

# **Biotech Daily**

# Tuesday April 21, 2009

Daily news on ASX-listed biotechnology companies

- \* ASX DOWN, BIOTECH EVEN; CATHRX UP 17%, VIRALYTICS DOWN 10%
- \* HADASSAH TAKES 19.9% OF IMMURON FOR ANTIBODY COLLABORATION
- \* IMMURON ORAL ANTIBODY 'GENERALLY RECOGNIZED AS SAFE'
- \* NEUREN TRADING HALT ON 1320% PRICE JUMP
- \* SUNSHINE HEART IMPLANTS FIRST TWO US AORTA CUFFS
- \* DR PAUL MACLEMAN QUITS HATCHTECH FOR GENETIC TECHNOLOGIES
- \* PROGEN DIRECTOR STEPHEN CHANG TO SELL 'SUBSTANTIAL' SHARES
- \* CHEMGENEX 1-FOR-14 RIGHTS ISSUE TO RAISE UP \$7.4m
- \* USCOM MONITOR 'RELIABLE' FOR PREGNANCY
- \* NORWOOD TO EARN \$952k FROM UK ASSET SALE

# MARKET REPORT

The Australian stock market retreated 2.43 percent on Tuesday April 21, 2009 with the S&P ASX 200 down 91.6 points to 3,677.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, four traded unchanged and five were untraded.

Cathrx was best, up 10 cents or 17.2 percent to 68 cents with 1,475 shares traded followed by Sirtex up 10.4 percent to \$2.65 and Biota up nine percent to 78.5 cents.

Optiscan and Polartechnics climbed more than eight percent; Alchemia and Antisense were up more than six percent; Clinuvel, Novogen and Phosphagenics rose more than five percent; Impedimed put on four percent; Living Cell was up 3.7 percent; Heartware, Pharmaxis and Tissue Therapies rose more than two percent; with Resmed up 1.7 percent. Outside the Top 40, Prima rose 88.2 percent to 6.4 cents with 159.3 million shares traded or 72 percent of its share register turned over in one day.

Viralytics led the falls, down 0.4 cents or 10.3 percent to 3.5 cents with 344,208 shares traded, followed by Starpharma down 9.1 percent. Nanosonics and Tyrian lost eight percent or more; Universal Biosensors fell 7.9 percent; Bionomics and Phylogica were down 6.7 percent; Cellestis lost 5.3 percent; Genera fell 3.2 percent; Acrux, Chemgenex, Genetic Technologies, Peplin and Prana shed more than two percent; with Circadian and Mesoblast down more than one percent.

#### **IMMURON**

Immuron says Israel's Hadassah Medical Center will acquire 19.99 percent of the company and collaborate on an antibody-based oral immune modulation collaboration. Immuron said it would acquire a novel oral immune modulation technology from Hadassah Medical Center's commercialization arm, Hadasit.

The company said the combination of oral immune modulation with Immuron's existing oral protein and antibody technology "could yield a convenient, all-natural, side-effect-free approach to diseases with multi-billion dollars markets, including metabolic syndrome, hepatitis C and type 2 diabetes.

Immuron said Hadassah scientists had shown their oral immune modulation approach, used in combination with Immuron's dairy-derived polyclonal antibodies and other proteins, could directly affect the activity level of regulatory T-cells, which have profound effects in controlling the inflammation in many diseases.

The company said the novel approach had shown positive effects in several validated animal models of human disease, including type 2 diabetes and metabolic syndrome. Immuron said it would focus its initial clinical development effort on metabolic syndrome, chronic hepatitis C and liver cancer, with clinical trials expected to begin for metabolic syndrome and hepatitis C shortly after the acquisition, which requires shareholder approval at a proposed extraordinary general meeting in May 2009.

In addition to the intellectual property, Hadasit will provide discounted clinical and laboratory services, providing Immuron with efficiencies in its cost structure for human clinical trials.

Immuron commissioned Biocomm Squared to assess the scientific and economic foundation of Hadasit's intellectual property.

The full report is available at: <u>http://www.immuron.com</u>

Immuron said the products were intended to be marketed as a medical food in the US and under similar classifications in other countries and the company expected it could introduce commercial products for some indications shortly after the trials, within two to three years.

Immuron said the new platform technology would provide an additional layer of patent protection to strengthen the existing Immuron pipeline products which target traveller's diarrhoea, HIV/AIDS immune depletion, mucositis and influenza.

Immuron said metabolic syndrome was defined as a combination of abdominal obesity, hyper-lipidemia and insulin resistance and up to 25 percent of the Western population have manifestations of this disorder including 45 million Americans.

Non-alcoholic steatohepatitis is one stage on the spectrum of non-alcoholic fatty liver disease with 8.6 million obese adult Americans potentially affected and 30.1 million Americans may have the milder steatosis. No effective medical therapy is currently available for patients with non-alcoholic fatty liver disease.

Hepatitis C affects up to three percent of the world's population with up to four million patients in the US having chronic hepatitis C.

Immuron said Hadassah's Prof Yaron Ilan will be the company's chief medical officer and continue to serve as a Department of Medicine director and deputy dean of the Hebrew University-Hadassah Faculty of Medicine.

Immuron chief executive officer Dr Zeil Rosenberg said the transaction was "a turning point for Immuron in its quest to lay a firm scientific foundation for its own technology to address large unmet medical needs".

Immuron fell 0.6 cents or 10.9 percent to 4.9 cents.

#### **IMMURON**

Separately Immuron said its hyper-immune oral antibody formulation derived from cow's immune milk has been "self-affirmed with 'Generally Recognized as Safe' or GRAS status. Immuron said an independent expert panel of recognized physician experts supported the GRAS status, a format defined by the US Food and Drug Administration.

The company said that as a result of the expert panel determination, Immuron's bovine colostrum powder nutritional platform was "safe for use as an ingredient in food products, paving its way to be marketed for use in already established nutritionals and functional foods, or as a medical food, based upon scientific data, especially from clinical efficacy studies already underway".

Immuron said that according to the FDA, self-affirmed GRAS status was awarded to any substance that is generally recognized among qualified experts as having been adequately shown to be safe under conditions of its intended use.

The company said the expert panel was composed of experts in pediatric immunology, infectious disease, nutrition and clinical trials who assessed published safety data from a large number of clinical and toxicology studies in reaching their conclusion.

Immuron chief executive officer Dr Zeil Rosenberg said that with GRAS safety affirmation and multiple ongoing clinical studies being developed in the US, Israel and Australia, "we have initiated partnership discussions with major consumer nutrition focused companies interested in HIV/AIDS, influenza and metabolic syndrome".

# <u>NEUREN</u>

Neuren has requested a trading halt "regarding the outcome of one of the negotiations" in its April 17, 2009 response to an ASX price query.

Trading will resume on April 23, 2009 or on an earlier announcement.

Neuren's chief financial officer Rob Turnbull told Biotech Daily that the request followed continued high volume trading in Neuren shares.

Yesterday, Neuren closed up 48.1 percent to four cents with 33.2 million shares traded. Today, Neuren's trading halt was in place after the share price jumped 3.1 cents or 77.5 percent to 7.1 cents with 21.9 million shares traded.

Most individual trades were for fewer than 100,000 shares with the single largest trade one for 374,388 shares.

Mr Turnbull said that despite a 30 percent turnover of the share register in four trading days, none of the trades had led to anyone becoming a substantial shareholder with many individuals entering and departing the share register.

Last Thursday (BD: Apr 16, 2009) Neuren requested a trading halt following an ASX query on its 420 percent share price jump from 0.5 cents to 2.6 cents.

Neuren's share price climbed from 0.9 cents on April 15 as much as 188.9 percent to 2.6 cents during trading on April 16, prior to the halt being called. A total of 6,675,429 shares had been traded when the halt was called, with a total value of \$110,613.

Neuren closed at 0.5 cents on April 7, rising to 0.6 cents on April 8 and April 9, 0.7 cents on April 14 and 0.9 cents or April 15, with 1,765,165 shares traded. The first purchase today was at 1.5 cents a share.

Neuren traded between 13 cents and six cents for most of 2008 tumbling to half a cent on its Christmas Eve announcement that its phase III trial had shown Glypromate to be equal to placebo in its phase III trial for neuro-protection in cardiac surgery (BD: Jan 2, 2009).

The company has a pipeline of compounds and is preparing for a phase II trial of NNZ2566 for traumatic brain injury with the Walter Reed US Army Hospital.

Neuren was up 3.1 cents or 77.5 percent to 7.1 cents with 21.9 million shares traded.

#### SUNSHINE HEART

Sunshine Heart says that the first two C-pulse aorta cuffs were implanted in patients at the University Medical Center in Columbus, Ohio, last week.

The implants were the first in a 20-patient clinical trial approved by the US Food and Drug Administration and expected to be completed by the end of 2009.

Sunshine Heart said the C-Pulse systems were implanted by the chief of cardiothoracic surgery and director of cardiac transplantation and mechanical support Dr Benjamin Sun. Dr Sun said C-Pulse was "highly innovative and implanted with a simple, low-risk

minimally invasive surgical procedure" and had the potential to offer a new therapy option for the treatment of moderate heart failure.

Sunshine Heart medical director and the inventor of C-Pulse aorta cuff Dr William Peters said the company had demonstrated in prior clinical studies that the system increased blood flow to the body and to the heart muscle itself.

Sunshine Heart chief executive officer Don Rohrbaugh said completion of the initial C-Pulse implants in the US was "a major milestone for ... the only non-blood contacting heart assist device in clinical trials".

"C-Pulse is designed for Class III heart failure patients and these are defined as suffering continuing debilitating symptoms despite maximum drug therapy," Mr Rohrbaugh said. Sunshine Heart was unchanged at eight cents.

# **GENETIC TECHNOLOGIES, HATCHTECH**

Hatchtech chief executive officer Dr Paul MacLeman has been appointed chief executive officer of Genetic Technologies effective from May 4, 2009.

Genetic Technologies has had a run of controversy since an investigation of the company's share dealings by the Australian Securities and Investments Commission in 2007 (BD: Mar 8, 2007) which culminated in co-founder and former chief executive officer Dr Mervyn Jacobson and his daughter Tamara Milstein with a total of 672 charges of market manipulation (BD: Dec 12 and 15, 2008) and son in law and former Genetic Technologies chief operating officer Geoff Newing charged with 192 counts of market manipulation (BD: Dec 17, 2008).

Dr Jacobson took control of his company at the November annual general meeting (BD: Nov 19, 2008) seeing the removal of directors, chairman Henry Bosch, managing director and chief executive officer Michael Ohanessian, former federal treasurer John Dawkins, David Carruthers and Monash University deputy chancellor Dr Leanne Rowe. Although Dr Jacobson owns more than 40 percent of the company, the resolution was

passed by 194,595,828 votes (88%) to 24,721,283 votes.

The company has been searching for a chief executive officer since that meeting. Dr MacLeman has been the chief executive officer of Hatchtech since 2005. The unlisted company has investors including GBS Venture Partners and Ausbiotech director and former Phylogica chief executive officer Dr Stewart Washer as its chairman.

Dr MacLeman is a registered veterinary surgeon and holds additional qualifications including a Masters of Business Administration, a Graduate Diploma in Technical Management and a Graduate Certificate in Engineering and was previously chief operating officer of Imugene and vice-president of Agenix.

Dr MacLeman said Genetic Technologies had revenues and positive cash flows from licencing and its genetic testing businesses and it was "poised to become a sustainably profitable business able to bring new, high value products to market".

Dr Washer said Hatchtech was conducting a search for a new chief executive officer. Genetic Technologies fell 0.1 cents or 2.44 percent to four cents.

# PROGEN

Progen says director Stephen Chang will sell some of the 811,530 shares in which he has an interest into the \$1.10 buv-back.

Progen previously said Mr Chang had not decided on whether or not he would accept the buy-back offer for any of the 811,530 shares in which he has an interest.

The company said Mr Chang intends to accept the buy back offer "for a substantial portion" of his Progen shareholding".

"Mr Chang's interest is held through a self-managed superannuation fund and he has been advised to take steps to re-balance its portfolio to better meet the investment objectives for such a superannuation fund," Progen said.

The shareholder meeting to approve the off-market share buy-back will take place at 10:00 tomorrow April 22, 2009 in Brisbane.

The offer is subject to this shareholder approval.

Acceptances of the buy-back up to \$40 million, close on April 24, 2009. Progen was unchanged at 85 cents.

# CHEMGENEX

Chemgenex hopes to raise up to \$7.4 million through a one-for-14 non-renounceable share rights offer at 43 cents a share.

Chemgenex said the rights issue followed the recent \$10 million placement and funds would be used to complete clinical development and regulatory filings in the US and Europe for omacetaxine; progress discussions to secure distribution partners outside the US; and prepare for the commercial launch of omacetaxine in the US.

The record date is April 29, 2009 and the offer closes on May 22, 2009.

Chemgenex said ABN Amro Morgans had underwritten \$5 million of the offer.

Chemgenex fell one cent or 2.25 percent to 43.5 cents.

# USCOM

Uscom says a new study validates the use of ultra sonic cardiac output monitor in pregnancy.

Uscom said yesterday that the study was published in the Australian and New Zealand Journal of Obstetrics and Gynaecology by a team from the Department of Obstetrics and Gynaecology at South Australia's University of Adelaide Lyell McEwin Hospital.

The company said the study assessed the feasibility and reproducibility of the monitor's use on pregnant women and established normal values for circulation during pregnancy which would serve as reference values for detection and management of maternal hypertension.

Uscom said hypertension or pre-eclampsia in pregnancy is a common and life-threatening condition for the mother and child and required well-guided clinical care.

Central to this effective management is the measurement of cardiovascular function, which is currently performed by complex and expensive methods, but which can be improved and replaced by Uscom.

The study of 172 pregnant women found the Uscom determined values were consistent with current published data using other methods, and that correlation of measures by different observers was good at 94 percent and 96 percent.

Uscom fell two cents or 3.23 percent to 60 cents.

# NORWOOD

Norwood Abbey says Norwood Immunology has sold its equity in Bestiwil Holdings NV and subsidiary Virosome Biologicals NV.

Norwood Abbey owns about 20 percent of the London Alternative Investment Market listed Norwood Immunology.

The company said the Norwood Immunology extraordinary general meeting overwhelmingly approved the sale to Mymetics which transferred an initial payment of EUR5 million (\$A9.2 million) to Norwood Immunology.

Norwood Immunology announced a special dividend of one pence per share, to be paid from the proceeds of the Mymetics transaction and was examining its future strategy. Norwood Abbey is continuing discussions with a view to consummating a merger. A further announcement will be made in due course.

With the confirmation of the Norwood Immunology position, Norwood Abbey said it was working to complete its half-yearly accounts to have its securities reinstated to ASX trading during May.

Norwood Immunology said payment for Bestewil included the EUR5 million in cash EUR2.5 million in Mymetics five percent convertible loan notes, repayable with accrued interest 36 months from completion, with further consideration and royalties from Mymetics based on milestones being achieved in the business sold.

Norwood Immunology said the total to be paid in the special dividend was EUR2.58 million on May 8, 2009, providing about EUR516,000 or \$A952,000 to Norwoon Abbey. Norwood immunology said it would publish recommendations for the future of the company including a possible share buy-back, with an alternative of a special dividend, by May 31, 2009.

Norwood Abbey is suspended and last traded at 0.6 cents.