technology and develop growth-oriented businesses," Mr Combet said.

PRIMA BIOMED

Prima says its one-for-four options offer raised \$1,547,574 through applications for 77,378,699 options at two cents, exercisable at 20 cents each by June 19, 2017.

Prima said that the funds, along with the \$5 million raised in the recent share purchase plan were for three phase II trials of CVac in additional cancer indications and to continue the ongoing ovarian cancer clinical program, manufacturing optimization programs and general working capital (BD: May 15, 2013).

Prima said last month that it was attempting to place up to \$15 million in shortfall shares. Prima was up 0.2 cents or 3.1 percent to 6.7 cents with 2.1 million shares traded.