



Biotech Daily

Tuesday August 6, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PHARMAXIS UP 6%, BENITEC DOWN 11%**
- * **COCHLEAR REVENUE DOWN 3% TO \$753m, PROFIT UP 133% to \$133m**
- **CEO DR CHRIS ROBERTS: AUSTRALIAN REGULATION CONCERN**
- * **MEDICINES AUSTRALIA: MORE DRUGS EXPORTED THAN CARS, ALCOHOL**
- * **BENETIC LICENCES ddRNAi TO REGEN FOR CANCER VACCINES**
- * **TGA APPROVES ISONEA AIRSONEA WHEEZE MONITOR**
- * **MALAYSIA'S RC PRECISION TO MAKE BLUECHIIP EQUIPMENT**
- * **M&G GROUP BUYS 2m MORE GI DYNAMICS SHARES**
- * **ASIA UNION DECREASES, DILUTED to 10% IN TISSUE THERAPIES**

MARKET REPORT

The Australian stock market slipped 0.11 percent on Tuesday August 6, 2013 with the S&P ASX 200 down 5.7 points to 5,105.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and three were untraded.

Pharmaxis was the best, up one cent or 6.1 percent to 17.5 cents with 2.2 million shares traded.

Tissue Therapies climbed 5.9 percent; Phosphagenics was up 4.8 percent; Avita, Genetic Technologies and Prima were up more than three percent; GI Dynamics rose 2.2 percent; Cochlear, Osprey and Viralytics were up more than one percent; with Nanosonics and Starpharma up by less than one percent.

Benitec led the falls, down four cents or 11.4 percent to 31 cents with one million shares traded, followed by Alchemia down 10 percent to 31.5 cents with 615,050 shares traded.

Bionomics fell 4.2 percent; Allied Health and Anteo lost more than three percent; Circadian, Neuren and Patrys shed two percent or more; Living Cell, Mesoblast, Psivida and QRX were down more than one percent; with Acrux, CSL, Heartware, Resmed and Sirtex down by less than one percent.

COCHLEAR

Cochlear says revenue for the 12 months to June 30, 2013 was down three percent to \$752,721,000 with a net profit after tax up 133 percent to \$132,563,000.

In 2012, Cochlear chief executive officer Dr Chris Roberts said that with the recall of the Nucleus 500 series implant and the re-entry of competitor Advanced Bionics, the company lost about five percent of market share to 65 to 70 percent, leading to a fall in revenue for the 12 months to June 30, 2012 of four percent to \$778,996,000 with a net profit after tax down 68 percent to \$56,803,000. (BD: Sep 12, Dec 20, 2011; Aug 7, 2102).

In 2011, prior to the recall, Cochlear posted record revenue for the 12 months to June 30, 2011 of \$809.6 million with net profit after tax of \$180.1 million (BD: Aug 9, 2011).

Today, Dr Roberts told a teleconference that although the revenue and profit figures were lower than in August 2011, "a record number of recipients globally have our implants" with the Asia Pacific region a "stand-out" area for sales.

Dr Roberts said that Cochlear had about a 65 percent share of the market and had lost about five percentage points since the Nucleus 5 series product recall.

"We believe we are competitive," Dr Roberts said.

In a media release to the ASX, Cochlear said Asia Pacific sales were up 20 percent to \$147.6 million, Americas sales were down four percent to \$284.4 million, with Europe, Middle East and Africa sales down one percent to \$283.0 million.

Dr Roberts said that the company had focused on the Nucleus 6 system which had been granted Conformité Européenne (CE) mark approval and described the functions of the remote and control system as the most advanced (BD: Jun 3, 2013).

"The Nucleus 6 is a wonderful, wonderful product," Dr Roberts said.

Dr Roberts said that the investment in research and development on the Nucleus 6, and foreign exchange had impacted on revenue and the cost of goods to sales margin increased from 28.9 percent in 2011-'12 to 29.1 percent for the year to June 30, 2013. The media release said that the investment in research and development was up five percent to \$124.7 million or 16.0 percent of revenue.

Asked about the European approval of the Nucleus 6 system, Dr Roberts said the Australian regulatory system needed change.

"It's harder to get approval in Australia as an Australian manufacturer than if you're a foreign manufacturer, and it needs reform," Dr Roberts said.

"If we want to keep Australian manufacturing in Australia we need to something about country of origin approvals," Dr Roberts said.

"As an Australian manufacturer, it is easier to get our products approved in Europe than in Australia," Dr Roberts said.

Dr Roberts said there were some good people at the Australian Therapeutic Goods Administration who "know what is needed to be done but we need to change the legislation."

"We don't differentiate between major devices and minor tweaks to the design," Dr Roberts said.

Dr Roberts said that the TGA was not tax-payer funded but served both a public good and product approval role and other regions divided those roles.

Cochlear said the final 30 percent franked dividend would be up two percent to \$1.27 a share to be paid on September 19, based on a record date of August 29, 2013.

Cochlear said net tangible assets per share at June 30, 2013 was down 32 percent to 212.4 cents, diluted earnings per share was up 132.9 percent to 232.4 cents, compared to the previous year's 99.8 cents and it held \$53,689,000 in cash and cash equivalents at June 30, 2013, compared to \$68,486,000 at June 30, 2012.

Cochlear was up 85 cents or 1.4 percent to \$60.00 with 540,952 shares traded.

MEDICINES AUSTRALIA

Medicines Australia says that Australian Bureau of Statistics trade figures show that Australia earns more from exporting medicines than from either cars or alcohol.

Australian Bureau of Statistics data showed that all medicines including veterinary medicines earned \$3.9 billion the year to June 30, 2013, down from \$4.1 billion in the previous corresponding period, with all road vehicles increasing from \$2.8 billion to in 2011-'12 to \$2.9 billion for the year to June 30, 2013.

The 'International Trade in Goods and Services, Australia, Jun 2013' showed that Australia had improved its positive balance of trade by 19 percent to \$602 million for the year to June 30, 2013.

Medicines Australia chief executive Dr Brendan Shaw said that Australia "earns more money exporting medicines than that it does from exporting cars, wine or scientific instruments".

"Predictable policy changes are important for the industry's future," Dr Shaw said.

"That's why last Friday's sudden announcement in the Government's Economic Statement of changes to Pharmaceutical Benefits Scheme price disclosure policy without consultation was extremely disappointing," Dr Shaw said.

Dr Shaw said that medicine exports "held up well in the face of a high Australian dollar over the last five years" but had fallen from their peak of \$4.1 billion in 2009-'10.

A graph provided by Medicines Australia showed that road vehicle exports had fallen from more than \$4.5 billion in 2007-'08 to \$2.9 billion in 2012-'13, with alcohol also trending down over a nine year period, while medicines were on an upward trend from less than \$2.5 billion in 2003-'04 to the current \$3.9 billion..

"While there's been lots of debate about Australian industries and their future, we have a real opportunity to make the Australian medicines industry a key component of preparing the Australian economy for a post-mining boom future," Dr Shaw said.

"Australia already has competitive advantages in things like medical research, exports, clinical trials and specialist high-value manufacturing," Dr Shaw said.

"We have a real chance to build on this industry and make it one of Australia's leading industries of the future," Dr Shaw said.

"We can grow this industry even more from what it is today, provided we have predictable, stable policy settings that support the Australian industry," Dr Shaw said.

"That means predictable pricing policies for the Pharmaceutical Benefits Scheme and improving its processes for approving innovative medicines, as well as a re-commitment to the National Medicines Policy which recognizes the link between commercial viability and medicine supply," Dr Shaw said.

"It also means stable and strong intellectual property policies that support innovation and policies to grow the Australian medicines industry and its research," Dr Shaw said.

"A predictable policy framework that encourages the industry to supply medicines in a timely manner and build Australia's economic competitiveness is important to Australia's future," Dr Shaw said.

"Medicines Australia said that its election document had six commitments and called on all political parties to support the policies.

The document is at: <http://medicinesaustralia.com.au/issues-information/election-2013>.

BENITEC BIOPHARMA

Benitec says it has a licensing agreement with Regen Biopharma to develop cancer vaccines using its DNA-directed RNA-interference (ddRNAi) gene silencing technology. Benitec said that the San Diego, California- based Regen was a subsidiary of Bio-Matrix Scientific Group and the licence covered the application of its ddRNAi to silence indoleamine 2,3-dioxygenase (IDO) in dendritic cells.

The company said that IDO was associated with immune-suppression and was over-expressed in cancer.

Benitec said that Regen had produced pre-clinical evidence that modification of these cells, using ddRNAi targeting the silencing of IDO, should significantly enhance their efficacy as anti-cancer vaccine agents.

The company said a research article, entitled 'Silencing IDO in dendritic cells: a novel approach to enhance cancer immunotherapy in a murine breast cancer model' was published in the February 2013 volume of the International Journal of Cancer.

An abstract is available at: <http://www.ncbi.nlm.nih.gov/pubmed/22870862>.

Benitec said that the terms of the licence were commercial-in-confidence, but were within the expected guidelines for small biotechnology companies in the early stage of therapeutic development, with fees based on the achievement of agreed milestones.

Benitec chief executive officer Dr Peter French said that "using ddRNAi to manipulate dendritic cells to stimulate the immune system to kill cancer cells is an innovative concept for the treatment of cancer in a non-toxic manner".

"Regen joins a growing list of biotechnology companies that have recognized the advantage of licensing Benitec's transformational gene silencing technology, ddRNAi, to develop novel therapies for human disease," Dr French said.

"For Benitec this provides the opportunity to generate additional evidence that validates and reinforces the potential of our platform technology," Dr French said.

Regen executive chairman Dr David Koos said that Benitec was "the leader in clinical development of ddRNAi, which allows for gene-specific surgery".

"By combining our existing data with the issued patents and experience of Benitec, we look forward to developing an immune-based, non-toxic, cancer treatment initially targeting breast cancer," Dr Koos said.

Benitec fell four cents or 11.4 percent to 31 cents with one million shares traded.

ISONEA

Isona says the Australian Therapeutic Goods Administration has approved its Airsona wheeze detection and monitoring device.

Isona said that listing on the Australian Register of Therapeutic Goods was "a critical company milestone" as it prepared to launch the device, which would enable wheeze rate monitoring through smart-phones and a cloud-based analytical system.

Isona chief executive officer Michael Thomas said the TGA listing "provided further validation of the company's technology, as well as the acoustic respiratory monitoring platform underpinning all Isona products".

"Inclusion on the TGA register is an important step for our Company as we complete the final stages of commercial launch preparation," Mr Thomas said.

Isona was up 2.5 cents or 4.2 percent to 62.5 cents with 3.3 million shares traded.

BLUECHIIP

Bluechiip says it has a supply agreement with the Penang, Malaysia-based RC Precision Engineering Sdn Bhd to manufacture and assemble its cryogenic storage equipment. Bluechiip said that with RC it had developed the manufacturing processes for the cryotags, cassettes and racks which form the basic storage hardware for bio-banks and their customers.

The company said that its Cryotag was used in storage containers such as cassettes and racks, which were stored in ultra-low temperature freezers and tanks in bio-banks.

Bluechiip said that RC specialized in contract manufacturing, engineering design and assembly services and provided customized equipment design for semiconductors, circuit boards, disc drives, and for the automation and packaging industries.

Bluechiip was unchanged at 17.5 cents.

GI DYNAMICS

M&G Investment Funds says it has increased its substantial holding in GI Dynamics from 53,066,996 Chess depositary interests (14.77%) to 55,265,110 CDIs (15.38%).

The London-based M&G group said it acquired the 2,198,114 shares for \$1,541,757 or 70 cents a share on August 2, 2013.

Last month, GI Dynamics said it had raised \$57.5 million in a placement at 53 cents a share (BD: Jul 3, 2013).

GI Dynamics was up 1.5 cents or 2.2 percent to 70 cents.

TISSUE THERAPIES

Asia Union Investment has decreased its holding in Tissue Therapies from 22,985,000 shares (10.74%) to 20,746,115 shares (9.68%).

The Sydney-based Asia Union said it sold 2,238,885 shares for \$370,723 or an average price of 16.6 cents a share.

Tissue Therapies was up 1.5 cents or 5.9 percent to 27 cents.