



# Biotech Daily

Thursday August 26, 2010

*Daily news on ASX-listed biotechnology companies*

- \* ASX, BIOTECH UP: CIRCADIAN UP 13%; PHYLOGICA DOWN 20%
- \* US COURT STEM CELL RESEARCH BAN 'POTENTIAL DISASTER'
- \* LEO KHOURI CLAIMS SOLAGRAN MISLEADING, DECEPTIVE CONDUCT
- \* AUSBIOTECH CALLS ON POLITICIANS TO SUPPORT INNOVATION
- \* TWO MORE COMPANIES SETTLE GENETIC TECHNOLOGIES CLAIM
- \* SIRTEX PROFIT DOWN 12% TO \$18.2m; REVENUE DOWN 2.4% TO \$72m
- \* MEDICAL DEVELOPMENTS PROFIT UP 8.3% TO \$879k; REVENUE DOWN
- \* ELLEX PROFIT UP 117% TO \$3.8m ON REVENUE DOWN 19% to \$47m
- \* AVEXA SETS DATE FOR CALZADA REQUISITIONED BOARD SPILL
- \* PHYLOGICA 1-FOR-5 RIGHTS ISSUE TO RAISE UP TO \$2.4m
- \* HALCYGEN APPOINTS PAN-MALAYAN AS SINGAPORE DISTRIBUTOR
- \* SELECT VACCINES REQUESTS CAPITAL RAISING TRADING HALT
- \* NEURODISCOVERY REQUESTS CAPITAL RAISING TRADING HALT
- \* BIO-MELBOURNE INVESTIGATES THE PRESSURE TO PATENT TOO EARLY

## MARKET REPORT

The Australian stock market was up 0.8 percent on Thursday August 26, 2010 with the S&P ASX 200 up 35.9 points to 4356.0 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, four traded unchanged and four were untraded.

Circadian was best, up 7.5 cents or 13.2 percent to 64.5 cents with 4,000 shares traded, followed by Viralytics up 7.1 percent to three cents with 437,000 shares traded. Genetic Technologies climbed 6.7 percent; LBT was up 5.3 percent; Heartware was up four percent; Biota, Novogen and Universal Biosensors were up more than three percent; Impedimed and Phosphagenics rose more than two percent; with Chemgenex, Mesoblast and Prima up more than one percent.

Phylogica led the falls, down 1.5 cents or 20 percent to six cents with 545,088 shares traded, followed by Sunshine Heart down 17.2 percent and Prana down 13.3 percent. Benitec lost eight percent; Antisense was down 6.7 percent; Living Cell, Pharmaxis and QRX were down more than five percent; Alchemia and Clinuvel fell more than four percent; Bionomics lost 3.6 percent; Optiscan shed 2.3 percent; with Acrux, Patrys and Sirtex down more than one percent.

## US DISTRICT COURT, STEM CELL RESEARCH

Australian and US researchers are concerned that a US District Court judgment halting human embryonic stem cell funding could harm global stem cell research.

In the District Court of Washington DC on August 23, 2010, Judge Royce Lamberth granted a preliminary injunction in favor of the plaintiffs in the case of Dr James Sherley et al versus defendants Kathleen Sebelius et al, preventing the use of Federal funds for human embryonic stem cell research.

The head of Monash University's embryonic stem cell differentiation laboratory Prof Andrew Elefanti said the ban was "potentially a disaster for stem cell research in the US". "From a pragmatic point of view of, if this block is upheld, most pluripotent stem cell researchers in the US will be forced to work with [induced pluripotent stem] cells, with all their inherent problems," Prof Elefanti said.

"There will be a flow on effect and this will hurt Australian scientists in terms of ability to collaborate with US groups and opportunity to access NIH funds for research," Prof Elefanti said.

The chief executive officer of the New York Stem Cell Foundation Susan Solomon said Judge Lamberth was "known to oppose stem cell research".

"We have been in touch with our colleagues across the country and we believe this decision will ultimately be reversed," Ms Solomon said.

In his decision Judge Lamberth said that the plaintiffs including Dr Sherley, Dr Theresa Deisher, Nightlight Christian Adoptions, Embryos, Shayne and Tina Nelson, William and Patricia Flynn, and Christian Medical Association brought the suit to prevent the defendants' 'Guidelines for Human Stem Cell Research' from taking effect.

Judge Lamberth said the plaintiffs sought "an order (a) declaring that the Guidelines are contrary to law, were promulgated without observing the procedures required by law, and constitute arbitrary and capricious agency action; and (b) enjoining defendants from applying the Guidelines or otherwise funding research involving the destruction of human embryonic stem cells".

On October 27, 2009, the Court dismissed the plaintiffs' suit, finding they lacked standing, but on appeal were allowed to proceed.

Judge Lamberth said stem cell research had the potential to produce medical breakthroughs in the treatment of many life-threatening diseases, but the research was "clearly research in which an embryo is destroyed".

"Despite defendants' attempt to separate the derivation of [embryonic stem cells] from research on the ESCs, the two cannot be separated. Derivation of ESCs from an embryo is an integral step in conducting ESC research," Judge Lamberth said.

He said that allowing Federal funding of ESC research, the Guidelines were "in violation of the [US Congress] Dickey-Wicker Amendment" which he said was unambiguous and prohibited research in which a human embryo was destroyed, discarded, or knowingly subject to risk of injury or death greater than that allowed under applicable regulations. Judge Lamberth said "the public interest weighs in favor of a preliminary injunction" to enjoin defendants from implementing the Guidelines because they allow Federal funding of embryonic stem cell research, which involves the destruction of embryos.

The New York Stem Cell Foundation said it regretted that the expansion of Federal funding for stem cell research was being held back.

"Today's court decision allows a vocal minority to hold science hostage to a narrow political agenda," the Foundation said. "Although we are confident that the court's decision will not be upheld, the net effect of this decision is to slow the progress of advancing revolutionary new therapies that have the potential to advance cures and successful treatments for a broad range of the diseases and conditions."

## BIOPROSPECT, SOLAGRAN, GUN CAPITAL MANAGEMENT

Gun Capital Management has filed a claim of misleading or deceptive conduct against Solagran, Solamind and their chairman and director Dr Vagif Soultanovich Soultanov. Gun Capital is associated with Bioprospect director Leo Khouri, a major shareholder in Bioprospect. Dr Soultanov through Solamind is a major shareholder of Solagran.

Both companies were significantly affected by the Opes Prime collapse.

Bioprospect lost 25.6 percent of its shares, while Solagran lost 42.6 percent of its fully paid shares and 21 percent of its partly-paid shares to the ANZ Bank, having gifted them to Opes Prime Stockbroking (BD: Apr 4, 9, 2008).

At that time the Takeovers Panel refused to commence proceedings on an application by Gun Capital Management, Bejjal and Exchange Minerals to prevent the ANZ bank selling Bioprospect shares exposed by the Opes Prime collapse (BD: Apr 18, 2008).

Shares held by Dr Soultanov and directors Denis Kilroy and Charles Pellegrino and others were placed in Solamind which gave its shares to Opes Prime (BD Aug 14, 2008).

Bioprospect and Solagran have been involved in agreements to develop Solagran's over-the-counter pine needle extract cure-all for veterinary use, but recently the two companies have had a series of disagreements (BD: Jun 28; Jul 29; Aug 4, 5, 13, 2010).

On March 3, 2010 Solagran said in a substantial shareholder notice that it owned 10.31 percent of Bioprospect.

In a directors interest statement on October 27, 2009 and in a substantial shareholder notice of November 9, 2009, Elias Leo Khouri, Bejjal Pty Ltd and Gun Capital Management said they owned 69,000,000 shares or 14.14 percent of Bioprospect.

In the claim to the Federal Court of Western Australia filed on August 24, 2010, Gun Capital Management filed a statement of claim and an application on consumer protection against Solagran, Solamind and Dr Soultanov.

The matter has been set down for directions on September 30, 2010.

Bioprospect was unchanged at 1.6 cents.

Solagran was up half a cent or 2.9 percent to 18 cents.

## AUSBIOTECH

Ausbiotech chief executive officer Dr Anna Lavelle has urged both major parties, the independents and Greens to support innovation in the biotechnology industry.

"As the fate of our next Government rests on the decision of three, possibly four, Independent MPs and one Greens MP, these politicians have the power to bring about real change" Dr Lavelle said.

"One of the greatest opportunities of these Independent MPs is to make a contribution to innovation by encouraging support from both major parties in their negotiations," she said.

Dr Lavelle told Biotech Daily that she was calling for support for Labor's 45 percent research and development tax credit Bill, which has been passed by the House of Representatives and is awaiting Senate debate.

The Labor Party has said it was determined to pass the legislation, the Liberal Party opposes it and the Greens are understood to support the legislation but have not committed to it.

"The greatest renewable resource in Australia is innovation," Dr Lavelle said.

"Encouraging innovation, particularly in the biotechnology space, will ensure a positive impact on the majority of key election issues - climate change, health, an aging population, food security and fuel security," she said.

Dr Lavelle said it was "folly for whichever party forms Government to continue relying on the success of an Australian economy based on resources".

## GENETIC TECHNOLOGIES

Genetic Technologies says it has settled patent infringement disputes with Beckman Coulter of Brea, California and Clinical Data of Newton, Massachusetts.

Genetic Technologies said the two companies had entered into appropriate settlement agreements following the patent infringement law suit filed by Genetic Technologies in the US District Court, Western District of Wisconsin in February this year (BD: Feb 16, 2010). The company said the commercial terms of these two settlements were covered by formal confidentiality provisions and could not be disclosed.

Genetic Technologies said it was engaged in discussions with other parties relating to the law suit and was also engaged in negotiations with other parties, outside of the law suit. Genetic Technologies was up 0.2 cents or 6.7 percent to 3.2 cents.

## SIRTEX MEDICAL

Sirtex says its net profit after tax was down 11.8 percent to \$16,080,000 for the 12 months to June 30, 2010 on revenue down 2.4 percent to \$72,089,000.

Sirtex said that net tangible assets per share was 89.9 cents at June 30, 2010, compared to 67.4 cents at June 30, 2009, up 33.4 percent.

The company said that diluted earnings per share was 28.8 cents compared to the previous year's 32.7 cents.

Sirtex said it would pay a dividend of 7.0 cents a share franked at 3.0 cents on October 14, 2010 with a record date of September 30, 2010, the same as the previous year.

The company said that dose sales of its SIR-Spheres for liver cancer increased by 14 percent and they were "a key measure of Sirtex's commercial progress".

Sirtex said revenue "was \$64.3 million, two percent below last year due to the continued strength of the Australian dollar and the weakness of currencies in the company's major markets of Europe and the US where over 95 percent of sales are made".

Sirtex chief executive officer Gilman Wong said the company had "delivered a credible result and is confident we will achieve growth in the medium and long term, given the large unmet clinical need for our product, strong global market position and exciting product development pipeline".

Mr Wong said Sirtex would continue to make significant investments in infrastructure to underpin growth and help meet demand from a growing global customer base.

Mr Wong said long term growth was supported by "a heavy investment in the sales, marketing, clinical support and technology development that will underpin long-term shareholder value".

He said investment in marketing rose 34 percent, clinical trial investment was up 14 percent, while research and development investment increased five percent.

Mr Wong said cash increased to \$41.4 million compared with \$26.5 million last year.

Sirtex fell seven cents or 1.4 percent to \$4.98.

## MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its net profit after tax was up 8.5 percent to \$879,000 for the 12 months to June 30, 2010 on revenue down 4.9 percent to \$8,296,000.

The company said that diluted earnings per share was 1.7 cents compared to 1.5 cents for the previous corresponding period and no dividend would be paid.

Medical Developments said its net tangible asset backing per share was 7.2 cents at June 30, 2010 a 24.1 percent increase over the previous year.

Medical Developments was unchanged at 20 cents.

## ELLEX MEDICAL LASERS

Ellex says its net profit after tax was up 117 percent to \$3,820,000 for the 12 months to June 30, 2010 on revenue down 19 percent to \$47,420,000.

The company said that diluted earnings per share was 4.5 cents compared to a loss of 29.6 cents for the previous corresponding period and no dividend would be paid.

Ellex said its net tangible asset backing per share was 23.1 cents at June 30, 2010 a 3.9 percent increase over the previous year.

Ellex was unchanged at 20 cents.

## AVEXA, CALZADA

Avexa shareholders will vote on the future direction of the company following Calzada's call to replace the existing board.

In a 19 page document to the ASX the two companies set out their opposing cases on the removal of the existing board of Joe Baini, Jet Soedirdja, Steven Crowley, Bruce Hewett and Iain Kirkwood to be replaced by Calzada director Bruce Rathie, Dr John Chiplin, Dr Stewart Washer and Dr David Fuller.

Avexa said Calzada had "not outlined a strategy or vision for Avexa that will benefit all shareholders" and said Calzada's concerns about the Avexa board were "without basis".

Avexa said that since Entrust Funds Management, the major shareholder of Calzada, had taken over that company the share price had declined.

Avexa said its directors had the necessary skills and experience to lead Avexa.

Calzada said that apart from Mr Baini, none of the current directors had experience with ASX-listed biotechnology companies and Mr Baini only had experience with Avexa.

Calzada said its proposed directors all had ASX biotechnology experience.

Calzada said Mr Baini was part of the board that voted unanimously to close the apricitabine or ATC program for HIV, before resigning from the board.

Calzada said it was not seeking control of Avexa with "only one Calzada representative" among the four proposed directors.

Calzada said it appeared that Mr Hewett and Mr Crowley were elected "with the apparent support of shareholders supportive of the ATC development program".

Calzada said it was seeking assurances that the independent review was "open and transparent and the final report is made available to shareholders".

Calzada said the existing board had a combined holding of less than 0.1 percent of the company, while Calzada held more than 16 percent.

The meeting will be held at Computershare, 452 Johnston Street, Abbotsford, Victoria on September 28 at 10am.

Avexa was unchanged at 2.9 cents.

Calzada was up 0.1 cents or 4.2 percent to 25 cents.

## PHYLOGICA

Phylogica expects to raise \$2.4 million through a fully underwritten one-for-five renounceable share rights offer at five cents a share.

Phylogica said each new share would come with a free attaching option exercisable at 15 cents with a term of one year. The rights issue is fully underwritten by Paterson Securities.

Phylogica said funds raised would be used mainly to scale-up its drug discovery and screening capabilities.

Phylogica did not state the opening, closing or record dates for the rights issue.

Phylogica fell 1.5 cents or 20 percent to six cents.

## HALCYGEN PHARMACEUTICALS

Halcygen says it has signed a distribution agreement with Pan-Malayan Pharmaceuticals Pte Ltd for the distribution of Doryx, Astrix and Eryc in Singapore.

Halcygen chief executive officer Dr Roger Aston said the distribution agreement would expand the company's sales in Asia.

Halcygen said Doryx and Eryc were oral antibiotics and Astrix was a low dose aspirin. The company said the products incorporated Mayne Pharma's drug delivery technology and were manufactured at the company's facility in Salisbury, South Australia.

Halcygen was up one cent or 1.7 percent to 59 cents.

## SELECT VACCINES

Select Vaccines has requested a trading halt pending an announcement on a capital raising.

Trading will resume on August 30, 2010 or on an earlier announcement.

Select Vaccines last traded at 0.4 cents.

## NEURODISCOVERY

Neurodiscovery has requested a trading halt pending an announcement on a capital raising.

Trading will resume on August 30, 2010 or on an earlier announcement.

Neurodiscovery last traded at 3.6 cents.

## BIO-MELBOURNE NETWORK

The Bio-Melbourne Network September 2, 2010 Bio-Briefing will discuss the best timing for obtaining patent protection.

Bio-Melbourne Network chief executive officer Michelle Gallaher said that Australia biotechnology companies and research organizations were often accused of trying to patent too early.

"The issue is whether companies are forced to patent too early by the nature of the Australian biotech industry, pressure to partner or to increase their perceived company value and whether there are alternative commercial strategies that are viable in the Australian environment," Ms Gallaher said.

Ms Gallaher said research organizations were "under constant pressure from scientists who want to publish [which] ,,, can be in direct competition with commercial imperatives".

The Network said the September Bio-Briefing would hear from Melbourne Ventures business development manager Dr Christophe Demaison, GBS Ventures partner Dr Andrew Baker and Davies Collison Cave intellectual property partner Mark Roberts.

The panel will explore alternative management strategies to extend the commercial life of patents without risking early disclosure as well as the question of whether Australian companies are letting their patent strategy dictate their business strategy.

The Bio-Briefing will be held on September 2, 2010 at Davies Collison Cave, Level 15, 1 Nicholson St, Melbourne with registration from 3:45pm.

For more information go to: <http://www.biomelbourne.org/events/view/142>.