



# Biotech Daily

Monday September 23, 2013

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: PRIMA UP 10%; ANTISENSE DOWN 18%**
- \* **WEHI: IRF4 TRANSCRIPTION FACTOR REGULATES IMMUNE T-CELLS**
- \* **ISONEA COMPLETES RENAISSANCE, AIRSONEA LAUNCH**
- \* **ALLIED 1-FOR-5 RIGHTS ISSUE FOR \$10m**
- \* **QBIOTICS RAISES \$6m**
- \* **BAILLIE GIFFORD INCREASE TO 12.4% OF COCHLEAR**
- \* **WEBINVEST TAKES 6% OF ONCOSIL**
- \* **TYRIAN, BAYER DIAGNOSTIQ LICENCE TO END**

## MARKET REPORT

The Australian stock market fell 0.46 percent on Monday September 23, 2013 with the S&P ASX 200 down 24.2 points to 5,252.5 points.

Eight of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and four were untraded.

Prima was the best, recovering 0.4 cents or 9.5 percent to 4.6 cents with 18.5 million shares traded, following last week's 50.6 percent fall (BD: Sep 19, 2013).

Alchemia and Pharmaxis climbed four percent or more; Anteo was up 3.3 percent; IDT, Psivida and Starpharma rose two percent or more; Sirtex was up 1.4 percent; with CSL up 0.65 percent.

Antisense led the falls, down 0.3 cents or 17.65 percent to 1.4 cents with 18.7 million shares traded, followed by Allied Health down 14.1 percent to 7.3 cents with 65 million shares traded and Living Cell down 12.9 percent to 8.1 cents with 5.8 million shares traded.

Circadian lost 7.1 percent; Cellmid and Ellex fell more than six percent; Reva was down 5.8 percent; Acrux and Benitec fell more than four percent; Impedimed, Nanosonics, Patrys and QRX shed more than two percent; GI Dynamics, Mesoblast, Phosphagenics, Tissue Therapies and Universal Biosensors fell more than one percent; with Cochlear and Resmed down by less than one percent.

## THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers have shown that the transcription factor IRF4 is a regulator of activated T cells and is essential for clonal expansion.

In a research paper entitled 'The transcription factor IRF4 is essential for T cell receptor affinity mediated metabolic programming and clonal expansion of T cells' published in Nature immunology, the Institute's Dr Axel Kallies, Kevin Man and colleagues demonstrated that interferon regulatory factor 4 (IRF4) was "induced in a T-cell receptor affinity-dependent manner and functions as a dose-dependent regulator of the metabolic function of activated T cells".

An abstract is at: <http://www.nature.com/ni/journal/vaop/ncurrent/full/ni.2710.html>.

"IRF4 regulates the expression of key molecules required for aerobic glycolysis of effector T cells and is essential for clonal expansion and maintenance of effector function of antigen-specific CD8+ T-cells," a summary of the research said.

WEHI said that the discovery could help develop treatments for blood diseases such as leukaemia, as well as autoimmune diseases, including diabetes or rheumatoid arthritis, and could be used to enhance immune response to HIV and other chronic infections.

The Institute said that the finding built on the 55-year-old theory of 'clonal selection' proposed by former WEHI director Prof Frank Macfarlane Burnet, which "revolutionized scientists' understanding of the immune system and how it functioned".

"Burnet's theory of clonal selection proposed a new model of how the immune system recognized and fought foreign invaders, stating that each immune cell was programmed to recognize a specific infectious agent," WEHI said. "Only when the right cell came into contact with an invader would it be activated and stimulated to clone itself, generating large numbers of identical cells to fight the infection."

WEHI said that Dr Kallies and his team showed how the body identified which killer-T cells were the most capable of fighting a particular infection.

"We found that a protein called IRF4 is activated in killer T-cell clones that are best equipped to recognize and fight an infection," Dr Kallies said.

"Burnet's clonal selection theory tells us that the best T-cell clones are selected by the immune system and produced in large numbers but, until now, we didn't know how this was regulated and what happened at the molecular level," Dr Kallies said.

"We discovered that IRF4 controls the mass production of 'elite' killer T-cells, as well as ensuring their survival and enhancing their performance by allowing them to take up large amounts of sugar and other nutrients," Dr Kallies said.

WEHI said that the research team found that IRF4 was produced at different levels depending on how well the killer T-cell recognized and bound infected cells.

"IRF4 was produced at the highest levels in cells that were the best at recognizing the foreign invader," Dr Kallies said. "This is how the immune system guarantees that the best killer T-cells survive, producing an 'army of clones' that maintain their killer function to fight the infection."

"Without sufficient IRF4, the immune system fails to mount a productive immune response," Dr Kallies said.

Dr Kallies said that IRF4 was being investigated by pharmaceutical companies as a potential therapeutic target.

"Targeting the IRF4 pathway could help us to control immune cells," Dr Kallies said. "For example, blocking the pathway to diminish proliferation of immune cells when they are out of control, as happens in blood cancers such as leukaemia or in autoimmunity."

"We could also enhance the activation of IRF4 to rescue T-cell clones that are not functional, as a way of boosting the immune response to overwhelming infections such as HIV," Dr Kallies said.

## ISONEA

Isona chief executive officer Michael Thomas is in Australia for this week's launch of the Airsona asthma monitor sensor by a company that has been effectively rebuilt.

Mr Thomas told Biotech Daily that Isona was "the only asthma monitor company in the world with an extremely easy-to-use sensor which can be used anywhere, anytime".

Mr Thomas said that the hand-held plastic tube Airsona with its push-up sensor was applied to the throat for 30 seconds to read breath sounds and transmitted the data through a smart-phone or tablet computer to a "cloud-based" algorithm which then analyzed the sounds.

Mr Thomas said the Airsona was approved for already-diagnosed asthmatics to monitor their asthma.

He said the initial target market would be the parents of children with asthma and the monitor could help them understand their child's acute asthma as well as build a long-term profile of when the child had asthma symptoms.

Mr Thomas said that the markets to be built by Isona started with electronic commerce and social media, followed by doctor adoption, pharmacy chains and finally business to business such as the government sector and school nurses.

Mr Thomas said the Airsona had Australian Therapeutic Goods Administration and Conformité Européenne (CE) mark approval and he hoped to have US Food and Drug Administration 510k pre-market authorization by the end of 2013.

Mr Thomas said that the Airsona sensor would be sold in Australia for \$169.95 which included a 12-month subscription to Asthmasense Prime which would provide the data to the user, including environmental information such as pollen counts.

He said that the Airsona data could be used to discover when and under what conditions people had the greatest incidence of asthma.

Mr Thomas said that the initial sales market was "geared to mothers with asthmatic children" to assist in the diagnosis on asthma, but would also detect the longer-term trends through daily monitoring and could be used to analyze the triggers for asthma.

Mr Thomas said that the Airsona and Asthmasense systems were the first in a pipeline of respiratory diagnostics.

"We are looking for a suite of products and diagnostics for a range of respiratory indications including cystic fibrosis, chronic obstructive pulmonary disease and obstructive sleep apnoea," Mr Thomas said.

Mr Thomas said that since he arrived at the company two years ago there had been a complete change of board and management from the original Karmelsonix that brought the Haifa, Israel-developed technology to Australia.

In its preliminary final report, Isona said it lost \$5,583,649 in the year to June 30, 2013 on revenue of \$75,562, of which \$64,703 was interest, with \$10,859 from sale of product, of which \$8,614 came from Israel and \$2,245 from the US.

Isona said that 3.5 percent of the sales value of products, including Asthmasense and the legacy diagnostics the Wheezeometer, Pulmotrack and Wholter, was paid as a royalty to Israel's Office of Chief Scientist for the original loan of NIS1,844,100 (Israel shekels) (\$A557,828) to develop the technology.

Isona had cash and cash equivalents of \$1,346,736 at June 30, 2013, but announced that it had raised \$13.5 million at 35 cents a share in July (BD: Jul 8, 2013).

Investment Holdings, an entity owned by gambling machine operator Bruce Mathieson increased its holding in Isona to 48,000,000 shares or 18.59 percent.

The company's market capitalization increased from \$7 million on August 31 2012 to \$169 million on August 31, 2013 (BD: Sep 2, 2013).

Isona was up four cents or 5.1 percent to 83 cents with 1.9 million shares traded.

## ALLIED HEALTHCARE GROUP

Allied Health says it has a fully underwritten non-renounceable one-for-five rights issue at five cents a share to raise about \$10 million.

Allied said the funds would be used to launch Cardiocel in Europe, scale up manufacturing and progress of US approval for Cardiocel as well as advance the Coridon therapeutic vaccine programs led by Prof Ian Frazer.

Allied chief operating officer Dr Julian Chick told Biotech Daily that \$3 million was earmarked to increase Allied's holding from 52 percent to about 60 percent of Coridon.

Allied said the funds would provide sufficient capital for the coming 12 months to complete initial sales of Cardiocel in Europe, results for the phase I herpes simplex virus clinical trial and prepare Prof Frazer's next human papillomavirus vaccine as a therapeutic treatment against cervical cancer

The company said that RBS Morgans had fully-underwritten the rights issue and an entity associated with the company's major shareholder, the Metal Group Pty Ltd, had sub-underwritten 50 percent of the rights issue.

The Metal Group is a company associated with Western Australian mining magnate Andrew Forrest.

Allied said that the record date would be October 1, the offer would open on October 3 and close on October 18, 2013.

Allied fell 1.2 cents or 14.1 percent to 7.3 cents with 65 million shares traded.

## QBIOTICS

QBiotics says it has raised \$6.35 million, providing it more than \$10 million for its two oncology drugs and wound healing treatment for human and veterinary pharmaceuticals. In June, the Yungaburra, Queensland-based QBiotics said it had commitments for \$8 million of \$10 million it hoped to raise at that time (BD: Jun 11, 2013)

The company said the offer was managed by its corporate finance manager Reuben Buchanan.

Mr Buchanan said that about 270 people invested amounts ranging from \$10,000 to \$500,000.

QBiotics chief executive officer Dr Victoria Gordon said the funds would support QBiotics "to reach some key milestones which could deliver significant value to our shareholders".

"We aim to complete our clinical phase I/II [trial] in humans for our lead oncology drug EBC-46, as well as develop the drug as a veterinary product to registration," Dr Gordon said.

QBiotics said in June that EBC-46 came from the North Queensland's rainforest blushwood and "demonstrated remarkable anti-tumor properties in clinical treatment of cancer in companion animals".

Today, the company said it expected to begin human trials of EBC-46 for head and neck cancer within six months, research and development work was underway with WH-1 for chronic wounds and the second oncology drug EBC-23 would move into early preclinical studies "in the near future".

Dr Gordon said that the company was considering a public listing in the future, "but for the time being, the focus is on achieving major milestones such as first-in-human trials and veterinary registration of EBC-46".

QBiotics is a public unlisted company.

### COCHLEAR

The Edinburgh-based Baillie Gifford & Co and associates have increased their substantial holding in Cochlear from 6,478,080 shares (11.36%) to 7,058,945 shares (12.38%). Baillie Gifford said it primarily sold shares in more than 60 small parcels between June 5 and 26, 2013 with the single largest sale 29,408 shares for GBP1,056,932 or GBP35.94 (\$A61.09) a share.

The company said it returned to buying Cochlear shares on June 27, with the single largest purchase 68,618 shares for GBP2,607,580 or GBP38.00 (\$A64.59) a share. In June Baillie Gifford and associates reduced their holding in Cochlear from 7,240,484 shares (12.69%) to 6,478,080 shares (11.36%), with the single largest sale 149,900 shares for GBP5,250,399 or GBP35.03 (\$A57.02) a share (BD: Jun 6, 2013). Cochlear fell 14 cents or 0.2 percent to \$59.25 with 250,614 shares traded.

### ONCOSIL

The Trinity Beach Queensland-based Webinvest says it has increased its holding in Oncosil from 12,432,673 shares (5.14%) to 19,133,067 shares (6.33%).

Although the difference in the number of shares cited was 6,700,394 shares, in his substantial shareholder notice, Webinvest director Otto Buttula said 6,785,156 shares were acquired on market on August 16, and September 6, and in a placement on September 20, 2013 for \$921,410 or 13.6 cents a share.

Oncosil fell half a cent or 3.45 percent to 14 cents with 2.8 million shares traded.

### TYRIAN DIAGNOSTICS

Tyrian says its non-exclusive licence with Bayer Cropscience AG for its Diagnostiq test for grain will be terminated on September 1, 2014 as per the agreement.

Tyrian said agreement began in 2012 and allowed Bayer to exploit an application on the Diagnostiq platform to generate an a-amylase analyte signal from grain samples.

The company said that, to date, no licence fees had been generated from the agreement and the termination would have no impact on its forecast cash flow or revenues.

In October 2012, Agenix licenced Tyrian's rapid point-of-care human Diagnostiq technology for \$500,000 in shares to be paid over two years (BD: Oct 25, 2012).

Tyrian was unchanged at 0.1 cents with 1.1 million shares traded.