Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: IMPEDIMED UP 9%, AVEXA DOWN 10%**

*** CLINUVEL CLAIMS POSITIVE PHASE III INTERIM RESULTS**

*** NEUREN TO CONTINUE NNZ-2566, CREATE JOINT VENTURE TRUST**

*** ATCOR UPGRADES REVENUE GUIDANCE ON 1st HALF 76% SALES SURGE**

*** FLUOROTECHNICS: ADELAIDE PROTEOMICS A 'REFERENCE CUSTOMER'**

*** GENERA DENIES AFR CAPITAL RAISING STORY**

*** ARANA EX-CEO DR JOHN CHIPLIN GOES WITH $347k**

*** XCEED DIRECTOR DR STEWART WASHER RESIGNS**

*** INCITIVE CEO DON HOME RESIGNS**

*** GIACONDA'S BOARD LOSES PROF TONY MOON, CHRIS BILKEY RETURNS**

MARKET REPORT

The Australian stock market fell 1.0 percent on Wednesday January 21, 2009 with the S&P ASX 200 down 33.8 points to 3,442.8 points. Nine of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and nine were untraded.

Impedimed was best, up six cents or 9.09 percent to 72 cents with 2,000 shares traded, followed by Chemgenex up three cents or 6.59 percent to 48.5 cents.

Heartware climbed 5.26 percent; Clinuvel was up 4.44 percent; Cellestis and Novogen were up more than three percent; Benitec, Bionomics and CSL rose more than two percent; with Optiscan up 1.59 percent.

Avexa led the falls, down 0.8 cents or 9.64 percent to 7.5 cents with 1.3 million shares traded, followed by Polartechnics down 7.14 percent to 13 cents and Alchemia down 6.9 percent to 13.5 cents.

Genera, Labtech, Phosphagenics, Ventracor and Viralytics fell more than four percent; Cytopia and Sirtex lost more than three percent; Biota, Mesoblast and Universal Biosensors shed more than two percent; with Acrux, Arana, Cochlear and Pharmaxis down more than one percent.

CLINUVEL

Clinuvel says interim phase III trial results show its photoprotective drug afamelanotide or CUV1647 is beneficial for patients with erythropoietic protoporphyria.

Clinuvel said erythropoietic protoporphyria (EPP) was a rare genetic and metabolic disease characterized by severe photo-toxicity of the skin resulting in intolerable pain, blistering and swelling typically of the hands and face.

The company said patients experienced aggravated symptoms of the skin following sun exposure, most commonly in spring and summer.

Clinuvel said the data came from the first 14 Swiss patients to complete the 12 month study period of 101 erythropoietic protoporphyria patients in Europe and Australia.

The study is expected to be completed by the end of 2009.

Clinuvel said the severity of photo-toxicity, determined as a primary endpoint to the study, was assessed by measuring the pain experienced during episodes of photo-toxicity using a standard visual analogue pain scale.

The maximum severity of phototoxic reactions was significantly reduced by afamelanotide treatment compared with placebo ($p<0.001$) and the total severity of phototoxic reactions was reduced during spring and summer by afamelanotide compared with placebo ($p=0.028$).

Skin melanin density, determined as secondary endpoint to the study, increased following afamelanotide treatment and then declined during the placebo treatment period as expected.

Clinuvel said there was a significant difference in the change from baseline in melanin density (skin darkening) for afamelanotide compared to placebo for the first two treatment periods, during spring and summer ($p=0.048$).

The company said no significant differences between the afamelanotide and placebo treated patients were seen for the number of photo-toxic reactions experienced, the amount of sunlight exposure or the quality of life measurements, but Clinuvel said that might have been due to the small numbers of patients ($n=14$).

The company said there were no afamelanotide-related serious adverse events or safety concerns identified during the study.

An independent data and safety monitoring board has reviewed the data on the safety and efficacy of afamelanotide in this clinical setting and consider it appropriate, and of benefit, to continue the study to its conclusion.

Clinuvel said that on completion of the study by the Swiss cohort of patients, all 14 patients requested continuation of the drug for photo-protection for the next 12 months. This compassionate use request was granted by the Swiss regulatory agency, Swissmedic.

Clinuvel's chief scientific officer Dr Helmer Agersborg said that in 2008 the US Food and Drug Administration, the European Medicines Agency and Swissmedic granted orphan drug designation for the treatment of phototoxicity in erythropoietic protoporphyria.

"The results of this trial are very encouraging," Dr Agersborg said.

The company's chief executive officer Dr Philippe Wolgen said Clinuvel was "most happy" with the results, "but safety remains the most important aspect we are looking at when evaluating afamelanotide as a new class of drug in preparation for marketing authorization in various markets".

"It is a very positive sign that all Swiss patients requested further medication after completion of the trial," Dr Wolgen said. "We are on schedule in our development of afamelanotide and look modestly but confidently ahead to late 2009, when we anticipate the final phase III results."

Clinuvel was up one cent or 4.44 percent to 23.5 cents.

NEUREN

Neuren says its compound NNZ-2566 proposed for phase II trials for traumatic brain injury with the US Walter Reed Army Medical Centre is “a valuable asset”.

Neuren said this view was “reinforced by recent discussions with potential investors and partners and continued support from the US Army”.

“We are in active discussions with a number of parties concerning an investment that would, by enabling Neuren to initiate the phase II trial in traumatic brain injury patients, result in realization of financial support previously committed by the US Army to cover certain costs incurred in relation to the phase II trial,” Neuren said.

The company said the most likely outcome of the discussions would be placement of private equity into a US-based subsidiary owned by Neuren.

Neuren said the investigational new drug application for the phase II clinical trial was in the final stages of preparation and expected to be submitted to the US Food and Drug Administration within the next few weeks.

Neuren said its directors and management “were naturally disappointed by the recently-announced results from the Glypromate trial (BD: Jan 16, 2009), “based on recent discussions, we believe that both potential strategic partners and investors appreciate that the results reflect a substantially lower incidence of cognitive impairment than expected rather than a demonstrable failure of the drug to reduce cognitive impairment”.

Neuren said that about 20 percent of all patients experienced any degree of cognitive impairment at 12 weeks and, among those patients who did exhibit some degree of impairment, a large proportion evidenced only a small decline compared to baseline (pre-operative) cognitive function.

Further, the incidence of adverse events in patients receiving Glypromate was not different than among those patients receiving placebo.

The six-fold lower mortality rate among patients receiving Glypromate compared to placebo, while not statistically significant, reinforced the company’s belief that the drug was safe and that development for traumatic brain injury is appropriate.

Neuren said that as well as continuing the development of NNZ-2566, it was “engaged in discussions to further increase the value of other assets”.

Neuren has agreed in principle with a New Zealand-based trust to establish a joint venture company to progress its discovery-stage cancer programs.

The trust, which will be identified when the contemplated transaction has been approved by both boards, has agreed to contribute up to NZ$1.1 million to support research and development expenses for Neuren’s TFF-1, TFF-3 and anti-human growth hormone programs in exchange for an equity interest in a new company majority owned by Neuren.

Neuren said it recently reacquired rights to the TFF-1 program while the partner previously referenced but not identified due to confidentiality would receive an option to take up commercial development at the end of 2009.

Neuren will retain the upfront payment already received.

The company said it was engaged in substantive discussions with various third parties with respect to licensing and/or co-development of additional neurology-focused assets including Motiva (nefiracetam), the diketopiperazine platform which includes the lead candidate NNZ-2591 and the neural regeneration peptides.

Neuren’s chairman Dr Robin Congreve said that despite the current challenges in the capital markets and the recent setback with Glypromate, “we sincerely hope that investors will recognize that the company’s board and management are fully committed to advancing the pipeline and to delivering value for shareholders through whatever means are most appropriate and achievable”.

Neuren fell 0.4 cents or 33.33 percent to 0.8 cents with 7.0 million shares traded.

ATCOR MEDICAL

Atcor says unaudited record sales of $5.4 million for the first half of the 2008-'09 year are a 76 percent increase over the previous corresponding period.
Atcor has developed and marketed the Sphygmocor system which measures central blood pressures and arterial stiffness non-invasively.
The company said that "on a constant currency basis, sales increased 64 percent over the previous corresponding period".
Atcor said US sales increased 125 percent for the first six month of the financial year, "reflecting increased demand for central blood pressure measurement using Sphygmocor in pharmaceutical clinical trials".
The company said European sales rose 26 percent and Asian sales grew by 11 percent following "a strong prior year performance".
Atcor chief executive officer Duncan Ross said "the strong sales momentum achieved in the past two years has continued and we maintain a healthy sales pipeline".
"Despite seeing some impact from the macro economic environment we have upgraded Atcor's full year sales guidance to an increase of 55 percent" for the financial year to June 30, 2009 compared to the previous year, "up from the 45 percent increase we anticipated in November".
"We expect full year sales of at least $10.0 million," Mr Ross said.
Atcor said its half-year results would be announced on February 19, 2009.
Atcor was up two cents or 12.9 percent to 17.5 cents.

FLUOROTECHNICS

Fluorotechnics says the Adelaide Proteomics Centre will act as a "reference customer" for its diagnostic gels and dyes.
Fluorotechnics said the Centre was "the largest and most important proteomics service provider in South Australia" and had agreed to become its "Australian reference customer" promoting the company's gels at conferences and meetings.
Fluorotechnics said the head of the Centre, Dr Peter Hoffmann, would organize a lecture tour in Australia about proteomics using Fluorotechnics' gels and dyes. Fluorotechnics' scientific marketing director Dr Reiner Westermeier will deliver lectures on the tour.
The Centre's head of 2D electrophoresis business Dr Megan Penno said she was "astounded by the ease and convenience of these new products".
"The Fluorotechnics 2D gels are easy to use and save enormous time so we can focus on real science. It relieves the burden of gel casting and I will never run home-made gels again," Dr Penno said.
The Adelaide Proteomics Centre is a joint venture of the University of Adelaide and Hanson Institute, established with support from the Australian Cancer Research Foundation.
The Fluorotechnics media release said the Centre offered researchers a state-of-the-art proteomics facility and services with the latest mass spectrometry technology to identify and characterize proteins and changes in protein expression.
Fluorotechnics said the Adelaide Proteomic Centre revenue had "already been taken into consideration in determining our expected sales in the 2009 financial year and hence those expectations are unchanged".
On December 18, 2009 Fluorotechnics said it expected "sales revenue for the year ending June 30, 2009 to be about $3.5 million short of the $7.5 million projected in the company's prospectus" (BD: Dec 18, 2008).
Fluorotechnics was unchanged at $1.00.

GENERA BIOSYSTEMS

Genera Biosystems says a report in today's Australian Financial Review does not correctly represent a brief interview with chief executive officer Dr Allen Bollands.
Genera said “the comment in the report that the company ‘intends to test the market for funds next month’ is not correct”.
“No decision has been made to raise capital either next month or at any other time,” Genera said.
Genera said that at December 31, 2008 it had a cash balance of $2.5 million.
“In the event that the company does raise additional capital, it is not the current intention of the board to raise funds through the issuance of ordinary shares at a price below the IPO issue price of 50 cents,” the company said.
Genera said a “current priority” was to pursue partnerships and licencing deals for the Ampasand diagnostic platform in selected jurisdictions which would provide the company with material upfront licence fees and milestone payments that would further enhance the company's cash position.
Genera said it remained “on-track to achieve registration of Paptype in Australasia and Europe” by the end of June 2009.
Genera fell one cent or 4.35 percent to 22 cents.

ARANA

In a media release to the ASX entitled ‘Matters for the information of the market’ Arana said former chief executive officer Dr John Chiplin received $346,667 in termination pay.
Arana said the payments followed the conclusion of his employment on December 31, 2008 and comprised a termination payment of $166,667 under the terms of his employment contract and $180,000 in relation to his short term incentive for achievement of specific goals by the company during calendar year 2008.
Arana said Dr Chiplin did not retain any entitlements to previously granted long term incentives.
The company also said it had acquired 166,227 shares at a cost of $143,800 in on-market transactions “to fulfill allocations of shares to certain employees under the rules of the performance share plan”.
Dr Steffen Nock was appointed acting chief executive officer on November 13, 2008.
Arana fell 1.5 cents or 1.69 percent to 87 cents.

XCEED CAPITAL

Xceed Capital says director Dr Stewart Washer resigned on January 19, 2009, due to other work commitments.
Dr Washer continues as chairman of the private biotechnology company Hatchtech as well as a director of the industry body Ausbiotech and a director of Healthlinx and New Zealand’s Genesis.
He is also an investment consultant to IB Managers Australian Biosciences Fund and a venture partner with the Swiss based Inventages Venture Capital life sciences fund.
Xceed was untraded at 2.5 cents.

INCITIVE

Incitive says chief executive officer and managing director Don Home will leave the company to take up a senior executive position with Abbott in the US in February.
Incitive chairman Mel Bridges will act as interim executive chairman and during the transition period Mr Home will remain a director of the company.
Incitive was untraded at three cents.

GIACONDA

Giaconda says Chris Bilkey has rejoined the board of directors as a non executive director and Prof Tony Moon has resigned from the board for health reasons.
Giaconda says Mr Bilkey was chairman of the board and left in August 2006.
Giaconda was untraded at 5.5 cents.