



Biotech Daily

Friday August 3, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ALLIED HEALTH UP 24%, BIONOMICS DOWN 7%**
- * **CSL CEO DR BRIAN MCNAMEE TO RETIRE IN 2013 FOR PAUL PERREAULT**
- * **SIRTEX PLANS TO 'TRIPLE US MANUFACTURING CAPACITY'**
- * **HEALTHLINX SELLS OVPLEX FOR \$250k, US MANE INC SHARES**
- * **HEARTWARE CLOSES WORLD HEART ACQUISITION**
- * **RESMED RECORD QUARTER, YEAR REVENUE, PROFIT**
- * **PSIVIDA TO RAISE \$5m**
- * **WEHI LEADS \$2.5M FAST-TRACK BREAST CANCER CENTER**
- * **IMPEDIMED CEO RICHARD CARREON SACKS 31% OF STAFF**

MARKET REPORT

The Australian stock market fell 1.12 percent on Friday August 3, 2012 with the S&P ASX 200 down 48.0 points to 4,221.5 points.

Eight of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and 10 were untraded.

Allied Health was the best, up 0.4 cents or 23.5 percent to 2.1 cents with 400,000 shares traded, followed by Resmed up 9.3 percent to \$3.30 with 17.6 million shares traded,

Impedimed climbed 8.1 percent; Universal Biosensors was up 3.45 percent; QRX, Sirtex and Tissue Therapies rose more than two percent; with Acrux, Cochlear and Starpharma up by less than one percent.

Bionomics led the falls, down two cents or 6.9 percent to 27 cents with 225,520 shares traded, followed by Phosphagenics and Phylogica, both down 6.7 percent to 14 cents and 2.8 cents, respectively, with 439,105 and 1.4 million shares traded, respectively.

Benitec and Viralytics lost more than five percent; Avita fell three percent; CSL, Mesoblast, Pharmaxis and Sunshine Heart shed more than two percent; with Anteo and Psivida down more than one percent.

CSL

CSL says that chief executive officer and managing director Dr Brian McNamee will be succeeded by CSL Behring president Paul Perreault, in July 2013.

CSL said that Dr McNamee was appointed chief executive officer in 1990, at the age of 33 years.

Dr McNamee graduated with Bachelor of Medicine and Bachelor of Surgery degrees from the University of Melbourne, prior to working with Fauldings and becoming the founding chief executive officer of Pacific Biotechnology.

In a media release, chairman Prof Shine said that long term succession planning for Dr McNamee had been underway for some time "in-line with our market announcement in December 2009 that Brian would continue as CEO for three to four years".

Prof Shine said that Dr McNamee would lead the organization until June 2013 and "run the business as normal giving us the continued benefit of his leadership right up to the hand over mid next year".

Prof Shine said that both the board and Dr McNamee "felt the time was right to pass the baton to the next leadership ... and he wanted to acknowledge Brian's extraordinary contribution both to CSL and the local and international pharmaceutical industry".

"Brian's achievement is the CSL you see today," Prof Shine said. "He and his talented team, many of whom remain part of the leadership, built it more or less from scratch."

"When Brian took over in 1990, CSL was a domestic-focused government enterprise," Prof Shine said. "Now, we are a proud Australian company; one of the world's largest global plasma therapeutics businesses."

CSL said it sold \$33 million of plasma therapies in 1991 and \$3.8 billion in 2011.

Dr McNamee said his experience with CSL starting as chief executive officer at 33 years of age had been a remarkable opportunity.

"Together we've built an exceptional business based on innovative [research and development], operational excellence, consistent delivery and absolute commitment to patients," Dr McNamee said.

"I am tremendously proud of the role CSL has played in providing life-saving medicines and our contribution to the development of new and better treatments," Dr McNamee said.

"CSL is in great shape, has its strongest ever [research and development] pipeline and is well placed to continue a story of growth and success," Dr McNamee.

Prof John Shine said that Mr Perreault had been "a highly effective global leader in his current role carrying responsibility for the CSL Group's international manufacturing and commercial operations across 26 countries which comprise over 85 percent of CSL Group revenues".

CSL said that Mr Perreault joined the company in 2004 as part of the Aventis Behring acquisition and previously was CSL Behring executive vice-president of commercial operations responsible for sales, marketing and commercial and business development. CSL said that Mr Perreault previously held key positions at Aventis Bio-Services, Aventis Behring and Wyeth-Ayerst Laboratories.

CSL said Mr Perreault held a Bachelor's degree in psychology from Orlando's University of Central Florida, had business management training at the Kellogg and Wharton schools of business and was chairman of the Plasma Protein Therapeutics Association.

The CSL media release came at the same time that the Australian Therapeutic Goods Administration made its database of adverse events publicly available, with one media report focusing solely on the adverse events relating to CSL's Fluvax.

The TGA has disputed the media report's confounding of correlation with causality.

The database is at: <http://www.tga.gov.au/daen/daen-entry.aspx>.

CSL fell \$1.07 or 2.6 percent to \$40.28 with 2.96 million shares traded.

SIRTEX MEDICAL

Sirtex says it plans to triple its manufacturing capacity of SIR-Spheres microspheres for liver cancer at its Willmington, Massachusetts facility.

Sirtex said that two new hot-cells, which process the radioactive yttrium-90 into SIR-spheres, along with ancillary equipment, would be installed and commissioned over the next 18 months, costing about \$4 million.

Sirtex chief executive officer Gilman Wong said the company had "a strategy for the business looking ahead at least eight years, termed our 2020 Vision [driving] our planning and investment decisions".

"SIR-Spheres microspheres dose sales grew by an unprecedented number during the financial year ended June 2012 and in our opinion growth of similar magnitude will continue, barring any extraordinary events," Mr Wong said.

"The expansion in dose manufacturing capacity is part of our 2020 Vision which sees a step change in growth following the publication of the results of some of our clinical studies," Mr Wong said.

"The first of these is the Sirflox clinical study set to complete recruitment early 2013 with the publication of the results expected at the end of calendar 2014," Mr Wong said.

"We believe that a positive result will drive a significant increase in demand for our therapy," Mr Wong said.

Sirtex was up 17 cents or 2.6 percent to \$6.63.

HEALTHLINX

Healthlinx says it has a conditional agreement to sell its Ovplex ovarian cancer diagnostic to the San Diego, California-based Mane Cancer Diagnostics Inc.

Healthlinx said that Mane was a privately-held diagnostics company with a focus on unmet oncology indications scheduled to list on the Nasdaq by the end of 2012.

The company said that Mane would acquire the majority of its intellectual property and commercial and distribution agreements including Ovplex in exchange for cash and scrip. Healthlinx said its immunoglobulin Y (IgY) assets were excluded from the transaction, but Mane had first option on the Immunoglobulin Y assets.

Healthlinx said it would receive Mane common stock representing 30 percent of the company and a cash payment of \$US250,000.

Healthlinx said Mane valued its assets at \$6.25 million and the agreement was conditional on Mane listing on Nasdaq by December 25, 2012, completing a \$US5.5 million capital raise, as well as due diligence, shareholder approval and other customary conditions.

Healthlinx said it would have one director in the Mane board and Mane would focus on completing studies and approvals to enable the sale of Ovplex in the US.

Healthlinx chairman Prof Greg Rice said the sale was "an exciting opportunity for Healthlinx" enabling the assets to be commercialized in the US States.

Healthlinx share price has fallen over the past seven years and its Ovplex diagnostic has been the subject of commentary by University College London's Gynaecological Cancer Research Centre and the Australian Department of Health and Ageing.

Despite repeated requests from Biotech Daily the company has not published sensitivity and specificity data, preferring to describe the test as 'more accurate' than CA125, which is one of the tests within the Ovplex panel.

Last year Healthlinx signed a funding agreement with La Jolla Cove Investors for up to \$US9 million (\$A8.8 million) over four years through the issue of up to three convertible notes with a face value of \$US3 million each (BD: Dec 8, 2011; Feb 13, 2012).

Healthlinx was up 0.2 cent or 100 percent to 0.4 cents with 31.8 million shares traded.

HEARTWARE

Heartware says it has completed the acquisition of World Heart Corp for about \$8 million, following approval by World Heart stockholders.

Earlier this year Heartware said it would acquire Worldheart for \$US8 million to be paid in shares of common stock or cash, at Heartware's election (BD: Mar 30, 2012).

Heartware chief executive officer Doug Godshall said at that time that the Salt Lake City, Utah-based Worldheart "has been an important participant in the development of ventricular assist therapies for many years and has amassed over 100 patents and patent applications".

Today, Heartware said it acquired all of the outstanding voting securities of World Heart for about \$US8,000,000 in Heartware common stock and each share of World Heart common stock had been converted into the right to receive 0.003 shares of Heartware common stock.

Mr Godshall said that "consistent with our goal to be a leader in the [ventricular assist device] market for years to come, we believe that bolstering our patent portfolio and adding World Heart's technologies broadens our options for the future".

Heartware said its stockholder approval was not required.

The company said that following the transaction and the issue of about 83,000 new Heartware shares to World Heart stockholders, it would have about 14,275,000 shares outstanding.

Heartware was untraded at \$2.43.

RESMED

Resmed has posted its 70th quarter of record revenue as well as a renewed record profit for the three months and 12 months to June 30, 2012.

Resmed said that revenue for the three months was \$US371.9 million up nine percent compared to the same period in 2011, with net profit after tax up 31 percent to \$US76.8 million.

Resmed said that for the year to June 30, 2012, revenue was up 10 percent to \$US1.37 billion, with net profit after tax up 12 percent to \$US254.9 million.

Resmed said diluted earnings per share for the year was US\$1.71, a 19 percent increase compared to the 12 months to June 30, 2011.

The company declared a 17 US cents per share quarterly dividend for shareholders at the record date of September 7, 2012.

Resmed was up 28 cents or 9.3 percent to \$3.30 with 17.6 million shares traded.

PSIVIDA

Psivida says it has an agreement with institutional investors to raise about \$US5.36 million in a direct offer of 2,494,419 shares of common stock and warrants for 623,605 shares.

Psivida said the stock and warrants (options) would be sold in units, with each unit consisting of one share and a warrant to buy 0.25 shares for \$US2.15 a unit.

The company said that each warrant would be exercisable at \$US2.50 within six months of issue.

Psivida said the proceeds would be used for general corporate purposes, including clinical trials for posterior uveitis and other business operations.

The company said that Rodman & Renshaw acted as sole placement agent.

Psivida fell three cents or 1.3 percent to \$2.22.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute for Medical Research says its Prof Geoff Lindeman will lead the Australian Centre for Translational Breast Cancer Research.

WEHI said the collaborative centre would fast-track promising new discoveries in breast cancer to the clinic with a \$2.5 million grant from the National Health and Medical Research Council of Australia announced by Federal Minister for Health Tanya Plibersek. WEHI said the Australian Centre for Translational Breast Cancer Research had been funded for five years through the NHMRC Centres of Research Excellence program and would carry out early-phase clinical trials of novel anti-breast cancer drugs and use personalized medicine to identify and select the best therapy for breast cancer patients based on their individual cancer type.

Prof Lindeman said he was delighted that the Federal Government had invested in translating breast cancer research from the bench to the bedside, to help the more than 13,700 Australians diagnosed with breast cancer each year and 2,800 women who die from the disease.

“Our goal is to help create a swift delivery system for cost-effective, personalized medicine for Australian breast cancer patients,” Prof Lindeman said.

“In Australia, one in nine women will develop breast cancer by the age of 85, but the types of breast cancer that they will develop varies greatly,” Prof Lindeman said.

“We need to continue to find new treatments and methods of identifying the best treatment for each individual patient, based on their particular cancer type, and this new collaboration will go a long way to helping us realise that,” Prof Lindeman said.

WEHI said the Australian Centre for Translational Breast Cancer Research would focus on three themes: undertaking early clinical trials to accelerate the evaluation of promising new breast cancer treatments; collecting clinical trial samples to help identify new cancer cell markers that would help predict a patient’s prognosis and alter their treatment; and economic modeling to inform the cost-effectiveness of breast cancer therapies in Australia.

“Our aim is to help bridge the current gap between world-class Australian research discoveries and their timely clinical application for breast cancer patients,” Prof Lindeman said.

“[The Australian Centre for Translational Breast Cancer Research] will benefit laboratory research and clinical care, as well as assist in training and mentoring the next generation of clinicians and clinical researchers to help Australia maintain its international reputation in breast cancer research,” Prof Lindeman said.

The Australian Centre for Translational Breast Cancer Research is a collaboration between the Walter and Eliza Hall Institute, Peter MacCallum Cancer Centre, the Royal Melbourne Hospital, Royal Women’s Hospital and the University of Melbourne.

In Sydney the Centre included the Kinghorn Cancer Centre at the Garvan Institute, Lifehouse at Royal Prince Alfred and Sydney Cancer Centre, the NHMRC Clinical Trials Centre and Sydney Catalyst.

WEHI said the Centre would exploit research from the newly established Victorian Comprehensive Cancer Centre, the Kinghorn Cancer Centre and Garvan Institute, in collaboration with Cancer Trials Australia and the ANZ Breast Cancer Trials Group.

WEHI said that funding for the Centre would begin this year.

IMPEDIMED

In an announcement entitled 'Strategic Realignment' Impedimed says will sack 31 percent of its staff "to focus on favorable reimbursement, accelerated adoption of our technology and disciplined execution".

Impedimed said that the company was reducing staff from 42 to 29 employees and delaying expansion into Germany and Japan.

The company said the actions would "better position Impedimed to create value for our shareholders and improve the quality of life for our patients".

Impedimed chief executive officer Richard Carreon said the company "deeply regret having to reduce our workforce".

"We thank those impacted for their significant contributions to [Impedimed]," Mr Carreon said.

"This realignment dramatically streamlines our non-core business activities to improve the company's cost structure and focus on the core lymphoedema business," Mr Carreon said.

Impedimed was up 1.5 cents or 8.1 percent to 20 cents.