# Biotech Daily

Wednesday August 17, 2011

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: ANTISENSE UP 14%, CATHRX DOWN 20%**

*** SCALE-UP, DEPLOYMENT ISSUES DELAY REVA STENT TRIAL 6 MONTHS**

*** BIOTECH WINS $2.2m OF COMMERCIALISATION AUSTRALIA'S $8m**

*** PATRYS COMPOUND ACTIVE AGAINST MULTIPLE MYELOMA**

*** PSIVIDA, HOSPITAL FOR SPECIAL SURGERY ORTHOPAEDICS TRIAL**

*** FDA ALLOWS NOVOGEN, MARSHALL EDWARDS PHASE I TUMOR TRIAL**

*** CORRECTION: AUSTRALIAN ETHICAL TAKES 8% OF NEUREN**

*** BIOTA REVENUE DOWN 78% TO $15m, PROFIT TURNS TO $28m LOSS**

*** CSL PROFIT DOWN 11% TO $941m; REVENUE DOWN 7% TO $4,322m**

*** IDT LOSS DOWN 20%; REVENUE UP 7% TO $13m**

*** IMMURON 1-FOR-5 RIGHTS ISSUE TO RAISE UP TO $4.4m**

*** HUNTER HALL REDUCES 1.5% IN FLUOROTECHNICS**

*** GARVAN'S PROF JOHN SHINE TO CHAIR CSL**

*** THREE IM MEDICAL RESOLUTIONS FALL, DR WILLIAMS PREVAILS**

## MARKET REPORT

The Australian stock market climbed 1.33 percent on Wednesday August 17, 2011 with the S&P ASX 200 up 56.6 points to 4303.9 points. Thirteen of the Biotech Daily Top 40 stocks closed up, 11 fell, nine traded unchanged and seven were untraded.

Antisense was the best, up 0.1 cents or 14.3 percent to 0.8 cents with 1.3 million shares traded, followed by Living Cell up 10.5 percent to 6.3 cents. Impedimed, LBT and Prima climbed more than seven percent; Phosphagenics was up 4.2 percent; Bionomics, Genetic Technologies and Psivida rose two percent or more; with Anteo and Mesoblast up more than one percent.

Cathrx led the falls, again, down two cents or 20 percent to eight cents with 22,000 shares traded, followed by Optiscan down 15.4 percent to 11 cents with 97,300 shares traded. Uscom lost 9.1 percent; Viralytics fell 6.7 percent; Patrys was down 5.1 percent; with Acrux and CSL shedding more than two percent.

## REVA MEDICAL

Reva says its coronary stent clinical trial has been delayed by up to six months, primarily due to some stents failing to fully open, following manufacturing scale-up.

The San Diego-based Reva Medical raised $85 million late last year to develop the Rezolve bio-resorbable drug-eluting stent to restore blood flow to the coronial arteries expecting the funds to take the company to a 50-patient Conformité Européenne (CE) mark pilot trial by July 2011 with approval in 2013 (BD: Dec 16, 17, 2010).

Today, Reva's co-founder, chairman and chief executive officer Bob Stockman told Biotech Daily those timelines had been pushed back by about six months following the failure of some of the stents to fully open when deployed in bench-top and animal tests.

Mr Stockman said that the company's stents had a 100 percent correct deployment prior to the scale-up of manufacturing and although he did not disclose the failure rate, said "the vast majority are deploying correctly".

Mr Stockman said his primary concern was safety and the stent would not begin clinical trials until the company was satisfied they had a device that deployed correctly.

He said the design was very complex with many moving parts and there would be several weeks of confirmatory testing.

Reva has planned a pilot safety trial of 50 patients with denovo coronary lesions to be conducted in Brazil and Europe, including a centre in Germany and would be followed up with imaging at 12 months.

The company said last year that the pivotal CE mark trial would involve "several hundred" patients and centres were likely to include Australia and New Zealand.

In its prospectus Reva said the company had an operational cash burn of $US12,569,000 for the year to December 31, 2009 and an unaudited burn of $US6,930,000 for the nine months to September 30, 2010, with cash and cash equivalents of $US6,147,000 at September 30, 2010.

In its half-year report to the ASX, Reva said the net loss for the six months to June 30, 2011 was $US10,484,000, but Mr Stockman said the funds raised in December 2010 were sufficient to take the company to CE Mark approval in 2014.

Mr Stockman told a teleconference today that the exit of Johnson & Johnson from the stent business was significant.

In an announcement on the delays in a notice entitled 'Letter to shareholders' Mr Stockman said Reva had announced in May that following critical parts shortages from a third party supplier, "we projected a three month delay to the start of our pilot study".

That announcement was on page six of a seven page 'Letter to shareholders'.

Biotech Daily apologizes for missing the announcement.

Today, Mr Stockman said in his letter to shareholders that Reva had "remedied the parts shortage; however, the new parts necessitated slight adjustments to the stent design and to the methods we use to compact the stent onto the catheter".

"We have implemented and are testing these new and subtle design and process changes to ensure that all portions of the stent open to their intended diameter upon balloon deployment so that we see the desired clinical outcome; this implementation is proceeding well as we have perfected even further the device's performance," Mr Stockman said.

"The impact of these final adjustments does have a cost: they must be evaluated and confirmed in various bench and preclinical tests, which take time," Mr Stockman said.

"It is important to note that the improvements we have made to the Rezolve stent in the past few months and those that are pending are each intended to ensure the device is reliable and safe," Mr Stockman said. "We do not intend to begin any human study until we are satisfied we have met these product goals."

Reva was unchanged at 67.5 cents.

## COMMERCIALISATION AUSTRALIA

Adelaide's Signostics ultrasound has won the single largest Commercialisation Australia grant with the two biotechnology recipients awarded $2.2 million of the $8 million round.
Signostics was awarded a $1,965,803 early stage commercialisation grant for its handheld ultrasound platform which it said was low-cost, adaptable to several clinical uses, in any medical centre or facility and reducing delays with procedures (BD: Mar 17, 2011).
Endoluminal Sciences was awarded a $227,500 proof-of-concept grant for a sealing technology for minimally invasive aortic valve replacement.
A media release from Federal Innovation Minister Senator Kim Carr said the project involved the demonstration of superior efficacy and positive user feedback, including ease of use and procedural compatibility the sealing technology on commercially available minimally invasive aortic valves.
Along with support for environmental and information and communication technologies other grants approved included $200,000 for a skin care cosmetics range, $50,000 for a hospital patient-care system and $16,160 for the 'Date or Dud' online multi-platform speed dating comedy show, naming former Prima Biomed chief executive officer Eugene Kopp as the contact for the company.
There appeared to be no 'conflict of interest' declarations relating to this round of grants.
In his media release Senator Carr said Commercialisation Australia had provided about $8 million for 19 innovative companies.

## PATRYS

Patrys says that preclinical work at the University Hospital of Würzburg shows activity of one of its compounds for multiple myeloma.
Patrys said multiple myeloma was a bone marrow cancer arising from plasma cells in the marrow.
The University Hospital of Würzburg's Dr Leo Rasche and lead investigator said that a major obstacle in the treatment of multiple myeloma was disease recurrence "due in part to the outgrowth of chemotherapy and novel agents-resistant plasma cells".
"This study shows that Patrys' product can specifically bind to multiple myeloma cells from both patients at the stage of primary diagnosis and also in relapsed individuals," Dr Rasche said.
"Patrys' product mediates cell death in primary cells-isolated patients and typical cell lines used to study the disease in vitro," Dr Rasche said.
"We believe these encouraging data provide sufficient proof of concept to warrant further study in multiple myeloma patients," Dr Rasche said.
Patrys chief executive officer Dr Marie Roskrow told Biotech Daily the name of the compound had not been released due to intellectual property concerns.
In the Patrys media release, Dr Roskrow said the studies offered "promise in the multiple myeloma space where there are few treatments available, except for chemotherapeutics".
"The potential for Patrys' product to be used in relapsed patients is particularly exciting," Dr Roskrow said.
Patrys said multiple myeloma was most common in people aged 60 years and older, with men affected more often than women.
In the US, an estimated 20,520 adults will be diagnosed with multiple myeloma, with an estimated 10,610 deaths from the disease expected this year, the company said.
Patrys said that the five-year survival rate for people with multiple myeloma was about 39 percent.
Patrys fell 0.4 cents or 5.1 percent to 7.4 cents.

## PSIVIDA

Psivida says it has an evaluation agreement for the Hospital for Special Surgery to investigate its drug delivery technologies in orthopaedics.

Psivida said the agreement with the New York City hospital followed the renegotiation of its collaboration agreement with Pfizer to focus solely on developing a bioerodible sustained release implant for glaucoma and ocular hypertension, a program in clinical trials (BD: Jun 15, 2011).

Psivida chief executive officer Dr Paul Ashton said the orthopedic evaluation agreement was important because the drug delivery technology was originally developed for ophthalmology and was being investigated in broader areas of medicine.

“We are excited to be working with Hospital for Special Surgery because of their long history of innovation and research in orthopaedic surgery,” Dr Ashton said.

The company said the Hospital for Special Surgery Founded in 1863 and was “a world leader in orthopaedics, rheumatology and rehabilitation”.

Psivida said the Hospital was a member of the New York Presbyterian Healthcare System and an affiliate of Weill Cornell Medical College.

Psivida was up 10 cents or 2.5 percent to $4.10.

## NOVOGEN

Novogen says the US Food and Drug Administration has approved 65 percent subsidiary Marshall Edwards phase I clinical trial of ME-143 (formerly NV-143) for tumors.

Novogen said the FDA approved the investigational new drug application for ME-143 its lead nicotinamide adenine dinucleotide phosphate (NADH) oxidase inhibitor and the company planned to begin a phase I trial of intravenous ME-143 by September, 2011.

Marshall Edwards chief executive officer Dr Daniel Gold said the trial approval was “a significant milestone for Marshall Edwards and more importantly a critical step forward in the development of a drug candidate that we believe has the potential to significantly improve the treatment of patients with cancer”.

“We are excited to get back into the clinic and are working diligently to initiate a phase I trial of ME-143 as soon as possible,” Dr Gold said.

Novogen said ME-143 was derived from an isoflavone technology platform that had generated a number of compounds with anti-proliferative activity against tumor cells in laboratory studies.

The company said that in pre-clinical studies, ME-143 demonstrated anti-tumor activity against a number of tumor cell lines, including breast, colorectal and ovarian and had shown an ability to enhance the cytotoxic effects of chemotherapy in pre-clinical studies.

Marshall Edwards said it owned exclusive worldwide rights to ME-143.

Novogen was up one cent or 5.6 percent to 19 cents.

## NEUREN PHARMACEUTICALS

Australian Ethical Smaller Companies Trust has corrected yesterday’s substantial shareholder notice saying its 96,153,840 shares amount to 8.42 percent of the company and not 10.55 percent as reported.

The error was made by Australian Ethical.

No sub-editors were harmed in making this correction.

Neuren was up 0.3 cents or 18.75 percent to 1.9 cents with 10.3 million shares traded.

## BIOTA HOLDINGS

Biota says its revenue fell 78.4 percent to $14,605,000 in the 12 months to June 30, 2011, taking last year's net profit after tax of $20,284,000 to a loss of $29,165,000.
The lower revenue was primarily royalties from Glaxosmithkline for Relenza which had record sales in the year to June 30, 2010.
Biota said its diluted loss per share was 15.4 cents compared to the previous year's earnings of 9.1 cents.
Biota said it had $70,011,000 in cash and equivalents at June 30, 2011 compared to $104,867,000 for the previous corresponding period.
Biota said the US Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA) $US231 million contract for the advanced development of laninamivir was more than the company's market capitalization and was "a game changing opportunity".
Biota chief executive officer Peter Cook said that while there was "a significant fall in Relenza royalties following the pandemic year, solid commercial progress continues to be made, such as the launch of Inavir in Japan, our second royalty generating product".
"The contract from BARDA for the advanced development of laninamivir in the US was one of the most significant events in the company's history," Mr Cook said.
"It provides $US231 million of non-dilutive funding and opens up supply opportunities for laninamivir to the US government," Mr Cook said.
Biota was unchanged at 89 cents.

## CSL

CSL says its net profit after tax was down 10.6 percent to $941 million for the 12 months to June 30, 2011 on revenue down 6.6 percent to $4,322 million.
CSL said net profit after tax was down $112 million and the company had "an unfavorable foreign exchange impact of $116 million", but "on a constant currency basis "operational net profit after tax grew 14 percent after excluding a one-off contribution form the sale of pandemic influenza vaccine (H1N1) in the prior period".
CSL said that its total ordinary dividend was constant at 80 cents with the final dividend also constant as 45.0 cents and franked to 4.4 percent payable on October 14, 2011.
The company said that basic earnings per share was 174.03 cents compared to the previous year's 185.77 cents.
CSL managing director Dr Brian McNamee said the result was "impressive" in a turbulent period.
"Despite the global economic instability CSL's performance has demonstrated its underlying momentum and resilience," Dr McNamee said.
"Our portfolio of immunoglobulins did particularly well," Dr McNamee said.
"Transition programs to new generation products, Privigen and Hizentra, are well underway and multiple regulatory approvals have been received to manufacture and distribute these products around the world," Dr McNamee said.
"New capacity for albumin is under construction at multiple sites and the board has approved the construction of a new Privigen manufacturing facility at our Broadmeadows site to support global demand," Dr McNamee said.
CSL fell 79 cents or 2.65 percent to $29.07 with 2.85 million shares traded.

## IDT AUSTRALIA

IDT says it net loss after tax for the 12 months to June 30, 2011 was down 85 percent to $236,000 with revenue up seven percent to $13,097,000.
IDT said the dilute loss per share fell 86.1 cents, from 3.6 cents in the year to June 30, 2010 to 0.5 cents a share for the year to June 30, 2011.
The company said it paid a fully-franked one cent per share dividend last year but would not pay a dividend this year.
IDT chairman Dr Graeme Blackman said the international pharmaceutical sector “faced many challenges” in the year to June 30, 2011 including a reduction in the number of opportunities for development and manufacturing contracts; an increase in competition; and Australian dollar impacts on revenue.
“My fellow directors and I are obviously disappointed about the performance of our share price over the last twelve months,” Dr Blackman said. “The revenue growth experienced during the reporting period by CMax, IDT’s clinical trials division and the current level of enquiry for clinical trial services, demonstrate a sustained improvement in the phase I/II clinical sector both within Australia and internationally,” Dr Blackman said.
Dr Blackman said the revenue benefits from commercialization would be seen in the coming financial year and beyond.
IDT was up five cents or 14.7 percent to 39 cents.

## IMMURON

Immuron hopes to raise up to $4,388,080 through a non-renounceable one-for-five share rights issue at seven cents a share.
Immuron issued an Appendix 3B New Issue request to the ASX asking to issue up to 62,686,862 shares and 20,895,621 options.
Immuron said that there would be one attaching option for every three new shares acquired, exercisable at 12 cents by December 15, 2013 and a top up facility would allow for the purchase of shortfall shares.
The company said the rights issue would fund the expansion of the market for Travelan; finalizing the investigational new drug application for non-alcoholic steato-hepatitis phase IIb trial, finalizing the animal trials for influenza and commencement of the phase I human trial and working capital.
Immuron said the record date for the rights issue was August 31, 2011, the offer would open on September 5 and close on September 20, 2011.
Immuron was unchanged at 72 cents.

## FLUOROTECHNICS

Hunter Hall Investment Management has reduced its substantial holding in Fluorotechnics from 20,869,971 shares (38.54%) to 20,000,000 shares (36.94%).
Hunter Hall said the 869,971 shares were sold for $11,047.45 or an average price of 1.27 cents a share.
Fluorotechnics listed on the ASX in 2008 at $1.00 a share with Hunter Hall holding 6,250,000 shares or 25.89 percent (BD: Sep 4, 2008) and acquiring a further 1,850,000 shares at 28 cents each in a placement and rights issue in 2009 (BD Sep 11, 2009).
In 2010 Hunter Hall increased its holding to 12,869,971 shares or 35.37 percent, when the company was trading at 32 cents (BD: Feb 1, 2010) increasing to 20,869,971 shares (44.27%) when the company was trading at 13 cents (BD: Jun 10, 2010).
Fluorotechnics was up 0.2 cents or 15.4 percent to 1.5 cents.

## CSL

CSL says that Garvan Institute executive director Prof John Shine will replace Elizabeth Alexander as chairman when she and director David Simpson retire on October 19, 2011
CSL said Ms Alexander and Mr Simpson would retire at the annual general meeting and Bruce Brook would be appointed a director effective from today, August 17, 2011.
The company said Mr Brook was “an experienced company director” with a professional and financial background.
CSL said Mr Brook was chairman of Programmed Maintenance Services and Boart Longyear and was previously chairman of Energy Developments and a director of Lihir Gold and Consolidated Minerals.
The company said Prof Shine had been a director since June 2006, was “a world leader in molecular biology” and was a pioneer of the US biotechnology industry.
CSL said Prof Shine would retire from the Garvan Institute of Medical Research at the end of 2011.

## IM MEDICAL

IM Medical has withdrawn two resolutions and former chairman Dr Laurie Williams’ defeated a third vote at the IM Medical extraordinary general meeting (BD: Aug 11, 2011).
Resolutions to sell the radiology business and approve a rights issue were withdrawn and a resolution to issue shares and options relating to converting loans was defeated, with 309,350,777 proxy votes against and 219,970,492 proxy votes in favor.
The re-election of directors Nigel Blaze, Paul Quarrell and Richard Wadley were passed by more than 2,140 million proxy votes in favor with more than 309 million proxy votes against.
The shares consolidation was passed by a larger margin.
Last week Dr Williams told Biotech Daily that he would take the company in a different direction to that proposed by the board, saying the Intelliheart business and radiology business both had value that he could unlock.
The company said it had withdrawn the rights issue due to market volatility triggering an opt-out clause for the underwriters.
IM Medical was untraded at 0.1 cents.