



Biotech Daily

Tuesday December 2, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECHS DOWN: NEUREN UP 16%, LABTECH DOWN 17%**
- * **GENETIC TECHNOLOGIES FREES OVARIAN, BREAST CANCER TESTS**
- * **BIO-GUIDE BRIEF: GTG AND CORPORATE PHILANTHROPY**
- * **NOVOGEN: NV-128 POTENTIALLY ACTIVE AGAINST CANCER STEM CELLS**
- * **NOVOGEN'S MARSHALL EDWARDS FILES FDA IND FOR TRIPHENDIOL**
- * **ELLEX 1-FOR-2 RIGHTS ISSUE TO RAISE 'UP TO \$3.4m'**
- * **SAFETY MEDICAL IN FINANCE TALKS**
- * **BONE: CLOSER TO \$1.5m CAPITAL RAISING**
- * **UNITED BIOSOURCE INCREASES TO 16.5% OF COGSTATE**
- * **BIOTECH REPRESENTED ON FUTURE MANUFACTURING COUNCIL**

MARKET REPORT

The Australian stock market followed Wall Street down 4.0 percent on Tuesday December 2, 2008 with the All Ordinaries down 145.6 points to 3,473.4 points.

Seven of the Biotech Daily Top 40 stocks were up, 18 fell, four traded unchanged and 11 were untraded.

Neuren was best, up 0.9 cents or 16.36 percent to 6.4 cents with 50,000 shares traded, followed by Circadian up 9.09 percent to 60 cents. Bionomics and Heartware both climbed five percent; Novogen was up 2.6 percent; with Acrux and Progen up more than one percent.

Labtech led the falls, down 2.5 cents or 17.24 percent to 12 cents, followed by Living Cell down 14.29 percent to 12 cents and Tyrian down 11.11 percent to four cents.

Genetic Technologies lost 10 percent; Avexa was down 9.09 percent; Clinuvel and Ventracor fell more than eight percent; Alchemia, Biota, Cellestis, Phosphagenics and Prana were down more than six percent; Benitec, Mesoblast and Starpharma fell five percent or more; Pharmaxis fell 4.26 percent; CSL, Resmed and Sirtex shed more than two percent, with Cochlear down 1.96 percent.

[GENETIC TECHNOLOGIES](#)

Genetic Technologies says its new board has “resolved to immediately revert to its original decision to allow other laboratories in Australia to freely perform BRCA testing”.

The company’s co-founder, director Dr Mervyn Jacobson, told Biotech Daily on November 19, 2008 that the new board would review the decision to enforce its genetic testing rights for BRCA1 and BRCA2 genes to determine predisposition to ovarian and breast cancer (see Biotech Daily; July 11, 2008).

Today Genetic Technologies said it would allow other laboratories free use of the tests. The company said it had “state-of-the-art testing facilities based in Melbourne, Australia, where it provides high quality, cost efficient genetic testing, including BRCA testing, within a very short timeframe”.

Genetic Technologies said it looked forward “to working positively with all its partners, including other public and private testing laboratories, to continue providing these world class testing services”.

Genetic Technologies fell 0.5 cents or 10.0 percent to 4.5 cents.

[MARC SINATRA'S BIO-GUIDE BRIEF: GENETIC TECHNOLOGIES](#)

I am all for corporate philanthropy where it can be argued that the benefits a company receives from such philanthropy outweighs its costs.

Unfortunately, it is only in rare circumstances that the benefits outweigh the costs and even in these cases the benefits are often intangible.

It is much better for companies to make as much money as they can for shareholders and then let those shareholders decide if they want to be philanthropic with the subsequent dividends or capital gains and, if so, who the beneficiaries of that philanthropy should be.

Today, Genetic Technologies, now under the control of Dr Mervyn Jacobson, reversed its contentious decision to enforce its rights over BRCA testing, forgoing revenues in the millions of dollars.

I know that many will be cheering the Genetic Technologies’ decision, today.

But, when I look at Genetic Technologies, I see a company that has had multimillion dollar losses for each of the last five years, totaling almost \$40 million dollars and a share price that has slid from \$1.00 in 2000 and from 30.3 cents to 15.3 cents in March 2007 and is now at 5 cents a share.

A company such as this should probably be focusing on something other than corporate philanthropy, such as how to create value for shareholders.

Marc Sinatra’s Bio-Guides

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[NOVOGEN](#)

Novogen says Yale University research shows that NV-128 has the potential to act against cancer stem cells as well as rapidly proliferating cells in solid tumors.

Novogen said a research team led by Prof Gil Mor studied the mTOR inhibitor and found “that NV-128 has a high level of potency against cancer stem cells.”

“In fact, of the investigational therapies Yale has tried, NV-128 is one of the most exciting to us,” Prof Mor said.

Published research indicates that mTOR pathways, in addition to their involvement in maintaining survival among rapidly dividing cells in established tumors, also guarantee survival in cancer stem cells.

Novogen said cancer stem cells were slowly dividing undifferentiated cells with the capacity to regenerate tumors rapidly after their surgical or chemical removal.

The company said the cells were becoming recognized as the underlying mechanism by which tumors recur and metastasize after primary treatment.

As such they represent a promising target by which improved cancer control may be achieved, Novogen said.

The company said NV-128 had been shown to function as a potent inhibitor of the mTOR pathway and therefore has the potential to be effective against cancer stem cells.

Novogen said it was aligning its research priorities for NV- 128 and other related pipeline compounds, to look specifically at their activity in cancer stem cells, providing the “opportunity to develop NV-128 and other potential derivatives not only for use as a therapeutic agent in established cancers, but also to target the stem cells which lead to cancer recurrence”.

The company said that at last year’s annual meeting of the American Association for Cancer Research, a presentation by one of the Yale team, Dr Ayesha Alvero, showed in animal studies that NV-128 not only significantly retarded tumor proliferation, but was more efficacious than other standard of care drugs and without apparent toxicity.

Novogen said this effect was shown to be due to caspase-independent pathways involving inhibition of the mTOR pathway.

Unlike analogues of rapamycin, like temsirolimus and everolimus, which targeted only mTORC1, NV-128’s capacity to dephosphorylate mTOR enabled it to inhibit both mTORC1 and mTORC2 activity, the company said.

This blocked growth factor driven activation of AKT and the potential for development of chemoresistance.

Novogen said that structurally NV-128 was an analogue of triphendiol and phenoxodiol, both of which are investigational drugs that have been licenced by Novogen to its majority-owned subsidiary, Marshall Edwards.

In contrast to phenoxodiol and triphendiol, NV-128 has been shown to induce caspase-independent DNA degradation and cancer cell death.

It appears that in conjunction with autophagy induction, NV-128 induces caspase independent cell death via the AKT-mTOR pathway resulting in beclin sequestration of Bcl-2, Bax up-regulation and mitochondrial depolarisation. As a consequence, endonuclease G translocates to the nucleus where it initiates DNA degradation and cell death.

This offers an opportunity for use as a monotherapy in chemoresistant cancers and enhanced efficacy against cancer targets less susceptible to phenoxodiol.

The option for co-administration of combinations of these drugs is also under investigation to extend the potential therapeutic range of this unique class of oncology compounds.

Novogen climbed two cents or 2.6 percent to 79 cents.

NOVOGEN

Novogen subsidiary Marshall Edwards has filed an investigative new drug application for triphendiol as a chemo-sensitizing agent in combination with gemcitabine.

Novogen said the application to the US Food and Drug Administration was to enable a phase Ib study of triphendiol in combination with gemcitabine in patients with non-resectable, locally advanced or metastatic pancreatic and bile duct cancers.

The company said triphendiol or NV-196 was an investigational drug in the Marshall Edwards oncology pipeline, being developed as an orally-delivered chemo-sensitizing agent, intended for use in conjunction with standard chemotoxic anti-cancer drugs for the treatment of late stage pancreatic cancer, cholangio-carcinoma, and melanoma.

Novogen said triphendiol was granted orphan drug status by the FDA for pancreatic cancer and cholangio-carcinoma in January 2008 (see Biotech Daily: January 23, 2008) and for treatment of stage IIb-IV malignant melanoma in February 2008 (see Biotech Daily; February 20, 2008).

Novogen said NV-196 was broadly cytostatic and cytotoxic against most forms of human cancer cells in vitro, and had been shown to cause cell cycle arrest, stopping cells increasing in number and to induce apoptosis (programmed cell death) in various cancer cell lines.

Novogen said biological studies suggested a mechanism of cytotoxicity that involved mitochondrial depolarisation and downregulation of XIAP.

The company said it exhibited high selectivity, little effect on non-tumor cells and no observable toxicity in animals at therapeutically effective doses.

In human studies conducted in Australia, no adverse events or side effects have been reported when administered to volunteers, the company said.

ELLEX MEDICAL LASERS

Ellex hopes to raise \$3.4 million through a one-for-two share offer of 34,265,420 shares at 10 cents a share.

The record date for eligible shareholders is December 10, 2008.

The offer opens on December 12 and closes on December 30.

Ellex said the offer was partially underwritten by Taylor Collison, which will subscribe for up to 32 percent of the shares on offer, giving a minimum subscription of \$1.1 million.

The company said the funds were for working capital and to retire debt.

Ellex fell 6.5 cents or 39.39 percent to 10 cents.

SAFETY MEDICAL PRODUCTS

Safety Medical says it is "in discussion with potential financing partners regarding the provision of funding for new product opportunities".

Safety Medical says discussions are incomplete.

Safety Medical climbed 3.5 cents or 43.75 percent to 11.5 cents.

BONE MEDICAL

Bone Medical says it is "progressing toward completion of a capital raising" of \$1.5 million. Bone said the raising was through a private placement to institutional and private investors for working capital and to support its commercialization of biopharmaceutical projects for bone disease including osteoporosis and arthritis

Bone was untraded at 30 cents.

COGSTATE

United Biosource Corp has increased its substantial shareholding in Cogstate from 9,846,463 shares (15.0%) to 10,842,045 shares (16.52%).

The Bethesda, Maryland based company said it bought the shares on-market between 14 cents and 18.99 cents a share between September 19, 2008 and November 21, 2008. Cogstate was untraded at 17 cents.

AUSTRALIAN GOVERNMENT - FUTURE MANUFACTURING COUNCIL

The Minister for Innovation, Senator Kim Carr, has appointed two biotechnology sector representatives to the 20-member 'Future Manufacturing Industry Innovation Council'. "The onset of the global economic crisis has made it more important than ever that Australia has a strong and globally competitive manufacturing industry," Senator Carr said.

"The future of Australian manufacturing is not in low-tech, high-volume sectors where we struggle to compete with low-wage economies," Senator Carr said.

"Our future is in high-tech, high-skill and high-wage manufacturing where we are competitive and where we have world-class capabilities and technology," he said.

"This council has been established to help build that future," Senator Carr said.

A Federal Government media release said the council would focus on "Australia's most innovative manufacturers - those that use advanced materials and processes to add exceptionally high value".

It gave as examples scientific and medical instruments industry, information and communications technology, renewable energy, specialist engineering, and aerospace.

The Council would also look at the growing area of manufacturing services and the opportunities for Australian manufacturers in the global response to climate change.

The Council chair is Philip Binns who has "extensive experience in many areas of high-technology, precision manufacturing, from product development to sales and exports" the media release said. Mr Binns is the general manager of Varian Australia.

"Council members will work with companies, researchers, government and unions to increase the manufacturing sector's capacity to take advantage of new technologies and new opportunities," Senator Carr said.

The Future Manufacturing Industry Innovation Council is the second of several Industry Innovation Councils to be established.

The 20 members of the Future Manufacturing Industry Innovation Council include Commonwealth Scientific and Industrial Research Organisation's Materials Science and Engineering Chief, Dr Calum Drummond and Cochlear senior vice-president Dr Bronwyn Evans. Two other members are Australian Manufacturing Workers Union national secretary Dave Oliver and Australian Council of Trade Unions president Sharan Burrow.